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RESEARCH ARTICLE

Stakeholder perspectives on the challenges surrounding management and supply of essential medicines

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Abstract

Background Shortages of essential medicines impact patient safety and raise the costs of medicines to consumers and governments. Ongoing medicine shortages have become a critical issue that threaten global access to medicines. *Objective* The aim of this study was to explore key stakeholders' perspectives on the challenges surrounding management and supply of essential medicines. *Setting* Western Pacific, Asia, Europe, North America, and Africa. *Methods* In-depth, semi-structured interviews with 47 participants were conducted across seven stakeholder groups globally. Stakeholders included government, academics, consumer groups, non-profit organisations, hospital healthcare providers, manufacturers, and wholesaler/distributors. A grounded theory approach was applied to qualitative analysis. *Main outcome measure* Stakeholders' perspectives on the challenges surrounding management and supply of essential medicines. *Results* This study showed that supporting consumer demand for a wide range of therapeutic products required increased resources and coordination. Four main themes were identified: (1) consumer demand for a wide range of individual therapeutic needs cannot be sustained by the supply chain; (2) there lacked a coordinated approach to manage medicine shortages throughout the supply chain; (3) there were gaps in communication throughout the continuum of the supply chain; and (4) both international and local disruptions contributed to vulnerabilities in the supply chain. *Conclusion* Prioritisation of supply, logistics, and budget decisions around essential medicines need to be clearly coordinated between stakeholders to mitigate medicine shortages. Financial structures should include resilience planning to support fair and equitable access to medicines that meet consumer needs.

Keywords Access to medicines · Drug shortages · Formulary · Medicine shortages · Procurement · Resilience · Supply chain

Impacts on practice

- To mitigate medicine shortages, the rationale for the variety and number of product choices needs to be clear to all stakeholders, in order to accommodate storage requirements, space, ordering, transportation, budget decisions and contingency planning around essential medicines.
- Investment in resilience planning, to support the ability to adapt to unpredictable circumstances, is needed to support expanded consumer demand (with appropriate financial support) to enable fair and equitable access to essential medicines.
- Aligning decision making priorities with procurement practices through multi-stakeholder cooperation encourages sustainable patient care.

Introduction

Globalisation of pharmaceutical distribution networks (supply chain), have led countries around the world to compete to procure their medicines (including raw ingredients) from the same suppliers [1, 2]. Disruptions in the supply chain have caused worldwide stock-outs (the temporary unavailability

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of medicines on the pharmacy shelf) and medicine shortages (a crisis situation caused by the inability to supply a medicine's active ingredient or formulation over an extended period of time) at the point of care [3, 4].

In the United States, the number of reported medicine shortages increased fivefold from approximately 60 in 2005, to over 300 in 2012 [5]. By 2015, this was reduced to approximately 131 medicine shortages [6]. Whilst clinically interchangeable substitutes were mostly available, the United States Food and Drug Administration (FDA) reported 89% of medicine shortages caused a safety issue or contributed to a drug-related problem, and 80% resulted in the delay or cancellation of a patient care intervention [7]. This was most concerning when medicine shortages involved essential medicines. Essential medicines satisfy the priority healthcare needs of the population, and are selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost effectiveness [8]. Shortages of particular medicines, including morphine, gentamycin, naloxone, furosemide, cytarabine and epinephrine, were deemed catastrophic as they are indicated for life-threatening diseases [7]. Hence, recent global medicine shortage crises and continued stock-outs have become a global experience, attracting widespread interest [9, 10].

Ongoing medicine shortages threaten the provision of patient care, strain resources needed to manage medicines supplies, and corrupt systems by driving prices up with emerging "grey markets" (unofficial or unauthorised supply channels that were unintended by the original manufacturer) [10–12]. Moreover, instability in the global supply chain amplifies the existing challenges around inequality of accessing lifesaving medicines [13–15]. The World Health Organization (WHO) has described this disparity in access to essential medicines as the 'global drug gap' [16], in which approximately one-third of the global population, and 50% in the poorest parts of Asia and Africa, do not have access to basic medicines [17, 18]. Therefore, already difficult-to-access essential medicines in low to middle income countries (LMICs) must also face additional global challenges and/or competition to source medicines during medicine shortages [19].

