

EAHP Academy Seminars 2018



An ACPE application based activity

Medicines Shortages – Causation and Approaches to Improvements

The Educational Need Addressed

Topics of EAHP events are fixed both in a **top-down** manner by the Scientific Committee and directly arising from the fields the members daily are moving in, such as:

- Politics
- Practice
- Education
- Current research and development
- New professional opportunities
- New technology
- New medicines
- New methodologies
- New treatments
- Research and development

and in a **bottom-up** manner by

- Proposals from members
- Surveys (responses at the Congress' Cyber Café) / Questionnaires (every five years)
- National associations based on their national strategies
- Focus groups
- Joint commissions
- Mandated members of the Scientific Committee.

This year's **Academy Seminar topics** are

- **Leadership and management**
- **Innovation**
- **Creativity**
- **Interpretation and anticipation of restricted medicines availabilities**

• Workshops and Interactive Sessions

Generally, topics will be approved by the EAHP Board. Educational need and gaps between best and current practice and actual versus desired skills respectively can be easily screened by the Scientific Committee from

- EC resolutions
- EAHP surveys (by Survey Monkey® or Adobe Acrobat® form generator)
- FIP statements
- Current agenda of the Board
- The Scientific Committee Meetings
- The General Assembly
- Evaluation of submitted abstracts for poster or oral presentation
- Past congresses' evaluations
- Existing data such as surveys, questionnaires, et cetera

The current educational event on Medicines Shortages is one of two events organised by EAHP in the course of the 2018 Academy. The events have been selected by the Scientific Board according to the criteria depicted above. They have been approved by the EAHP Board.

Medicines Shortages - Catalytic leverage and added values provided by hospital pharmacy

Medicine shortages (also referred to as drug shortages) have become a global phenomenon and are recognized to affect all health systems. It is a problem that has grown to become a crisis in terms of delivering patient care. For example, over 1400 products were reported to be in shortage in the Netherlands between 2004 to 2011. This concern is known to affect all countries in Europe and beyond including the USA, Canada, and Australia. Medicines affected by shortages include those used to treat cancer, infections, emergencies, cardiovascular conditions, anaesthetic products, neurology and many more. The major challenge is that the economic incentive system in place is aligned in such a way that participating stakeholders are motivated to maneuver themselves into a deadlock situation. A critical issue today is that the key players do not collaborate sufficiently to guarantee a security of supply of essential medicines. What is needed is a system perspective to understand and loosen this deadlock situation as well as to create innovative incentives on a legal and regulatory level.

Shortages result in the suffering of individuals and negative consequences for an economy. An option to overcome shortage situations is to use a different medicine as a substitute. However, alternatives are not always feasible and available. When shortages arise, risk increases through substitution from other excipients, other concentrations, foreign language vials, or untranslated package leaflets. Such risks have not yet been quantified in a scientifically credible way. Thus, a decrease of the number of shortages as a result of the project will have a global economic and societal impact which is in the interest of careers, patients, public health, and of taxpayers.

Hospital pharmacists intend to contribute to how medicine shortage problems can be detected, reduced, or avoided respectively by employing a systemic ecosystems perspective taking into account strategic and quality issues along the supply chain. A collaborative community of relevant stakeholders is to be established to overcome these reasons.

This EAHP Academy Seminar is intended to:

- disclose and unravel restrictive legal, economic, or organizational frameworks and routines, erroneous incentives in the supply chain, conflicts of interest, and problematic cost-benefit ratios that serve to exacerbate or create shortages;
- elucidate and approach the supply chain-inherent problems at every step from raw material up to the patient's need and outcome;
- identify coping strategies;
- provide tools to escape with threats from supply chain disruption.

It covers in introductory lectures and in workshops the following parts

- Stakeholders
- Causes / Erroneous incentives
- Impacts on Outcomes
 - Clinical outcomes
 - Economic outcomes
 - Patients Interests (QoL)
 - Approach to improvements
 - Systems Dynamics
 - Manufacturing and preparation
 - Resolution, Guidelines or reglementation?

