



Patient Safety Expectations of Insurers in Germany



1994 - 2016

Clinical Risk Management

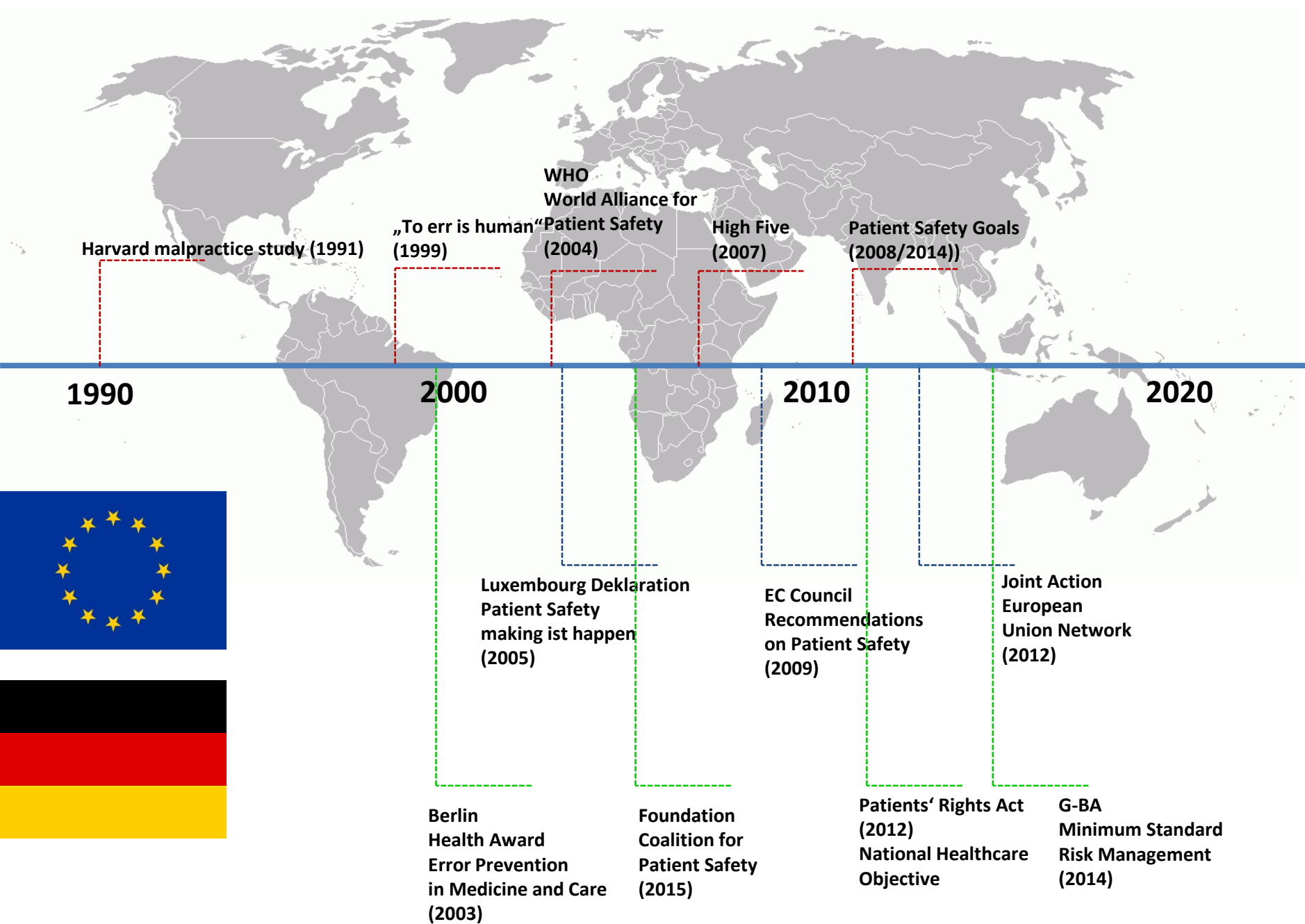


> 180.000

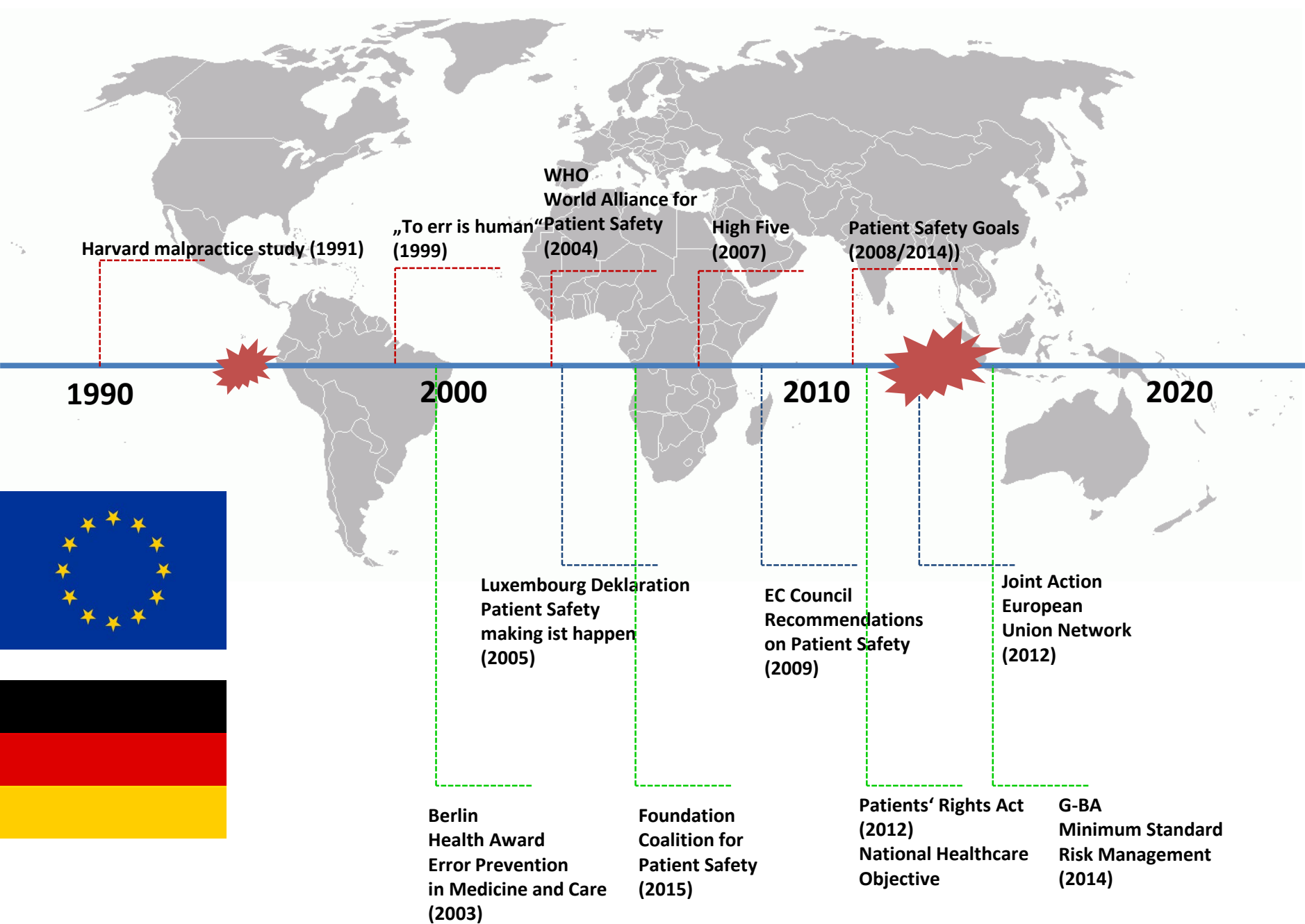
Claims

1100 Hospitals

Milestones



Milestones

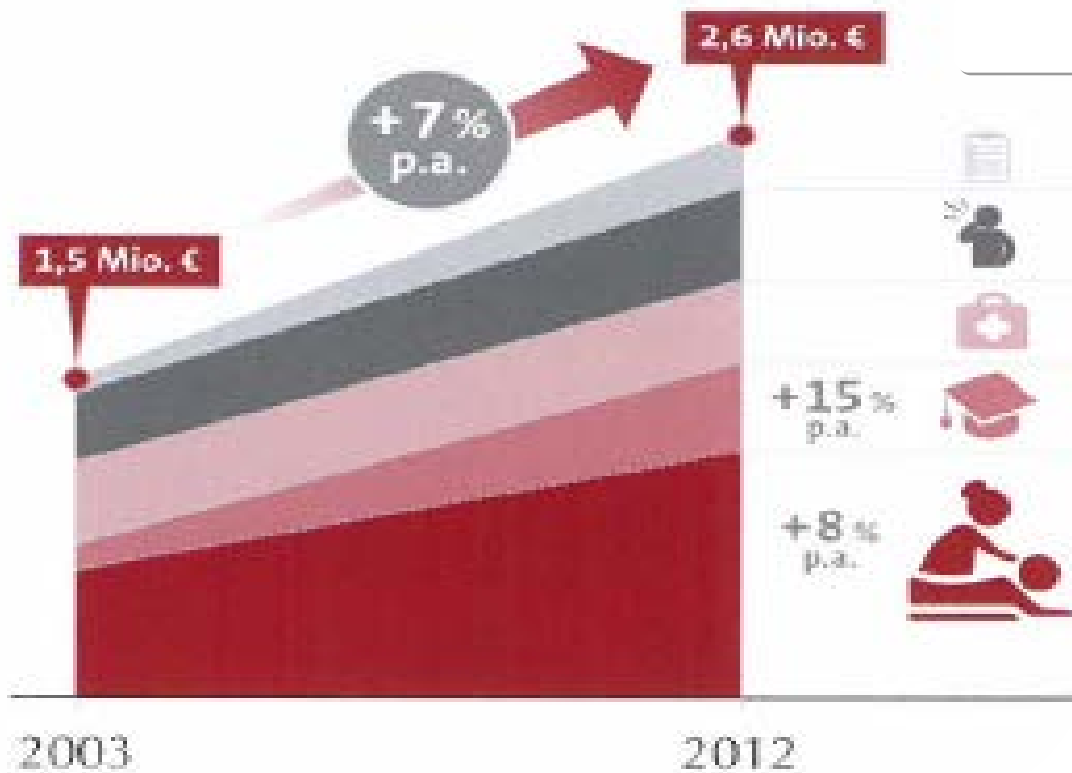




Insurance of medicine



main problem: obstetrics



Quelle GDV



Allianz

ERGO

R+V

VER | **SICHER** | UNGS
KAMMER
BAYERN



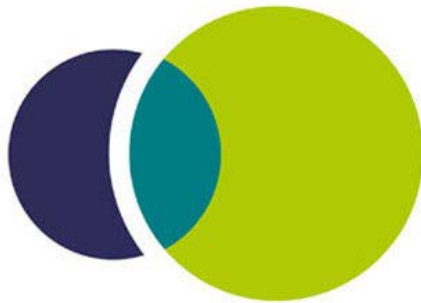
“The liability insurer, essentially, has the same wishes as the patient. Best possible treatment results combined with as little errors in treatment as possible“.

- Structured Patient Admission System ...
- Interdisciplinary Agreements
(horizontally, vertically, physicians/nursing staff, accompanying ward rounds)
- Delegating Medical Measures ...
- Medical Specialist Standard
(call / senior physician indications, attendance times, patient information, interdisciplinary on-call duty) ...
- External Human Interface Management