Addressing significant medicine shortages requires coordination between multiple stakeholders. Previously, the supply chain has been studied for specific practice settings, such as hospital pharmacy or manufacturing, but not at national or global levels [13, 20–22]. However, broader understanding of issues affecting stakeholders throughout the supply chain may offer insights into the management of medicine shortages. Further understanding is needed about how different elements of the supply chain and health systems operate, interact and impact access to medicines, in order to highlight management strategies that may reinforce and protect the supply of essential medicines. The aim of this study was to explore stakeholders' perspectives on the challenges surrounding management and supply of essential medicines.

Methods

Ethics approval

Ethics approval was obtained from the University of Sydney Human Research Ethics Committee.

Study design

Results and methods from this study have been adapted from a larger body of research [23–25]. A semi-structured interview guide ("Appendix 1") developed from the WHO Access to Essential Medicines Framework was reported in accordance with the Coreq-32 checklist guidelines ("see Appendix in electronic supplementary material") [17, 26].

Participants were recruited worldwide through purposive and snowball sampling approaches for in-depth interviews, from October 2012 to January 2015; when thematic saturation was achieved [25, 27–29]. Stakeholders included government, consumer groups, health providers, academia, pharmaceutical industry, wholesaler/distributer and non-profit organisations. Recruitment for the study targeted high level decision makers (e.g. experts, leaders, senior management) with essential medicines list (EML) experience, involved in policy making, medicines reimbursement and selection knowledge, as well as those with experience managing drug shortages. In-depth, face-to-face, teleconference and Skype interviews were conducted with participants.

Data analysis

Interviews were audio-recorded, de-identified, transcribed verbatim through electronic transcription services, and verified by the researcher. After this, all participants were given the option to verify their transcripts. An inductive approach to data analysis used iterative constant comparative techniques to extract themes and key concepts [29]. A grounded theory "approach" was adopted, through the use of tools such as open, axial and selective coding [29–33]. One researcher independently conducted axial and open coding thematic content analysis, then discussed and validated these with the research team. Selective coding and consensus was performed as a team, consisting of four experienced researchers, until consensus was reached. Although themes derived from open and axial coding have been made available [23–25]; results reported in this study reflect key themes from selective coding analysis. The iterative consultative approach offered reflexivity and explored relationships between themes and concepts. Reflexivity of data collection, interpretation and analysis was offered by the researchers' broad experiences working across multiple policy, pharmacy, patient care, industry and administrative settings, with international

experiences in both high income countries (HICs) and low to middle income countries (LMICs) [32, 34, 35].

Results

Forty-seven participants were recruited. From 96 stakeholders that were contacted, 24 did not respond, 23 declined to participate due to perceived limitation of expertise or time constraints, and 10 declined but referred a colleague. Interviews lasted a median of 60 min and interquartile range (IQR) of 45–69 min. Key stakeholders had experiences in multiple country settings, including: Canada, United States, Columbia, Netherlands, Denmark, Estonia, Latvia (and other Baltic countries), Tanzania, Zimbabwe, South Africa, Nigeria, Uganda, Namibia, Cameroon (and other French speaking African countries), India, Pakistan, Afghanistan, Bangladesh, Sri Lanka, Australia, New Zealand, Philippines, Fiji, Tonga, and Papua New Guinea. The broad range of expertise was representative of each WHO region: Panamerica, Western Pacific, South East Asia, Africa, and Europe. While representation was highest in the Western Pacific region due to the nature of the snowball technique, at least one stakeholder was interviewed from each region.

This study explored a broad, and often divergent, range of stakeholder views about what challenges surround the management of essential medicines. Four main themes were extracted from thematic analysis. One theme was influenced by patient care decisions made by clinicians and consumer (patient) demand for a wide range of treatment options, while the others were influenced by logistics management. The significant overarching theme that emerged was that having broad consumer choice (a wide range of options), in selecting therapeutic treatments or pharmaceutical product alternatives, had a major (negative/positive) influence on access disruptions to essential medicines. Therefore, wider therapeutic options required increased management of resources, due to the increased risk and coordination needed to maintain adequate access to a large range of required medicines including new or rare therapeutic entities. This was exacerbated by many different stakeholders making decisions in isolation, often without adequate communication.

