Title: Consultation on hub and spoke dispensing IA No: 9585	Impact Assessment (IA)		
RPC Reference No:	Date: 01/02/2022		
Lead department or agency: Department of Health and Social Care	Stage: Consultation		
Other departments or agencies:	Source of intervention: Domestic		
	Type of measure: Secondary legislation		
	Contact for enquiries:		
Summary: Intervention and Options	RPC Opinion: Not Applicable		

Cost of Preferred (or more likely) Option (in 2021 prices)									
Total Net Present Social Value	Business Net Present Value	Net cost to business per year	Business Impact Target Status Non qualifying provision						
£20.9m	£0m	£0m	Non qualifying provision						

What is the problem under consideration? Why is government action or intervention necessary?

The Community Pharmacy Contractual Framework (CPCF) for 2019/20 to 2023/24 sets out the vision for community pharmacy delivering more clinical services and becoming the first port of call for minor illnesses. The term 'hub and spoke' dispensing refers to arrangements where parts of the dispensing process are undertaken in separate pharmacy premises. The Medicines Act 1968 sets out the requirements relating to the operation of pharmacies and pharmacists. The Human Medicines Regulations 2012 governs the arrangements, across the United Kingdom, for the licensing, manufacture, wholesale dealing and sale or supply of medicines for human use including the governance of pharmacists selling or supplying medicines. The law currently only allows hub and spoke arrangements when the hub and spoke are pharmacies within the same legal entity. The Government would like to remove this restriction and facilitate all pharmacies to be able to develop or use external hub services.

What are the policy objectives of the action or intervention and the intended effects?

Permitting all pharmacies to access more efficient dispensing has the objective to free up pharmacists and their team's time for other clinical services. This should help to further integrate community pharmacy into the wider health system and to help reduce pressure on care elsewhere in the NHS. Greater use of automation would also contribute to the objective to improve patient safety through higher dispensing accuracy.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

- 1. Do nothing. The Medicines Act 1968 and Human Medicines Regulations 2012 would remain unchanged and hub and spoke dispensing could only take place within the same legal entity.
- 2. Implement changes to the Medicines Act 1968 and the Human Medicines Regulations 2012 to facilitate all community pharmacies and dispensing doctors to develop or use external hub services.

Option 2 is the preferred option.

Will the policy be reviewed? It will be reviewed. If applicable, set review date: 2022								
Is this measure likely to impact on international trade and investment?		No						
Are any of these organisations in scope?	Micro Yes	Small Yes	Large Yes					
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)		Traded: N/A	Non N/A	-traded:				

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible minister:	Han.	Date:	25/2/2022

Policy Option 1

Description: Business as usual **FULL ECONOMIC ASSESSMENT**

Price Base	PV Ba		Time Period	i	Net Benefit (Present Value (PV)) (£m)					
Year 2021	Year 2	2021	021 Years 10		Low: Optional High: Optional		Best Estimate:			
COSTS (£m)		Total (Constant Pric	Transition e) Years	(excl.	Average Annual Transition) (Constant Price)		tal Cost nt Value)		
Low			Option	al		Optional	C	Optional		
High			Optiona	al		Optional	C	Optional		
Best Estimate	!									
The "business	Description and scale of key monetised costs by 'main affected groups' The "business as usual" option is the counterfactual scenario, against which other options are assessed. The value of costs and benefits are therefore zero by definition.									
Other key non N/A	-monet	ised co	osts by 'main	affected gr	oups'					
BENEFITS (ENEFITS (£m)		Total (Constant Pric	Transition e) Years	(excl.	Average Annual Transition) (Constant Price)		Benefit nt Value)		
Low			Option	al		Optional	C	Optional		
High			Option	al		Optional	C	Optional		
Best Estimate	!									
-	s as usu costs ar	ual" op nd ben	tion is the co efits are ther	unterfactua efore zero l	al scena by defin		r options are assess	ed.		
Key assumpti	ons/sen	sitiviti	es/risks				Discount rate (%)			
N/A										
BUSINESS AS		•	·	anual\ C		Sooro for Business Im	upoet Torget (avalifed			
Direct impact Costs:	on busi	ness (i Benefi	-	Net:		Score for Business Im provisions only) £m:	ipact Target (qualityli	ıy		
CU313.		Denen	ແວ.	INCL.						

Summary: Analysis & Evidence

Description: Amend the Medicines Act 1968 and the Human Medicines Regulations 2012

FULL ECONOMIC ASSESSMENT

Price Base	PV Base	Time Period	Net Benefit (Present Value (PV)) (£m)				
Year 2021	Year 2021	Years 10	Low: 6.4	High: 53.3	Best Estimate: 27.3		

COSTS (£m)	Total Tra (Constant Price)	ansition Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	N/A		£5.2m	£42.2m
High	N/A		£38.9m	£320.5m
Best Estimate	N/A		£19.9m	£132.5m

Description and scale of key monetised costs by 'main affected groups'

The main quantified costs are associated with the set-up and operational costs of hubs. There are also set-up costs for spoke pharmacies reflecting investment in IT systems, training and process redesign.

Other key non-monetised costs by 'main affected groups'

BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	N/A		£6.0m	£48.6m
High	N/A		£45.5m	£373.8m
Best Estimate	N/A		£23.2m	£153.3m

Description and scale of key monetised benefits by 'main affected groups'

The monetised benefits relate to the reduction in operating costs at the spoke pharmacies due to the savings in dispensing time.

Other key non-monetised benefits by 'main affected groups'

Potential for reduced rates of dispensing errors and associated patient harm and time spent resolving errors. Potential for increased clinical service provision reducing pressure in other parts of the healthcare system and health improvement for patients.

Potential for calmer working environment at the spoke pharmacy to the benefit of staff and patients.

Key assumptions/sensitivities/risks

Discount rate (%)

3.5%

Assume pharmacy businesses with a dispensing volume across all their premises below 12m per annum could benefit from regulatory changes, and that only spoke pharmacies with a dispensing volume above 60,000 per annum would potentially make use of automated hub dispensing. 12% of potential beneficiaries would adopt hub and spoke within the next 5 years whilst a further 20% would adopt over the next 10 years. 40% of a pharmacy's items can go through the hub. There is a 40% time saving reduction on a cost of £1.20 to dispense a prescription item in a spoke pharmacy. There is a 40p per item cost of hub dispensing. This is a net saving of 8p per item in operating costs. The average set-up cost for spoke pharmacies would be £4,000.

Risk of potential impact on competition within both the pharmacy and wholesale sector.

BUSINESS ASSESSMENT (Option 2)

Direct impact on bu	ısiness (Equivalent A	Annual) £m:	Score for Business Impact Target (qualifying
Costs: N/A	Benefits: N/A	Net: N/A	provisions only) £m:
			N/A

Consultation on hub and spoke dispensing – Impact Assessment

Background

- 1. The Government's vision for community pharmacy is that it should provide an expanded clinical service as part of its contract with the NHS, helping to relieve pressures on other areas of the healthcare system. To achieve this, dispensing needs to become more efficient to free up pharmacists' time for other activities. Permitting all pharmacies to access more efficient hub and spoke dispensing is part of the Government's strategy to support this transformation.
- 2. The term 'hub and spoke' dispensing refers to arrangements where parts of the dispensing process are undertaken in separate pharmacy premises. Typically, there are many 'spoke' pharmacies to one 'hub' pharmacy. The concept is that the simple, routine aspects of dispensing such as assembling, and labelling can take place on a large scale in a hub that usually makes use of automated processes.
- 3. The Medicines Act 1968 sets out the requirements relating to the operation of pharmacies and pharmacists. The Human Medicines Regulations 2012 governs the arrangements, across the United Kingdom, for the sale and supply of all human medicines, including the requirements for pharmacists selling or supplying medicines. The law currently only allows hub and spoke arrangements within pharmacies that are part of the same legal entity. The Government committed to pursue removing this restriction to permit all community pharmacies to develop or use external hub services.
- 4. This public consultation considers removing the impediment that currently limits hub and spoke dispensing to being only between pharmacies within the same legal entity as well as proposing further amendments to legislation to ensure that patient safety is maintained. All of this will be facilitated by proposed amendments to both the Medicines Act 1968 and the Human Medicines Regulations 2012.

Rationale for Intervention

5. In July 2019, the Government announced a new five-year settlement for the Community Pharmacy Contractual Framework (CPCF). Together with NHS England and NHS Improvement, the Department of Health and Social Care has worked with the Pharmaceutical Services Negotiating Committee (PSNC) to develop a vision for the future of community pharmacy.

- 6. The vision is that community pharmacy will take on an expanded role in treating minor illness and improving medicines safety and optimisation, reducing pressures elsewhere in the health and care system. The NHS Long Term Plan commits to making greater use of pharmacists' skills.¹ To this end, the NHS will continue to pay £2.592 billion per year for community pharmacy services over the five years but will change the way funding is distributed across services.²
- Improving the efficiency of dispensing is central to this transformation. 7. Currently, medicines legislation only provides for hub and spoke arrangements when the hub and the spoke are pharmacies within the same legal entity. Therefore, currently only a few large pharmacy chains can make use of hub and spoke dispensing. Although smaller pharmacies could in theory make use of hub and spoke across their estate, they may lack access to capital and large enough prescription volumes to warrant investment in it. An estimated 30-40% of pharmacies in mainland Europe use automated dispensing. In contrast, less than 10% of UK pharmacy is automated (across all community, hospital, and prison settings)³. We do not have robust information on how many pharmacies in primary care use automation but are aware of only 6 pharmacy businesses out of around 3,000 across the whole sector that do. However, each of these businesses could represent several pharmacies dispensing a varying number of items, some of which use automation and some that don't. Consequently, trying to quantify the proportion of automation depends on the interpretation and makes it difficult to make comparisons to Europe.
- 8. Regulatory changes permitting all pharmacies to access hub and spoke dispensing means that new business models around hub and spoke can develop. That might mean that these businesses even though they can but don't do hub and spoke now, might do it post any regulatory change and consequently support the transformation strategy.

