bradscholars

Medicines Shortages Reporting Systems (MSRS): An exploratory review of access and sustainability

Original Research

Medicines Shortages Reporting Systems (MSRS): An exploratory review of access and sustainability

Emilia Vann Yaroson [a,*], Gemma Quinn [b], Liz Breen [b]

[a] *University of Huddersfield Business School, Charles Sykes Building, Queensgate, HD1 3DH, UK*
[b] *University of Bradford School of Pharmacy and Medical Sciences, Richmond Building, Richmond Road, Bradford, BD7 1DP, UK*

A B S T R A C T

Background: The efficacy of medicines depends on their accessibility and availability. Dedicated medicine shortage reporting systems (MSRS) have been set up in different countries, either mandatory or voluntary, following the recommendations of the World Health Organisation to ensure these.
Objectives: To explore how the Medicine Shortages Reporting System (MSRS) can tackle medicine shortages through improved access and sustainability.
Methods: Personnel directly involved in the reporting mechanisms for medicine shortages in eight (8) countries participated in semi-structured interviews. An interview protocol based on the Dynamic Capabilities View and Organisational Information Processing Theory (OIPT) was developed. It contained questions related to participant's views on the process involved in MSRS and how it was used to tackle shortages. Data were thematically analysed.
Results: Three core elements were identified to influence MSRS's ability to tackle shortages and ensure sustainability; (1) the ability to identify what information requirements the reporting system needs, (2) identify information processing capabilities, and (3) the ability to match requirements and information processing capabilities through a dynamic capability decision-making process. The dynamic decision-making process involves reiteratively sensing shortages by understanding and validating information received.
Conclusion: Building MSRS to tackle shortages for accessibility and sustainability is a systemic process that entails understanding the various elements and processes of MSRS. It includes defining medicine shortages, reconfiguring resources, defining accessibility and ensuring the system's sustainability. Our study provides insights into MSRS developed for mitigating medicine shortages and provides a framework for a sustainable MSRS. The findings extend the literature on medicine shortage management by identifying the various elements required to set up an MSRS. It also provides practical implications for countries that seek to establish MSRS to mitigate medicine shortages. Further studies could extend the number of participating countries to provide a clearer picture of the MSRS and how it can reduce medicine shortages.

1. Background

Billions of people take medicines every day. A report by Iqvia Institute[1] showed that global medicine use had increased at a 3% compound annual growth rate since 2014, with the volume of medicine use reaching 4.5 trillion doses in 2022. Medicines and vaccines are critical to fighting diseases globally.[2] They are among the most clinically cost-effective health interventions.[3] However, medicines can only be an effective intervention if accessible, available and in constant supply. Medicine shortages are common among healthcare providers worldwide, increasing alarmingly.'[4] The underlying causes of medicine shortages are multifaceted and complex.[5–10] These include regulatory changes[11–13] supply chain management issues,[4] political and monetary challenges,[14] natural disasters and pandemics.[15] These signal vulnerabilities in the pharmaceutical supply chain.

The COVID-19 pandemic further exacerbated the pharmaceutical supply chain's vulnerability. It threatened the global surge in the proliferation of falsified and substandard medicines. For instance, due to national treatment regulations, China and India (the world's largest pharmaceutical producers) were prohibited from exporting

products.[16,17] The uncertainty resulted in consumers engaging in panic buying/stockpiling and, in some cases, departing from the regulated medicine supply chain.[18] There was also agitation for potential vaccine shortage due to global demand for the essential Pfizer product, the logistical challenges in the product pipeline (cold transport/storage), and the more significant impact on LMICs.[19] That being the case, medicines shortages are a constant in the pharmaceutical supply chain.

Various solutions have been recommended to solve shortages, such as strengthening procurement for small markets and standardising and promoting longer-term procurement contracts.[11,12,14,20] Some of these solutions are time-consuming, technically complex and financially intensive.[21] Activities embarked upon to mitigate these shortages have negatively affected stakeholders. They include medication errors, adverse drug reactions, increased costs, stress on healthcare professionals, and sometimes patient death.[7,11,22–24]

The World Health Organization[21] urged member states to implement guidelines and reporting system strategies to mitigate shortages.[25] It offers a more specific solution as stakeholders are required to register shortages in advance to a medicinal regulatory authority and special initiatives in monitoring stock levels.[6,25–28] The reporting system's data can promote early anticipation of shortages and efficient supply forecasting, and many countries have since adopted these frameworks for reporting shortages. We argue that the absence of an international benchmark to guide stakeholders on how shortages should be reported may be responsible for the inability of these reporting systems to mitigate shortages. For instance, in EU countries, medicine authorisation holders (MAH) must report shortages two months before occurrence.[29] The EU market for medicines remains fragmented despite the EU having a single market and being the second-largest pharmaceutical market in the world.

With MSRS, stakeholders are expected to report any shortage experienced nationally regarding duration, causes and available alternatives (if known).[6,21] Some countries (e.g., Belgium, France, and Australia) have strict regulatory requirements and accompanying penalties for reporting shortages. In contrast, other countries (Denmark, Iceland, Ireland, Latvia, Norway, Slovenia, Switzerland and the United States) require voluntary notifications. In countries with voluntary notifications, shortages may be reported by wholesalers, pharmacists, patients and other healthcare professionals. In these instances, regulatory authorities may be required to confirm these shortages before further action is taken. These have highlighted disparities in data collection processes.

Existing literature examining the efficacy of MSRS has highlighted several shortfalls. These include a lack of a unified definition and limited information on the nature and scope of shortages.[6] Thus, if a manufacturer reported a shortage, assessing whether its competitors could buffer it was difficult. Tan et al.[27] also evaluated the Theraputic Goods Administration (TGA) efficacy, the Australian national monitoring of medicine shortages. They found that most healthcare professionals were unaware of the monitoring system despite experiencing shortages. Pauwels et al.[26] argued that most reporting systems' dimensions were not nationally focused. Assessing whether a medicine reported as a shortage was intended for a global or regional market was challenging. Similarly, these national reporting mechanisms are effective in countries with strict regulatory authorities with relatively advanced capabilities.[28] The issues highlighted in the literature signify a gap in understanding how reporting systems can enhance the decision process necessary to curb medicine shortages and foster sustainability. A recent communication by the European Commission,[30,] highlighted that the obligation of stakeholders to report shortages has not been compelling because of supply chain issues or commercial decisions.

The organisation information processing theory (OIPT) suggests that harnessing the benefits of an information processing system entails adequately identifying its needs and capabilities and how best to match them.[31] Within this lens, our study explores existing national reporting systems to identify the information processing requirements for MSRS.

These requirements are pertinent to ensure access. We also explore how these requirements can adequately match the national information processing capabilities and how sustainable the matching process is. The dynamic capability (DC) theory also provides a framework for understanding the matching process between the conditions and capabilities of national reporting systems. In doing this, we extend OIPT and medicine shortages literature.

We contribute to the existing literature by tackling the following research questions.

1. What are the information processing requirements for developing a national reporting system for medicine shortages?
2. How can a national reporting system curb medicine shortages with a particular focus on access and sustainability?

Our findings also have implications for policymakers as we identify information system requirements for MSRS and provide a framework for setting up national reporting systems. This paper is divided into four sections. The next, Section Two, outlines the methods used. The results and discussions are presented in Section Three, and conclusions are made in Section Four.

2. Methodology

Medicine Shortages Reporting Systems (MSRS) are used to mitigate the impact of medicine shortages. This section presents the methods used to address the research questions.

2.1. Design and settings

This study worked with personnel who had access to the reporting system in each country under study to explore the efficacy, accessibility, and sustainability of their medicine shortages reporting system. This study follows the recommendations from the Medicine Shortages Stakeholders Symposium held at the University of Bradford in September 2019.[32] This examination was guided by current research and thinking in this field.

2.2. Ethical consideration

Ethical approval was awarded by the University of Bradford. Participants were fully advised of the study's aims and objectives, and consent was provided at the time of interviewing.

2.3. Study design

This study aimed to understand how the Medicine Shortage Reporting System (MSRS) can be used to mitigate medicine shortages. An exploratory qualitative analysis approach was used to collect and analyse data to achieve the study's objectives. An interview protocol was designed based on extant literature and was deployed via semi-structured interviews. It allowed the researcher to probe further for clarity.[33] This process provided as much information as possible, addressed the study's underlying goals and adequately translated the interviewees' perspectives. The consolidated criteria for reporting qualitative research (COREQ) guideline was followed.

The semi-structured interview is suitable for exploring limited research areas (e.g., Medicine Shortages Reporting System) where detailed participant insights are required. The interview protocol was developed after an extensive review of relevant literature.[6,11,14,26,34–37]

The interview protocol (in Appendix A) focused on the efficacy, accessibility, and sustainability of the MSRS in mitigating medicine shortages. Therefore, the interview questions included exploring the reporting system's processes, the reporting system's integration, and the governance of the reporting system.