Theme 1: Consumer demand for a wide range of individual therapeutic needs cannot be sustained by the supply chain

The "just-in-time" supply chain model (producing or delivering goods just in time to be sold), is used to lower cost by reducing inventory held in stock.

> We create our own vulnerabilities with our just-in-time medication and our contracting processes (Participant 20—Government-Physician-Western Pacific).

Wholesalers and pharmacies must meet a wide range of individual needs which has become increasingly difficult to sustain due to resource and capacity limitations (e.g. shelf space, delivery times, staffing, expiry). This in turn reduces resilience, the ability for the system to adapt to unforeseen circumstances (e.g. environmental disasters, political events, financial crises, manufacturer/transportation disruptions).

> [With] distribution into Australia, there are long lead times because we're importing a lot of stuff. We've got distribution challenges. We're being asked to squeeze our margins because there's less money, because it's a commoditized market. We've actually put efficiencies [based on the just in time model] in there in an attempt to save money that has [instead] created inefficiency because now we are unable to react (Participant 18—Pharmaceutical Industry-Pharmacist-Western Pacific).

Despite the importance of empowering consumer choice, some participants highlighted that the availability of many therapeutic options to meet a broad range of individual needs, consumed large amounts of resources.

This has become increasingly difficult to sustain for both providers and payers. Consumers and third party payers (i.e. governments) need to communicate to providers (professionals who are purchasing medicines on behalf of consumers, such as manufacturers, suppliers of medicines, pharmacies) what they consider are priority medicines they need supplied, including high cost medicines and multiple brands for proprietary medicines.

> There are some drugs that are not needed in the system, but some people just want to have them. When you put restrictions to setting drugs that are really essential, it will help make healthcare workers be more focused and there will be conservation of resources. The resources you have will be directed to those drugs that are really essential to keep the facilities moving (Participant 6—Distributor–Pharmacist-Africa).

Instead, consumers demand more than can be provided sustainably by the supply chain.

> I think choice is very important and having as much information as possible in order to make an informed choice is actually more important. [But], consumers have to think much more about the trade off in paying for very expensive medicines that don't cure (Participant 44—Consumer–Teacher-Western Pacific).

Whereas, some participants were uncertain whether consumers played a role in managing the supply chain or address medicine shortages. Hence, consumer needs and expectations were important to consider in consumer communication and shared-decision making.

> If you pay for a service you have the right to demand something in return. You give a voice to people who have no voice. If you get something for free, like health care, people [patients], have no voice. And the dynamics change if people have to pay for services. But as people, we all are in our own way, very selfish (Participant 2—Nonprofit-Pharmacist-Europe/Africa).

> Not having medicines available can be devastating to people. But they have to know about it, and I don't know who would take responsibility for informing people (Participant 44—Consumer–Teacher-Western Pacific).

Theme 2: Lack of a coordinated approach to manage medicine shortages throughout the supply chain

Many stakeholders commented that there was a lack of cohesion and consultation between stakeholders regarding solutions to fix medicine shortages or offer sustainable supply solutions. Some highlighted that timing and reducing the duration of shortages was highest priority for stakeholders involved at the point of care. Unfortunately, all participants reported that they each fixed their problems instead of a cohesive approach with clear leadership.

> If [stakeholders] want consistency when there are shortages, they have to have a national approach how they'll allow products to be drip fed out to the market nationally. They're all different, but 80–90% of it can be a combined list. Unless you get all the states together, nothing's going to change (Participant 30—Wholesaler/Distributor-Business Management-Western Pacific).

In contrast, some participants viewed that poorly performed logistical activities were major contributors to medicine shortages (e.g. quantification [ordering, inventory update, stockpiling, expiry], forecasting, storage requirements, delivery, staffing, technology). This draws attention to the importance of well-trained healthcare providers who can communicate and advocate appropriate and cost-effective therapeutic options, to support consumer choice.