Government response to the 2016 consultation

9. The Government consulted on a similar proposal in 2016⁴ and the Department recently published the response⁵. Some respondents acknowledged potential benefits of hub and spoke dispensing, but a significant proportion of respondents could not support the proposals in their form at the time of that consultation, raising concerns about how it

¹ NHS England, NHS Long Term Plan, January 2019. https://www.england.nhs.uk/long-term-plan/.

² Department of Health and Social Care. Negotiations started for the Community Pharmacy Contractual framework 2019 to 2020, April 2019 https://www.gov.uk/government/news/negotiations-started-for-the-community-pharmacy-contractual-framework-2019-to-2020.

³ P3 Pharmacy. "10 things about...automated dispensing" p3pharmacy.co.uk <u>https://www.p3pharmacy.co.uk/10-things-aboutautomated-dispensing</u>

⁴ Department of Health, Amendments to the Human Medicines Regulations 2012: 'Hub and spoke' dispensing, prices of medicines on dispensing labels, labelling requirements and pharmacists' exemption, March 2016. Available at: <u>Amendments to the Human Medicines Regulations 2012: 'hub and spoke' dispensing, prices of medicines on dispensing labels, labelling requirements and pharamcists' exemption (publishing.service.gov.uk).</u>

⁵ Department of Health and Social Care, Pharmacy dispensing models and displaying prices on medicines: response to the 2016 consultation, November 2021. Available at: Pharmacy dispensing models and displaying prices on medicines: response to the 2016 consultation - GOV.UK (www.gov.uk).

- would work in practice across legal entities, including how patient consent, data protection and end-to-end accountability would be handled. Respondents also raised concerns about the potential lack of competition between hub service providers and associated impacts and risks.
- 10. As part of the CPCF five-year settlement negotiations, it was agreed to pursue legislative change to facilitate hub and spoke dispensing to be utilised by all pharmacies, and to work with the Pharmaceutical Services Negotiating Committee (PSNC), the representative body of all pharmacy contractors in England, to identify which models would allow the whole sector to benefit fairly. The Government has been working with sector representatives to understand and address concerns and explore additional safeguards as part of the regulatory change process. The gathering and testing of views more broadly are now being sought through a new consultation.

Objectives

- 11. The policy objective is to support all pharmacies to improve the efficiency of their dispensing through the option of entering into hub and spoke dispensing arrangements with other pharmacy businesses. This is to support and continue the implementation of the vision set out in the CPCF five-year deal for:
 - Community pharmacy to be the first port of call for minor illness, deliver more clinical services and to be better integrated in the NHS;
 - Community pharmacy to support the NHS long-term plan and improve quality;
 - Continued access to pharmaceutical services;
 - Guaranteed investment that gives community pharmacy clarity and certainty; and
 - Increasing efficiency by enabling transformation and use of new technology.
- 12. Greater use of automation in hub and spoke dispensing models also has the objective of contributing to improvement in patient safety through higher dispensing accuracy.

Policy Options

Option 1: Do Nothing

- 13. The Human Medicines Regulations 2012 govern the arrangements across the United Kingdom for the sale and supply of all human medicines, including the requirements for pharmacists selling or supplying medicines. Alongside the Human Medicines Regulations 2012, the Medicines Act 1968 sets out requirements relating to the operation of pharmacies and pharmacists. Section 10 of the Medicines Act 1968 allows 'hub and spoke' dispensing if the 'hub' and the 'spoke' pharmacy are both part of the same retail pharmacy business.
- 14. Under the do nothing option, the law would remain unchanged and continue to prevent different pharmacy businesses from entering into hub and spoke arrangements.

Option 2: Permit and facilitate hub and spoke dispensing across different pharmacy businesses

- 15. Option 2 proposes to make legislative changes to the Medicines Act 1968 and the Human Medicines Regulations 2012 to facilitate 'hub and spoke' dispensing between different legal entities. Whilst this would include the removal of the current restriction in section 10 of the 1968 Act, the policy proposals are broader to reflect the nature of the change and to ensure patient safety is maintained. This will make it possible for 'spoke' pharmacies to make use of the services of 'hub' pharmacies that are part of a separate business or to work together and invest in one 'hub' location. This will give community pharmacies a wider choice as to which business model they adopt. The proposal also enables dispensing doctors to avail themselves of a similar arrangement with a hub pharmacy.
- 16. The proposed changes to the Human Medicines Regulations 2012 and the Medicines Act 1968 will be enabling, meaning that pharmacies can choose to make use of hub and spoke dispensing models. There may be supplementary issues that would need to be addressed through NHS Pharmaceutical Services. For example, to ensure that the use of hub and spoke arrangements does not undermine market entry. These would need to be addressed in the usual way through discussion with PSNC and if needed amendments may need to be made to the Pharmaceutical and Local Pharmaceutical Services Regulations (PLPS).

Background

17. Community pharmacies are all private businesses that provide NHS pharmaceutical services as part of their business. In addition to income from the CPCF, pharmacies can be commissioned by local authorities (LAs) or local NHS teams to deliver services, as well by NHSE&I. They also generate private income from sale of over-the-counter medicines

- and non-NHS goods and services. As of March 2021, there were 11,185 community pharmacies in England⁶. Community pharmacies dispensed 1,015 million prescription items in 2020/21; an average of 7,565 items per pharmacy per month.
- 18. Anyone wanting to provide NHS pharmaceutical services is required to apply to NHS England to demonstrate that they can meet a pharmaceutical need as set out in a Pharmaceutical Needs Assessment (PNA) evaluated by the Local Authority Health and Wellbeing Board. There are exceptions to this, such as applications to provide pharmaceutical services on a distance-selling basis.
- 19. The way that community pharmacy is funded to provide NHS services also has an important influence on the sector. Community pharmacies are reimbursed over £8bn for drugs they purchase and dispense for the NHS, but nearly all of this covers the costs of the drugs. NHS payments to community pharmacies for services under the CPCF are broken down into two components: remuneration for providing services, including the single activity fee for dispensing; and medicines margin delivered through the reimbursement system. Remuneration represents £1.792bn, while reimbursement delivers a further £800m of medicines margin, giving total funding of £2.592bn.

Hub and Spoke Models

- 20. Dispensing covers a number of processes such as the receipt of a prescription, clinical and accuracy checks, sourcing, preparation, assembly and supply of medicines, and liaising with the patient to ensure they know how and when to take the medicine. Traditionally, all these different processes are done in a single pharmacy. The main existing models for pharmacy supply are:
 - Brick-and-mortar pharmacies; traditional street-side business that offers products and services to its customers face-to-face in a store; or
 - Distance Selling pharmacies (DSPs); type of pharmacy that works exclusively at a distance from patients.
- 21. Both brick-and-mortar and distance selling pharmacies would benefit from the proposed changes in legislation and be able to enter hub and spoke arrangements. Therefore, all pharmacies are considered in the assessment of potential take-up.
- 22. In a hub and spoke model, some of these dispensing processes are undertaken in a different pharmacy to the one where the prescription was presented or received. The consultation proposes two different hub and spoke dispensing models. In the first of the models, the patient presents a prescription to the 'spoke' pharmacy, who then sends that data to the 'hub' pharmacy to enable them to do some elements of the

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⁶ NHS Business Services Authority, October 2021. General Pharmaceutical Services in England 2015/16-2020/21. https://www.nhsbsa.nhs.uk/statistical-collections/general-pharmaceutical-services-england-201516-202021

dispensing process. Any dispensed medicines are sent from the 'hub' back to the 'spoke', who then supplies them to the patient. The second model is where a prescription is accepted by a 'spoke' pharmacy, which sends the data to the 'hub' pharmacy, which will then dispense the medicines and supply them directly to the patient (without reverting to the spoke). To support business resilience and flexibility, there is no proposed constraint as to how many hubs a spoke can enter into hub and spoke arrangements. Under the current proposals, in each model, which pharmacy does what part of the dispensing process can vary to allow hubs and spokes to adapt and innovate a dispensing process that works for their particular arrangement.

Dispensing Doctors

23. In addition to pharmacies, the proposal is to enable dispensing doctors to make use of pharmacy hubs if they so wish. Dispensing doctors are GPs who are also able to supply medicines to patients as part of their NHS service provision. They usually serve remote and rural areas where access to a pharmacy may not be readily available. It is proposed to allow dispensing doctors to access hubs to support their medicine supply to patients, although as part of this proposal, dispensing doctors may not themselves be hubs, as it is a requirement that a hub must be a registered pharmacy.

Accountability

- 24. Moving to a system where the 'hub' and 'spoke' could be from separate legal and commercial entities will require clear accountability between the two entities. By proposing that both the hub and the spoke are registered pharmacies, means that the hub and spoke dispensing process is covered end-to-end by one regulator, the General Pharmaceutical Council (GPhC) for pharmacies in Great Britain, the Pharmaceutical Society of Northern Ireland (PSNI) for pharmacies in Northern Ireland, and the Care Quality Commission (CQC) for dispensing doctors.
- 25. There will also be the requirement to have in place an agreement between the hub pharmacy and the spoke pharmacy to ensure there is accountability between the two organisations. It is proposed that there is flexibility for the spoke and hub to agree responsibility and accountability for each step in the dispensing process between themselves, but in all cases an agreement must be in place.

