











Dr. Torsten Hoppe-Tichy

Medicines Shortages

The Role of the Hospital Pharmacist

Pragmatic coping
Strategies in Hospital
Pharmacies



Abstract

In practice, hospital pharmacists have learned to spontaneously deal with shortages. In most cases, exchange within regional networks is practiced. Another current option is to import. This however switches the problem to an international level to the disadvantage of low-price countries suffering particularly from parallel exports. This presentation lists a couple of fast-track optional activities to bridge intermediate gaps in the supply chain irrespective of the long-term international situation.

Learning objectives

At the end of this session, participants will be able

To know further options to bridge supply chain gaps

To recognize that such actions only translocate the problem but do not resolve the global shortages problem



No Conflict of Interest



Agenda

Presentation of coping strategies and their outcome for

finances

physicians

nurses

patients

therapy

other hospitals

other countries

pharmacists



Just to make it clear

→ Drug shortages have finacial impacts for hospitals!

Antibiotics, Australia

Expenditures changed from 12 - 300%

Price savings in two cases (approx. -50/-10%)

Additionally, other costs associated with increased antimicrobial stewardship resources required to effectively manage antibiotic shortages are harder to quantify but likely to be significant also.

The national piperacillin/tazobactam and gentamicin shortages in our hospital were accommodated by increased use of high-cost and potentially less desirable antibiotics (...)



Pragmatic coping strategies are strategic approaches to overcome drug shortages



Possible Coping Strategies

new therapy guidelines/long term switch to other drugs

hospital pharmacy drug production

import of drugs from other countries

supplier assessment strategies

fine for breach of contract



Guidelines

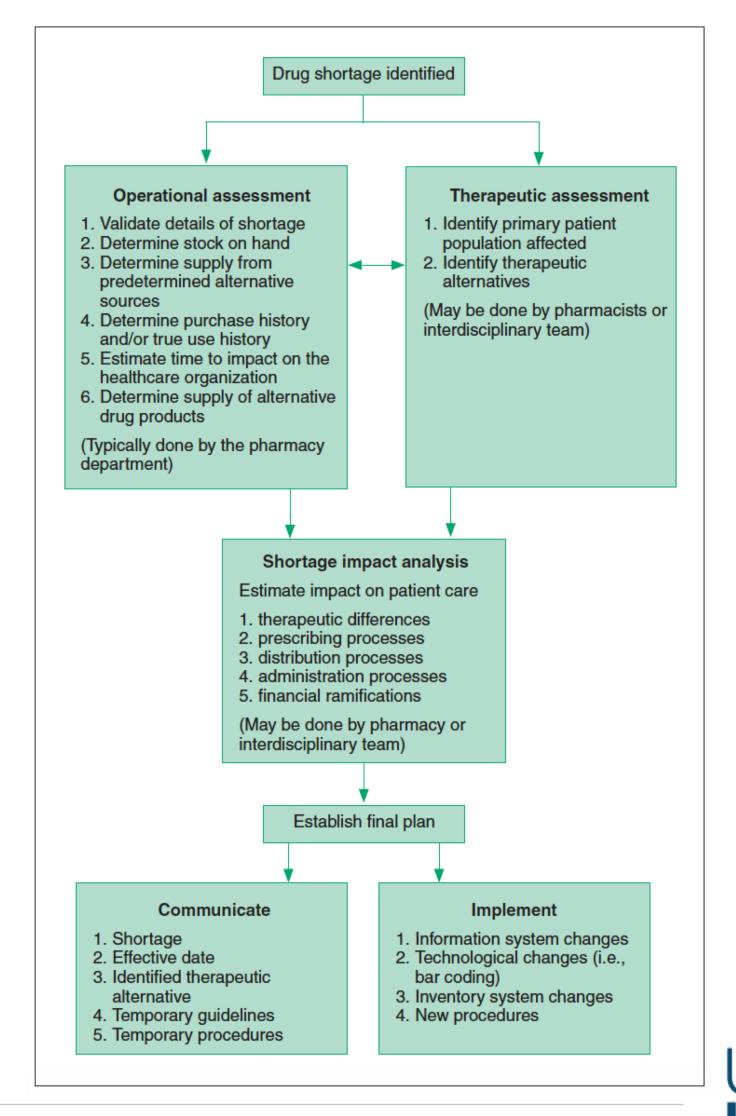
Guidelines have to be adopted to country specific rules/laws

- e.g. import possible?
- e.g. off-label-use allowed/reimbursed?

Interprofessional approach is mandatory

- → urgency?
- → evidence of use?

Figure 1. Process for decision-making in the management of drug product shortages.



