Hub & Spoke

Research review

National Pharmacy Association

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1.0 Executive summary

This research identifies that large scale automated dispensing remains very limited globally, despite the technology to facilitate being established for at least 15 years.

Two modes of automated dispensing are identified:

Automated Dose Dispensing (or ADD) whereby one or more medicines are dispensed into a container or pouch for a patient to take at a particular date or time[1]. This mode of automated dispensing is common across northern Europe and is discussed further below.

Standard Dispensing whereby medicines for a period of supply are dispensed either by original pack or into vials. This mode of dispensing – often referred to as Central Fill – is most frequently associated with dispensing loose pills into vials, and is most common in Northern America.

The exception to this is The Netherlands, where automated "central fill" using original packs, is common practice. Most multiple community pharmacies use this process, and circa one third of independent pharmacies use such a process provided by a 3rd party.

These modes of automated dispensing are discussed further in this section below, and in detail in the main body of the report.

1.1 Automated Dose Dispensing (or ADD)

ADD is common throughout Scandinavia and northern Europe, and has been established in several of these markets for at least 15 years.

The most established appear to be The Netherlands and Sweden.

ADD is considered to be mainstream in The Netherlands, and an example of pharmacy good practice, serving in the range of 400,000 principally elderly patients primarily in care homes. In Sweden this number is approximately 200,000.

Authoritative data on ADD is not maintained in any of these markets, and this paper has had to rely on local estimates.

[1] As defined by EDQM (European Directorate for the Quality of Medicines & Healthcare). Automated Dose Dispensing Guidelines. Version dated 26 September 2016.

1.2 Standard Dispensing (or "Central Fill")

1.2.1 Europe

The only European market to enable "central fill" is The Netherlands, where 3rd parties can dispense pre assembled standard prescriptions to pharmacies. No authoritative data is maintained on this market. However, most multiples use "central fill," in addition to circa one third of independents, who buy the service from their wholesaler.

Field visits were undertaken to The Netherlands, in addition to a telephone interview and email correspondence with KNMP. The Netherlands is discussed in detail at section 4.1 of this report. An in depth report on the field visits is also available.

1.2.2 Rest of the world

The highest volume, automated dispensing operations may be in the U.S, where it is it was estimated that 34% of all US retail pharmacy prescriptions were dispensed via central fill in 2016[2] (noting that major multiple chains account for more than 60% of US dispensing.)

The same report also observes the rapid decline of "pouch packaging" in the US from 2014 onwards, as patients failed to convert to the new system (after a rapid rise from 2010 to 2013.)

However, as central fill operations primarily serve proprietary businesses, definitive or authoritative data is not available in the public domain.

For example, Rite Aid opened a facility to serve up 1,100 owned pharmacies across 4 states in 2014. However, it is reported this facility is to close with the loss of more than 100 jobs as a result of the sale of Rite Aid stores to Walgreens. This would be one of the largest facilities identified by this research.

The U.S. remains more focussed on the filling of loose pills into patient vials, hence the phrase "central fill" by which centralised dispensing is generally referred in the US. The US and Canada are discussed in detail at sections 5.1 and 5.2 of the main report.

Distinctive characteristics of the US healthcare and pharmacy system, including much greater focus on dispensing loose pills into vials, mean learnings that are relevant to the UK from the US may be fewer rather than greater.

The Chronic Dispensing Unit (CDU) in Cape Town, South Africa may be the largest global reference site for single site, large scale centralised dispensing. Whilst the degree to which this facility is automated remains unclear, it dispenses circa 350,000 Patient Medicine Parcels per month to a network of more than 1,200 pharmacies and collection points.

[2] **Beyond the Counting Tray: Current and Emerging Pharmacy Automation and Technologies**. Christopher Thomsen, President, The ThomsenGroup Inc.
https://www.asapnet.org/files/January2016/Presentations/ASAPJan16_Presentation_11_Thomsen.pdf

The CDU is well documented via public sources. The one in depth independent study by Magadzire et al is sceptical as to whether hard, independent evidence to support its success is available. The CDU is discussed in detail at section 6.1 of the full report.

1.3 Conclusions

With the notable exception of the Netherlands, the large scale automated dispensing of original pack medicines to third party pharmacies is not apparently operational in any global market[3].

Where 3rd party automated dispensing has had most traction, in northern Europe, its focus is on multi dose dispensing.

The economic case for the aggregation and automation of dose dispensing appears to make good economic sense in principle. However, demonstrable cost benefit cases have not been uncovered by this research, and many independent researchers also point towards the absence of hard economic evidence to support further investment. In The Netherlands, where this mode of dispensing may be most embedded, pharmacies receive premium remuneration for ADD patients.

The majority of independent studies also identify a similar absence of definitive evidence in respect of patient safety.

Several studies identify that whilst accuracy gains may be made in the part of the process that is automated, new processes are introduced pre and post automation. New processes introduce new risks, and no studies that address the patient safety impact of the full end to end process have been conducted to date.

In the round, independent studies consistently question whether both the economic, or patient / consumer benefit cases for large scale automation have been established by independent data and evidence.

In light of the above, the following factors should be considered:

1. **Feasibility**. At the present time, there do not appear to be any large scale pharmacy hubs in operation serving more than hundreds of third party pharmacies and thousands of patients. Where automated volumes are greatest, they are concentrated on multiple chains, and also on loose pills counted into vials as opposed to original pack dispensing

2. **Economic.** Building on the above, several academic researchers have identified the absence of cost benefit cases in the automated dispensing scenarios they have researched. It would therefore be welcome to see evidenced cost benefit cases

3. **Patient safety.** Many claims for the patient safety benefits of large scale automation have been made. A much more conservative tone is observed amongst academic

[3] ~The apparent focus in the US in on loose pills into vials. It is possible large scale "central fill" facilities dispensing original packs are operational in the US, but this research has not identified them.

researchers, who note the case may not be proven one way or the other. More rigorous independent research is required.

A more detailed treatment of these factors, with supporting, referenced evidence, is set out at section 8.0 of the main report.

At a glance: useful facts & figures

OUTSIDE EUROPE

- 34% of all US retail pharmacy prescriptions were dispensed via central fill (noting that major multiple chains account for more than 60% of US dispensing.)
- US market leader McKesson claims its systems processed 157 million prescriptions in 2011. This is the single largest volume reported, although it is clear these volumes were achieved across multiple sites.
- McKesson state that successful operations can service up to 50% of total prescriptions via central fill
- The CDU (Chronic Dispensing Unit) in Cape Town had dispensed circa 18 million medicine parcels since foundation in 2005 serving at least 350,000 patients. It is one of the world's largest centralised dispensing units.
- "Pouch packaging" is reported as rapidly declining in the US from 2014 onward, after a rapid rise from 2010 to 2013) as patients fail to convert to the new system
- The CDU now outsources dispensing to a 3rd party at a cost of circa £1.30 per item (Rand 21.51) and serves a network of 1,200 pharmacies and community dispensing points

EUROPE

- Pharmacy2U (P2U) dispensed more than 250,000 items in December 2017, a run rate of 3 million per annum, from their automated facility in Leeds. P2U state their capacity is 1 million per month, or 12 million per annum. This is one of the world's larger automated facilities.
- At least 400,000 patients in The Netherlands are served by Automated Dose Dispensing (ADD) at a cost of circa Euro 3.45 per week. Dutch pharmacies receive premium remuneration for ADD patients.
- In Sweden, circa 200,000 patients receive their medicines via ADD
- Circa 200 of The Netherlands 600 independent community pharmacies outsource to 3rd party central fill providers at a cost of circa Euro 1.0 per item

- The market leading supplier of central fill to 110 independent pharmacies in The Netherlands operates 6 large scale robots across 2 sites. However, up to 40% of items are dispensed via their manual central filling hub (slower moving lines)

- 5 of the first 20 automated dispensing sites inspected independently by the Dutch health authority have ceased to operate since inspection. This is because automated dispensing was unregulated until recently, and standards have only recently been enforced.

- The large scale ADD machines in The Netherlands serve circa 2,000 patients per week, generating 40 – 45k personalised pouches per week.

- There are between 150 – 200 large scale ADD machines operating in The Netherlands across 5 major suppliers.

- If an average pharmacy in England serves 100 MDS patients, then more than 500 machines would be required (circa 1.2 million patients)

- The Dutch ADD market is worth circa Euro 72 million per annum (c £63 million.) At an equivalent volume and fee structure, the market value in England would be circa £250 million p.a.

- A Dutch independent pharmacy owner claimed his stock holding had reduced by as much as 50% due to central fill and other measures

2.0 Introduction

2.1 General introduction

This paper explores the deployment of large scale pharmacy automation globally, to help inform a sectoral response to any future discussion or consultation on the enablement of third party automated dispensing from hubs to spokes (frequently referred to as “hub & spoke”)

2.2 Methodology

This paper has been informed through

a. Extensive desk research
b. Structured questionnaire, circulated to PGEU members by PGEU secretariat, with replies forwarded back to the author
c. Structured questionnaires sent to markets identified via above process in which 3rd party automated dispensing is enabled.
d. Further email communication and telephone interviews with colleagues in PGEU member associations including The Netherlands, Sweden, Germany and Belgium.

In addition, through the desk research process, a review of independent studies into automated dispensing has been conducted.

a. Extensive desk research

Extensive, informed online research has been conducted, uncovering independent and proprietary studies and information sources. Greater significance has been weighted towards independent studies and reviews. Many useful proprietary sources of information have been found, but as these as are frequently published by an organisation wishing to promote the benefits of automated dispensing, greater weight has been assigned to independent sources when available.

In addition to published papers, sources of information have included national, regional and trade press, online videos and websites of relevant organisations. Care has been taken to reference sources quoted throughout the paper via footnotes.

b. Structured questionnaire, circulated to PGEU members by PGEU secretariat

A structured questionnaire was circulated to all PGEU members and administered via the PGEU secretariat. To date, 21 replies have been received. Those who did not reply included only smaller nations in terms of both population and GDP.

3rd party dispensing enabled	No 3rd party dispensing	No reply
Belgium	Bulgaria	Austria
Denmark	Croatia	Cyprus
Finland	Czech Republic	Greece
Germany	Estonia	Hungary
Netherlands	France	Greece
Sweden	Poland	Hungary
	Portugal	Iceland
	Romania	
	Slovakia	
	Slovenia	
	Spain	
	United Kingdom	
6 nations	**12 nations**	**7 nations**

6 nations confirmed 3rd party dispensing was enabled. It should be noted that Norway are not a PGEU member, but 3rd party dispensing is enabled, therefore at least 7 European markets are 3rd party dispensing enabled.

Questions asked:

a. Do you outsource some processes related to the preparation of the patient medication (excluding magisterial formula). This will include repeat prescriptions, split dispensing/unidose, selection labelling and packaging of medicines?
b. If you do, what licence does the organisation doing the initial preparation of the medicine hold (eg, a pharmacy licence, a wholesale licence or a manufacturing licence)
c. Are there any circumstances in which a pharmacy can supply a medicine to another pharmacy

c. Structured questionnaires sent to markets identified via above process in which 3rd party automated dispensing is enabled.

The following questionnaire was sent to markets where 3rd party dispensing is enabled: Belgium, Netherlands, Finland, Germany, Netherlands, Sweden. Replies have informed the report below. The questionnaire was tailored to be specific to local market terms.

1. Do you know how many pharmacies in Germany use the *Patientenindividuelle Verblisterung* mode of supply? I understand from your briefing note that this remains a rather exceptional mode of supply in Germany. Do you know how many pharmacies use this mode of supply?
2. Do you know how many patients in Germany use the *Patientenindividuelle Verblisterung* mode of supply? Do you know, or can you estimate, how many patients use this mode of supply? For example, we understand that about 180,000 patients in Sweden receive their prescribed medicines via automated MDD from pharmacies.
3. How many *"Blisterzentren"* operate in Germany? Please estimate if actual numbers are not available.
4. What type of business own these *"Blisterzentren"?* Are they owned by full or short line pharmaceutical wholesalers? Or are they owned by different types of business – for example, no pharmaceutical distribution specialists?
5. Are *"Blisterzentren"* dispenses sent direct to the patient's home or care facility, or are they are sent to a pharmacy for onward distribution?
6. Are the majority of *"Blisterzentren"* dispenses for elderly patients in care homes? For example, we understand in Sweden that 80% of patients are 65 years or older, with about 40% living in ordinary housing, and about 60% living in care home for the elderly. Is this the case in Germany?
7. How long have *"Blisterzentren"* been operational in Germany ? I understand from your briefing paper that this mode of supply has been possible since 2005?
8. Is *Patientenindividuelle Verblisterung* considered to be a positive development in Germany (a) by pharmacists (b) by pharmacy owners (c) by patients?
9. Will the Falsified Medicines Directive have any impact on *Patientenindividuelle Verblisterung* in Germany? I note the following in your briefing note "A new side aspect which is currently discussed is how such dispensing models fit into the new EU regulations against falsified medicines. All packages of prescription-only medicines will have to bear a 2D barcode from February 2019. How "Blisterzentren" or "Central Hubs" could fit into this new system, without opening the door to new risks of introducing potentially falsified medicines, is not clear."
10. Are any other types of large scale automated dispensing used in Germany? We are most interested in large scale automation or robotics used outside of community pharmacies. E.g. in regional or national distribution centres.
11. Are there any other developments or potential developments in Germany that may be relevant to this research?

d. **Further email communication and telephone interviews with colleagues in PGEU member associations including The Netherlands, Sweden, Germany and Belgium**.

Telephone interviews and email correspondence requesting further information were conducted with:

Michael Jung, In house lawyer, ABDA – Federal Union of German Association of Pharmacists

Johan Waller, CEO, Swedish Pharmacy Association

Frans Moss, Advocaat, KNMP – Royal Dutch Pharmaceutical Association

2.3 Terminology

This document uses a number of working definitions to ensure consistency and clarity. The following terms and working definitions are continued from (MH's original)

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 . We also refer to this type of operation as a Regional Wholesaler. 9

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.

The following new terms and working definitions have been introduced:

Automated Dose Dispensing (ADD) – A system to dispense an individual patient's regular medicines, with bags, containers, or a box with boxes, into which medicines are packed by machine in day or time specific units. Typically medicines are dispensed into hose pouches.

GDS – the term used specifically in The Netherlands for ADD. See section 4.1 for detailed definition

Baxtering – the colloquial term used in the Netherlands for GDS, sometimes abbreviated to "baxing,"

Central Fill – the term widely used in both the US and Netherlands to describe either manual or automated central dispensing of medicines forwarded in patient specific packaging to a forward pharmacy (i.e. "spoke") for supply to the patient.

"Blisterzentren" – translated from the German as "blister centres," this is the local term to describe ADD centres in Germany

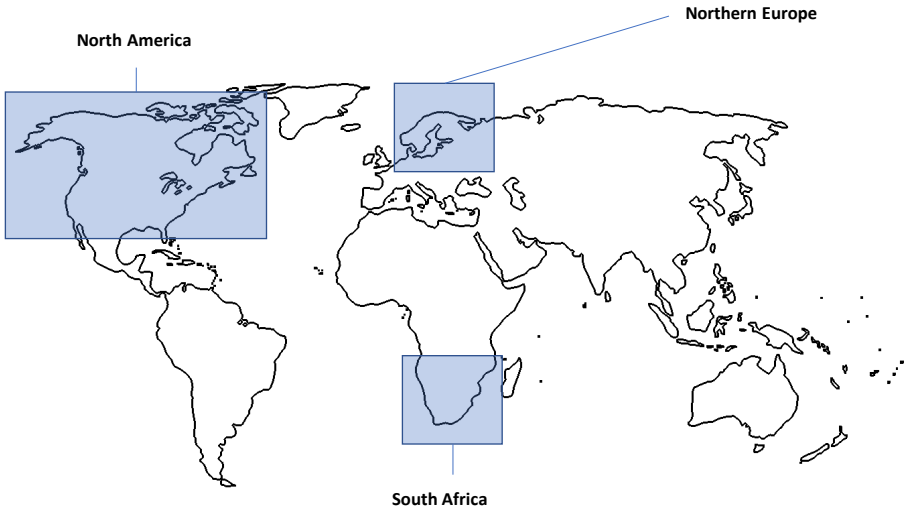
3.0 Current situation worldwide

Automated dispensing is widespread worldwide.

However, most automated dispensing remains operational on single sites such as hospitals and large community pharmacies.

The most documented centres of multi site automated dispensing are Northern Europe, North America and South Africa. Swedish researchers Bardage & Ling report in their 2016 study that automated dispensing is "increasingly used in the US and through Europe e.g., in Sweden, Denmark, Finland, Germany, The Netherlands and Norway."

This section will discuss the prevalence and features of automated dispensing in each of the above geographies.



The 3 main centres of automated dispensing appear to be Northern Europe, North America and South Africa.

4.0 Northern Europe

Automated dispensing is prevalent across Northern Europe, including the Scandinavian countries of Sweden, Norway, Denmark and Finland, as well as The Netherlands, Belgium and Germany.

By far the most common form of large scale automated dispensing is Automated Dose Dispensing, defined for the purpose of this paper as:

> *A system for an individual patient, with bags, containers, or a box with boxes, in which medicines by a distribution or packing machine are packaged in units per application time*[4].

In contrast, automated dispensing is much less common and less enabled across the rest of Europe including France, Italy and Spain.

Not only is large scale automated dispensing common across Northern Europe, but academic researchers have published studies into the benefits and disbenefits, including teams of academics from universities in Sweden, Finland, Denmark and The Netherlands.

1.	**A Systematic Review of Automated Dose Dispensing in Primary Health Care** Sinikka Sihvo, Jaana Isojärvi, Marja Blom, Marja Airaksinen and Antti Mäntylä Value in Health 14(7), November 2011
2.	**Patients' Perspectives on Automated Multi-dose Drug Dispensing** C Bardage and L Ring Journal of Community Medicine & Health Education, 2016, 6.1
3.	**Health care professionals' perspectives on automated multi-dose drug dispensing** Carola Bardage, Anders Ekedahl, Lena Ring Pharmacy Practice (Granada). 2014 Oct-Dec; 12(4): 470. Published online 2014 Mar 15.
4.	**Medication Incidents Related to Automated Dose Dispensing in Community Pharmacies and Hospitals - A Reporting System Study** Ka-Chun Cheung , Patricia M. L. A. van den Bemt, Marcel L. Bouvy, Michel Wensing, Peter A. G. M. De Smet Plos ONE, July 24, 2014
5.	**From machine to mouth How can automated dose dispensing lead to safer and more effective patient medication?** B Frøkjær*, L Thomsen*, H Herborg*, L Fonnesbæk**, G Pedersen** * Pharmakon, Danish College of Pharmacy Practice ** Danish Society for Patient Safety https://www.fip.org/files/fip/CPS/Charlotte_Rossing1_poster.pdf

[4] **Standard for automated drug distribution system**. Adopted during the meeting of the Executive Board of the KNMP. September 28, 2011 in The Hague

6. Impact of the automated dose dispensing with medication review on geriatric primary care patients drug use in Finland: a nationwide cohort study with matched controls
Juha Sinnemäki, Marja Airaksinen, Maria Valaste & Leena K. Saastamoinen

Scandinavian Journal of Primary Health Care. 35:4, 379-386,
DOI: 10.1080/02813432.2017.1398933

This section now describes the features of large scale automated dispensing in each of Sweden, Norway, Denmark, Finland, The Netherlands, Belgium and Germany.

As The Netherlands and Sweden are the leading proponents, this section focusses on those nations first.

4.1 The Netherlands

Medium to large scale automated dispensing is well established in The Netherlands, and has been for more than 10 years. In fact, The Netherlands may have embraced pharmacy automation more than any other market globally. There are 2 distinct forms of automated dispensing from hubs:

GDS (the local term for ADD)
Central fill

GDS

This mode of dispensing has been well established for over 10 years, and is referred to colloquially as "baxtering" (after the "baxter" pouches into which the medicines are inserted.)

The KNMP first issued a GDS directive in 2013, which it described as "care for patients with medicinal products in an individualised distribution form." The KNMP set out a number of definitions which are helpful:

GDS (Automated Drug Distribution System)
A system for an individual patient, with bags, containers, or a box with boxes, in which medicines by a distribution or packing machine are packaged in units per application
time.

GDS pharmacy
Pharmacy that has an automated drug delivery system for the packaging of medicines

GDS pharmacist
Pharmacist working in a GDS pharmacy. The established pharmacist is the responsible for the entire GDS process, but the GDS pharmacist does not have to be the established pharmacist.

GDS device
Device using which medicines are distributed and packaged in units per application time, and in the name of an individual patient asked.

GDS packaging
Packaging in which medicines are divided into units per time of administration and in the name of an individual patient (e.g. trays or baxter bags).

Local pharmacy
Pharmacy that accepts the prescription of the patient and the packaging of the administer medicines in units per application time by one

Primary packaging
The part of the original factory packaging that is in direct contact with it medicine.

Source: KNMP[5]

This mode of dispensing is considered good or best practice in The Netherlands to patients in care homes.

[5] **Standard for automated drug distribution system**. Adopted during the meeting of the Executive Board of the KNMP. September 28, 2011 in The Hague

This directive references that in 2011, the average number of patients per public pharmacy receiving GDS dispensed medicines was 181, and that number grew 22% between 2010 and 2011.