Transparency and Patient Choice

- 26. Moving to a hub and spoke dispensing model will mean that patient data will need to be shared between the spoke and the hub. Existing data protection regulations will apply, ensuring that confidential patient data will continue to be secure under the hub and spoke dispensing models.
- 27. What information patients needed to know in relation to the operation of hub and spoke dispensing was carefully considered in the development

of the proposals. For example, to enable patients to make an informed choice about which pharmacy they use. The consultation proposes that as a minimum, patients should be informed that a 'hub and spoke' arrangement is being operated and who is/are the hub/hubs that are being used. Furthermore, the consultation proposes that the address of the pharmacy that the patient should contact is included on the dispensing label.

Evaluation of costs and benefits

- 28. It is unclear when the first impacts incurred under the policy option will take place. This impact assessment therefore appraises over a ten-year period.
- 29. The consultation is being issued jointly by the UK Department of Health and Social Care and the Northern Ireland Department of Health, and the proposed changes would apply throughout the United Kingdom. This impact assessment appraises for England only.

Likely take up of hub and spoke arrangements

- 30. The proposed regulatory change is permissive. No pharmacy business would be required to set up, use or offer hub and spoke services. Estimates of potential sector-wide costs and benefits set out below are therefore based on scenarios informed by evidence from the sector, from other countries and from secondary care.
- 31. From our discussions with stakeholders and the responses from the 2016 consultation, a key determinant of the take up of hub and spoke style arrangements will be the scale of dispensing, and therefore the ability to benefit from economies of scale:
 - Hub facilities need a minimum level of throughput to be efficient. Our discussions with stakeholders suggested that, subject to capacity constraints, the higher the volumes and greater the level of automation the greater the efficiency benefits. Of the existing hubs that we are aware of, these tended to process at least 250,000 prescription items per week, or 12m items per year, and in some cases were much higher. We therefore assume that for pharmacy businesses that could do hub and spoke now, but their total dispensing volume is below this, they may currently lack the scale required to invest in their own hub and therefore could benefit from these proposals that would allow them to outsource their hub operations.
 - Spoke pharmacies also require a minimum volume to benefit from hub and spoke arrangements. Stakeholders told us that to be able to properly release capacity, there needed to be a predictable and sizable number of prescription items that could be sent to the hub each month. Without this, pharmacies would be unable to invest in new working practices to properly benefit from the released capacity.

From discussions with pharmacy businesses already operating hub and spoke models, many had a minimum item requirement before a pharmacy could utilise the hub, which tended to equate to approximately 5,000 prescription items per month.

32. Using data from the NHSBSA⁷ on the total number of NHS prescription items dispensed in 2020/21 for all pharmacy premises open on 31st March 2021, we calculated that the following numbers of pharmacy businesses could potentially benefit from the proposed policy. We assume that the 771 pharmacy businesses consisted entirely of pharmacies dispensing less than 60,000 items a year would not benefit from automation and hub arrangements, whilst those pharmacies that are part of businesses with total dispensing over 12m per year could already be using automation and so would be unaffected by the policy proposal. There are a total of 4,122 spoke pharmacies in the businesses we anticipate could benefit through the legislative changes, and this forms the maximum if there was 100% uptake.

Table 1: Potential beneficiaries from the policy

	Businesses	Spoke	Items per
		Pharmacies	year
Total pharmacy	3,035	11,185	1,022m
Number likely to already have sufficient scale for automation	12	5,352	483m
Number likely not to be large enough to benefit from automation	771	1,711	69m
Remainder who could benefit from legislative change	2,252	4,122	470m

- 33. However, as the proposed policy is permissive and there is no requirement for businesses to adopt a hub and spoke model, it is not clear what proportion of these potential businesses may choose to do so.
- 34. Although no published surveys on the intention of pharmacies to adopt hub and spoke are available, the Department of Health and Social Care has been passed the details of some private market research that has been carried out, which suggests that approximately 12% of independent pharmacies have definite intentions to adopt hub and spoke, whilst a further 40% are considering it. The Department did not carry out this research, and intentions can be a poor predictor of action, so this data should be treated cautiously.
- 35. If we assume that all pharmacies who indicated that they were definitely interested in hub and spoke were to adopt it within the next 5 years, and that half of those who were considering it would adopt within the next 10 years, this would suggest the following profile of take up. We consider variation in levels of adoption in lower and higher scenarios detailed later in the impact assessment.

⁷ NHSBSA, Management Information Spreadsheet (MIS) Report 2020/21. Total number of Single Activity Fees.

Table 2: Profile of hub and spoke adoption by potential beneficiaries (associated with legislative changes)

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Proportion of pharmacies using hub and spoke (dispensing below 60,000 items per year)	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Proportion of pharmacies using hub and spoke (dispensing above 60,000 items per year)	4.4%	8.8%	13.2%	17.6%	22.0%	24.0%	26.0%	28.0%	30.0%	32.0%
Number of spoke pharmacies using hub and spoke	181	363	544	725	907	989	1,072	1,154	1,237	1,319

Number of prescription items going to the hub

- 36. While it will differ for each model, it is likely that there will be some prescription items that are not suitable for dispensing at the hub. Stakeholders who currently dispense using automated hubs advise that these are generally controlled drugs, cold storage items, heavy items such as glass bottles, and split pack items (items prescribed in different pack sizes to those manufactured).
- 37. Some current hub operators also report an issue with direct to pharmacy lines (items that can only be purchased via one wholesaler determined by the manufacturer) since the hub may not be able to make those purchases on behalf of the spoke pharmacies.
- 38. As well as considering whether items are a compatible line with the hub there needs to be consideration of whether it is efficient to use the hub. This consideration is mainly in relation to how quickly the patient will need the prescription, since an average turnaround for a prescription using hub dispensing is 2 days. For example, it is usual for all acute prescriptions to stay at the spoke pharmacy and only repeat prescriptions to be dispensed at the hub.
- 39. The total number of prescription items per year has been gradually increasing over time but flattened in the last five years. There are ambitions⁸ to address the problem of overprescribing, in terms of optimising the use of medicines, developing better systems, and listening to the needs and preferences of patients. In addition, based on analysis by NHSE&I there are a number of factors which are expected to impact the number of prescription items going forward, some of which are expected to increase prescription items and others are expected to

⁸ Department of Health and Social Care, September 2021. Good for you, good for us, good for everybody, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/system/uploads/attachment_data/file/1019475/good-for-you-good-for-us-good-for-everybody.pdf

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decrease prescription items, for example reduction in items after the introduction of 90-day prescribing, and increased dispensing due to growth in diabetes prevalence. Based on this and the overall uncertainty in the expected number of items over coming years, throughout this analysis we have assumed that dispensing stays constant at 2020/21 levels and does not change.

40. Feedback from a number of retail pharmacies currently operating hub and spoke models suggests that a figure of approximately 40% to 60% of items can realistically go through a hub. Using the mid-estimate of this range, suggests the following number of items that could be sent to the hub each year. By year 10, this would be 75m items per year, equivalent to 7% of all dispensing. Benefits are not therefore based on a major shift in the sector.

Table 3: Profile of prescription items going through hubs (associated with legislative changes)

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Number of spoke pharmacies using hub and spoke	181	363	544	725	907	989	1,072	1,154	1,237	1,319
Number of items going through hub	10.3m	20.7m	31.0m	41.4m	51.7m	56.4m	61.1m	65.8m	70.5m	75.2m

- 41. We have assumed that businesses dispensing over 12m items per year already have sufficient scale to invest in their own hub. As shown in Table 1, NHSBSA data suggests that 12 businesses fall into that category. Central data on which pharmacy businesses make use of hub dispensing is not available. However, based on stakeholder discussions and a review of publicly available information, we estimate 6 of these 12 businesses are currently using hub dispensing, equivalent to 50%. We do not know why the remaining 6 businesses do not make use of hub dispensing.
- 42. The 6 businesses already operating hub dispensing account for around 370m items, but not all stores will necessarily use the hubs. Depending on whether we assume that 50% of all the dispensing goes through hubs, or 50% of items at eligible spokes, then this suggests the baseline before any legislative changes could be between 7% and 18% of all dispensing. The estimated 7% of items going through hubs due to this policy is additional to this, giving a total range between 14% and 25% in our central scenario.

Likely number of hubs

- 43. The number of hubs that might arise is difficult to predict as it will depend on the types of hubs that may be offered and the different range of possible providers.
- 44. For example, hub and spoke dispensing is often associated with automated dispensing and may include this, but not necessarily. Some

companies currently operating hubs with automatic machinery started with a hub using a manual dispensing line due to low capital investment and to prove the process worked. Once permitted, hub and spoke dispensing may be possible between two or more pharmacies on a local level without any automation, with assembly or part dispensing carried out manually.