2.4. Participants and demographics

A purposive sampling strategy was adopted.[38] Data were collected from personnel who had in-depth knowledge about the phenomenon under study and were directly involved in reporting medicine shortages was essential. The inclusion criteria were that all countries in the study had an established reporting system for medicine shortages. Participants were recruited through professional networks and referrals. Thus, data were collected from the following countries- Australia, Belgium, Denmark, Finland, Spain, Italy, Ireland, and the United States-using semi-structured interviews between March 2nd and July 8th, 2020. We emailed participants to explain the objective of our research, and consent was provided.

Table 1 summarises the countries that participated in the study and the participants' code.

2.5. Data collection

The context of MSRS is a novel phenomenon, so interviews were conducted to gain rich insights. Interviews are best suited when answering *'How'* questions.[39] The interviews were semi-structured as they permitted the interviewee to provide additional information and encourage freedom of expression. The interviews were conducted using secure telephone lines, digitally recorded with the respondents' permission, and fully transcribed to ensure the data's reliability and internal validity. Transcripts of interviews were sent back to participants to comment and/or make alterations that facilitated member checking and a method of quality control and validation.[40] The primary data collection source was semi-structured interviews. However, the study also relied on interviewees' documentation to facilitate evidence triangulation.[39]

2.6. Theoretical background

The WHO defined medicine shortages as the inability of supply to meet patient demand. The unavailability of medicine affects patients' quality of care and enhances financial complexities.[41] Medicine shortages are not new; however, the recent increase in medicine shortage reports calls for a more specific approach to tackling the problems.[4,42] A national system for early notification of medicine shortages has been identified as critical to addressing the issue[11,21,30] and has been adopted globally. The underlying idea is that the information generated will allow stakeholders to plan and prepare for a shortage, reducing its impact on patient outcomes.

There is a lack of consensus on the definition of medicine shortages, as provided in Table 2. Some studies regard a shortage of medicines as the inability of patients to access the required medication as and when due.[26] Other studies refer to medicine shortages concerning the pharmacies[43] or delays in supply on a specific day.[44] Some studies have focused on analysing shortages from a source perspective in examining definitions.[45] These definitions highlight significant differences in the

Table 1
Participating countries.

Country	Agency	Participants Code
Australia	Therapeutic Goods Administration	**AUS**
Belgium	Belgium Federal Agency of Medicines and Health Products	**BE**
Denmark	Amgros, Department of Logistics	**DN**
Finland	Finnish Medicines Agency in Finland	**FL**
Ireland	Health Products Regulatory Authority	**IR**
Italy	Regional Hospital, Milan.	**IT**
Spain	Spanish Agency for Medicines and Medical Devices	**ES**
United States	American Society of Health-System Pharmacists.	**The US**

Table 2
Defining medicine shortages.

Authors	Definition
Chapman et al. (2022)[25]	Consider a medicine shortage to exist when supply is insufficient to meet demand at the national level and may include both temporary and permanent discontinuations.
EFPIA European Federation of Pharmaceutical Industries and Association (2022)[47]	'The shortage of a medicinal product for human use occurs at a country level when supply does not meet the patient needs at a national level for a period of more than two weeks.'
European Medicines Authority (EMA) (2022)[48]	"'Shortage' means a situation in which the supply of a medicinal product that is authorised and placed on the market in a Member State (…) does not meet the demand for that medicinal product (…) at a national level, whatever the cause; "
ASHP-American Society of Health-system Pharmacists (2020)[43]	The supply issue affects how the pharmacy/dispenses a medicine product or influences patients' care when prescribers must use alternative agents.
Food and Drug Administration (FDA) (2019)[46]	A period when the demand or projected demand for the drug exceeds the supply of the drug
Beck et al. (2019)[49]	The unexpected unavailability of a drug, often without precise knowledge of when, or if, the desired drug will be available again, what alternatives are available, and/or what risks these alternatives entail.
Bochenek et al. (2018)[29]	A drug is unavailable when enterprises responsible for the drug's marketing cannot deliver that drug for an uninterrupted period of four consecutive days to the community pharmacies, hospital pharmacies or wholesalers in Belgium.
World Health Organisation (WHO) (2017)[21]	The inability of supply to meet patient demand.
De Weerdt et al. (2015)[46]	Drug shortages involve supply-side' and 'demand-side'. The supply side is defined at the 'pharmacy level'. It is defined as a situation 'when the Medicine Authorisation Holder (M.A.H.) cannot supply to wholesalers/pharmacies, or when the wholesaler cannot supply to pharmacies'. A drug shortage on the demand side implies a supply problem at the 'patient level' when pharmacies cannot supply the drug to patients.
Heiskanen et al. (2014)[11]	A medicine supply issue requires a change that impacts patient care and alternative agents.
Pauwels et al. (2014)[26]	Medicine shortages are shortcomings in the supply of a medicinal product, making it impossible for suppliers to meet the product's demand at the patient level. It affects all healthcare system stakeholders such as patients, pharmacists, clinicians, the pharmaceutical industry, and policy.
Gloor et al. (2013)[50]	Medicine shortages are the adverse effects on the continuity of supply and/or unavailability at the point of dispensing due to natural disasters, manufacturing problems, noncompliance with regulatory standards, packaging shortages and unexpected demand.
Dragic (2012)[44]	Medicine shortages are "every delay in monthly medicine supply".
Gu et al. (2011)[51]	The total supply of all clinically interchangeable versions of FDA-regulated medicines is inadequate to meet the current demand and user level.

scope of a medicine shortage and the time frame for a medicine to be classed as short in supply.[46]

Defining medicine shortages is pertinent as it aids in setting the scope of how issues of medicine shortages should be addressed. Therefore, it is imperative to identify the characteristics of medicine shortages to understand how the MSRS works successfully.

Medicine shortages can devastate the healthcare system.[7,11,22,25,52,53] It may compromise the quality of care and threaten patient safety. For instance, the European Association of Hospital Pharmacists (EAHP) showed that medicine shortages directly affected care cancellations, medication errors, suboptimal treatments, stress on healthcare workers and death of patients.[54] Postma et al.[55] showed that medicine shortages impacted clinical, humanistic and economic outcomes in the Netherlands.

Two theoretical lenses-the organisational information processing theory (OIPT) and the dynamic capability perspective were adopted to understand how medicine shortages reporting systems (MSRS) can be used to curb shortages. These will be explained in detail in the following sub-sections.

2.6.1. Organisational information processing theory (OIPT)

Organisational information processing theory (OIPT) concerns how organisations manage information in a complex environment with high uncertainties.[31] It offers perspectives on how organisations make sense of the information available in complex settings.[56] Thus, from an OIPT perspective, developing information processing capabilities is essential for organisations to effectively make decisions.[56] In this respect, information is viewed as a critical resource of the organisation and its structures, mechanisms and processes are designed based on the information flow.[57] Information quality is essential in addressing uncertainty within complex environments for improved decision-making. For information processing tasks, organisations need to determine the type of data, the requirements for data generation and processing and the decision-making level.[56]

Therefore, OIPT elements include its information processing requirements, capabilities and the ability to match the two.[58] Information processing requirements are the information an organisation requires to make decisions within a complex environment. OIPT stresses the importance of the fit between requirements and abilities as it permits insightful decision-making. To this end, organisations must determine their information needs and develop capabilities to match them.[31] For instance, countries faced with medicine shortages can resolve the issues by deciding how best to address them by analysing the information received through their reporting system. Sometimes, managers analysing these reports may become overwhelmed by the nature or frequency of communication. Thus, successfully mitigating medicine shortages relies on the fit between the reporting systems' requirements and information processing capabilities.

Managers are often tasked to make decisions when they encounter medicine shortages, which are complex and uncertain. It is critical to understand their information processing requirements. Several studies have used OIPT to validate the importance of information systems in several spheres of business operations and enhance decision-making capabilities.[59,60] However, limited studies have used this theoretical lens to analyse how reporting systems (MSRS) set for decision-making can mitigate disruptions. To this end, we extend the literature by providing empirical evidence.