> The problem is, because of poor quantification, or forecasting [on the part of] the facilities, facilities will not have a drug even if it's available at the medicines depot. They don't have enough skilled, experienced, qualified people to run the drug supply management chain. There's [also] no provision [in the system] for follow-ups for monitoring the performance of the companies (Participant 8—Nonprofit-Pharmacist-Africa).

Some stakeholders discussed that leadership and accountability of medicine shortages needed clarity and communication to improve engagement, including expanding roles for pharmacists and wholesalers/distributors.

> If nobody's in charge, it's going to be a big issue, that thorn in your side every day. If you dedicate a staff member in your pharmacy or organisation, you can refer to the expert in medicine shortages. The message is being delivered consistently, all the time, of what is available. It's about knowing your work environment, [and] having that organisational structure that says who's responsible for what, and proper training so people know who, when, and how to refer (Participant 1—Health Provider-Nonprofit-Pharmacist-Pan America/Africa).

Meanwhile, participants explained there were different priorities amongst stakeholders, leading to duplication of activities and isolated management according to the specific needs and capacity of each practice setting. Shared priorities were also not identified or communicated well between stakeholders.

> We're such a big country [Australia]. You might have an out-of-stock situation at the manufacturing level but there's plenty in the wholesale chain. There [might be] 50% of it [in one state] and they use 5% of it a year, and then none of it [in another state] but you need a lot of it. You can get imperfections in the supply chain that create artificial shortages. How do they get it to the place where it's needed? (Participant 26—Pharmaceutical Industry-Western Pacific).

Theme 3: Gaps in communication throughout the continuum of the supply chain

Results showed that communication gaps existed within organisations and also between stakeholders. An example of a significant gap identified in this study was communication surrounding medicine prices, impact on profit margins and cost savings. Many participants described tensions between stakeholders were caused by pricing of medicines and costs of services for a wide range of products, and put pressure on the system.

> Most of the old generic drugs are being forced to become cheaper. And that's causing the problem. [Today], ceftriaxone costs one dollar per vial. So, you can life-save for meningitis for less than you pay for a Mars bar (Participant 15-Health Provider-Physician-Western Pacific).

Meanwhile, consumers want to pay low prices for medicines, but concessions must support companies' ability to keep providing these essential medicines.

> …to stop people stockpiling, more and more manufacturers are asking us to restrict the supply to hospitals.

> We are the logical people to do it. But, nobody wants to pay us to do it, and that's the problem (Participant 29—Wholesaler/Distributor-Western Pacific).

Conversely, some participants explained the expiry and waste of medicines were costly consequences to providing essential medicine stockpiles or emergency use only medicines. They expressed caution around the practice of stockpiling in population pandemic planning or local practices.

> Stockpiling is extremely dangerous. [Although in one situation], stockpiling has worked for anti-retrovirals in Africa. IDA [International Dispensary Association] or the SCMS, [Supply Chain Management Systems] has stockpiles in South Africa that are able to supply to SCMS projects. It's a single payer. The US Government is paying for all those medicines, whichever country it goes to, so they are able to shift funds around in that way (Participant 43—Academic/Government-Physician-Africa/Panamerica).

On the other hand, some were frustrated with the lack of transparency and communication. Most participants demonstrated they had limited knowledge of how others managed medicine shortages. Meanwhile, all stakeholders agreed information sharing was limited and inconsistent, sometimes due to the lack of trust or communication between stakeholders.

> Manufacturers associations were removed from the committee because of conflict of interest. I don't see any conflict of interest with the public sector procurement agency because they have a responsibility for providing for the public sector. We shared changes in the treatment guidelines in advance with the distributors and told them what the new treatment guidelines were and to be aware that there will be a change in the market (Participant 43—Academic/Government-Physician-Africa/Pan America).

Alternatively, many participants claimed that prescribing practices did not provide a consistent pattern for procurement due to accommodation of many preferences and therapeutic options, and required prioritisation strategies to manage shortages.

> The [cancer] specialists, wanted to treat everything, but were dealing with repeated stock-outs and shortages. They would initiate a patient on [treatment], but would run out and then the child would relapse and be resistant. [So], they identified which were the priority conditions, [since] the budget [meant they] cannot have everything, and some medicines are more essential than others. [Finally] they came on board because we convinced them it was the stock-outs and [drug] shortages that were killing them (Participant 43—Academic/Government-Physician-Africa/Pan America).

