



## Improving Access for Drugs: The A4D Framework

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Many countries are increasingly facing drug shortages even during normal times. These shortages prompt fundamental questions why shortages happen, how they are linked, and what interventions can be effective. This paper contrasts medical criticality of the drug with its supply chain risk. We propose a simple visual framework to improve access for drugs by helping stakeholders to systematically deal with three key issues: gathering evidence, increasing alignment, and developing a system view. The framework introduces a 4-step improvement cycle (Analyze, Assess, Act, Align), inspired by the Plan-Do-Check-Act method commonly used in quality control. This paper describes the framework in detail, argues why it is necessary and how it can be used in different circumstances and for different purposes.

Key words: Drug Shortages; Supply Chain Risk; Medical Criticality; Stakeholder Alignment; System View

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# Improving Access for Drugs: The A4D Framework

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## 1 Introduction

Drug shortages, periods when demand for a drug exceeds supply, are increasingly a problem in Europe and other parts of the world (de Vries, Jahre, Selviaridis, van Oorschot, & Van Wassenhove, 2021; Ergun, Hopp, & Keskinocak, 2022). Consequences include considerable time and effort confronting shortages, delays in treatment, suboptimal treatment, and cancellation of care (FDA, 2019; EAHP, 2019). While Covid-19 put the spotlight on drug shortages, it is important to realize that these problems exist even in the absence of abnormal demand and supply shocks. The reality is that many countries have faced structural challenges for many years and have limited insight in how to resolve them. In the Netherlands, for example, the estimated annual total cost of drug shortages is between 45 and 105 million euros (MvVWS, 2019), while France has recently faced stockouts of essential drugs in all pharmacies, not for a few days but sometimes for months (Radio France Internationale, 2022).

Many countries are struggling with fundamental questions concerning drug shortages such as: What are the causes for shortages? What is their relative importance? How are they interconnected? Which interventions (measures to decrease the likelihood of shortages) are likely to be most effective, and at what cost? (van Oorschot, Van Wassenhove, Jahre, Selviaridis, & de Vries, 2022) To help answer these fundamental questions, we propose the **Access for Drugs (A4D) framework**, a simple visual framework consisting of four steps (the 4 'A's) inspired by the Plan Do Check Act (PDCA) cycle commonly used in process quality control. The A4D framework is designed to improve access for drug supply chains by systematically addressing the key issues outlined below. These issues have been highlighted in a recent extensive analysis of academic literature and published stakeholder reports on generic drugs, accounting for the majority of shortages in Europe (de Vries, Jahre, Selviaridis, van Oorschot, & Van Wassenhove, 2021).

First, there are many suggested interventions but there is a **lack of evidence of what works**. Most shortages are managed reactively instead of proactively, focusing "more on decreasing the effects of shortages or dealing with their consequences than on the underlying causes" (MvVWS, 2019). Many open questions on the best actions for different drugs, accounting for factors such as supply chain complexity, information availability, and drug criticality remain (Ergun, Hopp, & Keskinocak, 2022).

Second, there is a **lack of alignment** among stakeholders about causes of drug shortages. Reported causes differ substantially *between* and *within* countries. For example, (de Vries, Jahre, Selviaridis, van Oorschot, & Van Wassenhove, 2021) found that Belgian and UK stakeholders made no reference to the impact of prices and margins on inventories, while only the Netherlands and France reported effects of quality issues. In the UK, they found that while the National Pharmacy Association highlighted quota systems imposed by manufacturers as an important cause, the manufacturers pointed to parallel exports.

Finally, there is a **lack of a system view**. Stakeholders primarily suggest interventions that may work well for one drug in one country, without discussing the potential side effects of these interventions on other drugs and/or actors in different countries (van Oorschot, Van Wassenhove, Jahre, Selviaridis, & de Vries, 2022). Developing a system view includes understanding (differences in) stakeholder incentives and behavior in drug supply chains, which so far have been largely ignored (Ergun, Hopp, & Keskinocak, 2022).

Below we present the A4D framework in detail and show how it can improve access for drugs by helping stakeholders to systematically deal with the three key issues of gathering evidence, increasing alignment, and developing a system view.