2.6.2. Dynamic capability theory (DC) and MSRS

As defined by,[61] dynamic capability (DC) theory is the ability of a firm to strategically create, expand, or modify existing resources to adapt to changes within its external environment. The principle of DC explains how organisations sense, seize, and reconfigure their resources in adapting to the changes in their external environment to achieve sustainability.[61–63] DC is thus categorised into three phases-sensing, seizing and transforming. The sensing phase includes all the processes

that facilitate an organisation's collecting and analysis of information about its environment. At the seizing stage, sensed prospects are addressed through new methods and/or services. The seizing phase is all about responding to the information received; time is essential if identified opportunities are to achieve dynamism and sustainability.[64] The transforming phase of the dynamic capability view entails reconfiguring assets and enhancing existing capabilities. Operational efficiency is achieved at this stage through routines as it involves continuous monitoring, control, and adaptation to the external environment.[65] DC provides an analytical framework that aids in capturing how organisations respond and adapt to changes in their territory.[62] Therefore, addressing the rapid changes within an organisation's external environment requires the constant renewal and integration of both internal and external resources.[62]

In this study, DC is used to explore how MSRS can be developed to mitigate shortages. MSRS capabilities would require exploiting existing resources and creating new capabilities in seeking efficiency, adaptability, and sustainable practices. DC advocates that understanding the process of information systems capabilities is pertinent to fostering sustainability and competitiveness. Since this study seeks to understand how national reporting systems can mitigate the impact of medicine shortages, DC can be employed as a theoretical lens in explaining the development process.

Dynamic capability theory has been used to comprehend information systems development and operations.[66] Since information is not static, it is essential and informative to understand the development of these systems in motion. Thus, DC can be regarded as appropriate as it captures the capabilities of the processing systems.

The dynamic capabilities perspective as an analytical framework follows the 'theory matching' approach.[67] The matching technique has been used in several studies, such as.[68] It improves this research's rigour and external validity. Therefore, this study adopts the DC perspective, where the three constructs of sensing, seizing and transforming are used to analyse the data. It also facilitated subsequent discussions on how the MSRS can enable the fit between 'information processing requirements and its capabilities (see Fig 1).

2.6.3. Overview of the adoption of medicine shortages reporting systems (MSRS) in various countries

A MSRS is a tool to report shortages and facilitate information sharing among PSC stakeholders. The notion here is that if medicine shortages are reported accurately and timely, then the impact of a shortage can be mitigated.[21] Table 3 provides an overview of MSRS across various countries.

The US was one of the first countries to adopt a national reporting system through the Food and Drug Administration (FDA) for medicine shortages in 2011.[11,22] The American Society of Health-system Pharmacists (ASHP) maintains the database to notify healthcare professionals early of shortages. It thus facilitates preventing and mitigating the impact of medicine shortages. To this end, manufacturers must report to the FDA about possible discontinuations of medicines for severe or life-threatening conditions. It seems that these measures have had an impact. The number of shortages in the United States decreased by 24% in 2012 and 60% in 2013, respectively.[11] Acosta et al.[6] argue that the databases are not broad in scope as they fail to capture the necessary information required for forecasting and planning.

In Australia, the Therapeutic Goods Administration (TGA) has a dedicated website to notify and monitor Medicine shortages. It began in May 2014.[27] This reporting system was established as an information initiative for stakeholders to anticipate and plan for medicine shortages. However,[27] revealed that many healthcare professionals who participated in the study did not understand how the system worked or how to access the required information for effective planning. The study also did not reveal the timing for medicine shortage notification and how the data generated was employed.

In Finland, medical shortages are reported through mandatory

Table 3
Summary of MSRS across countries sampled in this study.

Country	Australia	Belgium	Denmark	Finland	Ireland	Italy	Spain	United States
Size of Country	Large	Large	Small	Small (2 wholesalers)	Small (2 wholesalers)	Large	Large	Large
Length of time reporting system has been in place	Jan 2014 was voluntary, Mandatory since January 2019	October 2018	April 2018	January 2020 it was updated.	September 2018	January 2019	January 2019	2001
Preferred form of the reporting shortages	Electronic not integrated	Electronic not integrated	Electronic not integrated	Manual	Manual collated and uploaded on the system	Manually collated and uploaded	Use of information technology	Electronic/not integrated
Reporting system control	The Commonwealth government. Australian government.	Belgian government/ Nationally	Danish medicine agency/ Amgros also has 5 local divisions	The government, Finnish medicine agencies	Health products regulatory authority and stakeholder based.	Italian medicines agency	Spanish government agency	American society for health pharmacists
Penalty	Yes	No	No	No	No	No	Yes	No
Accessibility	More detailed to the DOH	Some parts of the information received are made publicly available.	No	Not accessible to everyone since it is not mandatory	Transparency so it is open to everyone. All stakeholders	Authority only system	Authority-only system.	Public website, accessible to anyone who needs it
Legal implication	Yes	No	No	No	No	No	No	No

notifications from marketing authorisation holders.[35] Further, the Italian reporting system's scope encompasses various information. There are no limitations on the type of medicines included in the reporting system. All stakeholders of the health care system are eligible to submit reporting. However, in their study on reporting procedures,[26] found that only a limited proportion of the reported shortages were notified in advance. The complicated early anticipation by a health care professional jeopardised patient care. It implies that there was no notification period for reporting a shortage. Similarly, although over 50% of respondents of a European Association of Hospital Pharmacists (EAHP)[4] survey highlighted the mandatory reporting of medicine shortages by stakeholders in their respective countries, over 50% were unaware of a standard procedure and database. Experiences can be derived from cross-country comparisons, even if a given country's characteristics are not entirely consistent in geographical location, size, demography, economy, or type of healthcare system.

Following the preceding paragraphs, it is imperative to understand how different national reporting systems operate regarding accessibility, information requirements and usefulness in curbing shortages. This gap in knowledge forms the basis of this research study and subsequent analysis.

The call for a reporting system on medicine shortages rests on its information-sharing strategies. Information sharing has been identified as pivotal in building resilience in supply chains as both a recovery and a resistance element.[68,69] Information-sharing proponents argue that managing demand and supply-related information is critical for capacity building and decision-making when responding to environmental changes.[70]

Information sharing is the degree and willingness of stakeholders to share relevant critical information necessary to mitigate the impact of supply chain disruptions.[71] Information sharing enhances supply chain visibility, increases collaboration, and supports spreading information pertinent to supply chain members.[72] Thus, information sharing reduces the uncertainties associated with disruptions, fosters decision-making, and facilitates planning and recovery from disruptions.[73–75] Tools that facilitate information sharing include but are not limited to information technology (IT) systems.[76–78]

Some studies argue that enabling an information-sharing environment may not ensure proactive information-sharing.[79] For instance, managers may perceive information as a commercial resource that could be used opportunistically and are reluctant to share it.[70] Although many studies emphasize the benefits of information sharing in the supply chain, empirical evidence supporting these claims is limited.[80] Also, the lack of confidence in supply chain partners, absence of trust, power asymmetry and overdependence on information technology have been suggested as inhibitors of the efficacy of information sharing.[78]

Thus, researchers' divergent views indicate a dilemma regarding the benefits of information sharing and building resilience strategies. It is vital to comprehend the factors facilitating information sharing and how they can mitigate supply chain disruptions. These notwithstanding, harnessing the dividends of information sharing requires accurate timing and quality of information.

2.7. Harmonisation of medicine shortages management system

More recently, there has been evidence of regions attempting to harmonise MSRS activities. For example, the European Union (EU) is a single market and the second-largest pharmaceutical market in the world. In 2019, the European Medicines Authority[29] provided a unified process of how medicine shortages should be reported and addressed. This harmonisation report stressed the importance of tackling medicine shortages at national levels. It could only be reported to the Medicine Authority Holders (MAH) when a shortage affected more than one country. The EU provided tools and support in addressing critical shortages when the shortage spanned more than one country. This approach has multiple benefits to all state partners but, more importantly, offers additional support for smaller nations.

However, in defining national-level shortages, the[29] explained that logistics and/or national redistribution issues are not considered. It implies that Member States are responsible for managing and resolving shortages within their State Boundaries.[30] Due to the complex nature of the pharmaceutical supply chain, if these shortages are not adequately addressed at regional levels, they may spiral into national-level shortages with rippling effects across the boundaries of the Member States.[34]

The harmonised medicine shortages reporting in the EU also highlights differences in how Member States report shortages at regional and national levels. As stated in the communication brief, *'Individual Member States will determine the preferred method of notification (e.g. email, pdf form, online data collection system)'*,[30] pg. 11).

Data collection inconsistencies may affect data quality regarding validity, errors, and sometimes outdated information.[81] Coupled with the complexities of the pharmaceutical supply chain, this may have

adverse effects on the ability of the reporting system to tackle shortages. Our study seeks to address these underlying issues. We focus on how countries tackle varying perspectives of medicine shortages. Our aim is to ensure that these processes are accessible and sustainable within national boundaries and, as such, mitigate possible ripple effects.