- 45. For large automated hubs, we have discussed above the need for there to be significant volumes of activity going through the hub for these to be viable. For example, if we were to use the 12m minimum item threshold discussed above, then this would suggest that only 6-7 large automated hubs could be supported by year 10 of the proposed policy. However, this does not account for the possibility of a number of smaller, less automated hubs to be set up. Feedback from stakeholders on the viability of manual hubs was very mixed and so it has been difficult for us to determine the likelihood of these models arising, as such the majority of the analysis in this IA has focused on the large automated hub scenarios.
- 46. In addition, capacity and the number of hubs will also be affected by who the hub providers are. For example:
 - Large retail chains or distance selling pharmacies with large, automated hubs could expand their capacity. We would expect to see these businesses offer chargeable assembly of medicines services to independent and small multiple pharmacies.
 - Independent and small multiple pharmacies could co-operate and centralise assembly of medicines in one of their pharmacies or through setting up off-site hub facilities.
 - New large-scale hub facilities could be developed by the wholesalers or new companies, although they would need to have and use a registered pharmacy premises for the hub. Similar to the large retail chain hub scenario above, these hubs may be supported by existing infrastructure investments that improves the economic viability of setting up a hub. As a result, our initial assessment of a potential of 6-7 large automated hubs may be overly simplistic.

Set up costs

- 47. Capital costs would differ in scale and type depending on whether the capacity of existing services is expanded or whether new hub services were developed. Setting up new hubs would be likely to be costlier in terms of investment in automation and, potentially, new facilities and staff. Expanding capacity at existing hubs or expanding functionality of existing wholesalers to offer services to new pharmacy businesses would also incur significant costs. The cost of setting up a hub is beyond all but the largest pharmacies.
- 48. Small pharmacies are unlikely to have the volume to warrant investment in an automated hub by themselves and would therefore need to group

together. It's unclear what sort of investment would be plausible for smaller pharmacies and therefore how many pharmacies would be required to invest in a hub. Even if pharmacies could access the capital there would need to be consideration of whether the aggregate dispensing volume across the investors was sufficient.

- 49. After the floor space and equipment required for automation, stakeholders suggested another large cost driver was the architecture of compatibility and making systems real-time. Stakeholders stressed the importance of validating any new system and an ongoing quality assurance process, as well as the importance of being able to track information throughout the whole process. Both the hub and spoke pharmacies would need to invest in changes to their business processes and the integration of IT systems and logistics. Some spoke pharmacies might also require a change to their Patient Medication Record (PMR) system in order to be compatible with the hub.
- 50. Given that the hubs would be expected to process a larger number of prescription items with many spoke pharmacies and patients reliant on them, stakeholders also stressed the level of investment needed to ensure the resilience of the hub. For example, investment was required to make sure that there is back-up power supply.
- 51. With any change programme there would also need to be significant staff hours to manage that change and training in the spoke pharmacies. Stakeholders mentioned the onboarding of spoke pharmacies, and the need to prove a level of data input accuracy in order to continue using hub dispensing. There would also be a requirement to get people qualified and working at the hub.
- 52. As part of the 2016 consultation, respondents were asked to comment on the following assumptions used in the original 2016 analysis:

"A new, hub can serve, on average, 250 spoke pharmacies and such a hub would cost £5 million to build. A large hub can serve, on average, 1500, pharmacies and such a hub would cost £20 million to build. A collaborative hub will not require additional capital except for the introduction of automation."

- 53. Respondents provided a range of useful information that has been used to refine these estimates:
 - Cost figures for different-sized hubs were provided e.g. a manufacturer of robotic dispensing technologies operating in other countries suggested £1-2m for a hub serving 100 pharmacies, £0.5m for a hub serving 25 pharmacies.
 - The prospect of very large hubs serving 1,500 pharmacies at a cost of £20m was viewed to be unrealistic, with significant business continuity risks.

- Discussions with other stakeholders have suggested figures of between £5m and £8m for a large automated hub serving up to 200 spokes.
- Setting up hubs co-operatively across pharmacy businesses would involve costs other than automation, including investment in processes and integrating IT and logistics. A cost of around £4,000 for a spoke pharmacy was suggested.
- Many retail pharmacies already operating hub and spoke models also indicated that there were significant set up costs at the spoke pharmacy to train their staff and redesign their processes to maximise the benefits of hub and spoke arrangements.
- 54. For the central estimate presented in this IA, it is assumed that the average set-up cost for spoke pharmacies would be £4,000 reflecting investment in IT systems, training, and process redesign. Using average hourly wage rates for pharmacists, pharmacy technicians and dispensing assistants from the Annual Survey of Hours and Earnings⁹, and uprating these figures by 30% to account for non-wage costs such as pensions and NI contributions, this equates to approximately 70 hours of work for 4.8 full time equivalents¹⁰.
- 55. It has not been possible to determine the initial set up costs for hubs since we do not have a concrete assessment of the number and types of hubs that might open due to this policy. As previously discussed, both the types of hubs and who provides them may significantly impact on costs. At one extreme, if existing automated facilities were to extend their services to independent pharmacies, then there may be very limited set up costs as there would be limited need for new capital investment in infrastructure. On the other hand, the evidence received from stakeholders demonstrates the significant costs associated with building a new hub from scratch.
- 56. Although it has not been possible to determine the initial set up cost of hubs, when considering the operating costs of a hub, stakeholders mostly provided us with figures and insights that were inclusive of the initial investment costs, for example by factoring in depreciation and return on capital within their operating costs. To avoid double counting these costs, we therefore do not attempt to provide separate set up costs for the hubs, and instead incorporate these costs within the operating costs considered below.

 $^{^{9}}$ ONS, Employee earnings in the UK 2020.

 $[\]frac{https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/bulletins/annualsurveyofhoursandearnings/previousReleases$

¹⁰ FTE figures derived based on the average FTE per pharmacy by role from the 2017 Community Pharmacy Workforce

https://www.hee.nhs.uk/sites/default/files/documents/The%20Community%20Pharmacy%20Workforce%20in%20England%202 017%20-%20survey%20report.pdf

57. Combining the spoke set up costs with the previously estimated number of new spokes per year gives the following estimated set up costs:

Table 4: Profile of set up costs

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Additional spokes per year	181	181	181	181	181	82	82	82	82	82
Total set up cost at spokes (£m)	0.7	0.7	0.7	0.7	0.7	0.3	0.3	0.3	0.3	0.3
Hub set up costs				considere	d as part o	f hub opera	ating costs			

Operating costs

- 58. Stakeholders told us that the key operating costs associated with the hub would include:
 - The labour costs of running the hub, although this cost would vary depending on the level of automation at the hub. For example, if the hub were to handle the splitting of packs where the prescribed amount differed to the manufacturer's original pack size, then this would likely be an entirely manual process.
 - Engineering and IT support costs to maintain the machinery and resolve any issues.
 - Transport costs associated with delivering the medicine from the hub pharmacy to the spoke, however this could potentially be offset by fewer deliveries of medicines being required from wholesalers to the spoke.
 - Depreciation and capital costs needed to be factored in to account for the significant upfront investment required to set up the hub.
- 59. It is anticipated that these operating costs would be offset by savings at the spoke. Currently when prescriptions are received at the pharmacy, the following activities must be completed:
 - The prescription details must be entered into the pharmacy IT system (minimal if prescription sent via the electronic prescription service).
 - The medicine must be picked from the shelves and patient labels applied (which may require counting the quantity to be supplied and cutting and splitting packs).
 - Accuracy and other clinical checks must be performed.
 - The assembled medicine is set aside ready to be handed to the patient.

- The medicines are supplied to the patient, ensuring the patient knows how to take it and any queries including re-ordering are dealt with.
- 60. Under hub and spoke arrangements some of these activities could be removed from the spoke pharmacy. It would be for the hub and spoke to decide amongst themselves which pharmacy is best placed to carry out which of the above activities.
- 61. In addition, there are many functions in the pharmacy surrounding stock control; ordering, checking it off on arrival and storing it. Hub and spoke could lead to less stock being required at the spoke pharmacy consequently leading to less time required for stock management i.e. less to order, check on arrival and put away and less capital invested in stock.
- 62. Information on operating costs is extremely commercially sensitive, however stakeholders have indicated to us that:
 - The gross saving to the spoke may be in the region of a 40% to 50% time saving compared to in-store dispensing.
 - The average time to dispense a prescription item is between 2 and 3 minutes, although this depends on the complexity of the prescription, for example if it requires the pharmacist to split a manufacturer's original pack. For independent pharmacies this could equate to a figure of £1.20 per item dispensed.
 - A commonly cited figure for automated hub operating costs is 40p per item.
 - Overall, once the costs of the hub have been factored in the net savings can be quite marginal, and as low as 10%.
- 63. Applying a 40% time saving reduction to the figure of £1.20 to dispense a prescription item in an independent pharmacy would suggest a reduction of operating costs of 48p per item, which we then compare against the 40p per item cost of hub dispensing. Thus, suggests a net reduction in operating costs of 8p per item, or just under 7% saving. Sensitivity testing later in the impact assessment shows the breakeven point is a net reduction in operating costs of 2p per item, or a 2% saving, which we have reasonable confidence that pharmacies would achieve.