Target audience

Delegates nominated by their national associations should fulfil specific requirements such as

- be hospital pharmacists recommended by each country's national association president;
- be hospital pharmacists who have experience with medicines shortages in their hospital;
- be fluent in English;
- attend all seminar sessions;
- complete seminar evaluation form;
- contribute, give presentation and/or demonstrate knowledge gained during workshops and seminar concluding session;
- must be able to accurately disseminate the knowledge obtained during the academy seminar within their country via seminars or workshops and provide documentation that dissemination was done (i.e. national workshop agendas). The national associations then need to report back on how this was accomplished to the EAHP via the country report which is presented each year during the EAHP General assembly.

Links to the EAHP mission & goals and to the European Statements of Hospital Pharmacy

The main EAHP goal covered by the Academy Seminar on Medicines Shortages is to promote and facilitate activities to cope with shortages in the own hospital.

“Medicines Shortages” is covered by all sections of the European Statements of Hospital Pharmacy, i.e.

- Section 1: Introductory Statements and Governance (1.1, 1.2, 1.3, 1.5)
- Section 2: Selection, Procurement, and Distribution (2.1, 2.4, 2.5, 2.6)
- Section 3: Production and Compounding (3.1, 3.2, 3.3, 3.4)

- Section 4: Clinical Pharmacy Systems (4.1, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8)
- Section 5: Patient Safety and Quality Assurance (5.1)
- Section 6: Education and Research (6.2, 6.4)

Assessment of Learning Success

To evaluate the learning success as requested by ACPE and as defined by teaching goals and learning objectives, a Survey Monkey® driven online questionnaire will be used. This form is answered on day 1 as a baseline snapshot of existing knowledge and can be completed online on day 2 after the Academy Seminar to assess the learning success. The link will be communicated to the delegates during the Seminar. A participation certificate will be delivered by link after anonymous submission of the completed questionnaire.

Contents and Learning Objectives of the lectures

The Academy Seminar and Workshops show a main track from a general overview to national clinical implications. The focus is put and centred on the patient and on processes.

Hospital Pharmacists as troubleshooters

Dr Torsten Hoppe-Tichy [1], Ruprecht-Karls-University of Heidelberg, Germany

Linked to EAHP Statements

Section 1: Introductory Statements and Governance (1.1, 1.2, 1.3, 1.5)
 Section 2: Selection, Procurement, and Distribution (2.1, 2.4, 2.5, 2.6)
 Section 5: Patient Safety and Quality Assurance (5.1)

Abstract

Hospital Pharmacists are in the driver's seat of the pharmaceutical supply chain. They are mandated to provide the employer's patients with medicinal products and accompanying services. All troubleshooting and debugging actions arising from disruptions of the supply chain are a process which binds unnecessarily many human and technical resources. In this presentation some typical cases are presented as an inspiring start of the programme

Learning objectives

At the end of this session, participants will be able to:

- know hospital pharmacist's challenges in situations of non-availability of registered products;
- recognise the extent of the global phenomenon;
- participate and provide actively inputs in professional task forces to improve the shortages situation.

Educational need addressed

To deal with medicine shortages has become a daily business of Hospital Pharmacists. In practice, pragmatic procedures to open further supply sources are most currently used. There might be useful hints to be communicated to others and space for capacity building by

learning from colleagues.

Keywords: medicine shortages, global dimension, national patterns, hospital pharmacist's challenges, commonalities, improvement options, capacity building.

An international bottom-up approach – analysis of causation of shortages

Prof Dr Helena Jenzer [2], Bern University of Applied Sciences / University Hospital of Psychiatry Zurich, Switzerland

Linked to EAHP Statements

Section 1: Introductory Statements and Governance (1.1, 1.2, 1.3, 1.5)

Section 2: Selection, Procurement, and Distribution (2.1, 2.4, 2.5, 2.6)

Section 3: Production and Compounding (3.1, 3.2, 3.3, 3.4)

Section 4: Clinical Pharmacy Systems (4.1, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8)

Section 5: Patient Safety and Quality Assurance (5.1)

Section 6: Education and Research (6.2, 6.4)

Abstract

For two decades already, the medicines shortages situation keeps on deteriorating. To deal with medicine shortages has become a daily business of Hospital Pharmacists. Many attempts for improvements have been undertaken, however seldom comprehensively over the whole supply chain. Professional association from the clinical frame collaborate as far as possible and against all odds of administration. There are different interpretations in definitions, different positions and interests and several dependencies from third parties which all favour disruptions of the vulnerable supply chain. Responsibilities for patients are voluntarily neglected and ranked inferior as compared to interests of business and returns on investment. In this situation, no leadership is seen from governments to provide incentives and to line up interests. The most promising approach and a true perspective for a success story lies in the comprehensive approach involving all stakeholders.