2.8. Accessibility and sustainability of MSRS

Sustainability refers to developing the needs of the present without compromising future generations' ability to meet their own needs (World Commission on Environment and Development).[82] It refers to sustainability as the '*triple bottom line approach.*'[83] Sustainability is broad and complex, consisting of environmental, social, and economic issues.[84] It entails continuous learning to tackle environmental concerns effectiv[y]. Discussions around the sustainability of information technology systems are limited as most sustainability issues focus primarily on environmental and ecological issues.[85] A reporting system's sustainability requires close collaboration and information exchange among stakeholders enabled by information systems to mitigate distortion and generate solutions.[78] These include automation, information, transformation and infrastructure.[86] Automation involves automatic information notification, which is then transformed with available resources.

Accessibility of information systems refers to the capacity of users to retrieve desired information as required. It is defined by the information system features.[87,88] The dimensions of accessibility adopted in this study include access to information sources, the interface of information and the capacity to retrieve the information.[89] Therefore, this study explores the accessibility and sustainability of MSRS in tackling shortages.

2.9. Data analysis

The interview transcripts were imported into QSR N-Vivo Version 12. A research team member conducted the data analysis using thematic analysis to present a comprehensive account of themes related to the study's objectives. Therefore, this study followed the six-step method for theme development.[90] One researcher initially coded the interviews using open coding and constructs from the literature's dynamic capabilities and Organisational Processing Theory. Coding was achieved through repeated readings of the transcripts to understand the data and identify fragments that referred to various parts of the research questions. Two other experienced researchers in supply chain management and pharmacy reviewed these themes. Any areas of disagreement were resolved, and this was done to ensure the research's validity.[91] Verbatim quotes were also used to facilitate discussion and enhance the study's reliability.

3. Results

This study aimed to understand how the Medicine Shortage Reporting System (MSRS) is used to mitigate medicine shortages by exploring MSRS's use worldwide. A summary of MSRS dimensions for the sample of countries that participated in the study is provided in Table 3. The country sizes varied from small countries (two wholesalers, Finland and Ireland) to large countries with several logistic service providers, wholesalers, and manufacturers (Italy, US). The analysed data showed that apart from the US, which has had an MSRS since 2001, most countries have reporting systems under seven years old. Unlike Spain, which recently rolled out an integration plan with its General Practitioner database, the reporting systems examined in this study are not integrated into other databases.

The table also shows that the reporting systems in the US is nationally managed. However, the University of Utah privately runs the American Society for Health-System Pharmacists (ASHP) medicine shortage database. Amgros in Denmark contains information regarding

medicine shortages for hospital pharmacists. Reporting a shortage by stakeholders was only mandatory in Australia and Spain, with associated penalties.

Participants were asked to explain how their national reporting systems functioned, their accessibility, information requirements for shortages reporting, and the information transforming process capable of tackling shortages. After thematic coding, three core themes were highlighted. It was found that MSRSs are systemic and involve (1) identifying its information requirements, (2) Identifying the national information processing requirements, and (3) the dynamic capability of matching the ability to match 1 and 2 in its decision-making processes.

3.1. Identifying MSRS information processing requirements

The analysed data showed that identifying the processing requirements of the MSRS was critical. It involved the various phases that occurred when MSRS interacted with an uncertain environment. The respondents explained that these included defining medicine shortages, identifying the nature, causes, frequency, and duration of these shortages and the sources of the information on shortages.

3.1.1. Defining medicine shortages

The respondents stated that defining what constituted a medicine shortage (AUS, US) was essential as this formed the foundation for how stakeholders reported a shortage and how shortages were addressed. As revealed by the interviewees (ES, IR, DN, FL), the definition set out by the European Medicines Agency (EMA)[29] was adopted for countries in the EU. All stakeholders were made aware. Therefore, as defined by EMA, a medicine shortage is *the inability of supply to meet demand*'. The research respondents, however, explained that it was pertinent to understand what constituted supply and demand. Therefore, questions like the nature of the order, the geographical location of the shortage, and whether the shortage resulted from product discontinuation or product recall were posed to correctly understand the nature of the shortage.

3.1.2. Causes of medicine shortages

According to the respondents, understanding the root causes of a medicine shortage facilitated the velocity at which information was processed through the MSRS and enabled strategy development. The data analysed showed several causes of medicine shortages, ranging from manufacturing to logistic and regulatory issues, to name a few. A research respondent, IR, explained that it was imperative to ascertain the root causes of a shortage as tackling a shortage from the source could foster a quicker recovery mechanism. Thus, understanding the cause of a medicine shortage helped the MSRS focus their resources on tackling issues better. An example of this is provided below:

> *Because we have done significant research on the reasons behind the shortages and the implications for patients and healthcare professionals, that is our way of knowing what we need to focus on and what needs to be done.* FL.

3.1.3. Duration of shortages

The respondents indicated that stakeholders were required to indicate their duration in reporting and disseminating information about shortages. This was pertinent as it also determined the forms of strategies to adopt.

3.2. National information processing requirements

National information processing capabilities refer to the capacity to manage information received to support decision-making in a complex environment. These involve the capacity of the MSRS to acquire, record, retrieve and disseminate information related to medicine unavailability.[31] The analysed data showed that national information processing requirements included signal sources, notification periods, and forms of

reporting and disseminating information.

3.2.1. Information sources

The data analysis also showed that identifying information on shortages was essential to national information processing requirements. It depicted MSRS's ability to acquire information to tackle a shortage. Information about a shortage could emanate from a patient, pharmacist, wholesaler, or manufacturer. However, it differed among countries. For instance, in Ireland and Italy, patients could report if they experience a shortage, as shown in the statement below:

> *We can receive a signal of a shortage from anywhere. So, it could be a patient. It could be a pharmacist, a hospital, the wholesalers, or the manufacturer.* IT.

This was different in Spain, Belgium, and Australia, where patients' notification of shortages was not considered.

It is also important to note that the signal sources might be unreliable, predominantly if an MSRS relied on customers for sources. ES, a research respondent, pointed out that unreliable signal sources may lead to wrong decision-making processes and reduce the inability of the MSRS to provide mitigating strategies. Thus, signal sources must be deemed credible for an MSRS to be effective.

3.2.2. Frequency of notification period

According to the data analysed, the frequency of shortage notification was essential to the information process capabilities. It was a condition for stakeholders to notify the relevant authorities about a shortage. Timely notifications of shortages ensured the ability to develop strategies to tackle shortages. The respondents indicated that notification of shortages ranged from two (2) weeks to six (6) months, with thirty (30) days as the average notification time.

The respondents explained that the notification period for a shortage determined the strategies required in handling a shortage. For instance, BE, a research respondent, explained that a notification period within 1–6 months provided stakeholders ample time to plan and prepare for a shortage, thus mitigating its impact. Here, they could inform competitors to ramp up production if needed or seek to import if alternatives were unavailable. However, a notice received less than two (2) weeks before a shortage occurred restricted the strategies adopted. This implies that for an MSRS to develop the ability to mitigate the impact of medicine shortages, timely notification of shortages was imperative. Underlying the notification period is legislation. The data analysed suggests that the absence of legislation that forces stakeholders to report shortages influenced the notification period.

3.2.3. Forms of reporting and disseminating information

The analysed data showed that retrieving and disseminating information about shortages was a core component of the national information processing capabilities. If national shortages were reported manually (i.e., by completing a form and emailing it to the authorities), the process involved in developing strategies would be longer than when digital technologies were used. Similarly, disseminating information regarding shortages would be faster if digital technologies were adopted.

3.3. Dynamic capability of the decision-making process

The ability to match the information requirements of the MSRS and the national information processing capability required the dynamic capability of the decision-making process. This was critical to fostering the accessibility and sustainability of the MSRS. The decision-making process involved sensing, seizing and reconfiguring available resources.

3.3.1. Sensing

This involved recognising the MSRS environment. It denotes that understanding the type, duration, and causes of the shortages was

essential to developing strategies for tackling them. For instance, IR, a research respondent, explained that understanding the shortages on a per-product basis was important in their decision-making process when tackling shortages.

> So, if it comes from the MAH, what we do is get the information and ask what the specific product is; it is on a per-product basis, so we ask for the particular product when the shortage is going to start when it is
>
> e*xpected to end, what the cause is, that is essential, very important.* **IR.**

3.3.2. Seizing

Another step in the dynamic capability decision-making process involved seizing. This involved validating sources of medicine shortage notification, assessing the impact, seeking potential solutions and mobilising resources to address these shortages. As illustrated in the statements below:

> Once we validate the type of shortage, low, medium, or high, and different things, if the solution is that we can help and the MAH can provide the solution, that would be fantastic. We will try to help as much as possible. IR.

> Sure, so when we hear about a shortage, we first figure out all the different companies that make that drug, collect the national drug code numbers for each product, and then contact the manufacturer in the US.