## 2 The A4D Framework

The basic idea of the A4D framework is simple. Stakeholders should make decisions according to the **A4 principles** visualized in Figure 1 and detailed further in this section (**Analyze, Assess, Act, Align**):

- **Analyze:** let people with the right skills and training carefully evaluate the two critical dimensions of drug criticality and supply chain risk.
- **Assess:** make an informed decision to place the drug in the framework matrix (Figure 2), using the expert analyses and considering the interactions between the two dimensions.
- **Act:** determine the different options for interventions, considering context, regulations, and costs.
- **Align:** gather all relevant stakeholders who need to decide on the intervention and seek alignment in terms of execution (including required resources, timeline, responsibilities, and KPIs).

The A4D can be seen as a circular framework for continuous review to ensure interventions stay effective and aligned, even when the environment changes. Figure 1 provides a summary of the A4D framework; each step is discussed in more detail below.



Fig 1: schematic visualization A4D framework

### 2.1 Analyze

The first step is analyzing the drug. The A4D tool focuses on two dimensions: **medical criticality** and **supply chain risk**. Below, we discuss the core components of the dimensions in more detail.

**Supply chain risk** captures the likelihood of mismatches between supply and demand. Mismatches can occur because something happens with demand, supply, or with the coordination between demand and supply (Ergun, Hopp, & Keskinocak, 2022). To analyze supply chain risk, one therefore needs to consider *at least* the following factors:

- **Demand:** What is the likelihood and size of demand shocks, and how predictable are they?
- **Supply:** How connected/complex is the upstream supply chain, how easily can capacity be scaled up or down, and are there alternative suppliers?
- **Coordination:** Is information (preventively) shared across supply chain actors and is there a (risk of) lack of coordination (e.g., due to geopolitical tensions)?

**Medical criticality** determines the clinical value of a drug. For example, life-saving drugs should always be considered high criticality (insulin, blood thinning medications, antibiotics for the treatment of sepsis, etc.) while drugs that improve lifestyle are automatically low criticality (erectile dysfunction drug, etc.). Two other key dimensions are the amount of people depending on the drug and the possibility to subscribe alternative drugs. For example, drugs on which many people rely or that patients need to maintain good health and for which there are few alternatives are likely considered highly critical. To analyze medical criticality, one therefore needs to consider *at least* the following factors:

- **Clinical risk:** What is the impact (e.g., QALYs lost) of not having the drug?
- **Volume:** How many people are depending on the drug?
- **Substitution:** Do substitutes exist? How good are these substitutes?

More factors can be included based on contextual elements if deemed appropriate. However, it is important to remember that the main purpose of the analysis is to quantify drugs (and hence make them comparable) in terms of criticality for treatment and supply chain risk, not to develop a 'perfect' assessment mechanism. One should also keep in mind that the framework is dynamic and to be reviewed regularly. Therefore, it may be best to take a cautious approach in the initial analysis of risk and criticality, especially if different factors indicate higher or lower supply chain risks and/or medical criticality. We note in passing that supply chain experts determining risk are typically not the same people as medical experts deciding on criticality of the drug. This is precisely why we posit that our framework is necessary and useful. We will return to this later.

## 2.2 Assess

The next step is using criticality and risk assessment to categorize the drug. For this, we suggest the simple visual A4D classification matrix, as shown in Figure 2. The classification should be an informed decision after collecting the right information from supply chain risk and medical criticality experts. It should ideally be done by multidisciplinary teams capable of comparing and evaluating the information in light of potential interactions between the two dimensions.

The classification matrix splits each dimension into two, giving four categories in total. The split is such that the resulting categories require fundamentally different perspectives. Note that one can refine the dimension splits to obtain the desired level of granularity (high/medium/low, even a continuous scale) if necessary, but this is not our purpose. Rather, the matrix provides a simple way to position drugs relative to each other and realize different drugs require different types of interventions. This is in stark contrast to practice, where blanket policies (treating every drug the same) are still by and large the norm.

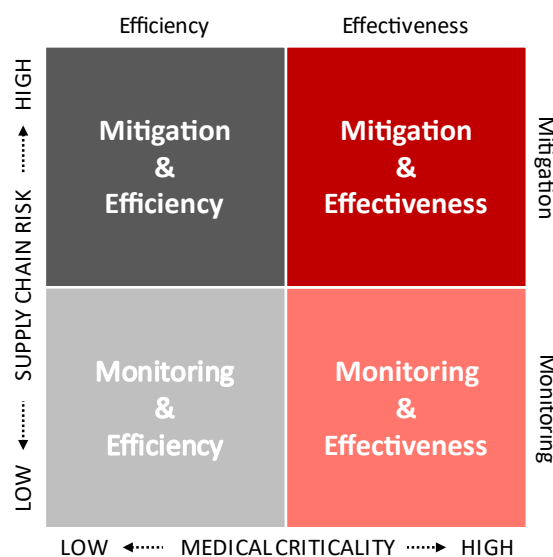


Fig 2: the A4D classification matrix

The dimension splits are obtained by taking an operational perspective. When optimally matching supply and demand considering uncertainty, there are two essential elements that need to be considered. Firstly, the relative cost of not being able to satisfy demand. In the case of drugs, this is captured by the medical criticality of the drug. That is, the higher the criticality, the higher the cost of not being able to satisfy demand for that drug. This leads to the first dimension split:

- **Efficiency (Low medical criticality):** Low medical criticality is associated with Efficiency, i.e., cost is a decisive element. Efficiency means that, while shortages should be avoided, this should not be at all costs. Occasional shortages are acceptable if this saves a substantial amount of money. Acceptance of some uncertainty and lack of control of supplies are part of good system design.
- **Effectiveness (High medical criticality):** High medical criticality is associated with Effectiveness. In contrast to Efficiency, Effectiveness means one should strive for full control, i.e., for a 'control tower' that continuously scans the whole supply chain and can act with anticipation and speed. Avoidance and/or prompt reaction to shortages clearly dominates cost-efficiency here.

The second essential element is the likelihood of mismatches between supply and demand, captured by supply chain risk. Low uncertainty means supply is quite predictable and hence shortages are unlikely. However, high uncertainty means shortages can be frequent and lengthy, justifying more substantial investments for mitigation. This thinking leads to the second dimension split:

- **Monitoring (Low supply chain risk):** the Monitoring approach is best suited for scenarios with low expected mismatch between demand and supply. This approach prioritizes preparedness for unlikely shortages. It focuses on monitoring the supply chain and having responsive mechanisms in place to address shortages when they occur, rather than extensive investment in risk mitigation.
- **Mitigation (High supply chain risk):** In scenarios characterized by higher expected mismatch between demand and supply, the Mitigation approach is focused on strategic decisions to reduce the risk of shortages occurring. This could mean stockpiling or reshoring manufacturing, particularly in situations of high criticality. Important to note is that this *also* requires monitoring the supply chains and having reactive systems to be in place in case a shortage occurs despite mitigation measures.

The A4D classification matrix introduces a pragmatic framework for classifying drugs and guiding decision-making. The two-dimensional split naturally leads to four categories for which clearly different interventions should be considered. Next, we will discuss the process of determining these interventions in more detail.

### 2.3 Act

The third step of the A4D framework is about determining the potential interventions for a given drug. Many if not all the frequently discussed interventions for drug shortages in the past years, such as keeping more inventory, reshoring, or government production of critical drugs, face limitations. Excess inventory risks inefficiency, reshoring may not adequately solve the problem, and government production could discourage innovation (Ergun, Hopp, & Keskinocak, 2022). It is important to realize that no solution is a universal miracle cure, that is, different drugs require different interventions.

To determine the right set of interventions for a given drug, one needs to combine the placement in the A4D classification matrix with contextual factors, and regulatory and cost considerations. Similar to the Assess step, this is ideally done by multidisciplinary teams capable of comparing potential interventions in specific contexts. We discuss below suitable types of interventions for the four categories in the classification matrix, which serve as the starting point for this process. Note that our goal is to remain high-level and focus on the principal differences between categories rather than the operational details of the interventions.

- **Monitoring & Efficiency:** For drugs in this category, one can establish monitoring systems to maintain a lean supply chain while remaining responsive to the unlikely occurrence of a shortage. With this approach, one can develop contingency plans for unexpected shortages while keeping a cost-efficiency focus.

- **Mitigation & Efficiency:** For drugs requiring cost-efficiency and mitigation, one can leverage data-driven forecasting to optimize inventory levels to balance shortage prevention and cost. One can also diversify the supplier base to minimize risks associated with dependencies on a single supplier.
- **Monitoring & Effectiveness:** When effectiveness is coupled with a monitoring approach, one should employ rapid response protocols, emphasizing surveillance systems to swiftly address unexpected, but critical drug shortages. One should also invest in collaboration networks to share information and resources, ensuring collective effectiveness in handling surprises.
- **Mitigation & Effectiveness:** For drugs requiring effectiveness and mitigation, one should consider preemptive stockpiling, and continuous investments in the supply chain, including potentially relocating upstream manufacturing to nearby locations, to enhance resilience and address potential shortages proactively.