Learning objectives

At the end of this session, participants will be able to:

- know about attempts to improve the shortages situation (COST Action CA15105 and other attempts);
- interpret definitions, positions, interests arising from different stakeholders;
- disclose erroneous incentives;
- identify vulnerabilities of the supply chain.

Educational need addressed

A number of improvements for an undisrupted pharmaceutical supply chain has been proposed in the past years. Most of them shed light on a distinct step of the supply chain. None has been brought a breakthrough. Although there are different national challenges in the EAHP member countries, harmonised patterns and commonalities in the fight against supply chain disruptions are more likely to lead to global stabilisation and improvement.

Keywords: medicine shortages, global dimension, national patterns, definitions, interests, positions, dependencies, hospital pharmacist's challenges, commonalities, improvement options.

The clinical needs

Nenad Miljković ^[3], Institute of Orthopaedic Surgery "Banjica", Serbia

Linked to EAHP Statements

Section 2: Selection, Procurement, and Distribution (2.1, 2.4, 2.5, 2.6)

Section 4: Clinical Pharmacy Systems (4.1, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8)

Section 5: Patient Safety and Quality Assurance (5.1)

Abstract

There is a clinical need to avoid and manage risks to patient health arising from medicine shortages and associated with introducing replacement/alternative medicines. Success of a dedicated healthcare intervention is assessed by the outcome. Therefore, the clinical need represents an estimate of an appropriate treatment strategy. Medicines represent an essential part needed to fulfil the expectations of both healthcare professionals and a patient when it comes to desired health outcomes. Non-availability of the right medicines induces serious uncertainties and deviations from the established treatments. These threats are of a particular importance in case of life-saving medicines such as anti-infectives, vaccines, and immunotherapeutics. In case of their non-availability a number of risks have to be considered along with the evaluation of substitute treatments.

Learning objectives

At the end of this session, participants will be able to:

- understand conflicts arising from not being able to fulfil clinical needs as for non-availability of medicines;
- estimate the optimal expected outcome related to a substitute medicine as compared to a medicine initially prescribed;
- recognise and forecast the threats to expected patients outcomes in case of non-availability of medicines;
- predict risks arising from lack of access to life-saving medicines.

Educational need addressed

Although there are different national challenges in the EAHP member countries, certain therapeutic groups such as anti-infectives or vaccines are more at risk to be out-of-stock. To understand the mechanisms leading to empty stocks of these groups is one of the keys to find coping strategies for all therapeutic groups.

Keywords: threads, risk factors and vulnerabilities, emergency medicines, life-saving medicines, risk of substitutions.

Social and ethical aspects

Dr Tomasz Bochenek ^[4], Medical College of the Jagiellonian University, Krakow, Poland

Linked to EAHP Statements

Section 1: Introductory Statements and Governance (1.1, 1.2, 1.3, 1.5)

Section 5: Patient Safety and Quality Assurance (5.1)

Section 6: Education and Research (6.2, 6.4)

Abstract

Successful or less successful fulfilment of clinical needs bring with it satisfying or unsatisfying outcomes. Benchmarks and statistics are assessed for clinical outcomes, for financial outcomes, and for quality-of-life outcomes. In times of economic restrictions, serious impacts are put on public health services, linked to ethical and payability of treatments. The conflict between different objectives of public health, business, finances, and humanity is a risk for social peace.

Learning objectives

At the end of this session, participants will be able to:

- understand the balance between different outcomes;
- assess points of view of clinicians, hospital directors, governments, industry, and patients;
- reproduce differences in the health care potency in European countries.

Educational need addressed

Outcomes are understood as clinical, financial, and quality-of-life results of patient cases. In all cases, outcomes are linked to sociological and ethical needs.