It appears that at least 360,000 patients regularly receive MDD packs via their local pharmacies from automated hubs, representing circa 2% of the total population. KNMP have reported they believe this number has plateaued in recent years[6].

No official data is maintained, despite the fact that the Dutch market is one of the best measured and monitored across Northern Europe.

Central fill

Ordinary prescriptions can also be fulfilled in The Netherlands by 3rd party hub operations. This is referred to locally as "central fill."

Data about "central fill" is elusive – "baxtering" is higher profile, and more widely researched and documented.

The same businesses as offer GDS also offer Central Fill.

KNMP issued standards for Central Filling in 2010. Key points to note include:

- The central filling process can be (a) fully automatic (b) semi-automatic or (c) manual.
- Medicines are not removed from their original packaging in central filling pharmacies.
- A central filling pharmacy must comply with the Medicines Act and the Medical Treatment Contracts Act (WGBO). The vast majority of pharmacies use the services of a specialized company, which is legally a pharmacy. Some pharmacies have their own central filling equipment.
- The central filling pharmacy is the legally responsible pharmacy, responsible for dispensing medication from anonymous stock in the name of the patient, medication monitoring and patient education. However, medication monitoring and patient education may be better carried out by the home pharmacy. Division of responsibilities must be recorded in the contract between central filling and home pharmacy.
- Final responsibility for all central filling activities rests with the established pharmacist of the central filling pharmacy.
- The home pharmacy must inform every patient that their medicines will be dispensed by a central filling pharmacy outside the home pharmacy. There is a process at the home pharmacy for patients who object.
- The home pharmacy is responsible for requesting the right drug in the right dosage for the right patient in accordance with a prescription signed by a competent prescriber
- After a check of the application, the central filling dispenser will make ready the medicines as requested

[6] Telephone interview with Frans Moss, Advocaat, KNMP, March 2018

- The central filling pharmacy is responsible for packing the right medicine in the right strength and quantity for the right patient on the basis of the right request.
- The central filling pharmacy is responsible for the label. The patient label must comply with the Medicines Act. On the label is the name of both the home and central filling pharmacy.
- The central filling pharmacy ensures that the manufacturer's leaflet is included in the medicine package and is delivered to the patient.
- The central filling pharmacy ensures that the prepared medicines are transported in proper central fill packaging which guarantees the integrity of the executed job
- The release of the finished drug is overseen by the established central filling pharmacist in accordance with a fixed procedure
- After receipt, the home pharmacy will arrange the storage of the ready medicines in such a way that the quality of the medicines are guaranteed.
- Opiates can be dispensed by a central filling pharmacy, provided that required conditions are met
- Fridge products may also dispensed by a central filling pharmacy if the required conditions are met
- The established central filling pharmacist is ultimately responsible for quality management
- An internal audit schedule is drawn up annually
- Every year an annual report outlines the overall picture of performance, with quantitative and trend analysis
- The central filling pharmacy that supplies medicines intended for individual patients, at all times, has the final responsibility for the medication supply as well for the related pharmaceutical care, unless the distribution of responsibility is otherwise laid down in a contract with the home pharmacy

Source: KNMP[7]

[7] **Standard for Central Filling** . Adopted at the meeting of the Executive Board of the KNMP on 28 April 2010 in The Hague. https://www.knmp.nl/praktijkvoering/richtlijnen/knmp-richtlijnen-praktijkvoering/knmp-richtlijn-central-filling-april-2010

4.1.2 Market structure

a. Retail market

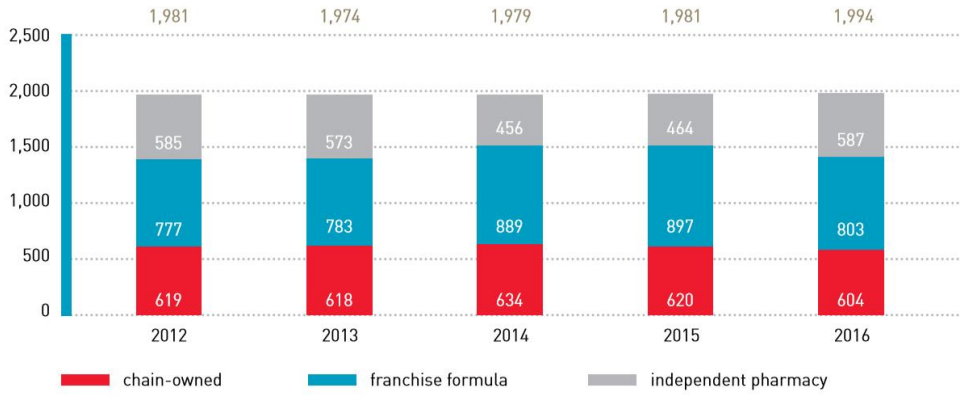
There are circa 2,000[8] pharmacies in The Netherlands, serving a population of circa 16.8 million. There is one pharmacy for every 8,390 heads of population, compared to 4,844 in the UK and 3,890 in Germany.

The Netherlands has a lower pharmacy density to population than most other northern European markets.

Market	Population per pharmacy
Belgium	2,208
Germany	3,890
UK	4,844
Sweden	7,745
The Netherlands	**8,390**
Denmark	20,009

The Dutch pharmacy market features a mix of chain-owned, franchised and independent pharmacies, with SFK reporting that 29.4% of community pharmacies remain in independent ownership.

Number of community pharmacies subdivided in chain-owned, franchise formula and independent pharmacies (2012-2016)



More public pharmacies in total but fewer chain-store and formula pharmacies.

Source: Foundation for Pharmaceutical Statistics | Stichting Farmaceutische Kengetallen

A similar proportion are chain owned (30.2%) with the largest single segment in the franchise category (40.2%)

[8] SFK – the statistical wing of KNMP – report that at the end of 2016, there were 1,994 community pharmacies in The Netherlands.

The largest chain is BENU, with circa 300 branches or 15% of the market. BENU was created in 2016 when the Mediq chain was acquired by one of the two largest wholesalers, Brocacef, which is a joint venture between Celesio and Phoenix. The consequent closure of 89 branches at the instigation of the Authority for Consumers & Markets (ACM) led to a retraction of the chain owned segment.

Walgreens Boots Alliance operate "more than 60 branches" under the Boots brand [9].

Alphega also have a presence with 103 branches listed on their local website [10]

b. Wholesale market

Four full line wholesalers operate in The Netherlands.

Brocacef serve circa 600 pharmacies, including the 300 BENU pharmacies which they own. Brocacef are a joint venture between Celesio and Phoenix. Phoenix is the senior partner, with a 55% share [11]. The business remains described as "A Phoenix Group company [12]" Turnover for 2016/17, including BENU pharmacies, was reported at E1,959 million. [13]

Mosadex are a co-operative wholesaler serving circa 700 pharmacies, operating 3 distribution centres. The organisation was founded by a group of pharmacists in 1986, and it's website describes it as having a "strong co-operative character." [14] Mosadex also run NAPCO, a negotiating group on behalf of their members to use scale to agree improved terms with Dutch healthcare insurers [15]. NAPCO stands for Dutch Pharmacists' Co-operative.

Pluripharm serve circa 300 pharmacies who are primarily independent (with some operating in small chains or groups), constituting circa 14% market share. As described further below, Pluripharm also operate Pluripack, a subsidiary specialising in "central fill" and "baxtering."

Pluripharm also operates a negotiating group, similar to but smaller than Mosadex, described above, called PACT [16].

SPITS are WBA owned, and the smallest of the full line wholesalers, with circa 10% market share (circa 200 pharmacies.)

There is an active short line market in The Netherlands. However, it is possible to buy medicines from short liners via full line wholesalers.

Most Dutch community pharmacies use a sole wholesaler.

All the businesses above offer 3rd GDS and Central Fill.

[9] Source: https://nl.boots.com/mijn-bootsapotheek/over-boots/
[10] Source: https://www.alphega-apotheek.nl/apotheekzoeker
[11] Source: https://www.mckesson.eu/mck-en/company/business-in-europe/netherlands
[12] Source: http://www.brocacef.nl/site/
[13] Source: http://jaarverslag.brocacef.nl/2016-17/
[14] Source: https://www.mosadex.nl/perl/site.pl/user/content/about
[15] See http://napco.nl/cooperatie/ for more information
[16] See http://www.pluripharm.nl/home/nieuwsPact.html for more information

c. Discussion

The Dutch market has notable differences to the UK.

The franchise sector is much further developed and significant in scale. Pharmacies typically serve a larger population than in the UK (noting that population density in The Netherlands is also higher than in the UK.)

The absence of a national health system also means the principal commercial relationships are with the insurance businesses. Independent pharmacies have formed negotiating groups aligned with wholesalers to seek to leverage scale advantage in these negotiations.

Typically Dutch pharmacies have a solus relationship with a wholesaler.

The insurers are highly commercial in outlook, and look to drive costs down. As a consequence, owning a community pharmacy in The Netherlands is considered much less financially attractive than in previous years.

4.1.3 Field visits

Two field visits were conducted, in addition to a telephone interview and email correspondence with KNMP.

Visit 1: (a) Zoetermeer and (b) Verpakapotheek

On Thursday 19 April, Mike Hewitson, Neil Bhayani and David Simons visited Apotheek Oosterheem in Zoetermeer, accompanied by Steffen Kramer of Willach, who kindly arranged the visit at the request of David Simons.

The group then proceeded to Verpakapotheek (literal translation: the packaging pharmacy) based in Warmond. The visit was arranged by David Simons.

Visit 2: (c) Pluripack and (d) Hoogeveen

On Thursday 26 April, David Simons visited Pluripack in Zwolle, organised by himself.

Pluripack then kindly accompanied David to visit a pharmacy that used their central fill service in Hoogeveen.

Telephone interview and correspondence with KNMP (Royal Dutch Pharmaceutical Association)

Overall context was provided by Frans Moss, in house lawyer at KNMP, by telephone interview and email correspondence.

Field visit a: Apotheek Oosterheem, Zoetermeer
Local "Hub & Spoke"

The Zoetermeer Health Centre Foundation owns 4 pharmacies: one located at the main health centre, and 3 others nearby. Until summer 2013, the repeat prescriptions were supplied by a central filling contractor. A local hub & spoke, or local central fill solution, was then established using Willach robotics. The reason for the visit is that this site is still promoted as local hub & spoke online. On visiting, we discovered the site was no longer operational as designed.

See video at: https://www.youtube.com/watch?v=G3EXSbzh_0c&t=193s

Zoetermeer is a quiet, modern commuter town, where many residents commute to work in the capital city of Den Haag located circa 16km to the west.

The pharmacy is located next door to a health centre, in a small town centre with an assortment of shops and commercial businesses.

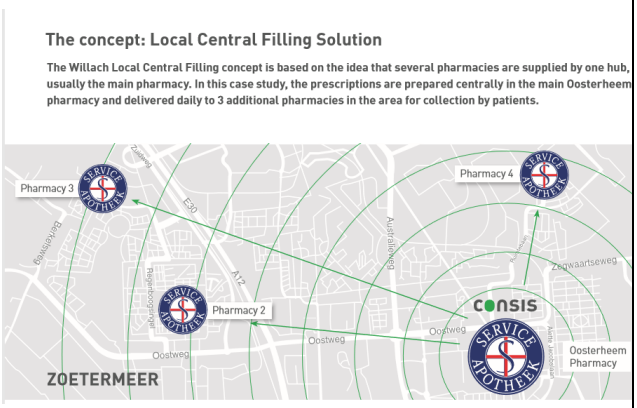
The pharmacy is the largest in a group of 4 serving the Zoetermeer area, and has a Consis (Willach) robot installed so that it can operate as a hub, or "local central fill solution."

The pharmacy is physically quite large, with an automated terminal at the entrance in which patients enter their details, six numbered service stations, and a very limited retail assortment, primarily of premium derma skincare ranges.

We were accompanied into a spacious working and dispensary area to meet Laurens Biesma, the pharmacist.

All prescriptions are transmitted via EPS, as the pharmacy system is 100% compatible with the health centre system, from all prescriptions for dispensing are transmitted. This is not always the case in the Netherlands, where there are three different pharmacy systems marketed. If the pharmacy and GP surgery systems do not talk to each other, then paper is used.

ORIGINAL CONCEPT: NO LONGER OPERATIONAL



The pharmacy has a large patients base of circa 23,000 patients , typically serving in the range of 300 – 600 patients per day. Demand can be unpredictable, and the automated system was installed to try to help even out demand.

The pharmacy estimated it has 1,400 patients on repeated medication, who receive up to a 3 month supply 4 times per annum.

The pharmacy employs:

- 23 assistants (most part time)
- 3 pharmacists
- 2 delivery drivers
- 3 robot fillers
- Total 31 staff (many part time, not FTEs)

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<td>1. Patients register at automated unit inside entrance</td>
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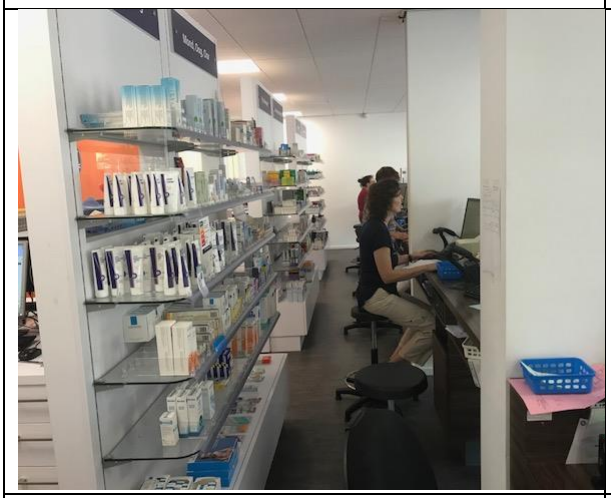
<td>  </td>
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<td>3. Staff sitting behind the numbered service stations</td>
<td>4. Mike & Steffen in the dispensary, with Laurens at the terminal. The automated system operated featured mono DOS screens.

The large cabinet system at the rear of the photo is the robot’s manual loading system, which 3 staff load each day, taking 2-3 hours. The racking to the right features larger lines which are too big for the robot</td>
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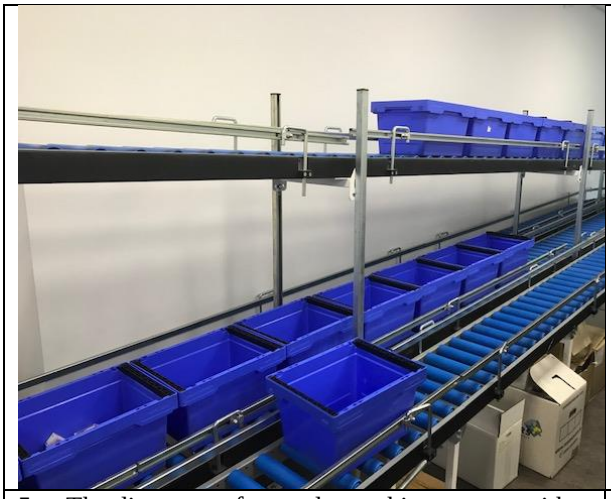
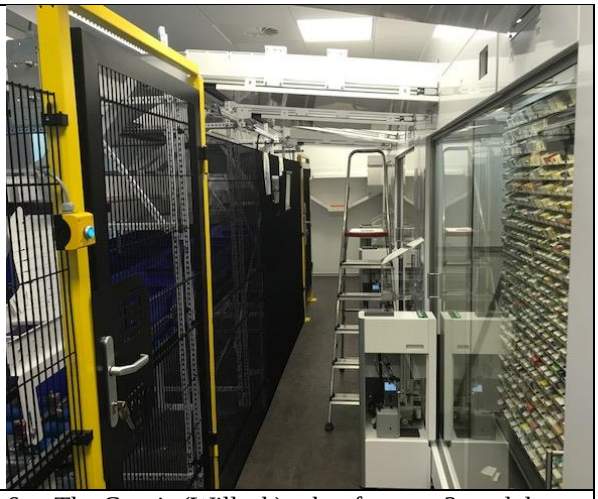
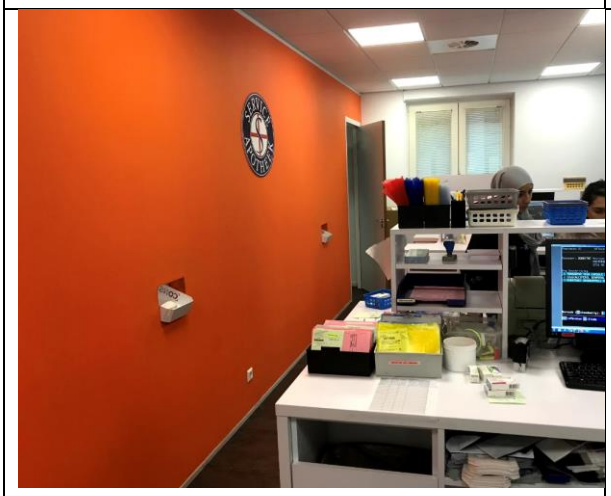
<tr><td>  </td><td>  </td></tr>
<tr><td>5. The dispensary featured a tracking system with totes into which dispensed medicines could be placed by the robot.

However, as the this pharmacy no longer operates as a hub, this facility was not in use during our visit</td><td>6. The Consis (Willach) robot features 3 modules (right of photo), which when operating as a hub / local central fill solution can dispense to the tote tracking system (to the left of photo, behind yellow gate)</td></tr>
<tr><td>  </td><td> 
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<tr><td>7. The robots also dispense to 2 “shoots” in the hub pharmacy dispensary from where medicines are transferred to the numbered service stations “front of house.”

(See sunk into the orange wall on the left of the photo.)</td><td>8. The pharmacy also offers a 24 hour collection service via PIN accessed lockers in a lobby area that is also used as the rear and goods entrance to the pharmacy. The lobby is also accessed via PIN.</td></tr>
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Metrics

- Serves 300 patients per day
- The hub can process up to 1000 scripts per day
- The robot can process up to 200 scripts per hour
- Up to 4k packages of stock are delivered per day
- It takes 3 staff 90 minutes to manually load the robot with 4k items
- A clinical check is performed at a workstation
- 1 member of staff delivers to spoke pharmacies
- Current volume: 45,000 items per month

Discussion

Even though this pharmacy is promoted online as an operating example of a local hub & spoke, it is no longer operating as a hub.

Whilst the pharmacy has doubled in patient base in 5 years since the automation was installed, it does not appear to have been able to absorb the increased demand versus capacity. It should be noted that during our visit the robot moved only rarely, and was not in operation for most of the visit, however. If capacity was an issue, additional or extended shifts could have been implemented (The robot and associated systems only operate during hours the pharmacy is open to the public.)

We considered it significant that this site is no longer operating as local hub. Clearly hubs need to be able to be scalable so as to absorb both increases and decreases in demand.

The Dutch model is also different to England and the UK in several important dimensions.

In the absence of an NHS, the key commercial interface appears to be between the health insurers and wholesalers. Dutch pharmacies are remunerated for the cost of the medicines by the patient's insurer at an agreed rate. The pharmacy visited was keen to stress that community pharmacies are very much at the receiving end, with little or no opportunity to improve terms offered.

Dutch pharmacies also mainly use a single wholesaler for all their supplies.

As a consequence, there does appear to be a competitive and unfettered market between insurers and pharmacies, with the insurers and wholesalers holding the market power. There appears to be a focus on reducing the cost burden for the insurer, as illustrated by one of the largest player's interest in moving to a 12 month period of supply.

Whilst clearly a well run pharmacy, the automated operation was not as impressive as the pharmacy in the round. For example, the robot relied on manual loading of boxes of medicines on a daily basis, by up to 3 members of staff for up to 3 hours.

The dispensing process, whether with original packs or via patient specific doses, does not enable itself to be readily, fully automated.

Field visit b: Verpakapotheek, Warmond
"The packaging pharmacy"

Verpakapotheek is a GDS and institutional[17] pharmacy, serving a number of hospitals, care and mental homes and prisons. Both standard, original pack and GDS pouch style dispensing were fulfilled from this site to these 3rd parties. Translated literally, Verpakapotheek means "the packaging pharmacy"

The facility is located on a small industrial park outside Warmond (see photo above.)

The focus of the visit was very much on GDS.

The business was founded by Jent Zijlkstra, an entrepreneurial pharmacist, who remains the main shareholder and "superintendent pharmacist", although he delegates day to day responsibility to Gert Nap, who hosted our visit.

They consider themselves as a small operator in the market, with two GDS machines, whereas the largest players operate up to 60 (eg. Brocacef, Mosadex)

Verpakapotheek are in the process of in sourcing their delivery drivers, having previously out sourced.

Whilst not directly involved in community pharmacy, Gert Nap (pictured) was able to make some very helpful insights and observations on the community pharmacy market in The Netherlands, on several occasions stressing that in the Dutch system, financial managers make the decisions. Decisions are not customer led, and quality suffers.

He estimated that up to 40% of patients aged over 65 received medicines via GDS pouches, and that pharmacies saw this as an earning opportunity as they receive a higher fee.

After several years of low to no regulation, the Dutch ministry of health has introduced a GDS quality certification system. In the first instance, a decision had to be made if a GDS site was a pharmacy or a pharmaceutical manufacturer. It was agreed GDS sites are pharmacies.