Table 5: Profile of operating costs

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Cost saving at spoke (£M)	5.0	9.9	14.9	19.9	24.8	27.1	29.3	31.6	33.8	36.1
Cost of operating hub (inclusive of capital costs and depreciation) (£M)	4.1	8.3	12.4	16.5	20.7	22.6	24.4	26.3	28.2	30.1
Net (£M)	0.8	1.7	2.5	3.3	4.1	4.5	4.9	5.3	5.6	6.0

- 64. We also triangulated this evidence against published data from other sources and found that these estimates of net savings are likely to represent a realistic but conservative estimate.
- 65. In a survey of EU member states, four out of 17 countries reported use of hub and spoke style dispensing arrangements (Germany, Finland, Belgium and Denmark). In addition, centralised automated dispensing is well established in Netherlands and Sweden, where they make extensive use of centralised dispensing for multi-dose dispensing i.e. dispensing for people who take multiple medications and have them put into single-dose, multi-medicine trays. However, there is little published evidence on the relative efficiency and safety of dispensing¹¹.
- 66. Evidence from using automated dispensing systems in secondary care is mixed. Three studies that quantified efficiencies of hospital pharmacy-based systems did find evidence that these reduced staff time on dispensing by between 20% to 30% (Annex A), and some evidence of reduced dispensing errors. However, the application of this evidence to community pharmacy is only limited, given the different scale, geography, and organisation of dispensing.

Fees charged between hub and spoke

- 67. Where the hub is a separate legal entity from the spoke, it is likely that the hub will need to charge the spoke for the services that they provide. We would expect that this charge would cover the operating costs of the hub plus a level of profit or margin for the hub.
- 68. It is not clear what sorts of fee structures might emerge (for example annual fees or a fee per item), nor the level that the fee might be set at. However, we note that the key impact of any fee would be to shift the operating costs of the hub from being borne by the hub to the spoke pharmacy. Since there is no requirement to use a hub, we would expect that a pharmacy would only choose to make use of hub services if the savings to the pharmacy net of any service fee charged by the hub remains positive. We would therefore assume that the impact of the service fee would be a mechanism by which the savings of hub and spoke are shared between the two organisations. This would affect the distribution of costs and benefits calculated above between organisations, but not the overall quantum.

Wider impacts of hub and spoke

- 69. Potential other impacts of hub and spoke arrangements include:
 - Reduced staff time on dispensing at the spoke pharmacy, freeing up time to provide other services.

¹¹ Rechel B. Hub-and-spoke dispensing models for community pharmacies in Europe. Eurohealth 2016; 24: 4. https://researchonline.lshtm.ac.uk/4650905/1/Rechel-2019-Hub-and-Spoke-Dispensing-Models.pdf

- Potential for reduced rates of dispensing errors.
- Potential for a calmer working environment at the spoke pharmacy.
- Impact on medicines costs.

Reduced staff time on dispensing at the spoke pharmacy

- 70. The 5-year CPCF deal agreed in 2019, envisages that both pharmacists' time and funding from the CPCF may be freed up, partly through the use of hub and spoke and that this will be used to fund the delivery of new pharmaceutical services by pharmacies. By allowing pharmacists to outsource some of the more technical, routine parts of the dispensing process, this could free up time for them and their staff to focus on providing a wider range of services for patients than can be done under the present regulations, while continuing to provide patients with the medicines they need.
- 71. This increase in clinical service provision may deliver benefits to both the NHS and community pharmacies as follows:
 - Increased clinical service provision will result in health improvements for patients. For example, if the pharmacist has more capacity to spend time with patients and provide advice on healthy living and selfcare, as well as delivering valued clinical services such as vaccinations, blood pressure monitoring and medication advice.
 - The increased capacity to see patients within pharmacies may also help reduce pressure on other parts of the NHS. For example, the Community Pharmacy Consultation Service is designed to allow pharmacies to take referrals for minor illnesses from NHS 111 and GP surgeries and there are ambitions to further roll this out to cover other health settings. Previous impact assessments considering the expansion of this service within the Community Pharmacy Contractual Framework has highlighted the potential for this service to significantly reduce the number of GP appointments and A&E visits required. A 2015 survey of GPs estimated that approximately 2% of GP appointments could have been dealt with by community pharmacy instead¹², whilst the PSNC community pharmacy advice audit¹³ found that almost half of patients who had an informal consultation in a pharmacy, would have visited their GP had they been unable to contact their community pharmacy.
 - Spoke pharmacies who offer additional clinical services can increase their income. For example, private clinical services could include the provision of private seasonal flu jabs, travel vaccinations, or test and treat services, whilst NHS services could include taking referrals from

¹² Primary Care Foundation, Making Time In General Practice, October 2015. https://thehealthcreationalliance.org/wp-content/uploads/2018/11/Making-Time-in-General-Practice-FULL-REPORT-06-10-15.pdf

¹³ Pharmaceutical Services Negotiating Committee, Pharmacy Advice Audit 2021. https://psnc.org.uk/wp-content/uploads/2021/05/PSNC-Pharmacy-Advice-Audit-2021-Report.pdf

the Community Pharmacy Consultation Service (£14 per consultation), the New Medicines Service (approx. £24 per consultation) or the Hypertension Case-Finding Service (£15 for a clinic check and £45 for ambulatory blood pressure monitoring).

72. However, it is difficult to further quantify these benefits as it is not known what mix of additional clinical services might be offered by pharmacists. It is also important to note that, where NHS clinical services are funded from the Community Pharmacy Contractual Framework, under the terms of the 5 year deal, the total funding envelope is currently fixed until the end of the 2023/24 financial year at £2.592bn. This flat cash funding deal will naturally constrain the amount of additional income that pharmacies can make from NHS services, at least in the short term.

Potential for reduced rates of dispensing errors

73. The National Reporting and Learning System (NRLS) is a largely voluntary scheme for reporting patient safety incidents. Data for 2019-20 shows that 4,669 incidents were reported in community pharmacy. The majority (3,763) of these related to medication and for 92% of incidents the reported degree of harm was no harm.

Table 6: Reported incidents by degree of harm¹⁴, by care setting, England: Apr 2019 - Mar 2020

Community Pharmacy	No Harm	Low	Moderate	Severe	Death	Total
Number of Incidents	4,300	273	72	4	1	4,650
Percent	92	6	2	0	0	100

- 74. The latest NPA quarterly medication safety update showed that the main contributing factors to patient safety incidents were work and environment factors (41% of incidents) which includes time pressures, understaffing and poorly organised working environments, as well as Look Alike Sound Alike factors (23% of incidents) such as similar name, similar packaging etc.
- 75. Automating elements of the dispensing process at the hub could improve error rates and patient safety. Evidence¹⁵ from those who have implemented and established hub and spoke systems with tracking technology indicate that automated systems had a dispensing error rate 6 times lower than manual processes (124 errors per 1m items for inpharmacy and 22 per 1m items in automated facilities), although some stakeholders have found reductions well in excess of this. The

¹⁵ Sample of CCA members dispensing 472m items in 2020, 82% of which dispensed in bricks and mortar pharmacies and 18% dispensed via automated hubs.

¹⁴ **no harm** – a situation where no harm occurred: either a prevented patient safety incident or a no harm incident; **low harm** – any unexpected or unintended incident that required extra observation or minor treatment and caused minimal harm to one or more persons; **moderate harm** – any unexpected or unintended incident that resulted in further treatment, possible surgical intervention, cancelling of treatment or transfer to another area, and which caused short-term harm to one or more persons; **severe harm** – any unexpected or unintended incident that caused permanent or long-term harm to one or more persons; **death** – any unexpected or unintended event that caused the death of one or more persons.

- automated processes also demonstrate an improved profile across the levels of harm when compared to in-house dispensing. However, stakeholders also pointed to new measures that have been put in place to improve error rates within their stores (such as new IT systems), which has served to reduce the differential between in store and hub dispensing.
- Moving to a system where the 'hub' and the 'spoke' are separate legal and commercial entities will require clear accountability between the two entities. Options considered included doing nothing, which would allow maximum innovation, but risks duplication of effort or steps being missed out. A further option would be for specific responsibilities of hubs and spokes to be set out in legislation, however this risks stifling innovation and the divide of duties may not suit all business models. Finally, a third option would be for there to be a legal obligation on both the hub and the spoke to form an agreement that ensures the division of responsibility and accountability between themselves, by agreeing who is specifically responsible and accountable for each step in the dispensing process including the clinical check. The Consultation proposes the third option. that there is flexibility for the spoke and the hub to agree responsibility and accountability between themselves. In all cases there is a legal obligation that there must be an agreement in place to ensure there is clear accountability and ownership for each step in the dispensing process.
- 77. Although pharmacies have an excellent safety record, there is evidence to show that automated dispensing has the potential to reduce errors, albeit marginally. Care needs to be taken in introducing hub and spoke dispensing so that any new process does not increase the risk of errors being made. In particular, stakeholders highlighted the need to have robust processes to ensure the accuracy of data entry. On balance, allowing the wider use of hub and spoke dispensing, and with it the use of automation with appropriate safeguards can have a positive effect on patient safety.
- 78. We do not know the health impacts of any potential reduction in dispensing errors, so these have not been quantified in this IA.

Potential for a calmer working environment at the spoke pharmacy

79. All stakeholders who already operate a hub and spoke model commented that most, if not all, pharmacies who had switched to using the hub and spoke model preferred it and were unwilling to switch back to the previous model. In particular, stakeholders noted the calmer working environment as well as the greater variety of roles for staff as they spend less time on traditional dispensing activities which also allowed more time to deal with patients and urgent or non-routine issues. There may also be benefits from spoke pharmacies having to hold less stock as this will result in a less cluttered work environment, and potentially free up space within the pharmacy to redesign the space, for example making room for patient consultation rooms to be installed.