Theme 4: Both international and local disruptions contributed to vulnerabilities in the supply chain

Many participants viewed that medicine shortages were caused by manufacturing and distribution issues. They felt helpless during medicine shortages, especially when they were caused outside their country (e.g. natural disasters, worker protests, manufacturing plant fires/equipment damage, transportation disruptions, product quality/damage, border delays). Furthermore, participants felt they had the capacity to address direct risks associated with their immediate work environments, rather than the continuum of the supply chain. Additionally, some stakeholders described that sudden regulatory decisions and changes in safety requirements (e.g. updates to regulatory safety standards, manufacturing, formulary) contributed to shortages.

> We make no [active pharmaceutical ingredient] API in Australia. We make our finished products overseas. [But] they have different quality standards. Globally, we're raising our quality requirements. [But], as soon as you get any variation from regulatory authorities and if it doesn't get through quality, there's a batch that you write off …There's a massive amount of wastage driven by quality (Participant 18—Pharmaceutical Industry-Pharmacist-Western Pacific).

Furthermore, many stakeholders discussed inequality of access was influenced by variable governance and enforcement of ethical practices, which often lacked transparency (e.g. substandard/counterfeit products, delayed payments). Most notably, in LMICs, concerns about financial inducements were hindrances to collaborative alliances.

> We have the national tender system, [but] provinces have the freedom to decide not to procure a particular item on national tender and get it instead on provisional tender. We've seen many examples of the price of medicines doubling because they acquire it at the provisional tender. The difference goes into people's pockets. So you have a lot of corruption in the procurement system. No amount of consultancy or technical assistance is going to improve things if that continues (Participant 8—Nonprofit-Pharmacist-Africa).

Discussion

Advances in medicine and the influence of powerful consumer advocacy have provided society with a wide range of therapeutic products and treatment options. Interestingly, this study revealed that the accommodation of greater consumer choice in medicines selection also required more complex management and coordination throughout the health system. Thus, this study expands our knowledge of

some of the shared decision-making needed to support this wide range of consumer choice, in order to facilitate and protect access to a sustainable supply chain. Furthermore, findings revealed that pricing and costs of medicines were a major source of dissonance between stakeholders and their management strategies. Interestingly, due to poor transparency, some collaborative alliances were hindered to avoid financial inducements from pharmaceutical companies to prescribers. Despite these challenges, findings also showed there were advantages to this complex system, underlining the importance of resilience in the supply chain.

Results in theme one, highlighted that consumer demand for a wide range of therapeutic products has become increasingly difficult to manage, as it requires greater resources, administration and evaluation. This confirms previous findings that the supply of medicines are likely driven by consumer demand and willingness to pay for a medicine they deemed "essential" in which essential medicines list cannot always accommodate [23–36]. However, this raised concern about what sources of information are available to the public and how direct-to-consumer advertising influences consumers. In some instances, consumers have been successful in lobbying governments to add highly expensive medicines to reimbursement lists for rare conditions [37–41]. In contrast, Wagner et al. [42] and Knaul et al. [43] suggested that even if lobbying was unsuccessful, many consumers will still access non-reimbursed medicines through out-of-pocket payment if they were deemed "essential" to the individual. Some stakeholders argued that restricting choice was perceived as taking away an individual's "voice" or autonomy to choose and influence decisions. Discourse between these values can subject the health system to judicial interventions that can reallocate funding to individuals that were not accounted for in planning or follow usual decision making processes [44]. Therefore, multilateral agreements between suppliers and consumers need to rationalise individuals' choices and the capacity to pay for those therapeutic options, which is challenging in itself to reach consensus.

Similarly, Barry and Edgman-Levitan's [45] and Patel and Pichardo's [46] positions on the importance of shared decision-making in patient-centred care, support that consumer empowerment through education can help individuals make more appropriate decisions regarding their care. Thus, consumers should be accountable, informed, and share responsibility for having a wide selection of medicines provided in the supply chain. Particularly, if they do not serve public health needs. Meanwhile, Stolk et al. [47] argued that health systems must support equitable access to essential medicines, including those for neglected diseases or require specialised care. Therefore, subsidisation schemes need to carefully consider ethical responsibilities for providing alternative funding that ensures public health needs are met and that individuals' needs are also supported [48, 49].