Assessing the impact of the shortages on the healthcare system was also a critical component of the dynamic capability decision-making process. These assessments were usually done with a clinical team (colleges and professional organisations) and pharmacists, for example, when required. This process depicts horizontal collaboration between expert healthcare professionals and the MSRS. It determines the level of resources and the necessary strategies to tackle the shortages. For instance, IR and ES as respondents indicated that the criticality of shortages was measured using a traffic light system of red, amber and green and/or ranked as high, medium or low. The effect of a medicine shortage was measured based on patient treatment continuity and the health system. Thus, if patient treatment continuity was not affected, it was termed a low impact. A medium effect was the likelihood that the shortage affected patient treatment continuity and the health system.

A research respondent (BE) further explained that patient treatment was usually affected due to the unavailability of alternative medications. The degree of importance of the shortage is related to the risk to patient safety or if competing manufacturers could not ramp up their production process. It was essential to understand the degree of impact of medicine shortages for better resource use because not all shortages are considered a public health issue, as reflected in the statement below:

> *I mean the degrees that … not every shortage is a public health issue because sometimes we have shortages. We have alternatives for medicines that are being effective in other programmes.* ES.

The findings further suggest that identifying the degree of impact was essential to determine how stakeholders would respond to the shortage. Thus, if it was a low impact, the Medicines Authorisation Holders (MAH) could proffer solutions. However, if the effects of the medicine shortage were deemed significant, the MSRS would have to seek solutions that may involve contacting alternative suppliers or MAH.

Adaptability, denoted through the availability of alternatives, was identified as a process by which the MSRS could mitigate disruption. The respondents explained that the decision-making process determined if the shortages could be tackled using alternatives and if these alternatives were available. Manufacturers of alternative products were informed about impending shortages to ramp up production to meet unexpected demand. However, respondents further explained that in most cases, the availability of alternatives might be costly for

stakeholders, mainly if the products were on a tender.

3.3.3. Reconfiguring resources

Based on the analysed data, resource reconfiguration involved identifying and/or adapting available resources, engaging in collaborative practices and system optimisation.

The data analysed indicated that the modification and optimisation of different aspects of the MSRS were pertinent to ensure the system's sustainability. For instance, the interviewees highlighted that they had started improving some system parts. These improvements include changing the system from a manual to a fully digitalised process to increase notification accessibility and frequency. Other forms of system optimisation identified include integrating other features into the system and improving accessibility. System optimisation increased visibility among stakeholders and reduced the level of complexity and the impact on patient care. As a research respondent, ES explained that they had recently integrated General Practitioners (GPs) in a specific region to the MSRS. The aim was to ensure GPs received instant notification of medicines in short supply.

Our analysis also showed that system optimisation was achieved through constant monitoring and control of the MSRS. AUS, a research respondent, explained that collaborative practices, such as joint planning, integrated activities, and trust, were also necessary to build resilience strategies. The interviewees stated that entrenching effective strategies required stakeholders' planning and involvement at various stages of the pharmaceutical supply chain. For instance, IR explained that there was no 'magic bullet' when developing strategies for mitigating the impact of medicine shortages because of the complexities involved. Hence, it was necessary to involve all stakeholders. These stakeholders ranged from healthcare professionals, the government, industries and patients, all working as a team. Thus, the collaborative practices involved having honest conversations with stakeholders, collectively agreeing on solutions to a medicine shortage.

However, the interviewees noted that some stakeholders either refused to share information or collaborate and wrongly defined the impact of a shortage. This hampered the MSRS's ability to mitigate the effects of medicine shortages. As explained in the statement below:

> Sponsors do not always want to publish medicine shortages. We require that stakeholders report critical and medium impacts. Even after defining this to sponsors, they do not want to report and assume they are low-impact shortages. AUS

After identifying them, the analysis further showed that they developed strategies to tackle barriers. For instance, an interviewee (US) explained that when faced with stakeholders refusing to communicate existing shortages, they published it on their website to tackle their lack of cooperation. Thus, to ensure the success and sustainability of the MSRS, it was pertinent to Identify barriers and challenges to tackle them adequately.

> So, we must find some processes that optimise; it's essential to know how a drug changes in … What do you call it? If you have a COVID-19 patient, which kind of drugs do you have to use in that situation? It's imperative to follow up with how many drugs for intensive care you have to have in stock or whether or not you have stock. DN

To further ensure the sustainability of MSRS, the ability to measure the system's efficiency and effectiveness was critical. The MSRS process efficiency measures used available data to ascertain how well the system performed, the impact on patient treatment continuity, and stakeholders' willingness to participate in the MSRS process. For instance, a research respondent explained that manufacturers' increased desire to share information was used to measure the system's efficiency.

> It is certainly getting more efficient, especially as more drug companies want to email us information. Then, we do not have to spend time on the phone waiting for them to review the information. US

Measuring the efficiency of the system facilitated system optimisation and enhanced collaborative practices. However, some respondents stated that the lack of standardised metrics reduced the ability to measure an MSRS efficiency adequately.

> I think it's challenging to identify metrics to tell you how effective the scheme has been in mitigating patient outcomes at the end of the day. AUS

3.4. Accessibility

Another essential dimension of the MSRS is accessibility. The analysed data showed that the capacity of users to retrieve information as required differed across users and countries. For instance, the interface of the information system and the capacity to access information is accessible to all stakeholders in Australia and Ireland but limited in Spain and the US, as evidenced by the statements below.

> To access the data collected, we publish information on our website. So we publish information about shortages. AUS.

> We have a platform that has been developed internally in which the cases are filed by us and also can be filed by the marketing authorisation holders, but, for instance, patients do not have access to this platform, so when we receive information from other means we upload it into the system, our officers do that. ES.

The findings, therefore, suggest the importance of identifying stakeholders when developing an MSRS. The type of healthcare system and associated governing bodies were also crucial in defining accessibility. For the healthcare systems within the EU, most of the information about shortages in their databases was provided by the MAH. Several databases on shortages were identified in the US, although the FDA is the central regulatory agency. It is, therefore, important to clearly identify a central point for accessibility for the various stakeholders.

4. Discussion

This study aimed to identify how MSRS tackled medicine shortages by exploring the sustainability and accessibility dimensions. There is a growing recognition that reporting shortages and actioning this information on time is integral to mitigating the impact of shortages and reducing the risk of patient harm.[4,30] To our knowledge, this is the first study to explore the accessibility and sustainability dimensions of MSRS. Previous studies have examined MSRS with a similar focus on addressing shortages and highlighting the need to define consistent medicine shortages across all the stakeholders.[54] For instance, Postma et al.[23] developed a framework to assess the impact of shortages on patients using data reported on shortages in the Netherlands. Their findings suggest that understanding the effects of medicine shortages is central to the decision-making process. Thus, the findings from our study demonstrate that MSRS can be employed as a valuable tool in mitigating the impact of medicine shortages. However, the impact is minimized by recognising the interdependence of the associated procedures and decision-making processes (see Fig. 2).

Three core elements that influence MSRS sustainability towards addressing shortages are identified in this study. (1) the ability to identify the requirements of the reporting system, (2) identify information processing capabilities, and (3) match requirements and information processing capabilities through a dynamic capability decision-making process. The dynamic decision-making process involved sensing shortages by recognising, standardising and validating information received and reconfiguring resources. This follows the findings by the EAHP, where respondents were unaware of a standard procedure and the existence of a database.[4] A summary is presented as a framework in Fig. 2. The findings extend the existing literature by providing empirical evidence on the need for a standard procedure for sharing information on shortages if MSRS is to effectively tackle shortages and ensure sustainability.

An important finding of this study is the organisational information processing dynamic decision-making process required to ensure the sustainability of the MSRS. The information processing requirements highlight the need for quality information in the decision-making process through a standardised definition of medicine shortages, identifying the reasons for shortages and validating information sources. This is also aligned with the accessibility dimension of MSRS, where determining who reports a shortage and who has access to the data and/or information is critical to the system's information quality. Processing capabilities require that information received is validated and available resources identified, including the system's capacity to process information received and disseminated.

Thus, the inability to understand, validate, process and disseminate information could create panic and hoarding. Sharing information using the MSRS provides avenues for standardised practice and identifying international best-practice therapeutic alternatives.[20] Being a reporting system, the analysed data emphasised the need for close collaboration and exchange of information among stakeholders. It aligns with the assertions where the emphasis is on collaborative practices.[78] These practices can limit information distortion and provide strategic solutions. More specifically, the need for digital transformation increases automatic information notification, enhances visibility and defines accessibility.[86]

Information and communication throughout the MSRS are mainly helpful for evaluating trends and maintaining appropriate supply levels to prevent avoidable shortages. It is achieved by sensing threats through already mapped-out dimensions of medicine shortages, such as an agreed national definition, notification process, and the ability to measure a shortage's impact. Also, collaborative practices such as having honest conversations among stakeholders, joint planning and integration increase the proactive capacity of the MSRS. These activities increase trust, information access and visibility.[93]

The timing of reporting a shortage is also crucial, as this may differ across the various levels of the supply chain. Manufacturers may be required to report their inability to meet national demand for three months, while pharmacists may be required to notify patients when they cannot dispense medicines to them within 72 h (about 3 days). The context should be decided and accessed properly when developing an MSRS.