To date, 20 sites have inspected by government inspectors. According to Gert, one site was closed down on the spot, two others closed down ahead of an inspection, and two withdrew from operating after the inspection (of the total of 20) Another 20 sites remain to be inspected.

5 pharmacists worked on site, across both GDS and institutional pharmacies. A typical GDS patient receives 20 pouches per week.

Gert described 3 modes of GDS dispensing:

a. Unidose: Single drug, single dose (i.e. 1 tablet per pouch only)
b. Combi dose: Single drug, multi dose
c. Multi dose: Multi drug, multi dose

Gert estimated the cost to fill a pouch ranged from E0.08 for Unidose to E0.15 for Multidose. On the basis of an average 20 pouches per week, this equates to E1.6 to E3.0 per patient per week, or E83 to E156 per patient per annum.

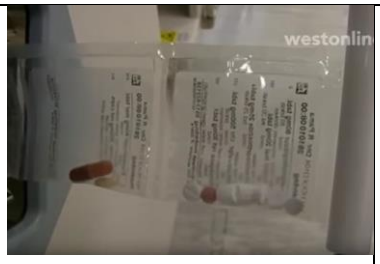
Changes to medication mid cycle are problematical. Therefore the aim is to synchronise where possible.

[17] The "institutional pharmacy" serves hospitals, mental care homes and prisons

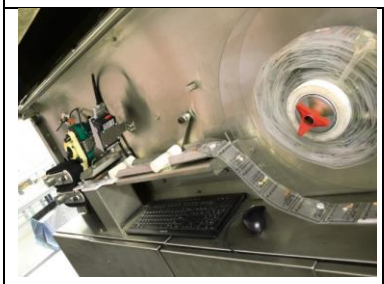
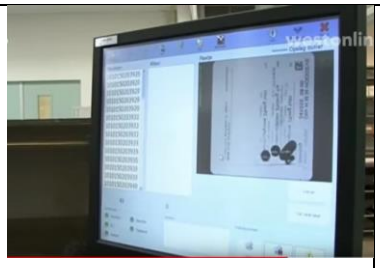
The GDS or Baxtering process at Verpakapotheek

1. Tablets are manually de-blistered into plastic trays, and then transferred to vials that can be inserted directly into the automated machinery. Every single vial is inspected and then signed off to be released by the superintending pharmacist. It is at this point that Verpakapotheek believe FMD requirements are discharged, and the tablets are decommissioned.

2. The tablets are then transferred to the machine dedicated cassette, and loaded into the automated machinery. Each machine can hold hundreds of lines.



3. Patient specific doses are then dispensed into pouches, which are stored on a reel.


4. The reels are then transferred to a new machine, which photographs every pouch for quality assurance / safety checking. All pouches where an adverse variance is identified are flagged with a green sticker for manual checking, and if required, re-working.

5. The pouches are then packed into patient specific boxes, and labelled, ready for despatch to dispensing pharmacy.

Metrics

- Small facility: 2 GDS machines on site
- Receive E1.6 to E3.0 per patient fulfilled per week
- Typical patient receives 20 pouches per week

Field visit c: Pluripack, Zwolle
Independent wholesaler providing central fill and GDS

Pluripack is located on an industrial estate on the edge of Zwolle, a city approximately 100km east of Amsterdam.

The visit was hosted by David Boerman, who had worked at the facility since launch, and was heavily involved in the design of all the relevant processes and in house software, and Anco van Marle, commercial director of Pluripharm (owner of Pluripack, and full line wholesaler.)

Pluripack was founded by local pharmacy owners 10 years ago as a "local central fill solution" to serve the pharmacies of Zwolle, which has grown organically over time. The Zwolle facility developed into a joint venture with Pluripharm, the 3rd largest wholesaler in The Netherlands serving circa 300 independent community pharmacies, before being fully acquired circa two years ago.

The site visited has been operational for 8 years, and serves 50 pharmacies. The whole site is registered as a pharmacy.

Pluripack operate a sister facility in Alkmaar which services a further 60 pharmacies.

Around 110 of Pluripharm's 300 customers buy into their "central fill" service.

The Alkmaar facility also has a manual central fill solution for slower moving lines, which also serves pharmacies whose faster moving lines are dispensed from Zwolle.

The photo above is of the Alkmaar facility, not Zwolle as visited. However, the facilities have much in common.

Circa 30% of Pluripharm customers use their Central Fill service (50 pharmacies from Zwolle, 60 from Alkmaar.)

Each facility features 3 high volume, KLS robots (both Zwolle and Alkmaar.) The robots only store fast moving lines, so the Alkmaar facility also has a manual central fill solution for slower moving lines, which also serves pharmacies whose faster moving lines are dispensed from Zwolle. As many as 40% of orders require to be manually filled. The process could be automated but it remains more efficient / lower cost to remain manual.

Therefore no more than 60% of lines are filled via automation

Typically central fill pharmacies use central fill for 70% of all their prescriptions including the Benu chain of pharmacies.

The KLS robots were industrial scale robots and featured automated loading and chaotic storage. As described by the management, the robot works slowly but continuously, enabling high volumes to be achieved over time

Demand is variable, and front loaded towards the beginning of the week. Therefore the robots typically work until 2 or 3am on Monday or Tuesday, and for much shorter hours later in the week. The robot was hardly operational during my visit on a Thursday morning. Only 1 person was working in the facility during my visit. This can increase to 2 while busy.

All patient specific orders were automatically packed into large, transparent plastic bags. Each order was then adjusted by hand, and the plastic bags were manually reduced in size at end of process. This was the first manual intervention in the process.

The facility is best described as industrial rather than clinical facility. It did not have the hygiene or superficially clinical standards of the Verpakapotheek GDS facility. This facility was more akin to a retail home shopping facility than a clinical pharmacy.

The facility also featured a higher volume GDS or baxtering line than that visited at Verpakapotheek, featuring 7 high volume machines serving 15,000 patients.

Each Baxter robot holds up to 384 fastest moving lines, with slower moving lines fed manually into a bespoke console system, assisted by LED technology. The process was labour intensive, and essentially manual with technological assistance to improve accuracy and safety.

The "Baxter robot" hardware was designed 20 years ago, using Soth Korean technology, with only software upgrades since. For example, high quality laser printing is now enabled on pouches.

All robots featured photo driven quality control unit not directly in line with robot. This was to ensure if one line fails, then the other continues to operate.

Fewer lines appeared to be being intercepted than at Verpakapotheek. However, as the quality control system was photo driven, it was also less transparent.

Circa 20 staff were working during visit, with circa 40 heads employed across 2 shifts (7 – 2, 2 – 11)

Up to 15% of all prescriptions in a pharmacy can be fulfilled via the Baxter or GDS process.

This facility was more clinical in feel than the adjacent central fill facility. However, it still had industrial qualities, and did not have the same clinical, hygiene first feel of the Verpakapotheek facility.

Again in common with the central fill facility, the automated equipment worked continuously as opposed to quickly.

Both facilities were well run, and could be described as smooth operating, well run operations.

The facility was also trialling a tray based robot which dispensed directly into MDS style dosette trays. The robot was not fully operational. It had been bought on the basis that the supplier claimed it was lower cost than Baxter pouches. Local management was not yet persuaded…

Fee structure

Pluripack charge a Central fill fee of E0.60 per line with an average of 2.6 lines per prescription, therefore typically E1.56 per parcel

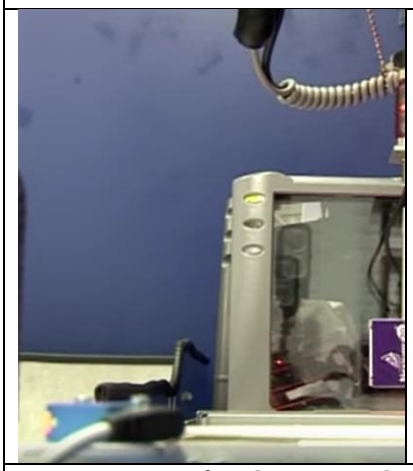
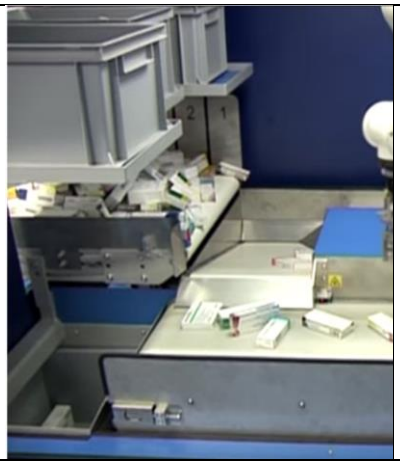
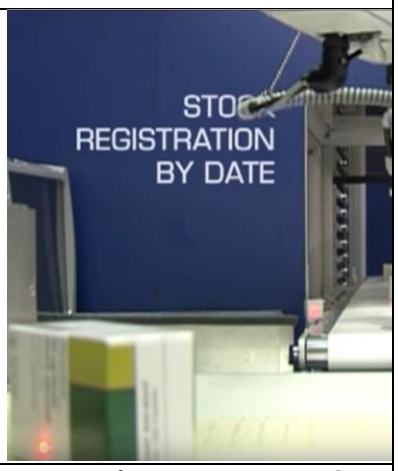
For GDS / Baxtering, Pluripack charge E0.45 per patient per day, therefore E3.15 per week.

Anco referenced E3.0 remuneration from insurer to pharmacy for Baxtering. On this basis, the cost would exceed the remuneration.

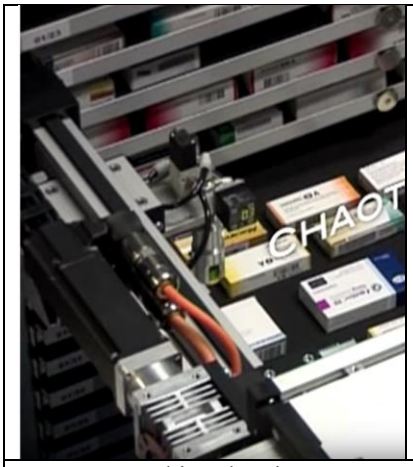
PLURIPACK CENTRAL FILL PROCESS

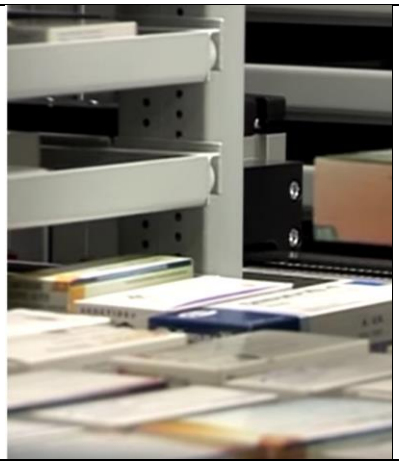
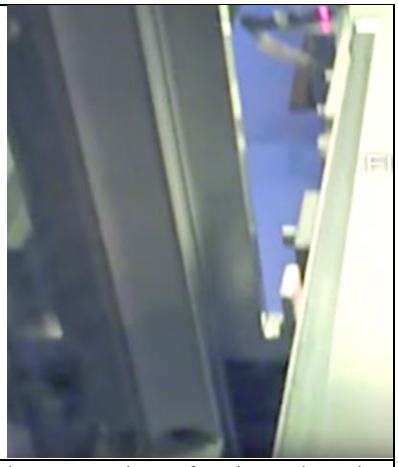


1. The industrial scale robot is automatically loaded. Boxes of medicines, in no particular order, are loaded into a hopper system…

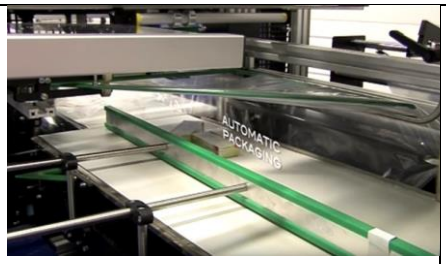
2. Boxes of medicines are identified by bar code and by size scanning. Date of storage is registered to enable a “first in first out” system to minimise risk of out of date stock.

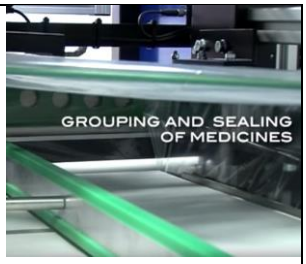


3. A cubic “chaotic storage” system is used. The computer knows where every box of registered stock is stored on the grid / cube, which is called off on a “first in first out” basis.


4. Patient specific orders are then picked by robotic arm directly from trays within the storage grid. The robotic arm moves the box of medicines to the exit point.





5. Each box is labelled, then automatically packed and grouped with medicines specific to that order, before being sealed in a patient order specific transparent plastic bag.

All images sourced from Bedrijfsfilm Central filling 2009, KLS Netherlands B.V. video at https://www.youtube.com/watch?v=h5lInWdy70A

Field visit d: Apotheek de Weide, Hoogeveen
Independent pharmacy using central fill

Anco van Merle organised a visit Apotheek de Weide in Hoogeveen, which is a Pluripharm customer, buy into its Central Fill service, but not its Baxtering service which it buys from another 3rd party.
Hoogeveen is a town with a population of 55,000, between the larger population centres of Zwolle and Gronigen, about 160km by road, north east of Amsterdam. The pharmacy is adjacent to a health centre, sharing common parking.

The pharmacy has recently won an award as "Best in The Netherlands" awarded by a mystery shopping process[18].

The pharmacy features a smaller front of house than that visited in Zoetermeer, with three numbered service stations, but a much wider range of OTC and other retail ranges.

Fixtures and fittings were of a high quality, and maintained to a high standard. Despite its smaller size, there was a higher flow of patient traffic than in Zoetermeer.

Patients registered at a smaller, more discrete unit on entering the pharmacy than in Zoetermeer

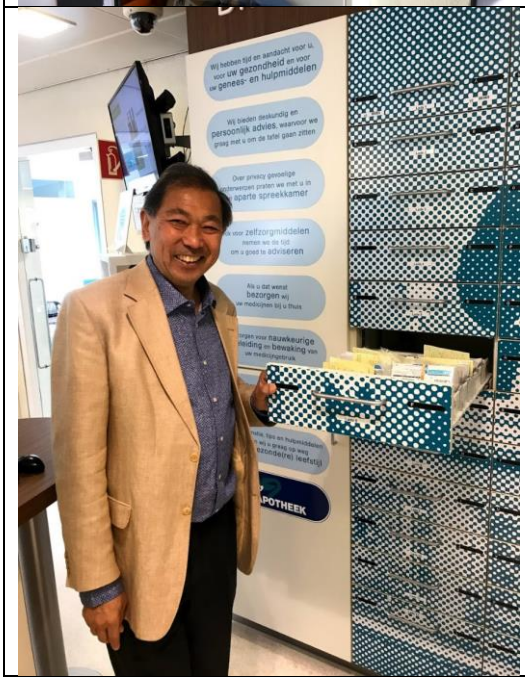
[18] https://www.hoogeveenschecourant.nl/ondernemen/actueel/530375/apotheek-de-weide-is-beste-apotheek-van-nederland.html

Centrally filled prescriptions were delivered to the pharmacy overnight, so that all prescriptions required in advance are available for the working day.

The delivery is made by Pluripharm to a secure lobby at the rear of the pharmacy. The delivery driver has a key for entry. All other doors leading out of the lobby remain locked and secure. This is common practice in The Netherlands, where wholesalers typically only deliver once per day between 5 and 9am. A photo of the access door can be seen below.

Centrally filled prescriptions are then filed in drawers using "track & trace" software, where the location of each patient's in the drawer system is recorded against the patient. Eg. Drawer 6, location V1.

An effective system to "track & trace" pre assembed prescriptions may be a criteria for success for central fill.



The pharmacy retained a greatly reduced stock holding to service acutes / walk ins.

The pharmacy also featured a robot which was now primarily used for storage. The robot did not appear to be utilised at anything approaching full capacity.

The pharmacy enjoyed an extremely large (and well organised) dispensary. In fact, this may have been the best organised dispensary I have visited.

A separate room was dedicated to Baxter patients, photographed above.

Discussion

This was a smaller pharmacy than Zoetermeer, but extremely well run and organised, as I hope is evident from the photos.

The pharmacy appeared well to generously staffed, especially in light of both central fill and GDS services. The pharmacy had re-designed its standard processes around central fill, which clearly accounted for the majority of lines.

The robot did not appear operational during my visit, but was described primarily as an efficient storage solution.

The dispensary / back shop was very large, as illustrated by the fact that a separate room was dedicated to GDS patients.

The owner suggested central fill had enabled the pharmacy to reduce its own stock holding by more than 50%, but also stated that wholesalers have worked with pharmacies to reduce stock levels over many years. It should be noted I was accompanied on the visit by a senior director of the wholesaler, but it did appear the pharmacy enjoyed a very constructive relationship with the wholesaler.

This despite the fact that this pharmacy bought in GDS / baxtering from another supplier, with whom it had entered a long term agreement previously. I was led to believe such an arrangement is not uncommon.

The pharmacy did feature a consulting room, but seemed more focused on core dispensing than clinical services. As such, the staffing levels appeared high given central fill and GDS were both outsourced.

4.1.4 Learnings from field visits

Apotheek Oosterheem in Zoetermeer was no longer operating as a hub.
Despite being designed to serve 4 pharmacies – 3 satellite "spokes" in addition to the base "hub" pharmacy – this was no longer the case. The primary reason given was the rapid growth of the base pharmacy. However, the managing pharmacist on site told us there were problems in terms of compatibility even with the "spoke" pharmacies owned by the same business. In addition, the automated hub appeared to have potential capacity that was not being utilised. For example, the robot could work outside core opening hours to serve the satellite "spokes." It appears significant that this site is no longer operating in the way in which it was originally designed.
The reason to build a "local central fill solution" was to reduce cost of using a "3rd party central fill" solution
The managing pharmacist on site told us the reason for building a "local central fill solution" was to reduce the cost of using a 3rd party service. He noted that when "central filling" was introduced into the Netherlands, the promise was that costs would reduce over time. However, the opposite has proved to be the case. This is a warning for the UK. Caution should be exercised towards claims by those promoting "hub & spoke" that costs will reduce over time.
"Central fill" and "baxtering" were both introduced by entrepreneurial pharmacists and pharmacy owners
Innovation in automation in The Netherlands was driven by independent entrepreneurs from within the profession. As they sought to expand, investment capital was brought in from outside interests including the wholesalers. The wholesalers have become the dominant interests over time.
The wholesalers have become the dominant interests in both the "central fill" and "baxtering" markets
As noted above, despite origins in the independent sector, over time the wholesalers have become the dominant interests in both "central fill" and "baxtering" over time. This has been accelerated by businesses such as Brocacef and Mosadex adopting "central fill" to service their own branch networks.
DTP (Direct To Pharmacy) arrangements tilt the playing field in favour of the largest, full wholesalers
The commercial director of Pluripharm, an independent full line wholesaler, believed they would find it very difficult to compete in the UK given DTP arrangements. His view was

that any pharmacy seeking a "central fill" solution would require a solus relationship with only one wholesale partner.
Central fill requires new operating practices in "spoke" pharmacies to deliver any potential benefits
The Zoetermeer pharmacy told us that it required 2 to 3 hours effort every morning to sort the incoming patient specific parcels from the 3rd party central fill provider before they moved to their own, local solution. This was a major factor in their decision to build a local solution. The Hoogeveen pharmacy had adopted operating practices to accommodate "central fill." For example, by implementation of the "track & trace" system, along side specific storage solutions to accommodate. This will require further investment by pharmacies who wish to adopt "central fill," in terms of staff training and capital investment in storage solutions. These additional costs should not be under estimated, and factored in to any business case.
Whilst "central fill" suppliers indicated costs would decrease over time, the opposite has proved true and costs have increased
This lesson should be borne in mind as it is highly likely proponents of "hub & spoke" in the UK will make a similar case.
"Baxtering" is the norm in The Netherlands
Pouch dispensing – aka "baxtering" – is now embedded in pharmacy practice in The Netherlands. It is well liked and part of the fabric. Up to 40% of all patients receive their medicines in this way.
Pharmacies do receive additional remuneration for "baxtering"
One reason for such widespread adoption of "baxtering" is almost certainly because pharmacies receive increased remuneration. Health insurers typically pay a weekly premium of up to £3.00 for every "baxter" patient (E156 per annum)
Dutch pharmacies only deal with a single wholesaler
Most, if not all, Dutch pharmacies have a solus relationship with a single wholesaler. It is possible to source medicines from short liners through the single full line wholesaler with whom the pharmacy has the solus relationship

Wholesalers only make a single delivery each day before the pharmacy opens
Pharmacies receive a single delivery each day, typically between 5am and 9am. All deliveries are complete before the pharmacy opens, and pharmacies are confident they have the medicines required for the day's business ahead of them. Deliveries are made to a secure lobby, where the delivery driver either has access via PIN or his own set of keys. Some deliveries are through the night. Emergency, same day deliveries can be arranged at a premium.
The "baxtering" process is intrinsically complex and labour intensive
"De-blistering" is a complex, labour intensive process. Smaller sites need to de-blister all medicines prior to automated dispensing (eg. Verpakapotheek) Larger sites such as Pluripharm are able to source some medicines in non blistered format that eases transfer to the automated equipment. Even after de-blistering, the process remains complex and labour intensive, with multiple opportunities for human error. The process is not fully automated, but required multiple manual interventions, Different sites favour different manual interventions.
Fully automated dispensing is a misnomer. All automated processes observed feature significant levels of manual intervention and processing.
The most automated process observed was the Pluripack "central process," where the most significant manual intervention was to manually reduce the size of the patient specific packaging at the end of the dispensing process. However, it is only cost efficient to automate dispensing of the fastest moving lines. 40% of all orders require to be fulfilled via a manual process at another site. Manual interventions present opportunities for (human) error, and this should always be borne in mind when assessing patient safety claims.
Circa 30% of independent pharmacies in The Netherlands buy into 3rd party central fill solutions
Whilst all wholesalers offer central fill as a service, circa 30% of independents buy into such a service. This information is quoted by Pluripack management. No official data is maintained across the sector. The overall proportion for all pharmacies in The Netherlands will be higher as chains and franchises have a higher level of uptake.