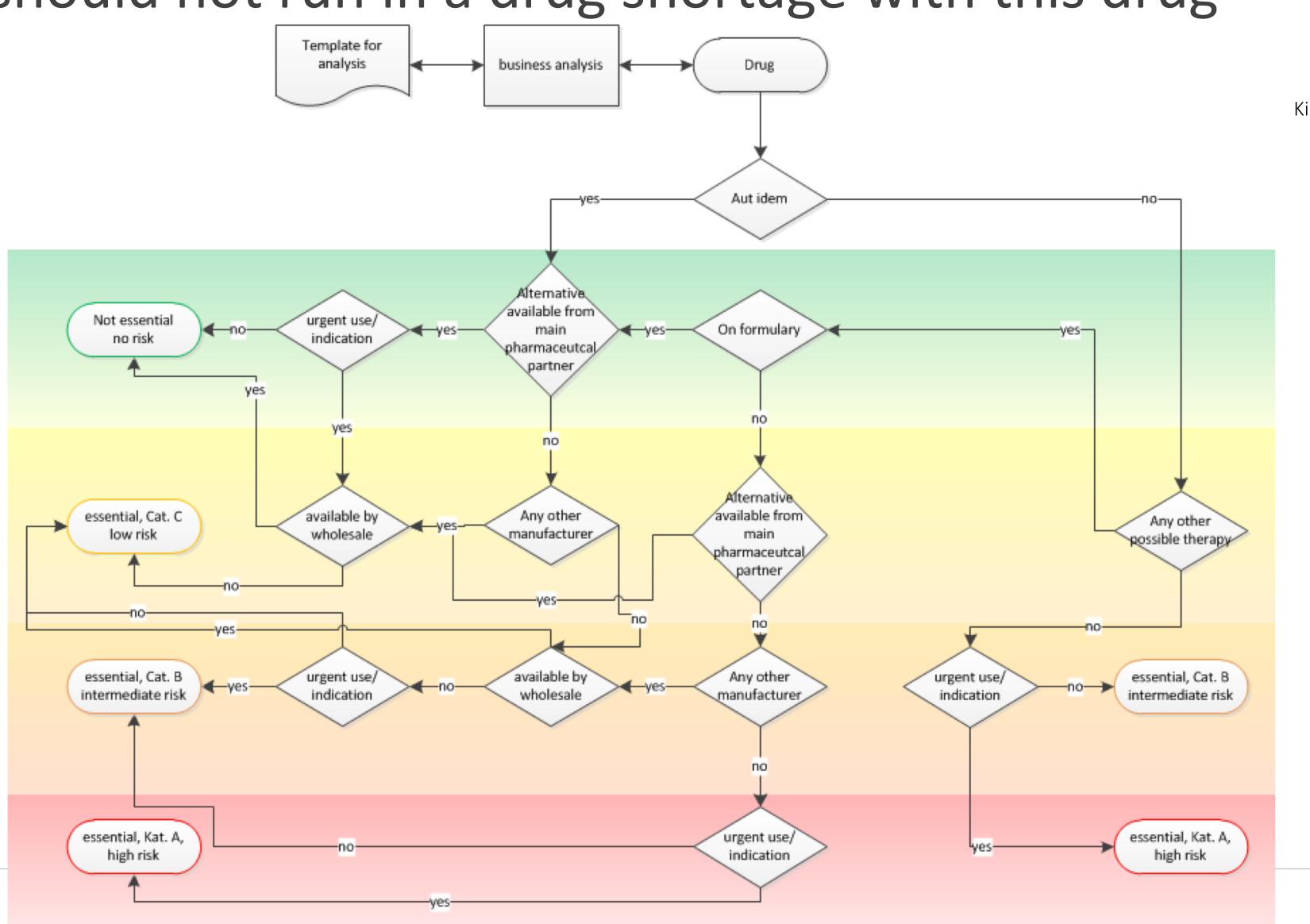
Be prepared!

increasing number of drugs on stock



Classifying Drugs

"We should not run in a drug shortage with this drug"