Underlying the efficiency, accessibility, and sustainability of the MSRS is the human element, which is critical. The effective matching of the information processing requirements and capabilities and the dynamic decision-making is hinged on the skills and competence of a human element. It promotes smart working, and a more sustainable information reporting system.[91] Education and training on using MSRS at various stages is critical to its effectiveness.

Discussions around accessibility and availability of information about shortages and challenges are also important when designing an MSRS. Making information available to stakeholders is pertinent. It would help with more proactive responses, such as identifying suitable alternatives. However, excessive information sharing may lead to supply chain crises such as panic buying and hoarding.

To ensure the sustainability of the MSRS, it is pertinent to increase system optimisation, accessibility and functionality regularly. Also, careful monitoring is required to improve the system and ensure its objectives are met. This can be achieved by ensuring that resources such as time, staffing, training and financial requirements are harnessed to this endeavour.

A summary of the process of setting up a medicine shortage reporting system within national boundaries is presented within a framework in Fig. 2. The framework shows that effectively tackling shortages and developing a sustainable reporting system entails matching the information system requirements to the national systems processing requirements. However, this transcends beyond the definition, causes and duration of shortages. It also includes mobilising and assessing resources, optimising the available systems and regularly validating decisions taken.

5. Conclusion

This paper explored the role of MSRS in mitigating medicine shortages with a specific focus on efficiency, accessibility, and sustainability using the organisational processing information dynamic capability model. Data was collected by interviewing personnel in charge of these systems (MSRS) in eight countries. Our findings highlighted the various processes involved using an MSRS to address shortages. The analysis showed the ability to identify the requirements of the reporting system and the information processing capabilities; matching the requirements and information processing capabilities through a dynamic capability decision-making process was critical in ensuring sustainability. The findings indicate that the dynamic capabilities matching process involves understanding and validating information sources and identifying resources. The study concludes that an MSRS is a systemic information-sharing cycle that involves harnessing dynamic capabilities at various phases to mitigate the impact of medicine shortages.

This study extends the literature on medicine accessibility by providing greater transparency of MSRS and demonstrating how MSRS can address shortages and ensure sustainability. The findings also contribute to the dynamic capability literature on the role of collaboration and interactions between stakeholders in the dynamic capability decision-making process of the MSRS.

5.1. Limitations and future research

The data collected for this study occurred during the disruption of COVID-19, limiting the number of participating countries. Therefore, it could be interesting to conduct further studies to extend the number of participating countries to provide a clearer picture of the MSRS and how it can address the issue of medicine shortages. Most of the countries sampled in the study (6 out of 8) are full member states of the European Union (EU), where there is an attempt at harmonising how medicine shortages are reported and, as such, may bias the results. Introducing new legislation aims to further harmonise EU member efforts and practices to reduce the frequency and impact of medicines shortages.[30] Whilst the findings of this study may not be couched in the current EU context, they still provide valuable insights into the composition and functionality of reporting systems. Future studies should examine more countries outside the EU that have reporting systems to verify and establish an existing framework. This study also focused on only one MSRS per country, while some countries, like the US, had more than one MSRS. Further research should include all MSRS within a country to facilitate cross-case synthesis. It could also emphasize the sensing and
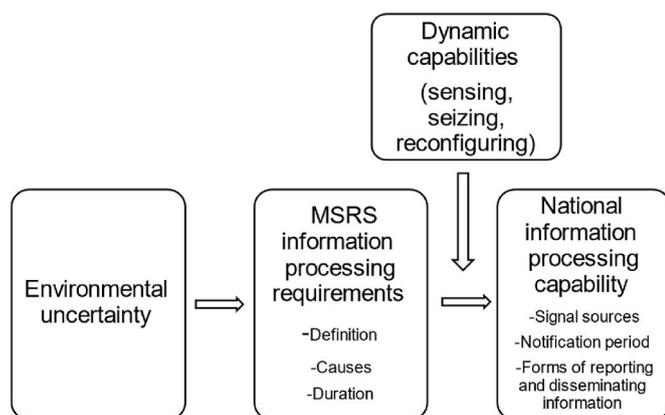

Fig. 1. Organisational information processing dynamic capabilities theoretical lens for MSRS
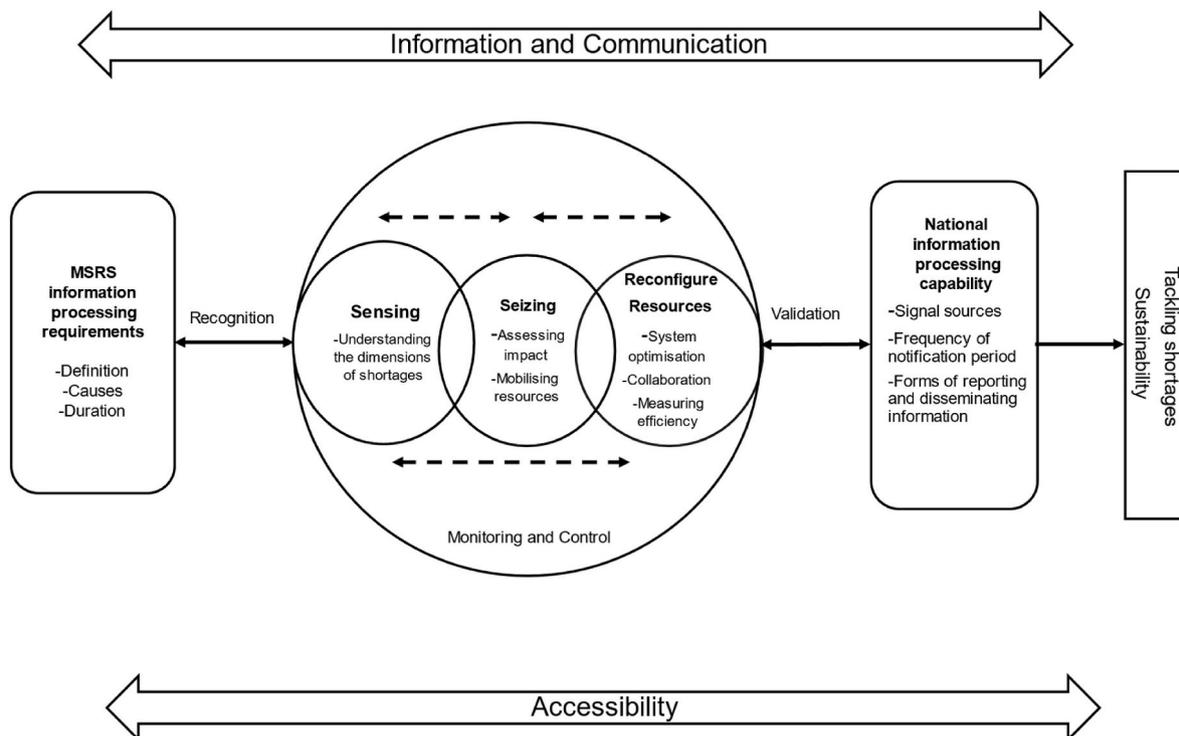Source. Adapted from Egelhoff[92](1999, p. 345).

Fig. 2. A framework demonstrating inputs for a sustainable MSRS.

transforming stages of the dynamic capability perspectives and the recovery stages of building resilience strategies. Similarly, we collected data from experts involved in medicine shortages reporting at various levels in the pharmaceutical supply chain, where the perceptions may vary. Future studies should establish an underlying definition.

CRediT authorship contribution statement

Liz Breen: Writing – review & editing, Validation, Supervision, Resources, Project administration, Conceptualization. **Gemma Quinn:** Writing – review & editing, Conceptualization. **Emilia Vann Yaroson:** Writing – original draft, Methodology, Investigation, Formal analysis.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.sapharm.2024.02.010.