Automated dispensing solutions require significant capital investment
The Pluripack central fill site featured 3 industrial scale robots to service circa 50 pharmacies, and 6 “baxtering” robots to service 15,000 patients. The central fill robots are major plant in particular. All these forms of automated dispensing require significant capital and revenue investment, including software development and training. Shareholders and investors will require a return on investment which must factored in to any economic or cost benefit scoping.
Automated dispensing requires clear and strong regulation from the onset
GDS / “baxtering” was a market driven solution in The Netherlands, which remained unregulated for many years. The need for regulation has only recently been identified. Of the first 20 automated dispensing sites inspected by the regulator, 25% have either been closed by the inspector, or elected to cease operating as a GDS site.

Academic literature review & references

1. Medication Incidents Related to Automated Dose Dispensing in Community Pharmacies and Hospitals - A Reporting System Study.
Ka-Chun Cheung , Patricia M. L. A. van den Bemt, Marcel L. Bouvy, Michel Wensing, Peter A. G. M. De Smet,
Plos ONE, July 24, 2014

A 2014 study entitled "Medication Incidents Related to Automated Dose Dispensing in Community Pharmacies and Hospitals - A Reporting System Study[19]" was published by a team of Dutch academics based at, amongst other establishments, Radboud University Medical Centre and Utrecht Institute for Pharmaceutical Sciences. The study's objective was to "provide insight into the nature and consequences of medication incidents related to ADD, as reported by healthcare professionals in community pharmacies and hospitals."

Key findings and observations included:

> *Early studies have confirmed that automated medication dispensing systems minimize medication dispensing errors and save time for the pharmacy dispensing staff.*
>
> *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]*
>
> *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.*

The authors concluded that "more research is needed to study the impact of ADD on elderly people," observing that

> *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).*

[19] **Medication Incidents Related to Automated Dose Dispensing in Community Pharmacies and Hospitals - A Reporting System Study.** Ka-Chun Cheung , Patricia M. L. A. van den Bemt, Marcel L. Bouvy, Michel Wensing, Peter A. G. M. De Smet, Plos ONE, July 24, 2014

The authors added:

An important recommendation for preventing reoccurrence of ADD related incidents is to perform a double check on data entering into the pharmacy information system. Furthermore extra care should be taken during and after relocation of the patient.

ADD MAY ALSO INTRODUCE NEW TYPES OF MEDICATION ERRORS

Cheung, van der Bent et al, 2014

Discussion

Automated dispensing is both widespread and well established in The Netherlands.

Nonetheless, from the perspective of the independent pharmacy owner, the following appear significant:

- The small independent group of pharmacies in Zoetermeer established a hub because the promised benefits of 3rd party central were not being realised. 3rd party costs were higher, and effort and resource in pharmacy continued at a higher level than forecast. Their solution was to build their own solution.

- That solution is no longer operational. The rapid growth of the base pharmacy is a mitigating factor. Nonetheless, the complexities of operating as a central hub to 3 smaller pharmacies appears to have outweighed the anticipated benefits.

- Up to one third of independent pharmacies in The Netherlands buy into 3rd party central fill services from their wholesaler. Around two thirds therefore do not.

- Both central fill and GDS services are dominated by wholesalers. It appears both services were first established by entrepreneurial pharmacists, but over time have sold out and given way to the wholesalers (noting the "big 3" of WBA, Celesio and Phoenix are less well established than in the UK.)

- The independent pharmacy visited that was using 3rd party central fill successfully had clearly adapted its working practices to accommodate. This is an essential component for success. The cost of additional investment in storage units and training should be factored into any business case.

- The fact that Dutch pharmacies receive premium remuneration for GDS patients appears to be a significant factor in both its growth and establishment

From the supply perspective, the following appear significant:

- The GDS process remains fundamentally complex. De-blistering is labour intensive and therefore costly. Whilst the smaller operator visted – Verpakapotheek – deblistered all medicines, the larger operator, which was also a wholesaler – Pluripack – received some medicines in de-blistered format.

- Neither GDS sites were fully automated – both featured significant manual intervention

- Neither was the central fill operation at Pluripharm fully automated. All orders featured a manual intervention at packaging stage. As many as 30% of all prescriptions cannot be dispensed by automated equipment as they feature a slow moving line.

Even in a geographically small country such as The Netherlands, with a high population density, 3rd party automated dispensing providers chose to operate smaller, regional facilities.

For example, Pluripack operate 3 GDS facilities, and 2 central fill facilities in a geography with a population a quarter that of UK, and a population density 1.5 times that of the UK.

On this basis, a comparable operator in the UK with 14% market share might require 18 GDS facilities and 12 central fill sites.

At a national level, this would suggest a need in the UK for something in the region of 128 GDS or MDS sites. The number of central sites that would be required is more problematical to estimate, but to supply 100% of independent pharmacies based on Pluripack volumes could require as many as 300.

These extrapolations are merely indicative, but it is clear from The Netherlands that a scenario which has been described whereby as few as 4 or 6 automated sites could service the UK does not align, by some considerable distance, with the situation observed in The Netherlands.

Finally, it must also be highly significant that as many as 25% of all sites inspected by the health authority have ceased to operate, indicating poor practice was commonplace and became well establish in the period of several years during which 3rd party automated dispensing ran without regulation.

4.2 Sweden

As long ago as the 1980s, Sweden replaced manual repackaging of multi-dose medications from pharmacies with automated multi-dose drug dispensing. The medicine agency of Sweden published guidelines on dose dispensing in 2010 (Sinnemaki, Sihvo et al. 2013). Sweden has per capita the largest number of patients receiving multi-dose dispensing worldwide (Waller 2018). In 2009, there were 185,000 patients using automated dose dispensing (ADD) (Sinnemaki, Sihvo et al. 2013) There are now approximately 200,000 patients receiving multi-dose dispensing.

About 35% change annually, as many are older people who die (Waller 2018). About 80% of users in 2011 were 65 years and older (Bardage, Ekedahl et al. 2014).

In 2011, about 40% lived in ordinary housing, while about 60% lived in nursing homes (Bardage, Ekedahl et al. 2014), while in 2018 about 50% of recipients of multi-dose dispensing are living at home and 50% are living in nursing homes (Waller 2018). Multi-dose drug dispensing can only be prescribed by a physician. The decision for a patient to have multi-dose dispensing is made entirely by their physician. It is a medical decision and there are no government guidelines as to who would be eligible.

All the MDD patient's medication (including OTC) is then transferred to a national prescribing database accessible to all prescribers and pharmacies. It is mandatory to update this patient information every 12 months.

Multi-dose dispensing is prescribed for patients who would otherwise have difficulties handling their medications. While these are predominantly older people, they also include younger people, such as those with certain disabilities (Waller 2018). Multi-dose dispensing is reimbursed and covered by the Swedish Pharmacy Benefit.

There was a state monopoly in the pharmaceutical market from 1971 to 2009. This provided ideal conditions for setting up a nationwide system for pharmaceutical dispensing. Multi-dose dispensing started out as a low-tech business, but became more automated over time (Waller 2018).

The state monopoly was disestablished in 2009. Until early 2013, only the National Corporation of Swedish Pharmacies offered automated multi-dose drug dispensing. Since then, other companies have also been offering this service (Bardage, Ekedahl et al. 2014). There are now three major players on the multi-dose dispensing market, with the state provider accounting for approximately 30% of the market. It is considered necessary to have at least 40,000 patients for a provider to operate profitably (Waller 2018).

Competition for contracts with county councils, which are paying for multi-dose dispensing, is fierce. Dose factories used to be paid a premium for the medicines as well as the packaging, with approximately 6 Swedish Crowns per day and patient for the packaging. Payment for packaging has recently declined to zero or even less, with providers paying for the right to provide multi-dose dispensing, making profit only from the margin on the medications (Waller 2018). While county councils are paying for multi-dose dispensing, cities benefit most, as they have to pay for care for older people (Waller 2018).

The multi-dose pharmacy (called “dose pharmacy” in Sweden) has the same legal permit and status as an ordinary community pharmacy. Whether dispensing is done in a centralized or automated way is left to the pharmacies to decide. Provided by the dose pharmacy is a box with all medications, multi-dose and other medications that the patient is taking. Dispensing is done by the dose pharmacy, as patients simply pick up the medicine from the community pharmacy. However, medication is also sent to patients’ home. There is one pharmacy that only operates online. They have the same permit as the community pharmacy or the dose pharmacy (Waller 2018).

References
Bardage, C., A. Ekedahl and L. Ring (2014). "Health care professionals' perspectives on automated multi-dose drug dispensing." Pharm Pract (Granada) 12(4): 470.
Sinnemaki, J., M. Airaksinen, M. Valaste and L. K. Saastamoinen (2017). "Impact of the automated dose dispensing with medication review on geriatric primary care patients drug use in Finland: a nationwide cohort study with matched controls." Scand J Prim Health Care 35(4): 379-386.
Sinnemaki, J., S. Sihvo, J. Isojarvi, M. Blom, M. Airaksinen and A. Mantyla (2013). "Automated dose dispensing service for primary healthcare patients: a systematic review." Syst Rev 2: 1.
Waller, J. (2018). Personal communication, 14 February 2018.

Academic literature review & references

More independent, academic research has been undertaken in Scandanavia, and Sweden in particular, than other geographies. This research has often looked at experience and evidence outside Scandinavia has well.

Bardage and Ring, based at the University of Uppsala, have undertaken some of the most authoritative research in the field, from both patient and practitioner perspective.

2.	**Patients’ Perspectives on Automated Multi-dose Drug Dispensing** C Bardage and L Ring Journal of Community Medicine & Health Education, 2016, 6.1
3.	**Health care professionals’ perspectives on automated multi-dose drug dispensing** Carola Bardage, Anders Ekedahl, Lena Ring Pharmacy Practice (Granada). 2014 Oct-Dec; 12(4): 470. Published online 2014 Mar 15.

In respect of healthcare practitioners’ perspectives, which was the earlier of the two studies first published in 2014, the authors observed, in line with many other studies, that:

> *There are few studies evaluating the consequences of automated MDD with regard to patient safety, and those that investigate this issue are not very extensive.*
>
> *The professionals generally had a positive attitude to automated MDD with regard to improved medication adherence, but said they believed that the electronic prescribing system posed a safety risk for patients*

Once again stating “To the best of our knowledge there are no conclusive studies with regard to patient safety and adherence using automated MDD” the authors continue:

> *However, some Swedish studies have indicated an association between poor quality of drug treatment among the elderly using automated MDD compared with medicines*

prescribed and dispensed individually in the manufacturers' packs from pharmacies.13,14 Comprehensive literature reviews reveal that studies comparing automated MDD from pharmacies with medicines prescribed and dispensed individually in manufacturers' packs from pharmacies are few and inconclusive.

The authors asked how could multi drug dispensing be improved? 44% of physicians replied that communication with pharmacies could be improved, while 55% of nurses indicated there needed to be enhanced cooperation to minimize medical errors.

The authors also noted that:

The physicians commented that the new prescribing procedure for automated MDD is complicated and poses a risk for patient safety.

This study was followed up with further research into the patient perspective, published in 2016, with authors taking the view:

In general, the patients expressed that they were satisfied and felt secure with ADDs, but called for better information about the purpose and goal of their treatment and treatment related changes.

Adherence and safety issues, as well as, information about sachets contents need to be further looked into

Ling & Bardage, 2016

Almost all the independent research into automated dispensing concludes that safety issues need further research, and no one states either authoritatively or categorically that there are patient safety benefits.

However, the authors take a more positive, but nuanced, stance on the economic benefits stating:

Deliveries of multi-dose drugs, using ADDs, from the pharmacies implied time and cost saving among ward staff. As a consequence, almost all municipalities in Sweden, in order to cut labour costs for nursing staff, increasingly ordered ADDs from pharmacies

It should be noted the time and cost savings are implied, and supporting data or evidence to corroborate is not presented.

Again, the authors asked how could multi drug dispensing be improved?

Forty percent of the patients called for better information from prescribers about the purpose and goal of treatment, and twenty-five percent called for better information on changes in drug treatment. Thirty-five percent commented on the importance of there being only one medication list shared between health-care, pharmacies, and

> *ADD distributors. They highlighted the importance of attached or otherwise available information focusing on which pills are which, preferably with a picture and/or description. Twenty-four percent of the patients reported that the opportunity to communicate with the pharmacies could be improved. Twelve percent called for expanded pharmacy opening hours for collection of sachets. Twenty-six percent expressed a desire to collect at any pharmacy. Some commented that they would like to have the sachets sent home*

In conclusion, the authors found that:

> *In general, the patients expressed that they were satisfied and felt secure with ADD, but called for better information about the purpose and goal of treatment and changes in drug treatment*.

At the same time they noted that "patient safety aspects are challenging to assess" and "Further research is warranted with regard to the follow-up and evaluation of effects and safety as well satisfaction for patients using ADD."

Discussion

ADD is well established in Sweden, not least as it is funded by the system. It appears to have plateaued in terms of population penetration, and further automation such as central fill does not appear to have gained traction.
Patients and practitioners are broadly satisfied, and municipalities in Sweden believe in the economic benefits (but not necessarily underwritten with hard evidence.)
Independent researchers remain neutral in terms of the patient safety benefits.

4.3 Germany

Automated dose dispensing (ADD) has been operational in Germany for a number of years through *"blisterzentren"* (translated as "blister centres")

The *"blisterzentren"*serve nursing or care homes, and in common with other Northern European markets, no authoritiative data is logged or maintained.

ADD in Germany is less well reported than in, for example, The Netherlands and Sweden. However, given the nature of the German economy and health system, it was considered helpful for this paper to learn more about the situation there.

This information has primarily been gained through written communication and structured discussion with Michael Jung of ABDA.

It was not possible to offer a reliable estimate, other than to state this remains a "somewhat exceptional" mode of supply. Certain large pharmacies specialise in supply to care homes, and operate *"blisterzentren"* in house.

ABDA estimated that between 10 and 20 *"blisterzentren"* are operational across Germany, serving circa 100,000 patients. As stated previously, in the view of ABDA, no authoritative records are maintained.

There is a Federal Association of Patient Individual Medicines Verblisterer (BPAV) which maintains a website listing 16 blister companies it represents (http://www.blisterverband.de/mitglieder-19581.html) Furthermore, the "Verblistern" website appears to be maintained on behalf of this niche industry in Germany, which currently logs a total of 35 *"blisterzentren"* of which 7 are no longer operational.

BLISTER CENTERS

FOR THE PRODUCTION OF PATIENT-INDIVIDUAL DRUG BLISTER ACCORDING TO § 13 AMG

(please report changes!).

1. Dual-Med , 01609 Gröditz: *Manufacturer's* license *since 09/2010*
2. blisterzentrum-saxony , 01920 Panschwitz-Kuckau
3. MyCARE Homeservice , 06886 Lutherstadt Wittenberg: *Manufacturer's* license *since 08/2008*
4. Blisterzentrum Rudolstadt , 07407 Rudolstadt: *Manufacturer's* license *since 07/2010*
5. Medipolis (Blister Center Central Germany), 07743 Jena: *Manufacturer's* license *since 12/2009*
6. Berlin Blister , 14532 Kleinmachnow : *Manufacturer's* license *since 2014*
7. a.novum Blister Centrum Berlin / Brandenburg GmbH & Co. KG: *dissolved*
8. Blisterzentrum Bernau , 16321 Bernau: *Manufacturer's* license *since 08/2012*
9. Blister-pac , 18437 Stralsund: *Manufacturer's* license *since 01/2010*
10. Blisterzentrum Nord , 19061 Schwerin: *Manufacturer's* license *since 10/2008*
11. Multidos , 21220 Seevetal: *Manufacturer's* license *since* 04/2010
12. Holstein Blister , 23812 Wahlstedt
13. Weser-Ems-Blister , 26219 Bösel: *Manufacturer's license since 12/2011: insolvent*
14. Apoblist , 27356 Rotenburg / Wümme: *Manufacturer's license since 04/2010: currently no longer available*
15. Blister-Care , 31785 Hameln: *Manufacturer's* license *since 11/2009*
16. Blister Center OWL , 33611 Bielefeld: *Manufacturer's license since 10/2009*
17. Blister-Express Blisterzentrum Mittelhessen , 35614 Aßlar: *Manufacturer's* license *since 07/2010*
18. Blisterzentrum Niedersachsen, 38102 Braunschweig: " The society is dissolved "
19. BLISTERpharm ® , 41236 Mönchengladbach
20. Blister Center Dormagen , 41539 Dormagen
21. Steinweg Medical , 44575 Castrop-Rauxel
22. Migasa Blister Center Nordhorn , 48527 Nordhorn: *Manufacturer's* license *since 04/2011*
23. Kölsche Blister , 50679 Cologne
24. Rheinland Blister, 51381 Leverkusen
25. Blister Center West , 53121 Bonn
26. Blister Center Aschaffenburg , 63739 Aschaffenburg
27. Blister Centrum Luh Rhein Main, 65189 Wiesbaden: Bankruptcy applied for 10th of July 2015
28. CogiPharm , 66564 Ottweiler
29. 7x4pharma , 66663 Merzig - Machine dismantled!
30. Blisterzentrum Baden-Württemberg , 71106 Magstadt: *Manufacturer's* license *since 12/2010*
31. German Blister Society, 76532 Baden-Baden
32. Blister Center Südbaden , 79224 Umkirch
33. Blister Center South-East , 83395 Freilassing: *Manufacturer's* permission *according to §13?*
34. Blisterzentrum Süd , 86641 Rain / Lech: *expansion to the Blisterzentrum stopped*
35. Blister Center Middle Franconia , 90411 Nuremberg

Source: http://verblistern.info/blog/blister-zentren/

The same website lists 30 *"blister-apotheken"* or "blister-pharmacies" but also recognises that the list is incomplete and seeks further feedback. (http://verblistern.info/blog/blister-apotheken/)

The "*Blisterzentren*" were originally founded by pharmacists. Since then they have become operated by capital investors including wholesalers.

The "*blisters*" have to be sent to a pharmacy for onward despatch to the care home or patient. Direct deliveries to care home or patient are not permitted.

This mode of supply has been operational in Germany for more than 10 years. At first, the uptake level was expected to be between 10% and 20% of all patients, and the centres were seen as much greater threats than has been the reality.

For example, the market leader in Sweden, where ADD is longer established, set up a centre in northern Germany near Hamburg. However, the centre was not a success and closed within 2 years.

In the view of ABDA, the pharmacy sector has adopted ADD somewhat reluctantly, recognising the risk that pharmacies might become more distanced from patients.

ADD in Germany has primarily been a marketing instrument for sales to care and nursing homes. A contract is required to supply a nursing home, and to be able to supply the medicines in blister format is seen as a sales tool to help win the contract.

The German Health Funds will not pay for the additional cost.

Recent criminal laws with regard to corruption in health care[20] may present a complication, as some pharmacies have been offering blisters as what appears to be a loss leader, and this may be problematical under the new laws.