## 2.4 Align

After assessing the drug and determining appropriate interventions, stakeholders can still disagree in which box a drug fits and/or what the best intervention would be, e.g. whether stockpiling is a good idea, or better interventions are available. This might also depend on the context (e.g., the United Kingdom versus the Netherlands). Clearly, in drug supply chains it is natural to expect misalignments, e.g., between manufacturers and doctors. However, a system cannot function properly if stakeholders are misaligned, with higher costs (e.g. because of emergency measures), more shortages, and less resilience as consequences.

The final step of the A4D framework is about improving alignment by making implicit assumptions visible and showing differences in opinion. It aims to improve mutual understanding and strive for better alignment over a variety of groups, stakeholders, and/or disciplines by jointly analyzing questions such as:

- How large is the misalignment in terms of classifying drugs in different boxes? What types of drugs are typically placed in different boxes? Which boxes are mostly concerned? What is the potential consequence (cost/shortage) of this misalignment?
- Do different stakeholders (e.g. hospitals, distributors) have consistent placement differences? What could be the set of underlying reasons?
- Do placements in different countries differ and why? What contextual factors drive these differences (e.g. size of the country, GDP, local manufacturing)?
- Would collaboration (e.g. between sets of well-chosen countries or at EU level) change placement of a drug?
- If all stakeholders place a drug in the same box but vote for different interventions, what drives this behavior (incentives, trust, risk, cost, decision power, etc.)?

Note that misalignment is an important risk by itself as it can lead to mismatches, lack of clarity, finger-pointing, etc. This is why the A4D framework is circular, as new insights on (mis)alignment inform the Analyze step and subsequent steps. The process is iterative for continual improvement or to react to dynamically changing environments.

## 3 Applications of the Framework

Our A4D framework has multiple potential uses. We discuss the most promising ones below and link them to the three key issues in increasing access for drugs: gather evidence of what works, increase alignment, and develop a system view.

### 3.1 Gather evidence of what works

The first step is clearly to increase understanding. The framework invites stakeholders to consider how the two essential dimensions of medical criticality and supply chain risk dynamically interact. Placing a drug in a particular box of our framework requires one to explicitly consider both dimensions, which may reveal that one has

insufficient or incorrect understanding of one of them. Proper understanding would increase the probability that a drug is placed in the right box of the framework. This subsequently allows one to consider suitable interventions, like stockpiling, and to experiment, i.e. to measure the impact of these interventions in practice. Increasing understanding showcases the great potential of the simple visual framework for training purposes. Experts can help practitioners to correctly evaluate both dimensions and hence place the drug properly in the framework. They can then explain the different interventions, their feasibility, and pros and cons in particular environments. Good training can lead to systemic correct placement of drugs in the framework per drug category and/or geographical area.

It should be evident that understanding and training are also the basics of pedagogy in formal teaching programmes, i.e. the framework can be introduced in curricula. Supply chain students can learn to appreciate the link of their designs and processes to availability of drugs and understand the link to criticality. I.e. when should the supply chain go for minimum cost and when for maximal speed and flexibility? Similarly, pharmacy students probably have little or no understanding of supply chain designs and processes, and their associated risks. Understanding better how the supply chain, and particularly the risk in the supply chain, affects drug availability would most certainly be an asset. We therefore strongly plead for introduction of adequate courses in the respective programs. It is perfectly possible and potentially very useful to develop interactive simulation tools to allow groups of students to experiment with the framework. The understanding, training, and teaching efforts discussed above are steps which we deem necessary to move to considered actions and measurement of their impact, i.e. to get a better grip on what works and what does not. Clearly, there is a need for careful design of pilot experiments using the correct measurements to gather more experience of what works in what circumstances. This element is beyond the scope of this paper.

### **3.2 Increase alignment**

The simple visual A4D framework can be a powerful tool for alignment efforts. It is obvious that drug supply chains involve many stakeholders with potentially very different objectives which may be quite misaligned at times. It should also be clear that alignment, or lack of it, depends on the drug as well as the stakeholders (e.g. producers, distributors, doctors). Bringing different stakeholders together to engage in open discussions based on their placement of a drug in the framework can be an eye-opening experience. Understanding different perspectives and hearing the underlying arguments is not a guarantee for better alignment but it is certainly the first step in the process. Understanding different perspectives and expectations can be followed by better negotiations and indeed improved alignment, particularly in agreed-upon processes and actions. Needless to say - the interactive simulations referred to above can be a great way to create a gaming environment suitable for fruitful alignment discussions.