References

1. IQVIA (2020) Global Medicine Spending and Usage Trends - IQVIA https://www.iqvia.com/insights/the-iqvia-institute/reports/global-medicine-spending-and-usage-trends [Accessed, 20/10/2023]2.
2. World Health Organization. *Addressing the global shortage of, and access to, medicines and vaccines Report by the Director-General BACKGROUND*. Vol. EB142/13.. Geneva: World Health Assembly; 2018:50.
3. Park C, Wang G, Durthaler JM, Fang J. Cost-effectiveness analyses of antihypertensive medicines: a systematic review. *Am J Prev Med.* 2017;53(6):S131–S142.
4. European Association of Hospital Pharmacists (Eahp). *EAHP2023 Shortage Survey Report Shortages of Medicines and Devices in the Hospital Sector – Prevalence, Nature and Impact on Patient Care.* 2023.
5. Breen L, Yaroson E. Medicine shortages are already a reality, but a no-deal Brexit could make it worse. The Conversation. https://theconversation.com/medicine-shortages-are-already-a-reality-but-a-no-deal-brexit-could-make-it-worse-102218; 2019.
6. Acosta A, Vanegas EP, Rovira J, Godman B, Bochenek T. Medicines shortages: gaps between countries and global perspectives. *Front Pharmacol.* 2019;10. https://doi.org/10.3389/fphar.2019.00763.
7. Tucker EL, Cao Y, Fox ER, Sweet BV. The drug shortage era: a scoping review of the literature 2001–2019. *Clin Pharmacol Therapeut.* 2020;108(6):1150–1155.
8. Shukar S, Zahoor F, Hayat K, et al. Drug shortage: causes, impact, and mitigation strategies. *Front Pharmacol.* 2021;12, 693426.
9. Vann Yaroson E, Breen L, Hou J, Sowter J. The role of power-based behaviours on pharmaceutical supply chain resilience. *Supply Chain Manag: Int J.* 2023;28(4):738–759.
10. Yaroson EV, Breen L, Hou J, Sowter J. Examining the impact of resilience strategies in mitigating medicine shortages in the United Kingdom's (UK) pharmaceutical supply chain (PSC). *Benchmark Int J.* 2023.
11. Fox ER, Sweet BV, Jensen V. Drug shortages: a complex health care crisis. *Mayo Clin Proc.* 2014;89(3):361–373.
12. Heiskanen K, Ahonen R, Kanerva R, Karttunen P, Timonen J. The reasons behind medicine shortages from the perspective of pharmaceutical companies and pharmaceutical wholesalers in Finland. *PLoS One.* 2017;12(6), e0179479.
13. Francas D, Mohr S, Hoberg K. *On the Drivers of Drug Shortages: Empirical Evidence from Germany.* Forthcoming: International Journal of Operations & Production Management; 2023.
14. Walker J, Chaar BB, Vera N, et al. Medicine shortages in Fiji: a qualitative exploration of stakeholders' views. *PLoS One.* 2017;12(6), e0178429.
15. Badreldin HA, Atallah B. Global drug shortages due to COVID-19: impact on patient care and mitigation strategies. *Res Soc Adm Pharm.* 2021;17(1):1946–1949.
16. European Pharmaceutical Review (EPR). *India to restrict 10 per cent of medicine exports due to coronavirus.* 2020.
17. Wong A, Wilkinson A. *China Imposes New Export Restrictions for COVID-19 Medical Products (twobirds.Com).* 2020.
18. Sim K, Chua HC, Vieta E, Fernandez G. The anatomy of panic buying related to the current COVID-19 pandemic. *Psychiatr Res.* 2020;288, 113015. https://doi.org/10.1016/j.psychres.2020.113015.
19. Schiffling S, Breen L. The UK's speedy COVID-19 vaccine rollout: surprise success or planned perfection? *The Conversation.* 2021.
20. Shi Y, Yang P, Li X, et al. Combating drug shortages in China: surveillance warning and practice standardisation. *Int J Clin Pharm.* 2020;42:309–314. https://doi.org/10.1007/s11096-020-00987-5.