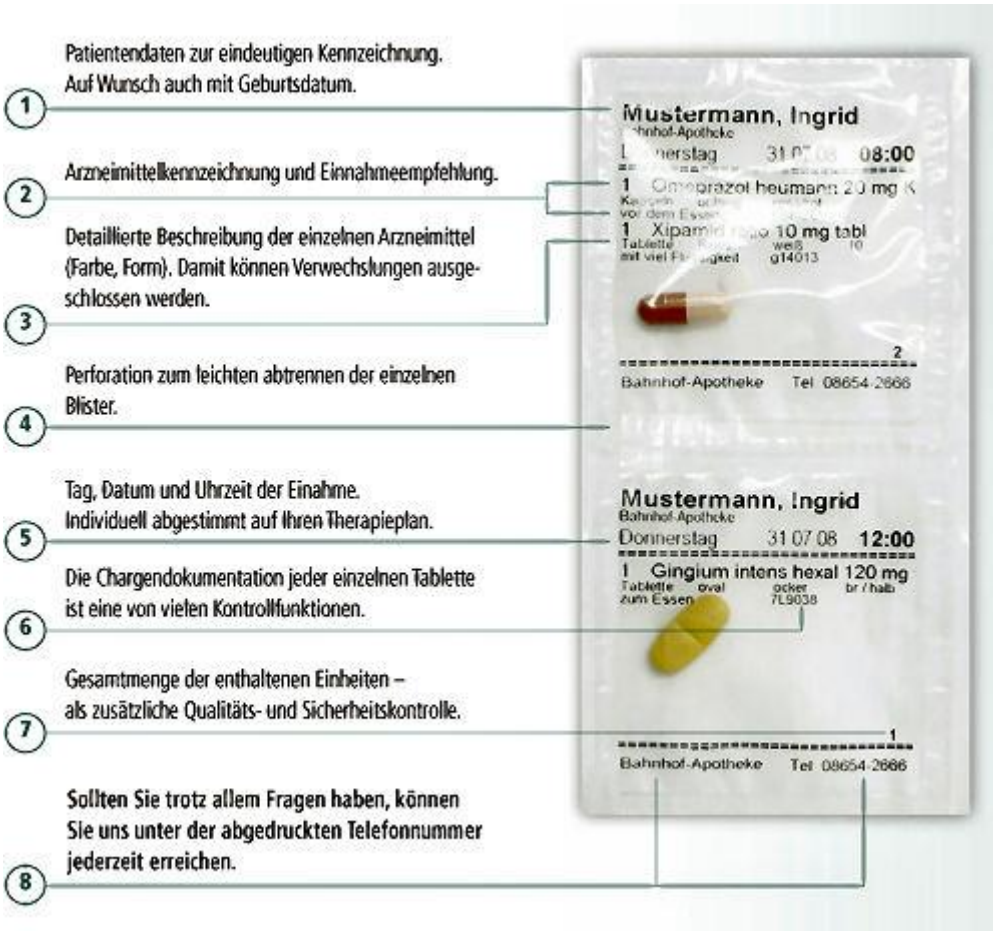
Manual picking into blister packs also happens in some German pharmacies, but cost is an issue

Re-imbursement in Germany is against original / full packs only, and this mitigates against ADD.

Some care homes run their own in house ADD operations

The "pouch" model is most common – other models do exist but are generally more expensive (and cost is an issue as identified previously.)

[20] Law on Combating Corruption in Health Care (Sections 299a , 299b)



Source: http://verblistern.info/blog/aenderungen-im-schlauchblister/

German pharmacies receive a fixed dispensing fee of €8,35 per package of prescription-only medicine), and a mark-up of 3% of the wholesaler trade price.[21]

[21] Dr. Linda Schollenberg. ABDA – Federal Union of German Associations of Pharmacies. Via PGEU.

Academic literature review & references

No specific independent studies into automated dispensing have been identified by German authors or universities.

The BPAV sponsored a study conducted by the Institute of Health Economics which identified the following, noting this cannot be considered independent research.

Facts and figures on blinding

Savings and added benefits of patient-specific blistering:

Result	source
Time savings of 5.5 minutes per week / patient = savings of € 0.94 per week / patient (22%)	(AOK Bavaria) Neubauer & Wick (2011)
Positive assessment of patient blinding: 78-82%	Ibid.
27% less hospital stays (> 500,000 € / year), 26.3% less length of stay (from 10.6 to 7.8 days)	(AOK Northeast) Leker et al. (2011)
16% drug expenditure reduction (from € 184,778 to € 155,879)	Ibid.
Improved adherence by 14.30%	Schneider et al. (2008)
Time savings of 84% (from 17.54 to 2.80 min per resident / week)	IfH study (2011)
20% savings on overdosing and underdosing u. 1% avoidable prescription errors; total expenditure savings of € 13.9 million	Lauterbach et al. (2004a)

The data listed here are only excerpts from a comprehensive study produced by the Institute for Health Economics (IfG) on behalf of the Federal Association for Patient-Individual Pharmaceutical Blister Packers (BPAV). It analyzed numerous studies on the added value of patient-specific blinding and came to an overall conclusion:

"All studies of patient-specific drug blinding have only positive and statistically significant effects with regard to direct and indirect patient-relevant added benefit and state that patient-specific drug blistering makes a considerable to considerable but at least minor contribution to improving the quality of care, morbidity, and quality of life supply economy. "

The study as PDF version can be found under the following link .

Source: http://www.blisterverband.de/verblisterung-18363.html

Discussion

ADD in Germany is neither as widespread nor mainstream as in, for example, The Netherlands or Sweden. It appears to be tolerated by both the pharmacy profession and the authorities, and is not actively promoted.

It is very clearly associated with care homes.

Germany is the home to several leading suppliers of pharmacy automation, and it should be noted that despite this, large scale automated dispensing has not become well established in Germany.

The German model of automated dispensing does not present the UK or England with great insight, and does not appear applicable to the UK.

4.4 Denmark

In common with other Scandanavian countries, ADD is active in Denmark, having been enabled by executive order in February 2003.

Laegemiddelstyrelsen, the Danish Medicines Agency, issues guidelines on Dose Dispensing, last updated on 1 August 2014[22].

Dose dispensing can be provided to specific patients, individuals, institutions and companies. All prescriptions issued in Denmark, including ADD, are recorded on the National Prescription Registry.

Public data and information is limited, but the following has been corroborated by Merete Kaas at Danmarks Apotekerforening (Association of Danish Pharmacies).

In Denmark, the "spoke pharmacy" orders the patient's medicines from other pharmacies with permission to establish dose packaging. When the dose dispensed medicines are received at the "spoke pharmacy," this pharmacy supplies the medicines to the patient. The "spoke pharmacy" has to check that the dispensed medicines are correct compared to the prescription.

The automated dose dispensing is handled by private community pharmacies with a permission to establish dose packaging function for trade with dose dispensed medicines to other pharmacies[23].

Academic literature review & references

4. From machine to mouth How can automated dose dispensing lead to safer and more effective patient medication?

B Frøkjær*, L Thomsen*, H Herborg*, L Fonnesbæk**, G Pedersen**
* Pharmakon, Danish College of Pharmacy Practice
** Danish Society for Patient Safety

https://www.fip.org/files/fip/CPS/Charlotte_Rossing1_poster.pdf

This poster published online offers helpful insight from both the Danish College of Pharmacy Practice and Danish Society for Patient Safety.

Observations included:

> *The literature is inconclusive as to whether ADD is safe way of dispensing medicines. ADD reduces dispensing errors. Errors occur in other steps of the medication use process as a result of the legal, economic and organisational framework*

[22] Laegemiddelstyrelsen.dk
[23] Communication via PGEU

Health professionals' perspectives on ADD vary and should be equally considered to improve ADD implementation

User perspectives on ADD deserve more attention in the future
ADD reduces medication waste, medication costs, and nursing hours when treatment is stable.

THE LITERATURE IS INCONCLUSIVE AS TO WHETHER ADD IS SAFE WAY OF DISPENSING MEDICINES

Frøkjær, Thomsen el al, 2014

4.5 Finland

ADD was first launched in Finland in 2002, and enabled through legislation in 2011. The service is delivered nationally through community pharmacies that purchase dose dispensing via the hose dose bags from three providers.

In 2011, a team of Finnish academics reported that about 300 out of a total of 600 community pharmacies provide the ADD service. At the end of 2016, the number of patients in Finland was reported 49,500 and seen to be increasing (unpublished data received from the Social Insurance Institution). This number has recently been corroborated by the Association of Finnish Pharmacies, who also confirm there are 3 active ADD centres in Finland.[24]

The Association of Finnish Pharmacies recommends that each patient's medications should be reviewed in the community pharmacy before they are enrolled in the ADD service. The Ministry of Social Affairs and Health recommends that medications for the elderly should be reviewed at least once per year.

In Finland, in common with most other geographies, most ADD patients are geriatric with multiple morbidities and medications.

Normally in Finland, drugs are dispensed for 3 months in packages of 30 or 100 tablets. However, ADD patients are dispensed 14 days of medication in hose pouches. The shorter period of treatment is believed to be one reason why independent research reported reduced drug wastage with ADD.

Finnish pharmacies receive an administration fee of €2.17 (excl. VAT) per item, which is not dependent on the number of packages sold (added to the retail price of prescription medicines and self-care medicines dispensed by prescription.)[25] Pharmacies also receive margin remuneration determined by medicine tariff for POM and OTC medicines. However, the pharmacy´s margin is reduced by a progressive pharmacy tax that is paid based on the annual turnover of the sales of prescription and OTC medicines.

[24] Vesa Kujala. Association of Finnish Pharmacies. Communication via PGEU.
[25] Monna Apajalahti-Markkula. Association of Finnish Pharmacies. Communication via PGEU.

EVIDENCE … INDICATES THAT CHANGES IN THE WORK PROCESS CAN LEAD TO NEW KINDS OF MEDICATION ERRORS

Sihvo, Isojärvi et al, 2011

Academic literature review & references

As noted previously, Scandinavian universities and academics appear to have taken a greater interest in automated dispensing than, for example, the US. This is the case in Finland where two independent studies have been published despite the relatively small size of the market.

5.	**A Systematic Review of Automated Dose Dispensing in Primary Health Care** Sinikka Sihvo, Jaana Isojärvi, Marja Blom, Marja Airaksinen and Antti Mäntylä Value in Health 14(7), November 2011
6.	**Impact of the automated dose dispensing with medication review on geriatric primary care patients drug use in Finland: a nationwide cohort study with matched controls** Juha Sinnemäki, Marja Airaksinen, Maria Valaste & Leena K. Saastamoinen Scandinavian Journal of Primary Health Care. 35:4, 379-386

Sihvo et al's systematic review conducted in 2011 made a number of observations in line with more recent studies, in particular that "Further evidence is needed to draw sound conclusions on ADD's outcomes."
Interestingly, they found

> *"Evidence from hospital settings indicates that changes in the work process can lead to new kinds of medication errors [25,26]. For example, nurses check the medicines less carefully because they rely on the automation.*

Again, in common with other studies for example in South Africa, they report

> *"Even though evidence for the benefits of the ADD service in primary healthcare is limited, the service is officially implemented and widely used in the Nordic countries*

These authors' specific research found that:

> *The findings of this review suggest that patients using the ADD have more inappropriate drugs in their regimens, and that ADD may improve medication safety in terms of reducing the discrepancies in medication records*

Before recommending that:

> *Further evidence is needed to draw sound conclusions on ADD's outcomes.*

Sinnemaki et al's study is one of the most recent to be published (in 2017.) This research found that

Drug use was decreased after initiation of the ADD service in primary care patients over 65 years compared to matched controls in this 1 year cohort study

But in common with many other researchers added

Further studies should be conducted in order to explore the causality, assess the ADD service's impact on drug use quality and costs, as well as impact of accompanied prescription review on positive outcomes.

4.6 EVIDENCE FOR THE BENEFITS OF THE ADD SERVICE IN PRIMARY HEALTHCARE IS LIMITED

Sinnemäki, Airaksinen et al

4.6 Elsewhere in northern Europe

ADD is also active in both Norway and Belgium.

ADD has been established in Norway since at least 2012, when it was reported in an academic study by Wekre, Bakken, and Garåsen[26]

The study reported that:

> *The GPs in Trondheim showed a positive attitude to multidose drug dispensing both before and after the implementation. Increased workload was reported, but still the GPs wanted the system to be continued*[27]

Likewise, the Association Pharmaceutique Belge (APB) has confirmed that "it is allowed for Belgian community pharmacists to outsource the technical operations of unidose repacking by a robot of solid oral medicines for a specific patient.[28]"

[26] **GPs' prescription routines and cooperation with other healthcare personnel before and after implementation of multidose drug dispensing.** Liv Johanne Wekre1-3, Kjersti Bakken4, Helge Garåsen15, Anders Grimsmo13. Scandinavian Journal of Public Health, vol. 40, 6: pp. 523-530. , First Published August 7, 2012.
[27] Ibid
[28] Confirmed by Jan Saevels & Lieven Swanepoel via email communications

5.0 North America

Automated dispensing is active and operational in both the US and Canada. This section will review the current situation in both those countries, which feature provincial or state base legislatures which often set the regulatory environment for pharmaceutical practice.

5.1 USA

In July 2003 the US Drug Enforcement Agency (DEA)[29] first permitted central fill pharmacies to prepare prescriptions on behalf of retail pharmacies where the central fill pharmacies have a contractual agreement to provide such services if the pharmacies do not share a common owner.

In a 2016 conference presentation to the American Society of Pharmacy Automation[30], it was estimated that 34% of all US retail pharmacy prescriptions were dispensed via central fill (noting that major multiple chains account for more than 60% of US dispensing.)

The same report also observes the rapid decline of "pouch packaging" in the US from 2014 onwards, as patients failed to convert to the new system (after a rapid rise from 2010 to 2013.)

[29] **Federal Register**. 23 June 2003, effective 24 July 2003.
[30] **Beyond the Counting Tray: Current and Emerging Pharmacy Automation and Technologies**. Christopher Thomsen, President, The ThomsenGroup Inc.
https://www.asapnet.org/files/January2016/Presentations/ASAPJan16_Presentation_11_Thomsen.pdf

This is the same mode of dispensing described as ADD elsewhere in this paper, which is now successfully embedded in Sweden & The Netherlands. The success of this model in Northern Europe should be offset against its decline in the US.

McKesson appear to the market leader with at least 11 central fill facilities in 2016[31]. A 2011 video claimed its systems had processed 157 million prescriptions per annum. This is the highest volume figure this research has uncovered. However, as McKesson are a system provider as well as service provider, it is not clear how many sites and 3rd parties this volume is dispersed across. It is clear this volume is dispersed across multiple sites.

Other suppliers include Pack4U and TCGRx.

The majority of automated dispensing in the US is intra company, where an automated facility services pharmacies owned by the owner of that facility.

An example of this is set out in the Kroger Pharmacies case study below.

A description of a new proposed central fill facility to Rite Aid pharmacies was presented to the New Jersey Board of Pharmacy in August 2016. This is attached as an appendix.

The facility in Del Ran, New Jersey is described as serving 1,100 pharmacies across 4 states.[32] No volume data is available.

The Philadelphia Inquirer and Daily News reported on 24 January 2018 that McKesson had filed to close this facility with the loss of 102 jobs as a consequence of the sale of Rite Aid stores to Walgreens[33].
.

[31] Source: **New Jersey Board of Pharmacy minutes**, August 2016
[32] Ibid
[33] www.philly.com, January 24 2018.

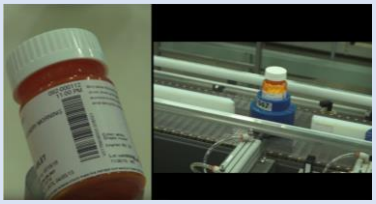
Case study: Kroger Pharmacies
Medium scale central fill

Kroger. Columbus, Ohio, USA.

- Opened 2010 to serve 196 Kroger pharmacies across Columbus & Cincinatti regions.
- Relocated & upgraded in 2013. 33,000 sq ft. 120 employees.

- **Prescription bottle focused**.

- 72 cannister cells containing fastest moving drugs.
- 6 Parata robots also containing fast moving drugs
- Supported by manual pick stations
- 7 autobaggers (4 for orders of 5 or more items)
- Dispensed in plastic heal sealed bags
- Same day & next day branch deliveries
- Uses McKesson software / technology






WALGREENS & AUTOMATION

Given the scale of the Walgreens US operation and its global vertical integration with Alliance, it appears to be under invested in centralised automation compared to competitors.

Walgreens launched a nationwide central fill operation in March 2009, centred on a hub in Orlando, Florida.

The same operation appears to have closed in April 2017.

Online searches for Walgreens and "pharmacy automation," "central fill" and other related terms bring back very few references.

Given the scale of the US operation, this raises the question of "why?"

Sources:
Drug Topics, Mar 1, 2009
Orlando Business Journal, Feb 2, 2015

It should be noted that US dispensing appears to be much more focussed on loose pills in bottles than original pack dispensing – hence the terminology "central fill."

It should also be noted that filling prescription bottles locally at a community pharmacy dispensary is highly intensive manual labour, and the efficiency gains through automated centralisation are almost certain to be far greater than for automated centralisation of original pack dispensing. This is a specific area that merits further research and analysis.

In December 2016, McKesson's High Volume Solutions division launched "Central Fill As A Service[34] ™ [35]." This appears similar to the Hub & Spoke arrangements proposed by DH in 2016 in so far as a third party is marketing centralised dispensing to pharmacies which it does not own. There is no documentary evidence that any small to medium sized pharmacy chains, to whom the service is targeted, are using this service. It should be noted that when a public company such as McKesson launch a new service via press release, as was the case above, it is commonplace to follow up with public announcements and/or information to communicate the success of the new service. At this stage, no such information has been released.

A video describing McKesson High Volume Solutions (HVS) can be viewed at: http://www.mckesson.com/pharmacies/mail-order/central-fill/. A high level view of processes deployed is set out in the case study below.

[34] http://www.mckesson.com/about-mckesson/newsroom/press-releases/2016/mckesson-introduces-central-fill-as-a-service/
[35] It should be noted McKesson have trademarked the name "Central Fill As A Service"

Case study: McKesson High Volume Solutions
Central Fill As A Service

Multi step process: mainly automated with manual intervention

1. Labelling & tare weight
2. Fill & tare weight
3. Fastest moving lines are filled from 8 litre capacity Kalesh cells at 99.9% accuracy
4. The next cohort of fastest moving lines are filled from Parata Uber Cells
5. The third cohort of fastest moving lines are dispensed by Parata Count Ahead robots
6. The fourth and final cohort are dispensed from Parata Express robots
7. Unit of Use prescriptions (i.e. original packs) can be auto dispensed by Mighty Mac robots, with the labels manually applied by employees
8. De-puckering (as required)
9. Auto bagging by patient prescription
10. Auto sorting into totes for despatch to pharmacies

See video at: https://www.youtube.com/watch?v=VdHcq0_zq_M

- McKesson systems processed 157 million prescriptions in 2011

McKesson's Vice President of Sales for HVS gave an informative interview to ComputerTalk[36] magazine, which included the following points (The full interview is attached for context as an appendix)

> "*I think it's also important to note that there's really no pure central fill anymore. Instead the facilities have a more hybrid role, giving pharmacies the ability to do different things that make use of the technology and process that go well beyond filling prescriptions to return them to the store for dispensing to the patient*
>
> *But even at a central site, you want to make sure that you are only automating when it makes sense. You have to look at your volume for a particular category of dispensing. It can often be the case that a manual process will continue to work very well up to a certain point and then, that's when automation will make financial sense and you will want to look at that investment*
>
> *Successful operations have achieved upwards of 50% of total prescriptions filled at central. 25% should be considered the minimum to have a positive impact.*
>
> *Most successful central fill operations look to reduce or hold net labor use across the enterprise, By taking the fulfillment activities out if the local pharmacies, labor can be reallocated and held stable while growth continues*
>
> *pharmacy operations should see a net reduction in overall inventory stock levels across the enterprise*
>
> *Successful operations …see a net reduction of incidents after implementing central fill*

Key take outs from the above interview for the purposes of this paper include the observation "*there's really no pure central fill any more*," and that successful operations have "*achieved upwards of 50% of total prescriptions filled at central*" while "*25% should be considered minimum to have a positive impact.*"

> THERE'S REALLY NO PURE CENTRAL FILL ANYMORE… EVEN AT A CENTRAL SITE, YOU WANT TO MAKE SURE THAT YOU ARE ONLY AUTOMATING WHEN IT MAKES SENSE
>
> Joe Tammaro, McKesson's Vice President of Sales

An example of the Requirements for Central Filling of Prescriptions in Washington State is attached as an appendix. Similar documentation for many other US states is available online.

[36] http://www.computertalk.com/feature-stories/exclusive-web-content-more-on-central-fill-q-a-with-mckesson-s-joe-tammaro

Academic literature review & references

Compared to Northern Europe, and indeed South Africa, independent academic studies of automated dispensing in the US are scarce. The overwhelming body of information in the public domain is proprietary, and therefore oftentimes conflicted.

The one independent study found to be of value for this purposes of this paper was published in 2010 in the New England Journal of Medicine, and was focused on the effect of bar code driven automation in hospital pharmacy.

7. **Effect of Bar-Code Technology on the Safety of Medication Administration.**

   Eric G. Poon, Carol A. Keohane, Catherine S. Yoon, Matthew Ditmore, Anne Bane, Osnat Levtzion-Korach, Thomas Moniz, Jeffrey M. Rothschild, Allen B. Kachalia, Judy Hayes, William W. Churchill, Stuart Lipsitz, Anthony D. Whittemore, David W. Bates, and Tejal K. Gandhi.et al.

   The New England Journal of Medicine. May 6, 2010

Key observations of value to this paper included:

> *Use of the bar-code eMAR substantially reduced the rate of errors in order transcription and in medication administration as well as potential adverse drug events, although it did not eliminate such errors.*

Further noting, however, that:

> *Previous research in human-factors engineering also suggests that new errors may be introduced if busy clinicians are asked to select medications from a list of multiple medications due to be administered and then to document the administration times*

The authors further recommended that organisations interested in investing in patient safety technology should consider a range of factors including “adequate training, onsite support, adequate hardware, and a responsive software-development team.”

Crucially for the purpose of this paper they add:

> *future studies should evaluate vendor solutions implemented in the community setting*

Despite this paper being published in 2010, studies evaluating benefits of automated dispensing technology in the US community setting appear to be absent, and studies worldwide still relatively few.

NEW ERRORS MAY BE INTRODUCED

Poon, Keohane et al

Discussion

Whilst centralised dispensing by third parties using both manual and automated processes has been enabled in the US since 2003, data corroborating its patient safety and economic benefits are notable in their absence.