- Staff are likely to also benefit from less time spent on managing stock and putting away inventory.
- 80. These improvements to the working environment could in theory also have knock on benefits for staff morale and job satisfaction, ultimately leading to improved staff retention and participation rates. However, it has not been possible to quantify these benefits.
- 81. An improved environment could also have benefits for patients of entering a clearer, calmer environment in a pharmacy with potentially more space for consultation, which may encourage patients to seek out a pharmacy as the first port of call. It could also contribute to lower errors as the pharmacy team have time to spot issues and deal with them.
- 82. One stakeholder also noted that an unexpected benefit during the pandemic where concentrating dispensing activity in their hub helped to improve their business resilience in response to Covid-19 restrictions. For example, it was easier to implement infection control processes and manage staff sickness for one hub location, compared to multiple spokes.

Impact on medicines costs

- 83. Where pharmacies choose to make use of hub and spoke models of dispensing, it is assumed that the responsibility for purchasing medicines prepared and assembled by the hub will move to the hub, who will in turn need to recharge the spoke for the costs of these medicines. As hub pharmacies are likely to have a higher volume of dispensing, they may be able to negotiate better deals with wholesalers. To the extent that these savings are then passed onto spoke pharmacies, the spokes may also experience a cost saving.
- 84. This could also result in savings for NHS spend on medicines since, under the terms of the Community Pharmacy Contractual Framework, pharmacies are able to earn margin on the medicines that they dispense if the reimbursement price exceeds the price that they can source the medicine at. This retained medicine margin contributes to the provision of pharmaceutical services alongside the other agreed fees and allowances. Under the contractual framework, the total allowed medicine margin is currently set at £800m per annum and is measured through an annual survey. If this survey were to find that the amount of medicine margin earned had increased, then downward adjustments may be made to reimbursement prices, resulting in savings to the NHS.
- 85. However, it is also important to note that total expenditure on medicines could risk increasing as well as decreasing. For example, there is a risk that the hub pharmacy may have less incentive to make good purchasing decisions if the cost of medicines is wholly passed through to the spoke pharmacy. Due to the size of hub pharmacies, they may also be less flexible in who their suppliers are (for example, if guaranteed volumes and supply resilience become of more importance due to the

higher volumes at stake) and less able to switch at short notice to take advantage of temporary price deals, because for example they have set up their automation equipment to handle certain pack sizes. However, if spoke pharmacies were to end up getting a materially worse deal on the underlying cost of medicines, they would factor that into their decision on whether to use hub services, so would not anticipate an increase over and above the efficiencies generated.

- 86. Even where hub pharmacies do secure a better price due to their size, there is no guarantee that this saving will be passed onto the spoke pharmacies, and indeed, it may be the case that they could charge a slightly higher price as a way of recouping the service costs of the hub. This would have potential implications for NHS spend on medicines, depending on how the data were collected. Changes may be required in how the Department monitors medicines selling prices in conjunction with the PSNC to ensure that the medicine margin arrangements can take account of the purchases and services of hubs.
- 87. Finally, we note that there is potentially a risk that, if wholesalers themselves choose to offer hub services, the spoke pharmacy might need to purchase all their medicines from the wholesaler. Smaller wholesalers could potentially decline in number resulting in less competition and an increase in medicine prices more generally. However, this risk will in turn depend on the number of hubs that enter the market and the degree of competition between them. Another possibility is that where smaller wholesalers choose to also offer hub services, they will need to expand the range of products that they offer, which will enable them to compete more effectively with the full-line wholesalers.
- 88. As a result of all these considerations, it is not possible to determine what the ultimate impact on medicines prices might be.

Other factors which interact with hub and spoke

89. It is also important to note that a number of other factors such as original pack dispensing, skill mix and funding and fee structures have a relationship with hub and spoke, as they have the potential to increase any efficiency that may be available from the use of large remote pharmacy hubs assembling medicines for dispensing at community pharmacy spokes. In particular, it is important to note that DHSC recently consulted separately on proposals to implement original pack dispensing ¹⁶. Original pack dispensing is anticipated to positively impact on the efficiency savings identified in this IA as it will reduce the average dispensing time for both the hub and the spoke, as well as allowing more items to be compatible with automated dispensing machines. These potential interactions have not been considered within the above calculations of this IA.

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¹⁶ Department of Health and Social Care. Original pack dispensing and supply of medicines containing sodium valproate, November 2021 https://www.gov.uk/government/consultations/original-pack-dispensing-and-supply-of-medicines-containing-sodium-valproate

Impacts on Small and Micro Businesses

- 90. For hub and spoke, there is an opportunity for smaller businesses, even where they legally could use hub and spoke now to benefit from the proposals. Under current arrangements, they are less likely to be able to have the economies of scale required to benefit from automation within its own business or be able to make a financial case for the investment to build a hub. By removing the legal barrier to the use of hub and spoke dispensing across different legal entities, this would enable smaller businesses to use a hub of another business or build a hub of its own and offer its services to different pharmacies. However, some small businesses would still be limited by the assumption that a dispensing volume of at least 60,000 items per year is required to realise benefits under hub and spoke.
- 91. Note that the proposals are entirely permissive and small businesses could choose whether to engage in hub and spoke dispensing or not. Therefore, we assess the proposal would be taken up only where it would generate net benefits and so is expected to have a net zero to net benefit impact on SMEs.
- 92. Looking at our analysis of the number of companies that we have assessed to potentially benefit from hub and spoke arrangements, we have been able to classify them as follows:

Table 7: Potential beneficiaries by pharmacy type

	Number of pharmacy stores	Number of businesses potentially benefitting	Total number of businesses	Potential beneficiaries as a proportion of all businesses
Independents	1	1,577	2,342	67%
Small chain	2-5	556	563	99%
Larger chain	6-20	94	94	100%
Small multiple	21-100	24	24	100%
Medium multiple	101-500	1	9	11%
Large multiple	501+	0	3	0%
Total		2,252	3,035	

93. If we assume that each pharmacy shop employs an average of 6 people (based on the HEE workforce survey¹⁷), this translates into the following number of small and micro businesses:

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¹⁷ The Community Pharmacy Workforce in England 2017 <u>The Community Pharmacy Workforce in England 2017 - survey report_0.pdf (hee.nhs.uk)</u>

Table 8: Potential beneficiaries by SME classification

	Number of businesses potentially benefitting	Total number of businesses	Potential beneficiaries as a proportion of all businesses
Micro business (1-9 employees)	1,581	2,347	67%
Small (10-49 employees)	601	607	99%
Remainder (50+ employees)	70	81	86%
Total	2,252	3,035	

94. As can be seen, the vast majority (70%) of the beneficiaries from the proposed policy are expected to by micro businesses. Despite micro businesses benefitting the most, this is still a smaller proportion in relation to all micro businesses. In addition, we expect the majority of hub operators to be large organisations who have either already got hub facilities which they'll develop to offer to other businesses or have the access to sufficient capital to invest in setting up automated dispensaries. However, it may be the case that a number of small or medium businesses may choose to cooperate and set up a number of smaller sized hubs.

Summary of all costs and benefits

- 95. This section aggregates the quantified costs and benefits and explains how the overall societal impact of these is calculated and valued. The main quantified costs are associated with the set-up and operational costs of hubs. The benefits are the activity savings at the spoke pharmacy.
- 96. The assessment indicates that, in principle, any gains in dispensing efficiency and efficacy could be shared between hub operators, spoke operators, patients and the NHS. The costs and benefits of these different hub and spoke arrangements may result in different costs and benefits falling on different affected parties.
- 97. These results are summarised in Table 9 below. The present value of these benefits over the ten-year period is £191.7 million. The present value of the costs is £164.4 million, leading to an overall net present value (NPV) of £27.3 million.

Table 9: Aggregate impacts of proposed policy

0.7					,	8	9	10	
0.7	0.7	0.7	0.7	0.3	0.3	0.3	0.3	0.3	4.7
9.9	14.9	19.9	24.8	27.1	29.3	31.6	33.8	36.1	191.7
0.0	10.4	10.5	20.7	22.0	24.4	20.2	20.2	20.4	450.7
									159.7 27.3
8	9.9 3.3 9.9	3.3 12.4	3.3 12.4 16.5	3.3 12.4 16.5 20.7	3.3 12.4 16.5 20.7 22.6	3.3 12.4 16.5 20.7 22.6 24.4	3.3 12.4 16.5 20.7 22.6 24.4 26.3	3.3 12.4 16.5 20.7 22.6 24.4 26.3 28.2	3.3 12.4 16.5 20.7 22.6 24.4 26.3 28.2 30.1

Dispensing Doctors

- 98. In addition to pharmacies, the changes in legislation will enable dispensing doctors to make use of pharmacy hubs if they so wish. Dispensing doctors are GPs who are also able to supply medicines to patients as part of the NHS service provision to their patients, and usually serve remote and rural areas. Aggregate dispensing volumes for dispensing doctors are around 7% 18 of that for all community pharmacies.
- 99. We have no specific evidence on the potential impacts for dispensing doctors, so these have not been included in the estimated impacts. For pharmacies we have assumed a minimum item requirement of 60,000 per year before a pharmacy could utilise the hub, but dispensing doctors have different operating models to pharmacies, making it difficult to extrapolate assumptions. There could also be issues around supply to rural areas which could factor into decisions on take-up of hub dispensing. Around 50% of dispensing doctors have a dispensing volume greater than 60,000. If we assume that dispensing doctors have comparable uptake and get a similar scale of benefit from the use of hubs, then the NPV could increase by around 12% or £3.2m.