21. World Health Organization. *Notification Systems for Shortages and Stockouts of Medicines and Vaccines: Technical Consultation Meeting Report.* World Health Organization; 2017. *July 2017* (No. WHO/EMP/IAU/2017.15).
22. Iyengar S, Hedman L, Forte G, Hill S. Medicine shortages: a commentary on causes and mitigation strategies. *BMC Med.* 2016;14(1):124.
23. Postma DJ, De Smet PA, Notenboom K, Leufkens HG, Mantel-Teeuwisse AK. Impact of medicine shortages on patients-a framework and application in The Netherlands. *BMC Health Serv Res.* 2022;22(1):1–12.
24. Videau M, Chemali L, Stucki C, et al. Drug shortages in Canada and selected European countries: a cross-sectional, institution-level comparison. *Can J Hosp Pharm.* 2019;72(1):7.
25. Chapman S, Dedet G, Lopert R. Shortages of medicines in OECD countries. *OECD-Shortages-of-medicines-in-OECD-countries.pdf (fondazionecerm.it).* 2022.
26. Pauwels K, Huys I, Casteels M, Simoens S. Drug shortages in European countries: a trade-off between market attractiveness and cost containment? *BMC Health Serv Res.* 2014;14(1):438.
27. Tan YX, Moles RJ, Chaar BB. Medicine shortages in Australia: causes impact and management strategies in the community setting. *Int J Clin Pharm.* 2016;38(5):1133–1141.
28. Fox ER, McLaughlin MM. ASHP guidelines on managing drug product shortages. *Am J Health Syst Pharm.* 2018;75(21):1742–1750.
29. European Medicines Authorities (Ema). *Guidance on Detection and Notification of Shortages of Medicinal Products for Marketing Authorisation Holders (MAHs) in the Union (EEA);* 2019. https://www.ema.europa.eu/system/files/documents/other/good_practice_guidance_for_prevention_of_shortages_en.pdf.
30. European Commission (Ec). *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Addressing Medicine Shortages in the EU on October 24th, 2023.* 2023.
31. Galbraith JR. Organisation design: an information processing view. *Interfaces.* 1974; 4(3):28–36.
32. Breen L. *Medicines Availability in the UK Pharmaceutical Supply Chain - Pharmacy and Medical Sciences - University of Bradford*; 2019. https://www.bradford.ac.uk/pharmacy-medical-sciences/researchinnovation/medicines-availability/.
33. Bryman A, ed. *Doing Research in Organisations (RLE: Organisations).* Routledge; 2013.
34. Yaroson EV, Breen L, Hou J, Sowter J. Resilience Strategies and the Pharmaceutical Supply Chain: The Role of Agility in Mitigating Drug Shortages. *Pharmaceutical supply chains-medicines shortages.* 2019:249–256.
35. Sarnola K, Linnolahti J. A regulatory perspective on the availability of medicines and medicine shortages in outpatient care: case Finland. *Int J Clin Pharm.* 2019:1–6.
36. Beck M, Buckley J, O'Reilly S. *Managing Pharmaceutical Shortages: An Overview and Classification of Policy Responses in Europe and the USA.* International Review of Administrative Sciences; 2019, 0020852318815330.
37. Alruthia YS, Alwhaibi M, Alotaibi MF, et al. Drug shortages in Saudi Arabia: root causes and recommendations. *Saudi Pharmaceut J.* 2018;26(7):947–951.
38. Etikan I, Bala K. Sampling and sampling methods. *Biometrics & Biostatistics International Journal.* 2017;5(6), 00149.
39. Yin RK. *Case Study Research.* 2014.
40. Cunliffe AL. Crafting qualitative research: morgan and smircich 30 years on. *Organisational research methods.* 2011;14(4):647–673.
41. Atif M, Malik I, Mushtaq I, Asghar S. Medicines shortages in Pakistan: a qualitative study to explore current situation, reasons and possible solutions to overcome the barriers. *BMJ Open.* 2019;9(9).
42. Hedman L. Global approaches to addressing shortages of essential medicines in health systems. *WHO Drug Inf.* 2016;30(2):180.
43. American Society of Health-System Pharmacists. Ashp. https://www.ashp.org/Drug-Shortages/Shortage-Resources/Drug-Shortages-Statistics; 2020.
44. Dragic J. Analysis of drug shortages in a hospital pharmacy. *Eur J Hosp Pharm Sci Pract.* 2012;19(2):130–131.
45. de Vries H, Jahre M, Selviaridis K, van Oorschot KE, Van Wassenhove LN. Short of drugs? Call upon operations and supply chain management. *Int J Oper Prod Manag.* 2021;41(10):1569–1578.
46. De Weerdt E, Simoens S, Casteels M, Huys I. Toward a European definition for a drug shortage: a qualitative study. *Front Pharmacol.* 2015;6:253.
47. European Federation of Pharmaceutical Industries and Association (EFPIA). *Medicine Shortages EFPIA Proposal for Action SHORTAGES EFPIA PROPOSAL FOR ACTION).* 2022. available at medicine-shortages-efpia-proposal-for-action.pdf [accessed 20/10/2023].
48. Bochenek T, Abilova V, Alkan A, et al. Systemic measures and legislative and organisational frameworks aimed at preventing or mitigating drug shortages in 28 European and Western Asian countries. *Front Pharmacol.* 2018;8:942.
49. FDA. *Drug shortages: root causes and potential solutions. Tech. rep., US Food & Drug Administration, Silver Spring, US.* 2019.
50. Gloor C, Dantés M, Graefenhain E, Pantazis A, Poole J, Pujol J. An evaluation of medicines shortages in europe with a more in-depth review of these in France, Greece, Poland, Spain, and the United Kingdom. *Bilgir Repor.* 2013.
51. Gu A, Wertheimer AI, Brown B, Shaya FT. *Drug Shortages in the US–Causes, Impact, and Strategies.* 2011.
52. Kaakeh R, Sweet BV, Reilly C, et al. Impact of drug shortages on US health systems. *Am J Health Syst Pharm.* 2011;68(19):1811–1819.
53. McLaughlin MM, Pentoney Z, Skoglund E, Scheetz MH. Projections for antiinfective drug shortages and time to actual resolution. *Am J Health Syst Pharm.* 2014;71(23):2074–2078.
54. Miljković N, Gibbons N, Batista A, Fitzpatrick RW, Underhill J, Horák P. Results of EAHP's 2018 survey on medicines shortages. *Eur J Hosp Pharm.* 2019.
55. Postma DJ, Notenboom K, De Smet PA, Leufkens HG, Mantel-Teeuwisse AK. Medicine shortages: impact behind numbers. *Journal of Pharmaceutical Policy and Practice.* 2023;16(1):44.
56. Trentin A, Forza C, Perin E. Organisation design strategies for mass customisation: an information-processing-view perspective. *Int J Prod Res.* 2012;50(14):3860–3877.
57. Nadler D, Tushman M, Nadler MB. *Competing by Design: The Power of Organisational Architecture.* Oxford University Press; 1997.
58. Zhu S, Song J, Hazen BT, Lee K, Cegielski C. How supply chain analytics enables operational supply chain transparency: an organisational information processing theory perspective. *Int J Phys Distrib Logist Manag.* 2018;48(1):47–68.
59. Srinivasan R, Swink M. Leveraging supply chain integration through planning comprehensiveness: an organisational information processing theory perspective. *Decis Sci J.* 2015;46(1):823–861.
60. Gupta S, Drave VA, Bag S, Luo Z. Leveraging smart supply chain and information system agility for supply chain flexibility. *Inf Syst Front.* 2019;21:547–564.
61. Helfat CE, Raubitschek RS. Dynamic and integrative capabilities for profiting from innovation in digital platform-based ecosystems. *Res Pol.* 2018;47(8):1391–1399.
62. Teece DJ. Explicating dynamic capabilities: the nature and micro-foundations of (sustainable) enterprise performance. *Strat Manag J.* 2007;28(13):1319–1350.
63. Majuri M, Halonen N. Capability building through dynamic capabilities and organisational learning. *Responsible Consumption and Production.* 2020:49–59.
64. Matysiak L, Rugman AM, Bausch A. Dynamic capabilities of multinational enterprises: the dominant logic behind sensing, seizing, and transforming matter. *Manag Int Rev.* 2018;58:225–250.
65. McDougall N, Wagner B, MacBryde J. Leveraging competitiveness from sustainable operations: frameworks to understand the dynamic capabilities needed to realise NRBV supply chain strategies. *Supply Chain Manag: Int J.* 2022;27(1):12–29.
66. Conboy K, Mikalef P, Dennehy D, Krogstie J. Using business analytics to enhance dynamic capabilities in operations research: a case analysis and research agenda. *Eur J Oper Res.* 2020;281(3):656–672.
67. Siems E, Land A, Seuring S. Dynamic capabilities in sustainable supply chain management: an inter-temporal comparison of the food and automotive industries. *Int J Prod Econ.* 2021;236, 108128.
68. Hendry LC, Stevenson M, MacBryde J, Ball P, Sayed M, Liu L. Local food supply chain resilience to constitutional change: the Brexit effect. *Int J Oper Prod Manag.* 2019;39(3):429–453.
69. Naghshineh B, Lotfi M. Enhancing supply chain resilience: an empirical investigation. *Continuity Resilience Rev.* 2019;1(1):47–62.
70. Colicchia C, Creazza A, Menachof DA. Managing cyber and information risks in supply chains: insights from an exploratory analysis. *Supply Chain Manag: Int J.* 2019;24(2):215–240.
71. Sá MMD, Miguel PLDS, Brito RPD, Pereira SCF. Supply chain resilience: the whole is not the sum of the parts. *Int J Oper Prod Manag.* 2020;40(1):92–115.
72. Datta S, Jauhar SK, Paul SK. Leveraging blockchain to improve nutraceutical supply chain resilience under post-pandemic disruptions. *Comput Ind Eng.* 2023;183, 109475.
73. Holweg M, Pil FK. Theoretical perspectives on the coordination of supply chains. *J Oper Manag.* 2008;26(3):389–406.
74. Ali I, Nagalingam S, Gurd B. Building resilience in SMEs of perishable product supply chains: enablers, barriers and risks. *Prod Plann Control.* 2017;28(15):1236–1250.
75. Fan Y, Stevenson M, Li F. Supplier-initiating risk management behaviour and supply-side resilience: the effects of interpersonal relationships and dependence asymmetry in buyer-supplier relationships. *Int J Oper Prod Manag.* 2020;40(7/8):971–995.
76. Brusset X, Teller C. Supply chain capabilities, risks, and resilience. *Int J Prod Econ.* 2017;184:59–68.
77. Ivanov D, Dolgui A. Viability of intertwined supply networks: extending the supply chain resilience angles towards survivability. A position paper motivated by the COVID-19 outbreak. *Int J Prod Res.* 2020;58(10):2904–2915.
78. Gu M, Yang L, Huo B. The impact of information technology usage on supply chain resilience and performance: an ambidextrous view. *Int J Prod Econ.* 2021;232, 107956.
79. Fawcett SE, Wallin C, Allred C, Fawcett AM, Magnan GM. Information technology as an enabler of supply chain collaboration: a dynamic-capabilities perspective. *J Supply Chain Manag.* 2011;47(1):38–59.
80. Kembro J, Selviaridis K, Näslund D. Theoretical perspectives on information sharing in supply chains: a systematic literature review and conceptual framework. *Supply Chain Manag: Int J.* 2014;19(5/6):609–625.
81. Tsvetanova A, Sperrin M, Peek N, Buchan I, Hyland S, Martin G. Inconsistencies in handling missing data across stages of prediction modelling: a review of methods used. In: *2021 IEEE 9th International Conference on Healthcare Informatics (ICHI).* IEEE; 2021, August:443–444.
82. Wced SWS. World commission on environment and development. *Our Common Future.* 1987;17(1):1–91.
83. Carter CR, Rogers DS. A framework of sustainable supply chain management: moving toward new theory. *Int J Phys Distrib Logist Manag.* 2008;38(5):360–387.
84. Gold S, Schleper MC. A pathway towards true sustainability: a recognition foundation of sustainable supply chain management. *Eur Manag J.* 2017;35(4):425–429.
85. Dao V, Langella I, Carbo J. From green to sustainability: information Technology and an integrated sustainability framework. *J Strat Inf Syst.* 2011;20(1):63–79.
86. Aral S, Weill P. IT assets, organisational capabilities, and firm performance: how resource allocations and organisational differences explain performance variation. *Organisation Science.* 2007;18(5):763–780.

87. Zhang M, Zhao X, Lyles M. Effects of absorptive capacity, trust and information systems on product innovation. *Int J Oper Prod Manag*. 2018;38(2):493–512.

88. Meechang K, Leelawat N, Tang J, Kodaka A, Chintanapakdee C. The acceptance of using information technology for disaster risk management: a systematic review. *Eng J*. 2020;24(4):111–132.

89. Culnan MJ. The dimensions of perceived accessibility to information: implications for the delivery of information systems and services. *J Am Soc Inf Sci*. 1985;36(5): 302–308.

90. Braun V, Clarke V. Conceptual and design thinking for thematic analysis. *Qualitative Psychology*. 2022;9(1):3.

91. Bednar PM, Welch C. Socio-technical perspectives on smart working: creating meaningful and sustainable systems. *Inf Syst Front*. 2020;22(2):281–298.

92. Egelhoff WG. Organisational equilibrium and organisational change: two different perspectives of the multinational enterprise. *J Int Manag*. 1999;5(1):15–33.

93. Barratt M, Oke A. Antecedents of supply chain visibility in retail supply chains: a resource-based theory perspective. *J Oper Manag*. 2007;25(6):1217–1233.