Keywords: medicine shortages, outcomes, ethics, sociological situation, payability of treatments, social peace.

Simulation of a complex network – a Systems Dynamics

(followed after the workshop by an Interactive Plenary and Podium Discussion “Analysis of the worldwide Medicines Shortages Problem”)

Prof Dr Stefan Grösser ^[5], Bern University of Applied Science, Switzerland

Linked to EAHP Statements

Section 1: Introductory Statements and Governance (1.1, 1.2, 1.3, 1.5)

Section 2: Selection, Procurement, and Distribution (2.1, 2.4, 2.5, 2.6)

Section 6: Education and Research (6.2, 6.4)

Abstract

System Dynamics is a recognised methodology for increasing the reliability of foresight. Instead of linear simulation, a non-linear growth curve is considered and simulated. Linear models are not satisfying in terms of precise prognostics. Unexpected events destroy calculations entirely. A more scientific approach of predicting growth curves is provided by the Systems Dynamics approach where not only single linear models are applied, but an interrelation between all stakeholders in a network.

In this session, the methodology of System Dynamics is transferred to the medicines shortages framework. Options to take measures for improvements of medicines supply will be outlined.

Future research bases on different methods of foresight.

Learning objectives

At the end of this session, participants will be able to:

- explain the Systems Dynamics approach of foresight;
- introduce to a simulation methodology of decision making in a complex network;
- understand the methodology of Systems Dynamics and its suitability to identify systems pitfalls in complex networks;
- derive conclusions from simulation to coping strategies of medicines shortages in the modelled system.

Educational need addressed

Industry and (pre-)wholesalers calculate and plan budgets using several methods of foresight. Linear foresight is erroneous and unforeseen events cannot be anticipated. More reliable and sophisticated methods of foresight and future research are needed.

Keywords: system dynamics, foresight, future research, non-linear prediction.

Pragmatic coping strategies in Hospital Pharmacies

Dr Torsten Hoppe-Tichy [1], Ruprecht-Karls-University of Heidelberg, Germany

Linked to EAHF Statements

Section 1: Introductory Statements and Governance (1.1, 1.2, 1.3, 1.5)

Section 2: Selection, Procurement, and Distribution (2.1, 2.4, 2.5, 2.6)

Section 3: Production and Compounding (3.1, 3.2, 3.3, 3.4)

Section 4: Clinical Pharmacy Systems (4.1, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8)

Section 5: Patient Safety and Quality Assurance (5.1)

Section 6: Education and Research (6.2, 6.4)

Abstract

In practise, hospital pharmacists have learned to spontaneously deal with shortages. In most cases, exchange within regional networks is practised. 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;
- recognise that such actions only translocate the problem but do not resolve the global shortages problem.

Educational need addressed

Pragmatic procedures to open further supply sources are most currently used. At the moment a shortage is encountered, it is not evident which one of the approaches is most effective. The patient case may be requesting the fastest option, although more expensive.

Keywords: effective coping strategies, improvement options, cost – benefit, cost - effectiveness.

Systematic attempts at a solution

Prof Dr Helena Jenzer [2], Bern University of Applied Sciences / University Hospital of Psychiatry Zurich, Switzerland

Linked to EAHP Statements

Section 1: Introductory Statements and Governance (1.1, 1.2, 1.3, 1.5)

Section 2: Selection, Procurement, and Distribution (2.1, 2.4, 2.5, 2.6)

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Section 5: Patient Safety and Quality Assurance (5.1)

Section 6: Education and Research (6.2, 6.4)

Abstract

In Switzerland, a nationally funded research projects maps the interests of the stakeholders and will clarify options for improvements. Major pitfalls in the system are the total absence of a leadership and of responsibility. Nevertheless, interviews have already brought insight into the willingness to contribute to a bottom-up approach and best and worst alternatives to negotiated agreements. BATNAs for industry might be a protection of trading and pricing liberty. WATNAs might be a regulation and further loss of return on investment. One of the main achievements obtained so far is a contract framework between the Swiss Federal Office for National Economic Supply (FONES) and those industries providing life-saving medicines. According to these contracts, industry keeps a minimal stock to warrant supply in times of particular politico-social and public health conditions.