In contrast, there is a view that consumer choice has become difficult to provide and sustain. According to Greene [36] and Duong et al [23], management of essential medicines has become more complex due to consumers' expectations and what is considered essential. Building on Wood and Gray's [50] comprehensive theory of collaboration, a wide range of therapeutic choices has created inconsistency and complexity throughout the supply chain. They agreed that increased complexity due to individualism and autonomy decreased an organisation's control over a domain [50]. Moreover, Bresser [51] viewed that some features of collaborative alliances were also likely to make systems more complex. Hence, providing many therapeutic choices in the supply chain and involving many stakeholders, has decreased a health system's ability to control formularies, keep up the supply of a wide range of products, minimise wastage, and store adequate supplies in dispensaries and warehouses of all products. Consequently, reimbursement of medicines has become more complex and challenging to manage, with the rise of consumer advocacy in the decision-making process. This emphasises the importance of consumer awareness of the complexities around prioritising medicines, as well as regulation and restrictions on medicines advertising to consumers and prescribers [52, 53].

Results described in themes one and three demonstrate that amongst the gaps and vulnerabilities explored in this study, pricing and costs of medicines were identified as a critical source of divergence between stakeholders. Participants had highly skewed views around what was considered reasonable cost savings for public tenders and individual patients, versus what was considered adequate profit margins and sustainable financial structures. Furthermore, as suggested by Wilson et al. [54], even though a medicine was approved for reimbursement, frequent changes of supplier contracts created fragmented management by stakeholders. This was further complicated by any spike in costs incurred due to unforeseen disruptions leading to shortages. According to Jahre et al. [13] and McBeath [55], business models with complex supply chains, highly regulated, that rely heavily on outsourced suppliers and/or apply lean business practices have been used to accommodate lower generic prices and consumer cost savings. This has created vulnerabilities in the supply chain due to increased reactivity, especially to unpredictable obstacles [2, 13, 55] Although Huff-Rouselle [56] and Tordoff et al. [57] suggested that governments were empowered by the ability to negotiate lower prices for medicines on behalf of the public; neither governments nor consumers received a "better deal" when medicines supply was not guaranteed [5, 10, 58]. Instead, reactivity in the health system has driven up costs, and resulted in higher incurred costs of medicines, use of human and financial resources, and susceptibility to coercion and corruption, such as failed or late payments [5, 10, 59, 60].

Similarly, these relationships were strained when pharmaceutical companies set exorbitantly high prices for medicines

[61]. Furthermore, the results in theme four revealed that a few participants described how prescribers were susceptible to financial inducements by pharmaceutical companies to prescribe their products. In line with Cohen et al. [62], some stakeholders (mostly those working in LMICs) reported concerns regarding unethical conduct and corruption in governance and financial interactions as major barriers that contribute to the local and international supply chain vulnerabilities. On the other hand, HICs also grappled with lack of transparency around pharmaceutical industry involvement and influences in decision-making. Fair pricing of medicines often remained problematic, despite pharmaceutical industry representatives being excluded from therapeutic committees to prevent companies from gaining financial advantage [63]. This confirmed that the complex interactions required to support consumer choices required greater transparency around formulary and government reimbursement decision-making.

Results from this study draw attention to the importance of improving resilience (the ability to adapt to circumstances) in the supply chain to manage the challenging differences between individual choices and health system priorities. On one hand, buffers in the system, such as pricing, therapeutic substitutions and backup suppliers across multiple stakeholders, have been implemented to improve resilience to unexpected supply disruptions or events [57, 64]. On the other hand, inconsistencies and complex interactions between stakeholders have made the logistics and timely access to medicines sometimes difficult to achieve [51, 65]. Thus, communication between systems may be more likely to fail. In such cases, participants described that improved supply chain resilience, would entail concessions made by all stakeholders and willingness to pay for contingency planning, such as shared risk coordination to absorb additional shortage costs or excess. Therefore, system buffers or resilience planning must account for the cost and provision of medicine shortages, extra shelf space in pharmacies and warehouses, and national redistribution strategies to reduce waste and expiry to rotate or move around supply. Meanwhile, still meeting consumer needs. Strategies to mitigate or prevent "all eggs in one basket" situations must be supported by all stakeholders and considered sustainable, which may be in contrast to current trends towards lean processes to improve efficiency [66]. Engagement of stakeholders through inclusion of wholesalers in therapeutic committees and expanding the role of pharmacists to include specialised formulary managers are amongst some strategies to open up channels of communication between stakeholders [25].