Impacts for the United Kingdom

100. The consultation is being issued jointly by the UK Department of Health and Social Care and the Northern Ireland Department of Health, and the proposed changes would apply throughout the United Kingdom. We do not have the same level of granularity on the pharmacy sector for Devolved Administrations, so this impact assessment has appraised for England only. If we assume that the impacts would be similar, and scale for the population (England population is 84%¹⁹ of UK population), then the NPV could increase to £32.5m.

Lower and Higher Scenarios

- 101. We have provided one central scenario but that should not reflect certainty in the results. The impact assessment has described the uncertainties across different areas and the difficulty in estimating the impacts of a permissive policy which could result in different business models to that on which the assumptions have been based.
- 102. We therefore also set out a lower and higher scenario. As previously discussed, private market research suggests that approximately 12% of independent pharmacies have definite intentions to adopt hub and spoke, whilst a further 40% are considering it. Feedback from pharmacies currently operating hub and spoke models suggests that a figure of approximately 40% to 60% of items can realistically go through a hub. Similarly, some pharmacy businesses already operating hub and spoke models had a minimum item requirement before a spoke could

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¹⁸ NHS BSA, PD1 Report 2020/21 https://www.nhsbsa.nhs.uk/prescription-data/dispensing-data/pd1-reports

¹⁹ ONS, Estimates of the population for the UK, England and Wales, Scotland and northern Ireland, 2020 <u>Estimates of the population for the UK, England and Wales, Scotland and Northern Ireland - Office for National Statistics (ons.gov.uk)</u>

- use the hub, which was around 60,000 prescription items a year, which is an assumption in the central scenario.
- 103. **Lower Scenario:** Like the central scenario, we assume that only spoke pharmacies dispensing over 60,000 items a year could use hubs, equivalent to a potential pool of 4,122 spoke pharmacies. We assume 12% (proportion who indicated that they were definitely interested) adopt hub and spoke within the next 10 years, and that none of those who were considering it would adopt it. This is equivalent to a take-up of 495 spoke pharmacies at year 10. This scenario also assumes that 40% of items go through the hub.
- 104. **Higher Scenario:** Of the spoke pharmacies dispensing over 60,000 items a year, we assume that 12% (proportion who indicated that they were definitely interested) adopt hub and spoke within the next 5 years, and that 40% (proportion that were considering it) would adopt it within 10 years. In addition, we assume that 25% of the 1,711 spoke pharmacies dispensing below 60,000 items per year take up hub and spoke within 10 years. This scenario also assumes 60% of items go through the hub. This scenario recognises that the information and modelling in our central scenario is primarily based on the experience of large pharmacy businesses who currently make use of hub and spoke. It therefore does not consider the possibility that alternative models of hub and spoke may arise over time, which may better suit smaller pharmacy stores and allow them to similarly benefit from more centralised dispensing models.
- 105. The results of these scenarios are summarised in Tables 10 and 11 below. The lower scenario is equivalent to 2% of items assembled at the hub by year 10 (20% when combined with baseline). The higher scenario is equivalent to 14% of items assembled at the hub by year 10 (32% when combined with baseline). The net present value is £6.4 million under the low scenario and £51.1 million under the high scenario.

Table 10: Lower Scenario - Aggregate impacts of proposed policy

Lower Scenario	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	NPV
Proportion of pharmacies dispensing below 60k/year using hub and spoke (%)	0	0	0	0	0	0	0	0	0	0	
Proportion of pharmacies dispensing above 60k/year using hub and spoke (%)	1.2	2.4	3.6	4.8	6.0	7.2	8.4	9.6	10.8	12.0	
Number of items going through hub (m)	2.3	4.5	6.8	9.0	11.3	13.5	15.8	18.0	20.3	22.6	
Set up costs at spoke (£M)	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	1.7
Cost saving at spoke (£M)	1.1	2.2	3.2	4.3	5.4	6.5	7.6	8.7	9.7	10.8	48.6
Cost of operating hub (inclusive of capital costs and depreciation) (£M)	0.9	1.8	2.7	3.6	4.5	5.4	6.3	7.2	8.1	9.0	40.5
Net Benefit (£M)	0.0	0.2	0.3	0.5	0.7	0.9	1.1	1.2	1.4	1.6	6.4

Table 11: Higher Scenario - Aggregate impacts of proposed policy

	Year	Year	Year	Year	Year	Year	Year	Year	Year	Year	NPV
Higher Scenario	1	2	3	4	5	6	7	8	9	10	INFV
Proportion of pharmacies dispensing below 60k/year using hub and spoke (%)	2.5	5.0	7.5	10.0	12.5	15.0	17.5	20.0	22.5	25.0	
Proportion of pharmacies dispensing above 60k/year using hub and spoke (%)	6.4	12.8	19.2	25.6	32.0	36.0	40.0	44.0	48.0	52.0	
Number of items going through hub (m)	19.0	38.2	57.2	76.3	95.4	107.7	120.0	132.4	144.7	157.0	
Set up costs at spoke (£M)	1.2	1.2	1.2	1.2	1.2	0.8	0.8	0.8	0.8	0.8	9.0
Cost saving at spoke (£M)	9.2	18.3	27.5	36.6	45.8	51.7	57.6	63.5	69.4	75.4	373.8
Cost of operating hub (inclusive of capital costs and depreciation) (£M)	7.6	15.3	22.9	30.5	38.2	43.1	48.0	52.9	57.9	62.8	311.5
Net Benefit (£M)	0.3	1.8	3.4	4.9	6.4	7.8	8.8	9.8	10.7	11.7	53.3

Risks and Sensitivities

- 106. Many of the assumptions in the impact assessment are based on evidence from the sector where they are already permitted to use hub and spoke dispensing. The proposed changes in legislation will facilitate two different hub and spoke dispensing models (spoke supplies medicine to the patient or hub supplies medicine to the patient) but we do not know what take-up will be of each of these models. It is reasonable to assume that the costs of these two models may differ, for example transport costs. However, stakeholders who were able to offer evidence which has informed this impact assessment only operate on the first model.
- 107. The key uncertainties in this IA are around the level of take up of hub and spoke services and the net level of savings to dispensing costs that could arise. Sensitivity analysis is conducted on each of these below. In our higher scenario we assumed that some of the spoke pharmacies dispensing below 60,000 items per year take up hub and spoke. This group of pharmacies is not considered further in the sensitivity analysis, and it only considers the potential 4,122 spoke pharmacies included in the central scenario which we think will benefit from the legislative change.

Changes in take up rates

108. Our central scenario assumed that 12% of pharmacies would adopt hub and spoke within the next 5 years whilst a further 20% would adopt over the next 10 years. This results in a 32% take up rate by year 10 of the policy proposal. Table 12 presents results of sensitivity analysis, based on alternative scenarios about take up of hub and spoke. All scenarios involve assuming a smooth take up trajectory over the course of the 5–

10-year appraisal period of this policy. Since the change in legislation is permissive, we have modelled the full range of uptake from 0% to 100%. We hope to use the Consultation to obtain a better sense of potential uptake.

Table 12: NPV for different rates of uptake of spoke pharmacies over 10 years

	10-yea	ar NPV
Percentage uptake	Uptake achieved by Year 5	Uptake_achieved by Year 10
10%	£11.0m	£7.0m
20%	£22.0m	£14.1m
30%	£33.0m	£21.1m
40%	£44.0m	£28.1m
50%	£55.1m	£35.1m
60%	£66.1m	£42.2m
70%	£77.1m	£49.2m
80%	£88.1m	£56.2m
90%	£99.1m	£63.2m
100%	£110.1m	£70.3m

109. This sensitivity scales the costs of the spoke and the hub at the same rate. There is a potential risk that there is overinvestment by the hub relative to the level of interest at the spoke. Since the majority of hub costs are likely to be fixed capital costs that cannot easily be changed in the short term, this would result in additional sunk costs being incurred. Ultimately hubs are private businesses who would need to conduct their own analysis and research into the level of market interest when deciding how much to invest in building hub capacity. The analysis in Table 13 suggests that, if we assume 70% of hub costs are fixed, then over investment by more than 10% results in a negative NPV. Similarly, Table 14 suggests that if 50% of hub costs are fixed, then overinvestment of more than 14% results in a negative NPV. This does suggest that is little scope for overinvestment, but we would expect hub businesses to invest in a reasonable and prudent way.