The A4D framework can also help uncover potential misalignments between different countries. First, they may have different analyses of criticality and supply chain risk for the same drug. This is not unexpected as demand and supply networks can be different across countries. Yet, investigating and discussing the reasons behind misalignments can lead to a better evaluation and, potentially, identifying alternative solutions. For example, one country might assign a lower supply chain risk for a drug due to a more reliable supplier network that another country is unaware of. Second, countries may find different interventions to be the most effective for drugs that they evaluate similarly. Discussions about these misalignments and their drivers can provide opportunities for learning and collaboration.

### **3.3 Develop a system view**

The complexity and sometimes opaqueness of drug supply chains, combined with the multiple stakeholders with different interests, clearly demands a system approach. Unfortunately, system approaches are not very prevalent, mostly because stakeholders find them complicated and difficult to operationalize. We agree with this assessment but would like to point out that the above steps of understanding, training, and teaching, building alignment, hopefully supported by pilots showing what works or not, are necessary prerequisites for building a successful system approach improving access for drugs. This framework attempts to provide a simple tool with concrete steps to help stakeholders move towards a system view without feeling overwhelmed by its complexities. One can imagine a control tower type of organization that would develop and use a system approach, e.g. a governmental or cross-industrial network initiative. We do not underestimate the difficulties of

establishing such control towers given their funding and particularly governance challenges, but Covid-19 was a wake-up call in that sense. A good control tower would have helped immensely.

Control towers can also be useful for routine operations by improving understanding in the complexities underlying the current frequent shortages. Clearly, a control tower taking a system approach may seem out of reach in many countries or regions. This does not mean that even small steps in trying to encourage different stakeholders to look beyond their own part of the system and their private interests could not be very impactful. Oftentimes, stakeholders are positively inclined, but they may fail to fully understand the impact of their actions on others and vice versa. In this we see again an important role for the A4D framework, as its systematic usage would make such impacts on others tangible and hence the overall system gradually less opaque, ultimately leading to increased appreciation of the system approach.

## 4 Conclusion

This paper suggests a simple visual framework for access for drugs (A4D), argues why it is necessary and how it can be used. Drug shortages are a big problem, even in normal circumstances where one would not immediately expect them. Rich countries like France are systemically suffering from long and persistent drug shortages, even for routine products. This justifies the simple framework we propose. The framework can be used in different circumstances and for different purposes as illustrated in the paper. We strongly believe that every effort to gather more evidence instead of relying on rumors or poorly substantiated opinions, to better align the many stakeholders (to understand, train, teach), and to move to a system view will pay off nicely. We realize that the framework is a simple tool and perhaps the first step in a continuous improvement loop. Tools need to be tested, be made user-friendly, and be carefully positioned in different contexts. They can be used or misused. They can be developed into more elaborate instruments, but all this goes beyond the ambition of this paper.

Importantly, the A4D framework, like any other framework for decision-making in complex supply chains, requires a well-functioning governance system that monitors the situation and decides when the situation is such that a new improvement cycle is necessary. Optimal design of such systems, enabling effective oversight, good governance, and appropriate decision power, is essential yet depends on many local, regional, and political aspects going beyond supply chain risk and medical criticality considerations, and is therefore also out of scope for this paper.

As always, the proof of the pudding is in the eating. We sincerely hope our framework will be tested and improved, and that it will be integrated into teaching and decision-making.

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## **BOX - Calibration and Testing**

The A4D framework can certainly benefit from calibrating and testing, especially when one compares different countries. For that purpose, we suggest the following steps:

1. Formalize scoring model for the risk-criticality matrix. One can discuss for ages how to evaluate risk or criticality. A multitude of scoring models is available in literature. We reiterate that our framework is meant to be actionable, i.e. we favor discussion over precision.
2. Ideally calibrate and test the framework with a few countries. Determine roughly a dozen drugs that are expected to cover all boxes and that are the same (or very similar) in the countries.
3. Have two or more experts per country independently place the drugs in the risk-criticality matrix to see how much the placement depends on the person or context, and potentially derive learnings from different placements.
4. Compare the placement across countries. Determine whether drugs are consistently placed in the same boxes and analyze differences. Determine whether these differences are based on 'true' differences in supply chain risk and criticality or not. If supply chain risk differs, determine whether influence/power plays a role.
5. Ask experts for each drug what the current policy is and compare differences across countries.
6. This may unearth where there are opportunities for fruitful collaboration (e.g. between a few countries or in the EU).