Strengths and limitations

These findings add to our global understanding of the challenges surrounding management and supply of essential medicines. This study described a broad, and often conflicting, range of views of stakeholders from multiple levels of the health system. This qualitative approach features perceived challenges experienced by stakeholders, and was not intended to be generalisable. Not all countries, range of healthcare systems, and individual circumstances were represented in this study. Nonetheless, it was still able to compare views of stakeholders from HICs and LMICs through the vast and overlapping experiences of the participants recruited. Although resources and technical processes varied between sites, organisations, countries and income levels; the general framework and management approaches were similar and vulnerable to global volatility.

Conclusion

This study has enhanced our understanding of how patient care decisions and logistics management influence access to essential medicines. Findings confirmed that business strategies that apply overregulation, increased process complexity, use lean business practices and/or rely heavily on outsourced suppliers make them vulnerable to global crisis and shortages. To support resiliency strategies and fund strategic system buffers, consumer education and multi-stakeholder agreements, must rationalise the broad range of individuals' choices and the capacity to pay for therapeutic options. Findings also highlighted that to mitigate medicine shortages, the value placed on choice needs to be clear to all stakeholders, in order to accommodate shelf space, ordering, and budget decisions around essential medicines. In particular, investment in resilience planning, to support the ability to adapt to unpredictable circumstances, is needed to account for expanded consumer demand and provide supporting financial structures to ensure fair and equitable access. However, cooperation between all stakeholders is critical to carve communication pathways that encourage sustainable patient-centred care, including alignment of decision making priorities with procurement practices. In summary, challenges to the supply and use of EMLs offer an opportunity to align the values of health system priorities with individual choice, and include these considerations and system buffers in supply chain models and regulatory decisions. Further work around resilience planning will help inform the level of investment required to offset losses incurred from continued medicine shortages and account for potential excess stock costs, as part of contingency planning.

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Conflicts of interest None.

Appendix 1

THE UNIVERSITY OF SYDNEY

Interview Guide

Title: The Management and Supply of Essential Medicines

Country: _____
Occupational Setting: _____
Profession: _____
Number of Years Practiced: _____
Gender: M / F
Age: _____
PBI Code: _____
Date: _____
Time Started:_____ **Time Completed:** _____
Location: _____
Interaction Type: **Face-to-Face** **Teleconference** **Skype**

The Role and Application of the Essential Medicines List:

1. Are you familiar with the Essential Medicines List in your country?
2. What does the concept of having an Essential Medicines List mean to you?
3. What makes a drug essential?
4. How is the concept of the Essential Medicines List applied in your practice setting?
5. Please describe examples of effective use of the Essential Medicines List in your practice setting.
6. Please discuss some barriers to the effective use of the Essential Medicines List in your practice setting.

The Appropriate use of the Essential Medicines List:

7. What factors influence how essential and non-essential medicines are used in your practice setting?
8. How does the essential medicines list affect your practice?

The Availability of the Essential Medicines List:

9. Have you encountered any difficulties obtaining any medicines from the Essential Medicines List? Please describe your experience.
10. Please describe the availability of medicines from the Essential Medicines List in your practice setting.

The Affordability of the Essential Medicines List:

11. How does the Essential Medicines list effect costs for individuals, health care professionals, health facilities/institutions, governments, and pharmaceutical manufacturers?

The Quality of Medicines from the Essential Medicines List:

12. Please describe the quality of essential medicines available in your country.

Other:

13. How does the essential medicine list effect patients and their health care experience?
14. In your opinion, what are the key issues surrounding the Essential Medicines List?

Additional Comments:

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