Learning objectives

At the end of this session, participants will be able to:

- acquire knowledge about first integral resolutions approaches;
- develop further resolution approaches for their own country and hospital;
- reconstruct to philosophy of stockpiling contracts with industry;
- animate responsibility sharing among the stakeholders in the supply chain.

Educational need addressed

Whereas causes of shortages are widely known, prevention and bridging gaps are not so clear at the moment of action needed. Finding solutions depends on a serious analysis of each one of the shortages. The amendment of such a deviation may however not be fast enough to be helpful for a given patient case.

Keywords: interests, positions, (in-)dependence, BATNA, WATNA.

How clinical needs could be met

Nenad Miljkovi? [3], Institute of Orthopaedic Surgery "Banjica", Serbia

Linked to EAHP Statements

Section 4: Clinical Pharmacy Systems (4.1, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8)

Section 5: Patient Safety and Quality Assurance (5.1)

Section 6: Education and Research (6.2, 6.4)

Abstract

This presentation will summarise a recent survey on risk considerations in the context of life-saving medicines supply.

Learning objectives

At the end of this session, participants will be able to:

- recognise the particular importance of keeping the flow of life-saving medicines from industry to the patients;
- identify disruption risk and propose preventing measures to assure availability of life-saving medicines.

Educational need addressed

Life-saving medicines and therapeutic groups such as anti-infectives or vaccines are in need of an urgent improvement of the shortages situation. Surveys are useful to shed light on clinician's and patient's perspectives of non-availabilities of certain medicines to find flexible options for pharmacotherapies.

Keywords: survey, life-saving medicines, clinician's perspective, patient's perspective.

Social and ethical framework and obligations to be met

Dr Tomasz Bochenek [4], Medical College of the Jagiellonian University, Krakow, Poland

Linked to EAHP Statements

Section 1: Introductory Statements and Governance (1.1, 1.2, 1.3, 1.5)

Section 4: Clinical Pharmacy Systems (4.1, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8)

Section 5: Patient Safety and Quality Assurance (5.1)

Section 6: Education and Research (6.2, 6.4)

Abstract

Harmonisation in Europe not only concerns economic levelling, but also access to high quality of health services and coverage of medicines supply. This presentation gives an insight in attempts to improve harmonisation in general and medicines supply in particular, as far as the social framework is suitable to be subject for harmonisation and economic-cultural levelling.

Learning objectives

At the end of this session, participants will be able to:

- assess the successful provision of equal medicines supply throughout Europe from a social point of view.

Educational need addressed

Outcomes can be improved if discussions are reframed to ethical values and just matters. For this, social partners have to give up particular interests and positions and “negotiate at a round table”.

Keywords: harmonisation, economic levelling, high quality of public health, social framework.

Contents and Learning Objectives of the workshops

WORKSHOP DAY 1

Workshop “Simulation Experimentation”

Prof Dr Stefan Grösser [5], Bern University of Applied Science, Switzerland

Linked to EAHP Statements

Section 1: Introductory Statements and Governance (1.1, 1.2, 1.3, 1.5)
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 Section 4: Clinical Pharmacy Systems (4.1, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8)
 Section 5: Patient Safety and Quality Assurance (5.1)
 Section 6: Education and Research (6.2, 6.4)

Abstract

In a partly interactive workshop, delegates get familiar with the previously presented software Vensim® by studying a business model case. Delegates experiment with a supply chain simulation about medicines shortages and explore a model.

Recommended Reading for the workshop:

chaffernicht/Groesser 2018, Wiley Publishing.

E-book (at a price of 16€, in German only)

https://www.amazon.de/Qualitative-Modellierung-mit-System-Dynamics/dp/1540707024/ref=sr_1_1?ie=UTF8&qid=1523077527&sr=8-1&keywords=stefan+groesser+qualitative+modellierung [6]

Learning objectives

At the end of this workshop, participants will be able to:

- use Vensim® for strategic foresight;
- experiment with a supply chain simulation about medicines shortages;
- assess the impact of assumptions used in the simulated model;
- explore what modification are to be expected following changes in decisions taken by stakeholders.