Whilst an informed conference paper in 2016 estimated that 34% of retail pharmacy prescriptions by volume were centrally filled, this set against the fact that 60% of US pharmacies are owned by major chains. If all major chains deploy central fill, then little over 50% of all their prescriptions are dispensed in this way.

Such a proportion is in line with the observation by a senior McKesson executive that "successful operations have achieved upwards of 50% of total prescriptions filled at central." Third party "central fill as a service" appears much less prevalent than central fill amongst owned estates, with market leaders McKesson only launching this as a marketed service in December 2016. No updates on the success of this service or otherwise are publicly available.

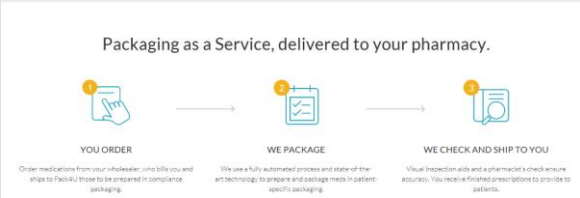
These developments should also be viewed in the context of a market where a much greater proportion of loose pills and tablets appear to be dispensed into vials and bottles than the UK and northern Europe, as well as against the reported rapid decline in "pouch dispensing" where patients are not successfully converting to a new mode of dispensing.

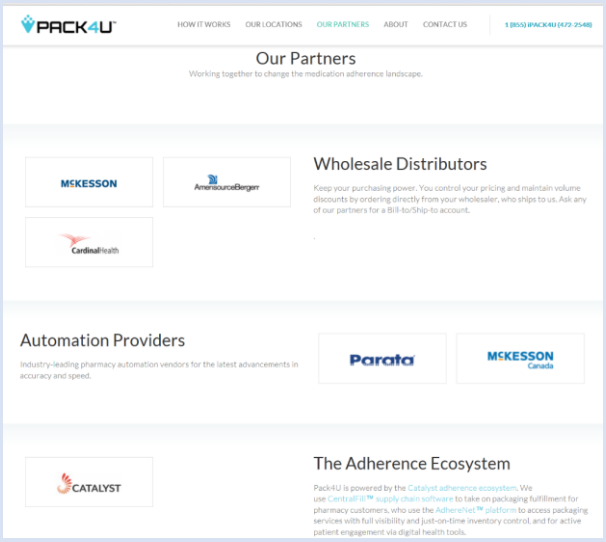
In the round, there are clearly significant learnings to be gained from closer study of the US market, not only in terms of the benefits and disbenefits of large scale automated dispensing, but also in the context of a market with notably different characteristics.

Case study: Pack4U
Central Fill As A Service

www.pack4u.com

Marketed to promote medicines adherence, Pack4U supply Packaging As A Service across US and Canada from 17 locations. Medicines are packaged into pouches familiar from the Northern European model. Cost is quoted as typically $25 per patient per month.





5.2 Canada

Centralised prescription processing, or central fill, is enabled in at least some Canadian provinces including Ontario, New Brunswick, Manitoba & Sasketchwan. For example, it was first enabled in Ontario in September 2005, where it was defined in the following terms:

> Centralized prescription processing (central fill) refers to a service one pharmacy provides to another where the central fill pharmacy processes a request from an originating pharmacy to prepare a drug order. Medications packaged by a central fill pharmacy are dispensed by the originating pharmacy pursuant to a prescription. Each participating pharmacy is required to be accredited by the Ontario College of Pharmacists.[37]

The best documented case study appears to be New Brunswick hospitals, where McKesson have established a Central Fill As a Service facility for 22 provincial hospitals, which has been operating since 2014.

[37] Ontario College of Pharmacists. Practice Policies & Guidelines. http://www.ocpinfo.com/regulations-standards/policies-guidelines/central-fill/

New Brunswick, Canada
Central Fill from hub to network of provincial hospitals

A 3rd party hub, managed by McKesson, serves 22 provincial hospitals across New Brunswick province. The hospitals are owned across 2 different organisations (Horizon & Vitalite)

Whilst New Brunswick covers a wide geographical area by British standards, it is small by Canadian standards, and operates only inter province. This is an example of a 3rd party hub operating across pharmacies owned by more than entity.

‹ *Implementation completed of an integrated pharmaceutical supply chain*

English français

Share:

All New Brunswick hospitals are now linked to the province's newly-integrated pharmaceutical supply chain which is co-ordinated through McKesson Canada's Moncton distribution centre.

"Integrating all 22 hospitals into this one solution is an innovative way to increase efficiencies in our health-care system, create jobs and savings in New Brunswick," said Premier Brian Gallant during a visit to the distribution centre today.

Fifty-three jobs were created through the partnership between the provincial government and McKesson Canada.

Each hospital is now equipped with AcuDose-RX automated dispensing cabinets in select patient areas. The cabinets automatically dispense the appropriate patient medication which reduces the chance of human error. The cabinets are designed with biometric technology which restricts access to authorized users.

McKesson Canada's Atlantic Central Fill Pharmacy prepares unit doses of most of the stock required to replenish the cabinets, which ensures just-in-time inventory. The packaging format aligns with the guidelines of the Institute of Safe Medication Practices and uses barcode technology for appropriate medication tracking such as for inventory and/or diversion purposes.

"We are focused on improving the cost and quality of health-care delivery for the benefit of the patient," said Alain Champagne, president of McKesson Canada. "This partnership has allowed us to redefine the pharmaceutical supply chain process for New Brunswick hospitals. Thanks to the strategic partnership created between the Department of Health, Horizon Health Network, Vitalité Health Network, Service New Brunswick and McKesson Canada, hospitals have timely access to the vital medications they need, no matter where they are located in the province."

The initiative is on track to save the province's health-care system about $3 million annually. The Saint John Regional Hospital was recently connected to the central pharmacy, marking the completion of the project.

Opportunities NB is providing McKesson Canada up to $850,000 in the form of a non-repayable conditional grant which is being used to off-set a portion of the job creation expenditures.

Founded more than 100 years ago, McKesson Canada is dedicated to delivering medicines, supplies and information technologies to the health-care industry to provide patients better, safer care.

https://www.mckesson.ca/-/implementation-completed-of-an-integrated-pharmaceutical-supply-chain

See also: http://www.nhlc-cnls.ca/wp-content/uploads/2016/11/Wilson_Pharmaceutical-Supply1.pdf

Academic literature review & references

Independent academic research from Canadian institutions is, in common with the US, somewhat scarce. This review has considered two published studies, both with focus on automation in a hospital setting.

8.	**Decentralized Automated Dispensing Devices: Systematic Review of Clinical and Economic Impacts in Hospitals.** Nicole W Tsao, Clifford Lo, Michele Babich, Kieran Shah, Nick J Bansback. Canadian Journal of Hospital Pharmacy. 2014 Mar-Apr; 67(2): 138–148.
9.	**Automated Medication Dispensing Systems: A Review of the Clinical Benefits, Harms, and Cost-Effectiveness.** Canadian Agency for Drugs and Technology in Health. 30 September 2010

Tsao et al, based in British Columbia, focus on ADD in hospital settings, with research published in 2014. In line with many other studies, they note "lack of reliable data remained a caveat."

When noting the higher level uptake of ADDs in US hospitals compared to Canadian (at 89% versus 53%), they note this has not

> *" not necessarily been the result of a drive for safer systems. They were initially employed in US hospitals to help capture all patient-specific financial charges, to ensure that a complete bill would be available on discharge, and to track narcotics and controlled substances in response to a federal monitoring system.5 Given that these benefits cannot be realized in the Canadian setting, it is unclear whether the uptake of expensive technology such as ADDs in Canadian hospitals (by 47% between 2007/2008 and 2009/2010) was cost-effective"*

The authors conclude:

> *ADDs have limited potential to decrease medication errors and increase efficiencies, but their impact is highly institution-specific, and use of this technology requires proper integration into an institution's medication distribution process. Before deploying this technology, it is recommended that Canadian hospitals carefully examine their current systems and the benefits they hope to gain with the changes.*

Before considering the next study, it is important to note the observation made by Tsao et al that its conclusions were "driven largely by unpublished data (cited as "Baker 2008") from Cardinal Health, which at the time owned Pyxis, a pioneer and manufacturer of ADD technology."

Automated Medication Dispensing Systems: A Review of the Clinical Benefits, Harms, and Cost-Effectiveness.
Canadian Agency for Drugs and Technology in Health.
30 September 2010

Even in light of the caveat above, the authors of the Canadian Agency for Drugs and Technology in Health report were cautious in drawing their own conclusions, referencing "a lack of comprehensive data on the financial impact of automation," and "the poor quality of resource use and cost data available in the literature." Furthermore, "most studies had important methodological shortcomings."
In respect of their own ward based research – the integrity of which is referenced above - the authors concluded:

> *The authors concluded that the implementation of a ward-based ADD in a hospital patient care unit can reduce costs while reducing error rates. In contrast, implementation of this technology in intensive care units results in a net increase in costs.*

IT IS UNCLEAR WHETHER THE UPTAKE OF EXPENSIVE TECHNOLOGY SUCH AS ADDS IN CANADIAN HOSPITALS … WAS COST-EFFECTIVE

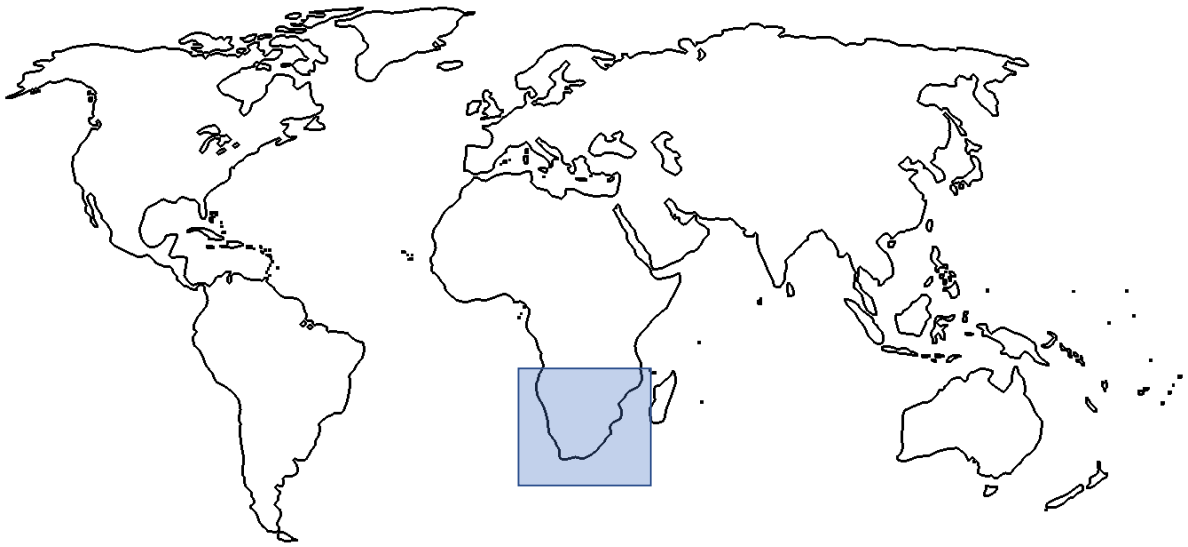
Tsao, Lo et al, 2014

Discussion

Canada is a vast nation, with many remote, small communities, which present significant challenges from a wider healthcare and pharmacy specific perspective.

Automated dispensing techniques appear to have been quietly adopted, although most data is available for hospital settings only.

6.0 Rest of the world



South Africa

Whilst the global centres of pharmacy automation are North America and Northern Europe, South Africa has also piloted a large scale, centralised dispensing model for patients with long term, chronic conditions in Western Cape province which is relevant to this study. In addition, in light of a the report from a government task force, pharmacy automation has recently become a hot topic of discussion in Australia.

6.1 South Africa

The Chronic Dispensing Unit in the Western Cape, based in Cape Town, is one of the largest centralised dispensing deployments globally.

Specifically designed to relieve pressure on hospitals in the province, the central dispensary services hundreds of community pharmacies and thousands of collection points throughout the province.

It appears the unit may have originally used manual processes, but appears more recently to have adopted automated technologies, where the facility now runs both manual and automated processes. In 2014, it was described as "automated to an extent."

In September 2017, the Western Cape Government reported that the CDU dispenses a monthly average of 380,000 Patient Medicine Parcels to patients at health care facilities in the Western Cape, including around 1,200 alternate collection points , on (with the sites managed by the Western Cape Government Metro District Health Services)[38]

To date, since foundation in 2005, approximately 18 million medicine parcels have been dispensed. It is currently estimated to serve at least 350,000 patients.

This research has been unable to identify a larger centralised dispensing unit globally for which public data is available.

The service is now outsourced, on a 5 year contract, with a fee for Patient Medicine Parcel of R21.51 (exc VAT), equivalent to circa £1.30.

The CDU has been widely documented, and appears to be a success, especially against the specific challenges of the Western Cape it was developed to address.

Informative public references include:

> Western Cape's Chronic Medication Dispensing Largest of Its Kind in Africa, Western Cape Government, 18 April 2012[39]
>
> The Chronic Dispensing Unit. 4th Annual Health Systems Strengthening Symposium. Tania Mathys. October 2015[40]
>
> UTi Chronic Medicine Dispensary Centralized Dispensing Unit. 23 October 2014.[41]

[38] **Medication Collection Points – the next step in improving patient centred health.** www.westerncape.gov.sa
[39] https://www.westerncape.gov.za/news/western-capes-chronic-medication-dispensing-largest-its-kind-africa
[40] http://www.anovahealth.co.za/wp-content/uploads/2015/10/Tania-Mathys-The-Chronic-Dispensing-Unit.pdf
[41] http://www.e-pharmac.co.za/wp/wp-content/uploads/2015/10/Ludo-Tandt-UTi-Pharma-Centralised-Dispensing-Unit.pdf

Academic literature review

As noted above, the CDU is widely documented and reported. However, there appears to be only one, rigorous, independent study conducted to date.

10. Improving access to medicines through centralised dispensing in the public sector: a case study of the Chronic Dispensing Unit in the Western Cape Province, South Africa

Bvudzai Priscilla Magadzire, Bruno Marchal, and Kim Ward

BMC Health Services Research. 2015; 15: 513. Published online 2015 Nov 17.

Magadzire et al produce an excellent and authoritative history and anlaysis of the CDU, which aims to "advance the understanding of the CDU and lay a foundation for future work that aims to improve the intervention and provide lessons for similar models."

In common with many other independent authors, they comment on the "dearth of literature on models of centralised dispensing" and observe that despite "limited evidence, centralised dispensing is gaining momentum in South Africa."

In conclusion:

> *existing evidence suggests to some degree that the CDU objectives have been achieved and cite benefits such as reduced waiting times [9, 10, 29], patients' improved experiences with healthcare services and their motivation to remain stable, increased time for patient counselling [9, 10], and pharmacists' ability to serve more than double the number of people they served prior to CDU implementation [29]. Despite these reported benefits, however, we report the difficulty to ascertain how most of the conclusions were reached, the sustainability of the gains and the inability to generalise the findings*

Finally, they recommend:

> *Investigating facility-specific characteristics, such as human resources, infrastructure and staff motivation [34] and the impact of the intervention on the healthcare provider, patient access to treatment and difficulties in implementation could also be necessary*

DESPITE LIMITED EVIDENCE, CENTRALISED DISPENSING IS GAINING MOMENTUM IN SOUTH AFRICA.
Magadzire, Marchal et al, 2015

6.2 Australia

Pharmacy automation has come into the spotlight in Australia recently as wider adoption was recently recommended by the Australian Government Productivity Commission[42].

A number of blogs and online articles have been published, but one independent academic study should be referenced, which is discussed below.

Academic literature review

11. Disruptive innovation in community pharmacy – Impact of automation on the pharmacist workforce

Jean Spinks, Ph.D., M.P.H., M.H.Sc.(PHP), B.Pharm., John Jackson, M.P.H., B.Pharm., Carl M. Kirkpatrick, Ph.D., B.Pharm., Amanda J. Wheeler, Ph.D., B.Pharm.

Research in Social and Administrative Pharmacy· May 2016

This study takes a global perspective, and specifically references the "'hub and spoke' model currently being debated in the United Kingdom." The specific point of interest for Spinks et al is the potential impact of automation on pharmacy workforce planning.

The study is amongst the most recent and authoritative, reaching a viewpoint that "on balance it is difficult to say if automated dispensing may improve, decrease or make no difference to consumer outcomes."

This diffidence is common with many other independent studies discovered in writing this paper.

Likewise, in common with other studies, Spinks et al identify there may be negative impacts on patient or consumer safety.

> *"The situation where an electronic prescription is sent from a prescriber to a centralized dispensing facility from which the medications are sent directly to the consumer may have negative impacts on consumer safety."*

In common with many others independent authors, they recommend that:

> *In terms of the next steps in pharmacy workforce planning, a more comprehensive analysis is warranted.*

ON BALANCE IT IS DIFFICULT TO SAY IF AUTOMATED DISPENSING MAY IMPROVE, DECREASE OR MAKE NO DIFFERENCE TO CONSUMER OUTCOMES.
Spinks. Jackson et al, 2016

[42] **Shifting The Dial: 5 Year Productivity Review**. Australian Government Productivity Commission. 3 August 2017.

7.0 The UK

This section focuses on the current state of automation within UK community pharmacy.

Even though the Department for Health & Social Care only has jurisdiction over England, most UK pharmacy businesses operate across the borders of the devolved jurisdictions of Scotland, Wales & Northern Ireland as a single entity.

Overview

Large scale automated dispensing is active in the UK at the largest wholesalers Alliance and AAH. Pilots are underway at Phoenix Rowlands and Well.

The largest scale site in the UK may be Pharmacy2U in Leeds.

Smaller scale automated dispensing is active at Mayberry Pharmacies in South Wales, and a small number of other sites.

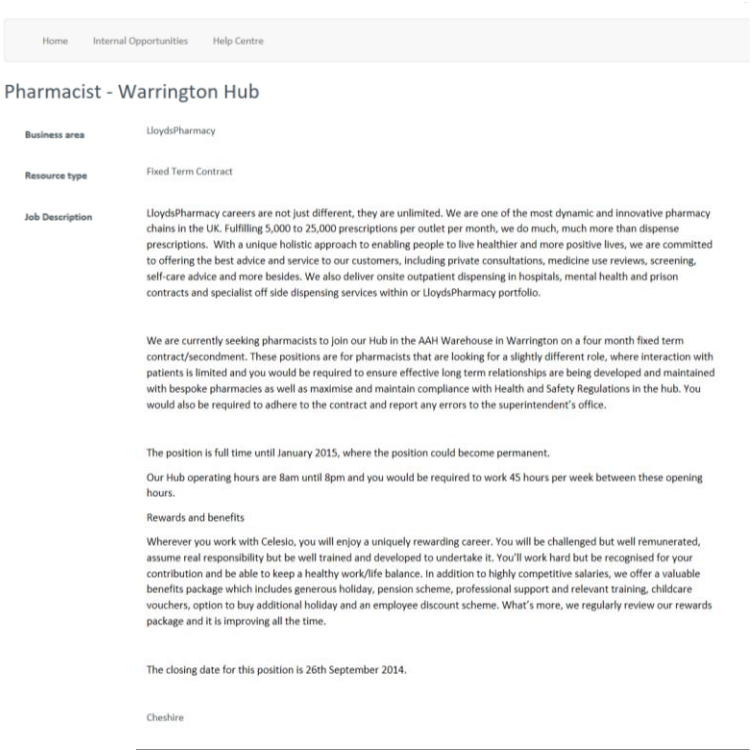
Facility	Commentary
AAH Lloyds Hub Warrington	This facility serves a closed but wide network of Lloyds pharmacies. It has operated as a manual hub for several years, and is currently in the process of automation. There is no public data on the volumes now being processed via automated equipment, nor the number of pharmacies or patients served.
Alliance Boots Hub Preston	Alliance Boots have trialled a dispensing hub in Preston to serve between 50 and 250 pharmacies. Further information is not available in the public domain.
Rowlands Location tbc	Rowlands are piloting use of ADD (automated dose dispensing) via the PilPouch system, as reported in PJ (14 Sept 2017) The PilPouch system is in line with many of those deployed in Northern Europe, and pouches will replace blister packs for MDS dispensing. Further details are not publicly available.
Well Stoke	Well stated in C&D on 13 Apr 17 that 6 of their branches were using the "hub & spoke" dispensing model, "working through the final polish for the system before we roll it out across the entire business, which we intend to do later this year." No further updates have been published. UPDATE as at 20 April. Chemist & Druggist reported that a "fair amount" of Well stores are now using "hub & spoke" centralised dispensing. According to Chris Ellett, Well Director of Transformation, the organisation continues to be in the process of "rolling that out," having made "some changes to the technology," further noting that "one thing I think we've done really well is we've kept our technology choice and our automation quite simple." He also notes that "from a dispensing perspective, we've proven that central fulfilment is safer."
Pharmacy 2 U Leeds	Potentially the largest operational hub in the UK. Whilst it does not serve a network of pharmacies, it serves a wide network of repeat patients dispersed across the UK. All patients operate within Pharmacy 2U processes so the network is closed but wide. In Dec 17, P2U dispensed 259k items, nearly 5 times the volume of the next largest pharmacy in England (Westons, also a DTP operator.) P2U state in a press release their facility has capacity for 1 million items per month (about 1.2% of national items per month) and represents a £3.5m investment.