(service providers; physicians with hospital affiliation, medical consultants, fee-based physicians, medical supply centers; selection / quality etc.)
- OT Management

- **Safety Audits**
- **CIRS**
- **Peer Review**
- **Case Conference / M&M Conferences**



ifo-Geschäftsklimaindex



**Dow Jones
Sustainability Indexes**





Sicherheitsindex

Patient safety is measurable



 **riskala**  **INDEX**

Messung der Patientensicherheit

Criteria for the Safety Index

- Probability of occurrence
- Extend of loss
- Efficiency of the prevention measure
- Degree of fulfillment



Klinik

Fachabteilung / Leistungsbereich(e)

(bit nach M)

Patienten

Exzellen

- Kli

98

Geschäftsführer

GRB Gesellschaft für Risiko-Beratung mbH

98

riskala.INDEX®





Was tun im Schadenfall ?

www.grb-app.de

Forecast Germany/Europe

Insurers will provide liability insurance cover only to those hospital operators who are practicing an **effective** clinical risk management geared to the avoidance of patient injuries and which **regularly measure the level of achieved patient safety**.

Such efficiency requires **that improvement of patient safety forms integral part of the corporate objectives**.

„Expanding the scope
of practitioners insurance
and establishing a dispute
Resolution
Mechanism“



**high reliability
organisation**

QM

RM

PSM

HRM

quality management

clinical risk management

patient safety management

1990

2000

2010

2020



Lake Silvaplana, Swiss 12/02/2015





Five principles of HROs

Preoccupations with failure

Reluctance to simplify

Sensitivity to processes

Reliability

Commitment to resilience

Deference to expertise

Anticipation

Resilience





PATIENT AND USER SAFETY WITH MEDICAL DEVICES

29. ANNUAL CONFERENCE CDGM - DCGM

Dr. Gabriela Soskutý
Beijing, 13. June 2106

B. Braun at a glance



56,000 employees



62 countries



Sales of 6.1 billion €



**3.7 billion € investments
in the last five years**



**229 million € in research
& development**



**> 5,000 products and
120,000 articles**

We are organized in four divisions



Hospital Care

product systems and services for infusion, nutrition and pain therapy.