Table 13: NPV for different rates of uptake of pharmacies over 10 years, fixed costs of hub assumed to be 70%

NID	\			Р	ercentage	e uptake a	at spoke (at year 10	0)		
NP	V (£m)	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
at	10%	7.0									
	20%	-22.5	14.1								
planned · 10)	30%	-52.1	-15.5	21.1							
	40%	-81.6	-45.0	-8.5	28.1						
uptake (at yea	50%	-111.2	-74.6	-38.0	-1.4	35.1					
upt (at	60%	-140.7	-104.1	-67.6	-31.0	5.6	42.2				
ıtage hubs	70%	-170.3	-133.7	-97.1	-60.5	-24.0	12.6	49.2			
enta hu	80%	-199.8	-163.2	-126.7	-90.1	-53.5	-16.9	19.6	56.2		
Percentage hubs	90%	-229.4	-192.8	-156.2	-119.6	-83.1	-46.5	-9.9	26.7	63.2	
ď	100%	- 258.9	-222.3	-185.8	-149.2	-112.6	-76.0	-39.5	-2.9	33.7	70.3

Table 14: NPV for different rates of uptake of pharmacies over 10 years, fixed costs of hub assumed to be 50%

iiub a	Southed	to be 30	70								
ND	\			P	ercentage	e uptake a	at spoke (at year 1	0)		
I NP	V (£m)	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
at	10%	7.0									
	20%	-14.1	14.1								
planned · 10)	30%	-35.2	-7.1	21.1							
_	40%	-56.3	-28.2	0.0	28.1						
uptake p (at year	50%	-77.4	-49.3	-21.1	7.0	35.1					
upt (at	60%	-98.5	-70.4	-42.2	-14.1	14.0	42.2				
ıtage hubs	70%	-119.6	-91.5	-63.3	-35.2	-7.1	21.1	49.2			
ente hu	80%	-140.7	-112.6	-84.4	-56.3	-28.2	0.0	28.1	56.2		
Percentage hubs	90%	-161.8	-133.7	-105.6	-77.4	-49.3	-21.2	7.0	35.1	63.2	
ď	100%	- 182.9	-154.8	-126.7	-98.5	-70.4	-42.3	-14.1	14.0	42.1	70.3

Net savings to dispensing from hub and spoke

110. Overall, our analysis has assumed a net 7% efficiency gain from use of hub and spoke models. In the below table, alternative net savings figures have been considered to understand their impact on the NPV. Due to the training and set up costs at the hub, a break-even figure of 2% efficiency is required for the 10-year NPV to be positive. As previously discussed, this figure compares favourably to evidence on efficiency gains of automated dispensing coming from the hospital sector, and with feedback received from stakeholders already operating hub and spoke models within their existing retail pharmacy operations.

Table 15: NPV for different levels of efficiency gain

Net efficiency gain	10-year NPV
5%	£19.3m
10%	£43.2m
15%	£67.2m
20%	£91.2m
25%	£115.1m

- 111. Additionally, stakeholders mentioned the following factors affecting their ability to realise further efficiencies from hub and spoke models and potentially increase the net 7% efficiency gain from use of hub and spoke models:
 - GP engagement and use of electronic repeat dispensing the earlier and more predictable prescribing is, the more efficiently workflow can be managed within the hub. Where prescriptions are issued late, they may not be eligible for hub dispensing if the patient is likely to need their prescription before the minimum turnaround time at the hub.
 - Patient timing if patients change their mind or require their medicines more urgently, then these may need to be fulfilled at the spoke.
 - Shortages and other stock restrictions (such as direct to pharmacy lines) may also reduce the number of items that can be fulfilled at the hub.
 - Other operating disruptions such as delivery delays or logistics interruptions.

Competition risks

- 112. Finally, as noted elsewhere in this IA, the proposed policy may have impacts on competition within both the pharmacy and wholesale sector, which must be considered. At one level, the proposed policy is intended to create a level playing field between large retail pharmacy chains and smaller independent pharmacies, by allowing the latter group better access to automation and new dispensing models that the larger retail groups already have. However, by concentrating larger volumes of dispensing activity within a smaller number of hub pharmacies, this potentially creates competition risks further down the supply chain.
- 113. It is difficult to determine the likelihood or size of this risk as there are so many possible scenarios that could arise. As previously discussed, the number of hubs and their likely size and scale will depend on the number and type of entrants into the market. We are aware of at least one new independent hub supplier intending to offer hub services to a large number of independent pharmacies, however we have less information

- on whether other smaller hub suppliers may also emerge, or whether the retail pharmacies already operating hub and spoke models may wish to extend their services to independent pharmacies.
- 114. In addition, other factors, such as the ease of switching between different hubs will also affect the degree of competition within the market. In our consultation, we propose that there will be no limits on the number of hubs that a single spoke can contract with.
- 115. The higher the degree of competition between hub pharmacies, the greater the share of benefits we would expect to fall on spoke pharmacies, whilst conversely limited competition over hub services may result in hub pharmacies capturing a larger share of the savings. However, it is also important to remember that spoke pharmacies are not required to contract with a hub, and so will only choose to do so if the terms of the arrangement are expected to be favourable to them.
- 116. Finally, as previously noted, the number and type of hub pharmacies that arise could also have implications for competition with the wholesale market. For example, if wholesalers themselves choose to offer hub services, a spoke pharmacy may purchase all their medicines from the wholesaler, which could serve to limit competition amongst wholesalers. Another possibility is that where smaller wholesalers choose to also offer hub services, they will need to expand the range of products that they can access to enable them to compete more effectively with the full-line wholesalers who may also be offering hub services.
- 117. These risks are mitigated by competition law which aims to promote healthy competition. It bans anti-competitive agreements between businesses and makes it illegal for businesses to abuse a dominant market position. The Competition and Markets Authority (CMA) identifies markets where competition is not working well and tackles the constraints on competition in these cases using the competition and enforcement tools that it considers most appropriate. They would have the ability to take action in the event that any anti-competitive behaviour was identified.
- 118. Access to a fair and competitive hub market that is not dominated by one supplier would be for the CMA to consider. Where a business grows through acquisitions, the CMA may investigate if it has jurisdiction to do so (i.e. if the target company has a UK turnover of £70m+ or the merger partners account for 25% or more of the supply of goods or services in the UK or a substantial part of the UK).

Maximum Theoretical Benefit of Hub and Spoke

119. Stakeholders currently making use of hub dispensing have mentioned several barriers to maximising the potential of hub and spoke. For example, original pack dispensing has the potential to increase any efficiency that may be available from the use of large remote pharmacy hubs assembling medicines, and earlier and more predictable prescribing could allow more throughput at the hubs. The below scenario

is provided to give a sense of what might be achievable if all these barriers were removed. This scenario covers all pharmacies, including those making use of hub dispensing under the current legislation and is therefore not an assessment of this specific policy to make legislative changes.

120. Repeat prescriptions make up around 77%²⁰ of all prescription items. We are aware that there will be some prescription items that are not suitable for dispensing at the hub. As a proxy we've considered NHSBSA data²¹ to determine that 78% of items dispensed are in "tablet" or "capsule" form. Combining these two bits of information could suggest that the maximum proportion of items that could be assembled at hubs is 60% (77% x 78%). If we also use the market research as a basis for assuming that 52% of the whole sector will be using hub and spoke dispensing at Year 5, then this translates to 320m items or 31% of all dispensing. The NPV under this scenario would be £162m. If the entire pharmacy sector took up hub and spoke dispensing by Year 5, then 60% of all dispensing would go through hubs and the NPV would be £312m.

Conclusions

- 121. Overall, the policy proposals to make legislative changes to the Medicines Act 1968 and the Human Medicines Regulations 2012 to facilitate 'hub and spoke' dispensing between different legal entities has a positive Net Present Value and therefore is the recommended option. The level of take up of hub and spoke services and the net level of savings to dispensing costs will be key in achieving the estimated NPV.
- 122. The proposals are enabling. Pharmacies are not required to operate hub and spoke dispensing and it will be for each pharmacy to decide if they want to utilise this model of dispensing. We assume a pharmacy will only choose to do so if the terms of the arrangement are favourable to them.
- 123. Wider non-quantified benefits are expected from the policy proposal such as a positive impact on patient safety, the benefits to patients and the reduction in pressure of the NHS of more services delivered in community pharmacy.
- 124. The number of hubs that might arise is difficult to predict as it will depend on the types of hubs that may be offered and the different range of possible providers. In turn, it is difficult to determine what impacts the proposed policy may have on competition within both the pharmacy and wholesale sector.

²⁰ Letter template (england.nhs.uk)

²¹ NHSBSA, Prescription Cost Analysis – England 2020/21 Prescription Cost Analysis – England 2020/21 | NHSBSA

<u>Annex A – Review of published evidence of automated dispensing</u>

Table A1 Summary of evidence on impacts of installing an automated dispensing system (ADS) on efficiency and patient safety

Publication	Setting	Study design	Impact on efficiency	Impact on patient safety
James et al. 2013.	UK hospital pharmacy dispensing ~2,000 items per week.	Before-and-after study.	Positive: median no. of items dispensed per person per hour increased from 9.20 to 13.17 (p-value < 0.001). Implies time saving of approx. 2 minutes (6.5 mins to 4.5), or 30% reduction in time per item.	Positive: fall in rate of prevented dispensing errors from 0.64% to 0.28% (p-value <0.0001).
Fitzpatrick et al. 2005.	UK hospital pharmacy dispensing ~3,000 items per week.	Before-and-after study.	Positive: reduction in staff time on dispensing from 458 to 371 hours per week. Coincided with increase in volume of dispensing. Implies minimum time saving of 2 minutes (from approx. 9 minutes to approx. 7 mins), or 20% reduction in time per item.	Positive: fall in rate of prevented dispensing errors (error rates and p-values not reported).
Franklin et al. 2008.	Two UK hospital pharmacies each dispensing ~4,000 items per week.	Controlled before-and-after study comparing different ADSs.	Positive: there was a significant reduction in median picking time per item, but no impact on labelling or assembly times.	Positive: fall in rate of prevented dispensing errors from 2.1% to 1.0% on site 1 (p-value < 0.05), 1.2% to 0.6% on site 2.

James LK, Barlow D, Bithell A et al. The impact of automation on workload and dispensing errors in a hospital pharmacy. *Int J Pharm Pract* 2013; 21: 92–104.

Fitzpatrick R, Cook P, Southall C et al. Evaluation of an automated dispensing system in a hospital pharmacy dispensary. *The Pharmaceutical Journal* 2005; 274: 763-765.

Franklin BD et al. An evaluation of two automated dispensing machines in UK hospital pharmacy. Int J Pharm Pract 2008; 16: 47–53.