Kim Green, March 2018, EAHP Congress



Classifying Drugs: Process

"aut idem" → same drug from other company Not essential (",customer-supplier relationship" exists) in the market: no risk no impact on quantity stored (stock) "aut simile", different dosage, different application form in the market, available from wholesaler: essential, Cat. C low risk information for users, no impact on quantity stored (stock) manufacturer without "customer-supplier essential, Cat. B relationship", not available via wholesaler: intermediate risk increased quantity stored no other manufacturer ("monopoly situation"): essential, Kat. A, high risk

other points to mention

urgency

import

formulary

production

increased quantity stored



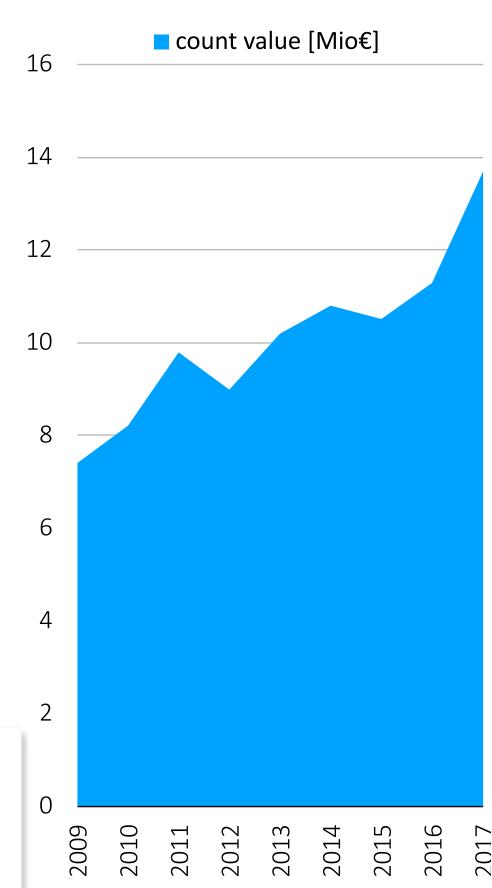
Classifying Drugs: What does this mean for the stock?

Increase in number stored for "critical drugs" will result in financial problems

Increase in dead capital (= count value of inventory) for the hospital pharmacy

Hospital will lose flexibility for capital investments

Is the financial problem just transferred from pharmaceutical industry to hospital pharmacy?





react!

→ try to import drugs from other countries



Import of drugs from other countries

Not possible in every country

Regulations around it

Risk of drug shortage for the next country

Price will be different → budget impact possible



Drug shortage UFH: Financial outcome

Import of UFH from

25.000 iE_{Import}: 14,38 €

25.000 iEratiopharm: 1,24 €

$$\rightarrow$$
 f=11,6



trying to be independent!

drug production by hospital pharmacy



Drug production to react on drug shortages

Barriers

regulation → general permission for hospital pharmacy, GMP etc.

financial investment/costs → rooms, machines, staff, etc.

time to start production → delay

make-or-buy decision



Drug production: What do others do?

US initiative

combat drug shortages

... ... will produce generic drugs that are in short supply

or

have experienced significant cost increases





September 7, 2018

Hospital Groups Launch Not-for-Profit Generic Drug Company to Help Combat Shortages, Price Increases

ASHP Applauds Market-Based Solution to Address Top-Priority Patient Care Issues

Seven health systems have joined together to establish <u>Civica Rx</u>, a new venture to help combat drug shortages and escalating drug prices. The not-for-profit company will produce generic drugs that are in short supply or have experienced significant cost increases. The consortium, led by Catholic Health Initiatives, HCA Healthcare, Intermountain Healthcare, Mayo Clinic, Providence St. Joseph Health, SSM Health, and Trinity Health, collectively represents about 500 hospitals nationwide.

Although ASHP does not endorse or promote any specific company or product, the organization is pleased to see the emergence of new and innovative market-based approaches aimed at addressing the profound problems associated with drug shortages and escalating drug prices that are affecting so many patients.



Outcome of coping strategies

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finances → transfer of "costs" from pharmaceutical industry to hospitals
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physicians, nurses → risk of errors increases

patients → different/"worse" outcomes already reported

therapy -> changes in therapy are often required

other hospitals → no help among each other, bigger hospitals/university hospitals are preferred

other countries → import can empty markets in other countries

pharmacists → workload



Conclusion (1)

In many cases *coping strategies* only shift the problem of drug shortages to other "organizations"

import -> emptying the market in other countries

quantity stored → emptying the market for other hospital pharmacies

switching drugs/other therapies → increased risk for medication errors

drug production -> increased workload for hospital pharmacies



Conclusion (2)

"treating the supplier"

penalties for breaching the (supply) contract are often only a blunt instrument

finding a new supplier is often not possible because of concentration of drug and raw material producers

customer-supplier relationships have changed in the age of drug shortages



"Essential drugs must be available at all time"

- What is an essential drug? → definition needed
- "Essential" → different definitions from different perspectives?
- Who should decide about "essential"?
- Any regulations needed?
- Is the WHO list a basis?¹
- Can an essential drug list overcome drug shortages?