Educational need addressed

A number of improvements for an undisrupted pharmaceutical supply chain has been proposed in the past years. Most of them shed light on a distinct step of the supply chain. None has been brought a breakthrough. System Dynamics is one of the promising innovative approaches to improve the supply chain by more precise non-linear foresight.

Keywords: Vensim®, foresight, future research.

WORKSHOP DAY 2

Parallel workshops World Café Style

Linked to EAHP Statements

Section 1: Introductory Statements and Governance (1.1, 1.2, 1.3, 1.5)

Section 2: Selection, Procurement, and Distribution (2.1, 2.4, 2.5, 2.6)

Section 3: Production and Compounding (3.1, 3.2, 3.3, 3.4)

Section 4: Clinical Pharmacy Systems (4.1, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8)

Section 5: Patient Safety and Quality Assurance (5.1)

Section 6: Education and Research (6.2, 6.4)

Abstract

There will be 5 parallel workshops in a World Café Style. This means that doors will be open for delegates to move from one room to the other to contribute with ideas to a common output. Workshop leaders will stay in the rooms and manage the steadily growing afflux of contributions.

The five workshops and the leaders are:

- “*Vulnerabilities*” (*Despina Makridaki, Lene Juel Kjeldsen*)
- “*Manufacturing Options*” (*Torsten Hoppe-Tichy*)
- “*Clinical needs*” (*Nenad Miljkovi?*)
- “*Social and ethical aspects of access to medicines supply*” (*Tomasz Bochenek*)
- “*Measures against causes of supply chain disruptions*” (*Helena Jenzer*)

An initial attribution of delegates to one of these five working groups is done according to their professional activity. After this organised start, delegates are free to move from one workshop to the other and place their contributions.

The declared aim of the parallel World Café Style workshops is to acquire knowledge and experiences of delegates as related to coping with the medicines shortages situations. To prevent a loss of time for organisation of the groups, the workshop leaders submit a first set of working documents such as brainstorming items, keywords and/or discussion issues extracted from their presentations as follows:

- A poster of a mind-map showing a classification of causes of shortages (“vulnerabilities of the supply chain”) (to be submitted by Helena Jenzer)
- A poster of coping strategies and approaches to counter the causes of disruptions of the supply chain (to be submitted by Helena Jenzer)
- A poster of options to activate the manufacturing pathway (to be submitted by Torsten Hoppe-Tichy)

- A poster of life-saving medicines at risk for frequent supply disruption (to be submitted by Nenad Miljkovi?)
- A poster of financial and socio-ethical arguments needing an intensified fight against the shortages (to be submitted by Tomasz Bochenek)

Delegates contribute with their creative proposals to an improvement of the medicines shortages situation. They place their inputs directly into the mind-maps, flow-charts, or bulleted lists.

Learning objectives

At the end of this workshop, participants will be able to:

- use the medicines shortages causes mindmap in their own hospital;
- use the medicines shortages coping strategies mindmap in their own country;
- contribute further to a harmonised international approach to find solutions for the steadily worsening flow in the pharmaceutical supply chain.

Educational need addressed

All elements of analysis of supply chain disruptions are useful for quality improvements in terms of plan – do – check – act cycles or structure, process, and outcome qualities. These kinds of quality need to be lived rather than only to be run through. A comprehensive overview over the elements is needed.

Keywords: medicine shortages, global dimension, national patterns, hospital pharmacist's challenges, commonalities, improvement options.

Last update: 23 August 2018

Links

[1] <http://www.eahp.eu/content/dr-torsten-hoppe-tichy-0> [2] <http://www.eahp.eu/content/prof-dr-helena-jenzer-0> [3] <http://www.eahp.eu/content/nenad-miljkovic> [4] <http://www.eahp.eu/content/dr-tomasz-bochenek> [5] <http://www.eahp.eu/content/prof-dr-stefan-groesser> [6] https://www.amazon.de/Qualitative-Modellierung-mit-System-Dynamics/dp/1540707024/ref=sr_1_1?ie=UTF8&qid=1523077527&sr=8-1&keywords=stefan+groesser+qualitative+modellierung