Mayberry Pharmacy Hub Blackwood, Gwent	Serving a closed and close networks of 7 pharmacies, all owned by Paul Mayberry (who is also Superintendent tbc). A good example of innovation and entrepreneurialism in the independent sector.

Case study: AAH Lloyds hub, Warrington
Hub located at wholesaler servicing vertically integrated pharmacies

The Lloyds hub pharmacy is located at the AAH facility in Warrington. It was originally trialled as a manual operation in 2008. In 2015 / 2016, up to £20m was invested to automate the facility it terms of both standard and MDS dispensing.

The site was visited, when still in prototype, by members of the original Hub & Spoke Task & Finish Group.



Home Internal Opportunities Help Centre

Pharmacist - Warrington Hub

Business area LloydsPharmacy

Resource type Fixed Term Contract

Job Description LloydsPharmacy careers are not just different, they are unlimited. We are one of the most dynamic and innovative pharmacy chains in the UK. Fulfilling 5,000 to 25,000 prescriptions per outlet per month, we do much, much more than dispense prescriptions. With a unique holistic approach to enabling people to live healthier and more positive lives, we are committed to offering the best advice and service to our customers, including private consultations, medicine use reviews, screening, self-care advice and more besides. We also deliver onsite outpatient dispensing in hospitals, mental health and prison contracts and specialist off side dispensing services within or LloydsPharmacy portfolio.

We are currently seeking pharmacists to join our Hub in the AAH Warehouse in Warrington on a four month fixed term contract/secondment. These positions are for pharmacists that are looking for a slightly different role, where interaction with patients is limited and you would be required to ensure effective long term relationships are being developed and maintained with bespoke pharmacies as well as maximise and maintain compliance with Health and Safety Regulations in the hub. You would also be required to adhere to the contract and report any errors to the superintendent's office.

The position is full time until January 2015, where the position could become permanent.

Our Hub operating hours are 8am until 8pm and you would be required to work 45 hours per week between these opening hours.

Rewards and benefits

Wherever you work with Celesio, you will enjoy a uniquely rewarding career. You will be challenged but well remunerated, assume real responsibility but be well trained and developed to undertake it. You'll work hard but be recognised for your contribution and be able to keep a healthy work/life balance. In addition to highly competitive salaries, we offer a valuable benefits package which includes generous holiday, pension scheme, professional support and relevant training, childcare vouchers, option to buy additional holiday and an employee discount scheme. What's more, we regularly review our rewards package and it is improving all the time.

The closing date for this position is 26th September 2014.

Cheshire

Case study: Alliance Boots "DSP" Preston

Hub located at wholesaler servicing vertically integrated pharmacies

The Boots "Dispensing Support Pharmacy" or DSP is a hub pharmacy based at the Alliance Service Centre, Preston that serves an unspecified number of Boots pharmacies. It is a Boots pharmacy registered with GPhC. The PJ reported it became operational in 2014, initially to service 50 pilot branches. There is little other online coverage. However, online ads for staff are placed regularly, and a video featuring a member of staff is posted on YouTube (see below.)

Senior Operative – Dispensing Support Pharmacy

Job reference: 73713BR

Location: Preston, Walton Summit
Shift pattern: Full-time, Part-time
Shift pattern: 16 to 24 hours per week, 25 to 34 per week, Over 35 hours per week

Function area: Warehousing
Contract type: Permanent

£8.50ph

Job Summary

This role is part of a new Boots support service located at Walton Summit, Preston. Boots Dispensing Support Pharmacy provides an efficient and unique dispensing support service for Boots stores. Under the leadership of a Pharmacist you'll support stores to ensure that patients receive the right medicines on time and help store colleagues provide complete care to their customers. Patient safety is at the heart of everything we do and as such there is a requirement for high standards of compliance with operating procedures and for order and quality.

Working in a fast paced environment the operation is efficient, modern and supported by automation and technology. You will be part of a team that picks & assembles orders for our stores to a high level of accuracy. You will be able to work at pace and demonstrate both thoroughness and attention to detail. Full training will be provided.

This role is part of a new support service and the Pharmacy is located at Walton Summit Preston and is co-located as part of the Alliance Boots group.

What we are looking for

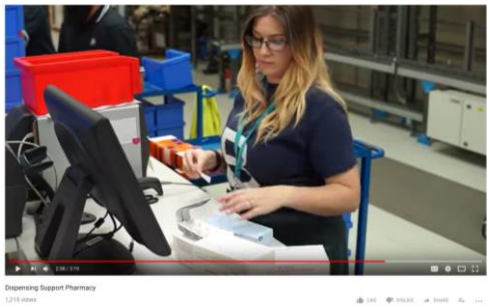
We're looking for really great people. It's all about working together as one great team – after all it's our people that are at the heart of our business. The role requires a team player who rises to the challenge of unplanned workload spikes. Ideally you'll have previous knowledge and experience of leading workstations, healthcare or automated operations and have the ability to work to defined productivity, accuracy and above all quality standards.

What will you be doing day to day

You'll be leading workstations and your duties may include any of the following activities:

- Assembling & labeling patient medications
- Supporting & coaching workstation colleagues
- Stock picking & packing
- Putting away stock
- Clearing waste & general housekeeping

https://www.boots.jobs/jobs/73713br-senior-operative-dispensing-support-pharmacy/



https://www.youtube.com/watch?v=C0Fo8fdsfyc

What happens?

Picking stock, applying labels, performing accuracy checks and bagging medicines will be completed in the dispensing support pharmacy. However, stores will be responsible for data entry into the patient medication record, the clinical check, the data accuracy check and handing or delivering prescriptions to patients.

The prescription will remain in the local pharmacy at all times. The pharmacist will submit details to the dispensing support pharmacy and the prescription will be matched to the patient's medicines when they arrive from the dispensing support pharmacy.

https://www.pharmaceutical-journal.com/news-and-analysis/news/rps-wants-to-see-if-boots-automation-move-frees-pharmacists-time/11135698.article

Discussion

The large, vertically integrated pharmacy chains in the UK such as Walgreens Boots Alliance and Lloyds Celesio McKesson appear to lag behind their sister companies in both northern Europe and north America in terms of large scale automated dispensing.

McKesson, whilst not operating owned pharmacies in the US, appears to be the market leader in terms of central fill in the US, and Celesio own a number of northern European wholesalers who are established ADD suppliers.

Walgreens Boots Alliance in the US, as discussed previously, do not appear to be in the vanguard of either central operations or pharmacy automation. However, WBA European operations, such as SPITS NV in The Netherlands, are established ADD suppliers. Phoenix Rowlands also have interests in ADD suppliers in northern Europe.

Given the knowledge and expertise of both Boots and Lloyds parent companies, the question must be asked why they appear to lag behind sister organisations in northern Europe in terms of ADD and other forms of dispensing automation? Are there local market conditions and characteristics that mitigate against in England and the UK?

Given the scale of both Boots and Lloyds estates in the UK, one might have expected them to adopt large scale automated dispensing sooner, to service their own estates, if the economic benefits or business case was established.

Lloyds Celesio have operated a manual central hub out of their Warrington depot for a number of years. Only recently, and possibly post McKesson acquisition, have they focused on the introduction of automation.

Both Boots and Lloyds have targeted care homes business, and the question, in light of the scale of their respective businesses in this field, must be asked as to why they have not chosen to automate sooner, given how well established such technologies in geographically proximate markets such as The Netherlands and Sweden.

In the meanwhile, entrepreneurial independent pharmacy businesses, who were pioneers in investing in single site robotics, have developed a small number of small to mid size automated hub operations that may be economically attractive to scale to the next level.

It may be that the Pharmacy2U operation in Leeds is both the largest automated facility in the UK that is currently operational, with the capacity to scale further.

However, the home delivery / direct to patient model does not appear to be profitable to them, which raises questions once again to the economic attractiveness and benefits of large scale automation. In particular, it raises the question of whether the scale benefits of a high volume central operation are offset by new costs such as additional supply chain and delivery costs.

In the same way that a number of academics have asked if patient safety gains in the automated part of the process may be offset by the new risks introduced by additional processes before and after automation, in combination with unintended consequences, are the economic gains of centralisation and automation being offset by similar factors?

Case study: Pharmacy2U
Large scale automated dispensing to internet and mail order patients

Currently fulfilling 250k items per month, this facility has the claimed capacity of 1,000,000 items per month. The warehouse was recently sold & leaded back to a logistics property investor for £2.8m (Oct 17)

A video of the Pharmacy2U automated facility can be viewed at:

You can hear more about the new facility here:

https://www.pharmacy2u.co.uk/news/pharmacy2u-unveils-3-5m-medication-hub/

How it works and key technical features

(NHS Repeat Prescription Service)

- **Prescription request.** Patients request their repeat prescription with Pharmacy2U online or by phone. Pharmacy2U then arranges the prescription with a patient's GP, who issues it via the NHS Electronic Prescription Service (EPSr2).
- **Pharmacist review.** One of Pharmacy2U's pharmacists checks all new prescriptions.
- **Clinical checks.** Accuracy and clinical governance is built into every step of the process. Prescriptions can be auto-labelled using the latest in drug code matching technology and checked for accuracy by qualified technicians.
- The technology includes a three-way barcode verification procedure, which is included in the patent application and ensures that pharmacy technicians place the correct label on the correct medicine.
- **Automated dispensing**. Two automated dispensing systems from Rowa Technologies by Becton Dickinson are housed within a secure medicine cabinet and can pick up to 32 prescription items every eight to twelve seconds.
- Pharmacy technicians working on the fast moving "pick by light" section can process a prescription item every three seconds
- **Bespoke packaging.** An automated packaging system from B+ Equipment reduces the size of each package to the exact size of the products inside – minimising waste and postage costs. The machine can produce up to 900 boxes per hour.
- **Order journey.** The storage and picking areas are approximately 650m² (the size of 2.5 tennis courts). Conveyor belts stretching 550m (nearly twice the height of the Shard building in London) navigate the order through the process.

8.0 Conclusions

The research undertaken to date has failed to identify any global reference sites for large scale, automated dispensing of medicines across a wide geographical area to 3rd party pharmacies.

The highest volume, automated dispensing operations may be in the U.S, but as they primarily serve proprietary businesses, definitive or authoritative data is not available in the public domain.

"Central fill as a service" has recently been introduced into the US, but no data on uptake levels is currently available in the public domain.

The U.S. remains more focussed on the filling of loose pills into patient vials, hence the phrase "central fill" by which centralised dispensing is generally referred in the US.

As such, combined with other distinctive characteristics of the US healthcare and pharmacy system, learnings that are relevant to the UK from the US experience to date may be fewer rather than greater.

One learning that may be applicable appears to be the relative failure of ADD in the US, where it is reported that patients have not been prepared to adapt to new modes of packaging, and after rapid growth, this mode of dispensing is now reported to be in equally rapid decline. The Chronic Dispensing Unit is South Africa may be the largest global reference site for single site, large scale centralised dispensing. However, it may only be recently that the CDU has invested in robotics and automation. Not only does South Africa, and Western Cape Province, face distinctive, local healthcare needs which the CDU was designed to ameliorate, but the independent research by Magadzire et al is sceptical as to whether hard, independent evidence to support its success is available.

Automated dose dispensing is common throughout Scandinavia and northern Europe, and has been established in many markets for at least 15 years.

The most established appear to be The Netherlands and Sweden, both of whom may claim to be the European leaders. Certainly ADD is considered to be mainstream in The Netherlands, and an example of pharmacy good practice, serving in the range of 400,000 principally elderly patients primarily in care homes.

The aggregation and automation of dose dispensing appears to make good economic sense, compared to the UK where manual MDS dispensing is dispersed across many thousands of individual pharmacy dispensaries.

However, if the economic and patient safety benefits were clear cut, it is reasonable to ask why large chains such as Boots and Lloyds have not invested in such processes and technology previously. Not only is the technology long established, but companies owned by

both Alliance and Celesio have been operating such technologies across northern Europe for many years.

It should be noted that authoritative, public data is not available in respect of the volume of patients or pharmacies being served by ADD. This presents a challenge to any pharmacy in taking a view as to the relative pros and cons.

However, given that both Boots and Lloyds parent companies not only own pharmacies in these northern European markets, which use ADD, but also wholesalers who provide such services, this should not present the same challenge to those organisations.

Given the ownership structures of such organisations, and their access to what should be high quality, rigorous data, the question again has to be asked "why have Boots, Lloyds, and possibly Rowlands, not invested in ADD in their UK businesses to serve their own estates?"

If any of these organisations support any move to larger scale automated, third party dispensing in the UK, in the absence of global reference sites, it could be reasonably expected that such organisations release supporting evidence in the event that their parent organisations run a facility with higher volumes than the Chronic Dispensing Unit in South Africa.

Boots UK actually own more pharmacies in the UK than there are in the whole of The Netherlands, therefore the economies should be there in their own estate alone.

New "hub & spoke" regulation to enable an organisation such as Alliance to gain the required scale to be economically viable should not be required.

The same argument can be asked of AAH Lloyds.

The academic literature reviewed remains unconvinced of any definitive claim to improved patient safety, almost unanimously calling for the need for further, more rigorous research, not least as whilst there may be patient gains in terms of the part of the process that is automated, new processes are introduced before and after automation that may generate new risks. Furthermore, there is the genuine risk of unintended consequences. One example given is nurses taking less care on the assumption the automation has dispensed accurately. New processes are required for the transfer of patient specific prescriptions to an automated hub for dispensing, and for the logistical supply of the picked and packaged, patient specific medicines.

The new process of packing and delivering patient specific packages into pharmacy specific totes also presents significant opportunity for error.

Anyone who has experienced a lost or misdirected home delivery will be aware of the risks and challenges this new process presents. Whilst automated or robot driven vehicles are in development, driving and delivering remains an intensely manual process at this time, and presents a significant range of opportunities for error.

In light of the above, a number of factors have emerged that should be taken into account.

These factors are set out below.

1. **Feasibility**. At the present time, there do not appear to be any large scale pharmacy hubs in operation serving more than hundreds of pharmacies and thousands of patients. Further, those that are largest in operation operate within closed networks where the pharmacies are all owned by the same organisation, working to common standard operating procedures.

   It is reasonable to expect that large, vertically integrated chains such as Boots and Lloyds would be best positioned to make large scale automation work for their owned, closed network pharmacies.

   It would therefore be useful to review the patient, operational and cost benefits evidenced by the large scale, automated hubs run by such organisations as and when they are in position to share.

2. **Economic**. Building on the above, several academic researchers have identified the absence of cost benefit cases in the automated dispensing scenarios they have researched. Evidenced cost benefit cases would aid understanding of these scenarios. In particular, it is noted that academic researchers identified unintended consequences and new work processes that could offset prima facie gains through automation.

3. **Patient safety**. A range of claims for the patient safety benefits of large scale automation have been made. There is a much more conservative tone amongst academic researchers, who note the case may not be proven one way or the other. More rigorous independent research is required.

These factors are now set out in greater detail with supporting evidence below.

1. The clear need for further research

Recommendation:
More independent, primary research into the benefits of large scale, automated dispensing, including patient safety, patient outcomes and cost benefits.

Why?

"To the best of our knowledge there are no conclusive studies with regard to patient safety and adherence" Bardage & Ring. 2016.[43]

"There are few studies evaluating the consequences of automated MDD with regard to patient safety, and those that investigate this issue are not very extensive." Bardage & Ring 2014[44]

"on balance it is difficult to say if automated dispensing may improve, decrease or make no difference to consumer outcomes." Spinks, Jackson et al, 2016[45]

"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." Cheung, van der Bent et al in 2014[46]

"In the implementation of ADD, healthcare providers may have focused on the advantages, but new technologies can also have unintended consequences" Cheung, van der Bent et al in 2014 [47]

"We report the difficulty to ascertain how most of the conclusions were reached, the sustainability of the gains and the inability to generalise the findings" Magadzire, Marchal & Ward[48]

[43] **Patients' Perspectives on Automated Multi-dose Drug Dispensing**. C Bardage and L Ring, Journal of Community Medicine & Health Education, 2016, 6.1
[44] **Health care professionals' perspectives on automated multi-dose drug dispensing**. Carola Bardage, Anders Ekedahl, Lena Ring, Pharmacy Practice (Granada). 2014 Oct-Dec; 12(4): 470. Published online 2014 Mar 15
[45] **Disruptive innovation in community pharmacy – Impact of automation on the pharmacist workforce.** Jean Spinks, Ph.D., M.P.H., M.H.Sc.(PHP), B.Pharm., John Jackson, M.P.H., B.Pharm., Carl M. Kirkpatrick, Ph.D., B.Pharm., Amanda J. Wheeler, Ph.D., B.Pharm. Research in Social and Administrative Pharmacy· May 2016
[46] **Medication Incidents Related to Automated Dose Dispensing in Community Pharmacies and Hospitals - A Reporting System Study.** Ka-Chun Cheung , Patricia M. L. A. van den Bemt, Marcel L. Bouvy, Michel Wensing, Peter A. G. M. De Smet. Plos ONE, July 24, 2014
[47] Ibid
[48] **Improving access to medicines through centralised dispensing in the public sector: a case study of the Chronic Dispensing Unit in the Western Cape Province, South Africa.** Bvudzai Priscilla Magadzire, Bruno Marchal, and Kim Ward. BMC Health Services Research. 2015; 15: 513. Published online 2015 Nov 17.

2a. The patient safety case remains unproven

Recommendation:
There is an absence of definitive evidence, which has given risen to concerns that gains in one part of the process may be offset by unintended consequences and new risks elsewhere in the end to end process.

Clear independent evidence of the patient safety benefits of automated dispensing from the start to the end of the process is therefore needed.

Why?

Bardage & Ring state in 2014: "To the best of our knowledge there are no conclusive studies with regard to patient safety and adherence using automated MDD.[49]

In a further study in 2016, the same authors observe that ""patient safety aspects are challenging to assess[50]" concluding that ""Adherence and safety issues…need to be further looked into [51]"

When undertaking a systematic literature review in 2011, Sihvo, Isojärvi et al concluded that "ADD may improve medication safety in terms of reducing the discrepancies in medication records. Further evidence is needed to draw sound conclusions on ADD's outcomes.[52]"

Most recently, in 2016 Spinks, Jackson et al observe that centralised dispensing "may have negative impacts on consumer safety"[53]

[49] **Health care professionals' perspectives on automated multi-dose drug dispensing**. Carola Bardage, Anders Ekedahl, Lena Ring, Pharmacy Practice (Granada). 2014 Oct-Dec; 12(4): 470. Published online 2014 Mar 15
[50] **Patients' Perspectives on Automated Multi-dose Drug Dispensing**. C Bardage and L Ring, Journal of Community Medicine & Health Education, 2016, 6.1
[51] Ibid
[52] **A Systematic Review of Automated Dose Dispensing in Primary Health Care**, Sinikka Sihvo, Jaana Isojärvi, Marja Blom, Marja Airaksinen and Antti Mäntylä, Value in Health 14(7), November 2011
-[53] **Disruptive innovation in community pharmacy – Impact of automation on the pharmacist workforce.** Jean Spinks, Ph.D., M.P.H., M.H.Sc.(PHP), B.Pharm., John Jackson, M.P.H., B.Pharm., Carl M. Kirkpatrick, Ph.D., B.Pharm., Amanda J. Wheeler, Ph.D., B.Pharm. Research in Social and Administrative Pharmacy· May 2016

2b. Unintended consequences: risk of new errors

Recommendation:
Clear evidence is needed to show that automated dispensing does not create a new range of medication errors not previously experienced with manual dispensing

Why?

Sihvo, Isojärvi et al identified that "Evidence from hospital settings indicates that changes in the work process can lead to new kinds of medication errors [25,26]. For example, nurses check the medicines less carefully because they rely on the automation. Therefore, it is important to involve parties of the medication process in the ADD implementation process. The work processes after ADD implementation of ADD should be assessed to ensure their safety in primary healthcare.[54]"

In separate research, Bardage & Ring noted "a few studies have outlined some potential factors contributing to dispensing errors [7-11]. Inadequate communication amongst members of the health care team, illegible medicine records, and concentration lapses or fatigue experienced during preparation has been suggested.[55]

"several studies have highlighted certain unintended consequences of its implementation, with some users either bypassing this technology or relying on it too much, thus increasing the risk of new errors[56]"

[54] **A Systematic Review of Automated Dose Dispensing in Primary Health Care**, Sinikka Sihvo, Jaana Isojärvi, Marja Blom, Marja Airaksinen and Antti Mäntylä, Value in Health 14(7), November 2011
[55] Ibid
[56] **Effect of Bar-Code Technology on the Safety of Medication Administration.** Eric G. Poon, Carol A. Keohane, Catherine S. Yoon, Matthew Ditmore, Anne Bane, Osnat Levtzion-Korach, Thomas Moniz, Jeffrey M. Rothschild, Allen B. Kachalia, Judy Hayes, William W. Churchill, Stuart Lipsitz, Anthony D. Whittemore, David W. Bates, and Tejal K. Gandhi.et al. The New England Journal of Medicine. May 6, 2010

3. No cost benefit case has yet been published
Recommendation: Clear evidence is needed to show that large scale automated dispensing processes in operation today deliver proven cost benefits
Why? Sihvo, Isojärvi et al also found that "Outcome measures associated with costs were missing from all the studies[57]" Magadzire et al note that ""limited studies have been conducted on the CDU, there is no baseline data and a comprehensive evaluation is yet to be conducted … However, despite this limited evidence, centralised dispensing is gaining momentum in South Africa.[58]" Sivho, Isojärvi et al state "Outcome measures associated with costs were missing from all the studies. In future studies, it would be essential to estimate costs and benefits from different stakeholder points of view. These stakeholders include healthcare decision-makers and providers, patients and relatives, community pharmacies, and public insurance."

[57] **A Systematic Review of Automated Dose Dispensing in Primary Health Care**, Sinikka Sihvo, Jaana Isojärvi, Marja Blom, Marja Airaksinen and Antti Mäntylä, Value in Health 14(7), November 2011

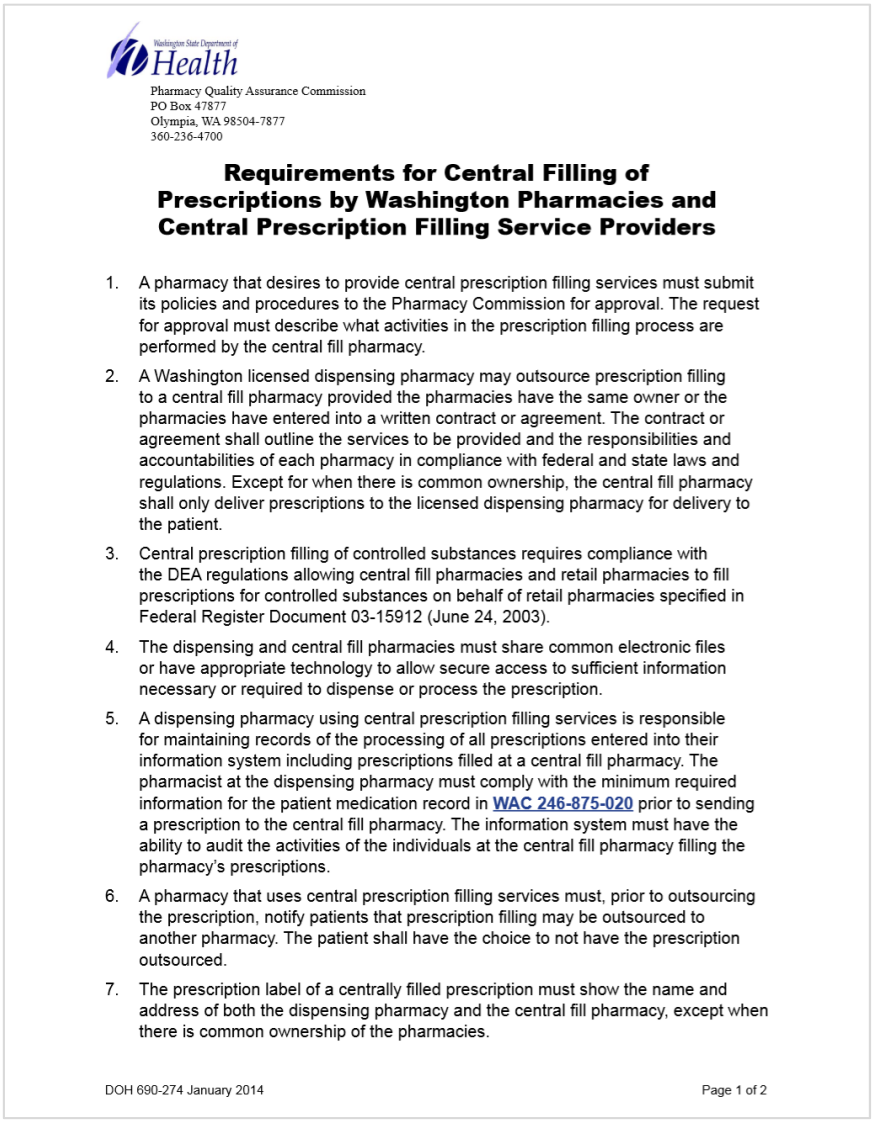
[58] **Improving access to medicines through centralised dispensing in the public sector: a case study of the Chronic Dispensing Unit in the Western Cape Province, South Africa.** Bvudzai Priscilla Magadzire, Bruno Marchal, and Kim Ward. BMC Health Services Research. 2015; 15: 513. Published online 2015 Nov 17.

Appendices

1	Requirements for Central Filling of Prescriptions by Washington Pharmacies and Central Prescription Filling Service Providers
2	Q&A with McKesson Pharmacy Systems & Automation High Volume Solutions VP of Sales
3	Rite Aid Central Fill Facility
4	Comparative data between European markets featured in this report

Appendix 1

Requirements for Central Filling of Prescriptions by Washington Pharmacies and Central Prescription Filling Service Providers



Washington State Department of Health

Pharmacy Quality Assurance Commission
PO Box 47877
Olympia, WA 98504-7877
360-236-4700

Requirements for Central Filling of Prescriptions by Washington Pharmacies and Central Prescription Filling Service Providers

1. A pharmacy that desires to provide central prescription filling services must submit its policies and procedures to the Pharmacy Commission for approval. The request for approval must describe what activities in the prescription filling process are performed by the central fill pharmacy.
2. A Washington licensed dispensing pharmacy may outsource prescription filling to a central fill pharmacy provided the pharmacies have the same owner or the pharmacies have entered into a written contract or agreement. The contract or agreement shall outline the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations. Except for when there is common ownership, the central fill pharmacy shall only deliver prescriptions to the licensed dispensing pharmacy for delivery to the patient.
3. Central prescription filling of controlled substances requires compliance with the DEA regulations allowing central fill pharmacies and retail pharmacies to fill prescriptions for controlled substances on behalf of retail pharmacies specified in Federal Register Document 03-15912 (June 24, 2003).
4. The dispensing and central fill pharmacies must share common electronic files or have appropriate technology to allow secure access to sufficient information necessary or required to dispense or process the prescription.
5. A dispensing pharmacy using central prescription filling services is responsible for maintaining records of the processing of all prescriptions entered into their information system including prescriptions filled at a central fill pharmacy. The pharmacist at the dispensing pharmacy must comply with the minimum required information for the patient medication record in WAC 246-875-020 prior to sending a prescription to the central fill pharmacy. The information system must have the ability to audit the activities of the individuals at the central fill pharmacy filling the pharmacy's prescriptions.
6. A pharmacy that uses central prescription filling services must, prior to outsourcing the prescription, notify patients that prescription filling may be outsourced to another pharmacy. The patient shall have the choice to not have the prescription outsourced.
7. The prescription label of a centrally filled prescription must show the name and address of both the dispensing pharmacy and the central fill pharmacy, except when there is common ownership of the pharmacies.

DOH 690-274 January 2014 Page 1 of 2

8. The dispensing pharmacy must designate staff members to be responsible for signing for the receipt of prescriptions delivered from the central fill pharmacy. The receipt must be maintained as part of the prescription records.
9. All pharmacies providing central prescription filling processing services to pharmacies in Washington State must be licensed in Washington.
10. An out-of-state pharmacy providing central prescription filling services must be licensed as a non-resident pharmacy.
11. The dispensing pharmacy and central fill pharmacy shall maintain a policy and procedure manual. The manual shall:
    a. Outline the responsibilities of each of the pharmacies;
    b. Include a list of the name, address, telephone numbers, and all license/ registration numbers of the pharmacies participating in the central fill prescription filling; and
    c. Include policies and procedures for:
        i. Protection of the confidentiality and integrity of patient information;
        ii. Maintenance of appropriate records to identify the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist who performed any processing;
        iii. Compliance with federal and state laws and regulations;
        iv. Operation of a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems; and
        v. Annual review of the written policies and procedures and documentation of such review.

Appendix 2

More On Central-Fill: Q&A with McKesson's Joe Tammaro

McKesson Pharmacy Systems & Automation High Volume Solutions VP of Sales Joe Tammaro gives *ComputerTalk*'s Will Lockwood his perspective on what pharmacies are doing with central fill and what questions you should be asking if you are looking to get started with it.

CT: What kinds of pharmacies are looking to central fill these days?

Joe Tammaro: Really all pharmacies: retail, hospital outpatient, long term care, etc. If pharmacies are looking to increase capacity, lower cost to fill, manage inventory better, and improve quality, central fill is a viable solution.

And I think it's also important to note that there's really no pure central fill anymore. Instead the facilities have a more hybrid role, giving pharmacies the ability to do different things that make use of the technology and process that go well beyond filling prescriptions to return them to the store for dispensing to the patient. So, we see a lot of pharmacies doing some mail order, specialty, or some LTC out of the central site.

CT: How can a pharmacy decide what the right technology is for a central fill operations?

Tammaro: Essentially, pharmacies need to assess what they currently dispense as well a plans for future dispensing needs. The technology can be fitted to automate those processes when it makes economical sense. Technology exists that can automate all processes and the automation provider along with the customer can evaluate what is the best fit — using data, discussions on what is important to the client, and evaluation of pharmacy regulations — for today and future needs.

But even at a central site, you want to make sure that you are only automating when it makes sense. You have to look at your volume for a particular category of dispensing. It can often be the case that a manual process will continue to work very well up to a certain point and then, that's when automation will make financial sense and you will want to look at that investment. The central-fill process and solutions are scalable, and make sense even for lower volume pharmacies.

CT: What kinds of questions should pharmacies ask prospective vendors?

Tammaro: We see savvy pharmacies looking at central-fill solutions ask "How are you the vendor going to fit your offerings to our needs?" They also want to know how we are going to support and optimize the installation, and they're not just talking about customer service and support. They want to know how we are going to help them keep this complex system and all the parts running most effectivley for their needs over the long haul. And it's worthwhile noting that central-site technology lasts a long time. We have systems out there that are 20 years

old. You tweak the components over time, but central fill will keep going and as a pharmacy you will want to make sure that your vendor is going to remain a partner for the long haul.

Finally, implementing central fill involves many complex systems interacting seamlessly and involves risk. Prospective customers should look at the experience and track record of the solution provider. They should talk to references and see sites that are similar in size and complexity to the one that they are purchasing. Not all systems are equal and certain technology does not scale up or down well.

CT: What are the most important metrics for gauging the impact of central fill and how/where do you collect the data for them?

Tammaro: At the end of the day, there are several key data elements to view the impact of central fill:

1. Central fill pull or efficiency rate: Basically this is the number of prescriptions processed at central fill divided by the total amount of prescriptions processed by the enterprise. The higher this rate is, the better. Successful operations have achieved upwards of 50% of total prescriptions filled at central. 25% should be considered the minimum to have a positive impact.
2. Overall net labor utilization: Most successful central fill operations look to reduce or hold net labor use across the enterprise, By taking the fulfillment activities out if the local pharmacies, labor can be reallocated and held stable while growth continues. After maturity, a pharmacies should be able to see a net overall reduction in payroll dollars per prescription filled.
3. Inventory reduction: When you consolidate inventory at central fill, increasing turn on that inventory and reducing the need to carry extra back stock at each and every local pharmacy, your pharmacy operations should see a net reduction in overall inventory stock levels across the enterprise.
4. Quality: Quality at central fill is much greater than at the local pharmacy level. Successful operations measure the frequency of misfills attributed to the fulfillment process — e.g., wrong product in the container, wrong label on the container, etc — and see a net reduction of incidents after implementing central fill.

CT: What are some benefits of central-fill that people unfamiliar the process might not expect?

Tammaro: A few come to mind. First, you see increased customer service and more time to implement revenue generating activities. Many operations utilizing central fill have chosen to take the labor and time savings generated and convert that into better service as measured by reduction in wait times, more time spent with customers for counseling, problem solving, etc. And then there are revenue generation activities, such as screenings, immunizations, MTM, etc

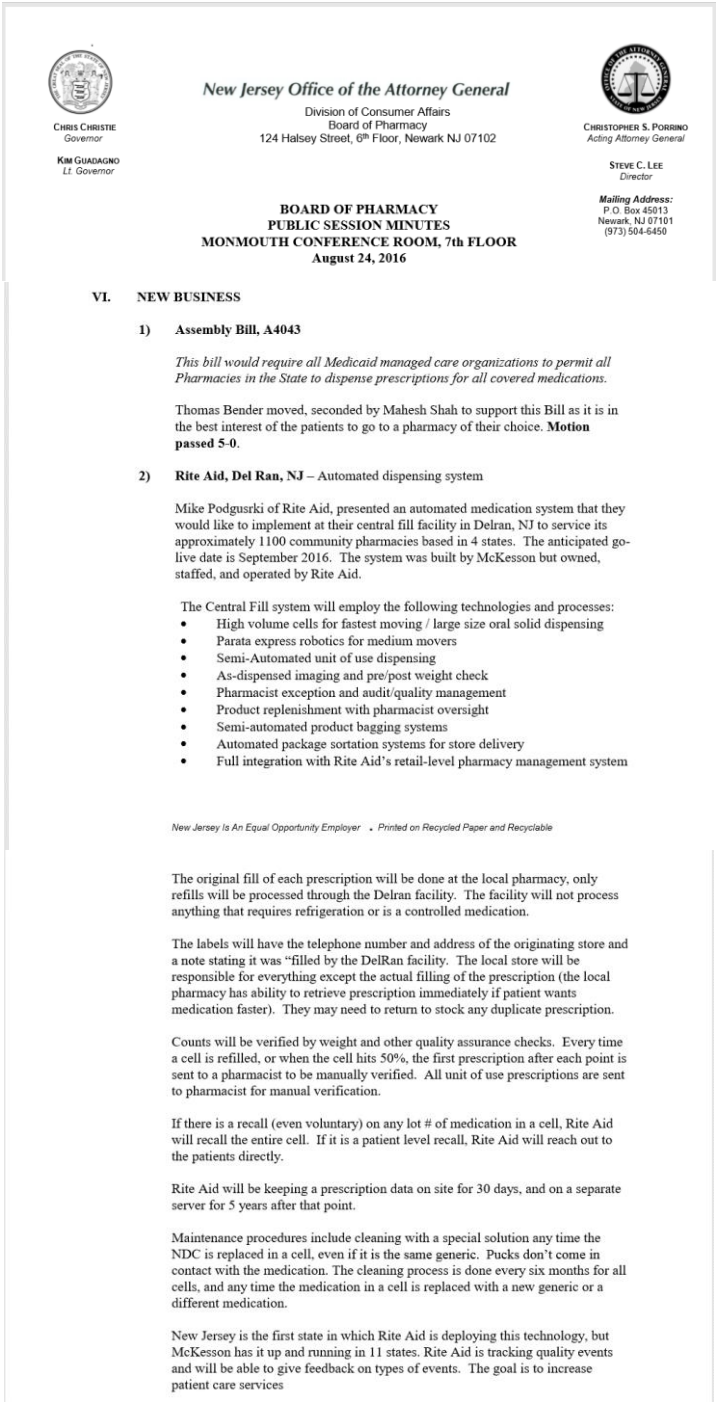
Second is a reduction in the need to remodel or expand the local pharmacy. By pulling volume out to central fill, local pharmacies can essentially process more prescriptions in their existing footprint and reduce the need to remodel or expand for higher volumes.

Next is more effective use of “technology” dollars. When budgets are tight, using technology dollars on a central site can often be done at a lower cost than having to automate all of the local pharmacies. The technology spend can be focused on making sure central fill is high capacity and capable of handing volume for many years to come, versus having to focus on incremental technology at many sites where it may not make sense. We see successful pharmacies being smart about this and realizing that central fill can make better use of their resources and let them be more selective about broader automation deployment. CT

http://www.computertalk.com/feature-stories/exclusive-web-content-more-on-central-fill-q-a-with-mckesson-s-joe-tammaro

Appendix 3

Rite Aid central fill facility



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BOARD OF PHARMACY
PUBLIC SESSION MINUTES
MONMOUTH CONFERENCE ROOM, 7th FLOOR
August 24, 2016

VI. NEW BUSINESS

1) Assembly Bill, A4043

This bill would require all Medicaid managed care organizations to permit all Pharmacies in the State to dispense prescriptions for all covered medications.

Thomas Bender moved, seconded by Mahesh Shah to support this Bill as it is in the best interest of the patients to go to a pharmacy of their choice. **Motion passed 5-0**.

2) Rite Aid, Del Ran, NJ – Automated dispensing system

Mike Podgusrki of Rite Aid, presented an automated medication system that they would like to implement at their central fill facility in Delran, NJ to service its approximately 1100 community pharmacies based in 4 states. The anticipated go-live date is September 2016. The system was built by McKesson but owned, staffed, and operated by Rite Aid.

The Central Fill system will employ the following technologies and processes:

- High volume cells for fastest moving / large size oral solid dispensing
- Parata express robotics for medium movers
- Semi-Automated unit of use dispensing
- As-dispensed imaging and pre/post weight check
- Pharmacist exception and audit/quality management
- Product replenishment with pharmacist oversight
- Semi-automated product bagging systems
- Automated package sortation systems for store delivery
- Full integration with Rite Aid's retail-level pharmacy management system

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The original fill of each prescription will be done at the local pharmacy, only refills will be processed through the Delran facility. The facility will not process anything that requires refrigeration or is a controlled medication.

The labels will have the telephone number and address of the originating store and a note stating it was "filled by the DelRan facility. The local store will be responsible for everything except the actual filling of the prescription (the local pharmacy has ability to retrieve prescription immediately if patient wants medication faster). They may need to return to stock any duplicate prescription.

Counts will be verified by weight and other quality assurance checks. Every time a cell is refilled, or when the cell hits 50%, the first prescription after each point is sent to a pharmacist to be manually verified. All unit of use prescriptions are sent to pharmacist for manual verification.

If there is a recall (even voluntary) on any lot # of medication in a cell, Rite Aid will recall the entire cell. If it is a patient level recall, Rite Aid will reach out to the patients directly.

Rite Aid will be keeping a prescription data on site for 30 days, and on a separate server for 5 years after that point.

Maintenance procedures include cleaning with a special solution any time the NDC is replaced in a cell, even if it is the same generic. Pucks don't come in contact with the medication. The cleaning process is done every six months for all cells, and any time the medication in a cell is replaced with a new generic or a different medication.

New Jersey is the first state in which Rite Aid is deploying this technology, but McKesson has it up and running in 11 states. Rite Aid is tracking quality events and will be able to give feedback on types of events. The goal is to increase patient care services

http://www.njconsumeraffairs.gov/phar/Minutes/pharmin_082416.pdf

Appendix 4

Comparative data between European markets featured in this report

	UK	Netherlands	Sweden	Germany
Capital	London	Amsterdam	Stockholm	Berlin
Area in km2	243,611	41,543	450,295	357,021
Population	63,896,072	16,779,575	9,658,301	80,800,000
Population Density per km2	263	404	23.5	230
Language	English	Dutch	Swedish	German
Currency:	British Pound (GBP)	Euro €	Swedish Krona (SEK)	Euro €
GDP per capita in Euro:	30,001	35,900	43,800	33,300
Number of Full-line Wholesalers:	10	5	2	13
Number of Public Pharmacies:	14,250	2,000	1,247	20,770
Number of Hospital Pharmacies:	334	150	110	420
Number of Dispensing Doctors:	2,062	400	na	0
Number of Warehouses:	55	13	5	113
Distribution System:	Multi channel	Multi channel	Single channel	Multi channel
Total wholesale sales (in EUR, without VAT):	11,261	4,458	4,171	27,168
Sales per inhabitant (in EUR):	176	167	363	336
VAT on medicines (RX & OTC):	20%	6%	None	19%
Average number of packages/orderline:	8	6	3.6	1.7
Percentage of orders taken by EDI:	97%	> 99%	99%	97%
Average delivery frequency per day:	3.0	1.0	1.0	3.0
Population per pharmacy	4,484	8,390	7,745	3,890

Source: GIRP

http://www.girp.eu/wholesalers-directory

	Finland	Norway	Denmark	Belgium
Capital	Helsinki	Oslo	Copenhagen	Brussels
Area in km2	338,145	323,802	42,895	30,528
Population	5,426,674	5,051,275	5,602,628	11,094,850
Population Density per km2	16	16	130	354
Language	Finnish, Swedish	Norwegian	Danish	Dutch, French, German
Currency:	Euro €	Norwegian Krone	Danish Krone (DKK)	Euro €
GDP per capita in Euro:	35,600	75,700	44400	34100
Number of Full-line Wholesalers:	3	3	2	17
Number of Public Pharmacies:	814	768	280	5024
Number of Hospital Pharmacies:	24	32	10	250
Number of Dispensing Doctors:	0	0	0	n/a
Number of Warehouses:	5	5	6	27
Distribution System:	Single channel	Multi channel	Multi channel	Multi channel
Total wholesale sales (in Mio EUR, without VAT):	1,544	1,163	946	4500
Sales per inhabitant (in EUR):	285	233	169	405.6
VAT on medicines (RX & OTC):	10%	0	25%	6%
Average number of packages/orderline:	n/a	6	6	2
Percentage of orders taken by EDI:	100%	98%	98%	98%
Average delivery frequency per day:	1.0	0.6	1.0	3.0
Population per pharmacy	6,667	6,577	20,009	2,208

Source: GIRP
http://www.girp.eu/wholesalers-directory

Research completed during 2018. Lead author David Simons