Aesculap

products and services for surgical processes and interventional cardiology.



OPM

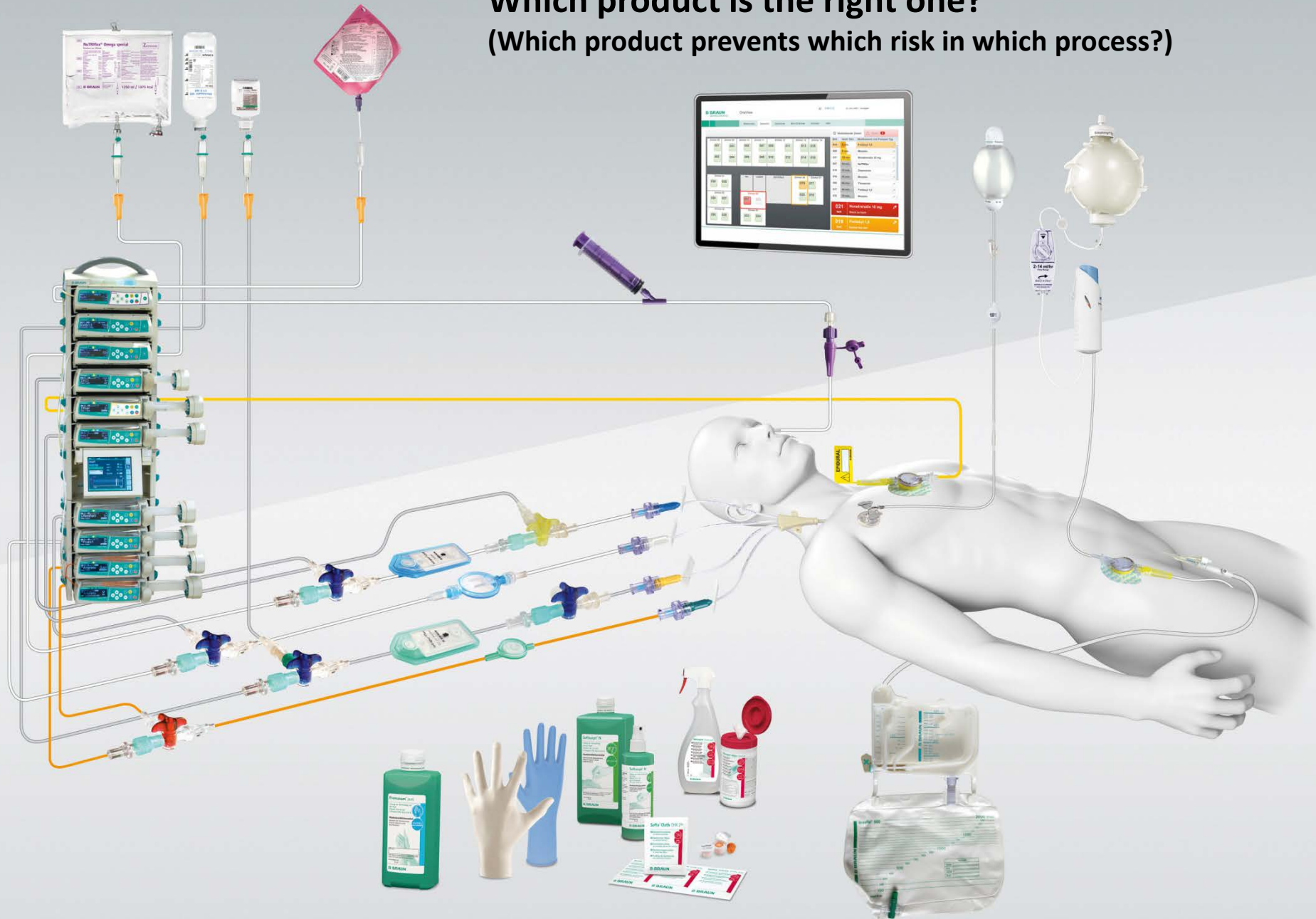
medical and pharmaceutical products for the outpatient market; services outside hospitals for long-term patients.



B. Braun Avitum

provider of dialysis centers and product systems in the field of extracorporeal blood treatment.

Which product is the right one?
(Which product prevents which risk in which process?)



Process: Standard drug infusion + bolus + flushing



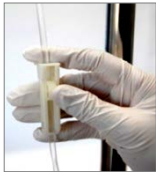
1. Drug Admixture (prepare drug in Solution container)



2. Drug Delivery (prepare IV-set, flush)



3. Patient Access (place IVC, flush)



4. Drug Delivery (connect IV-set)



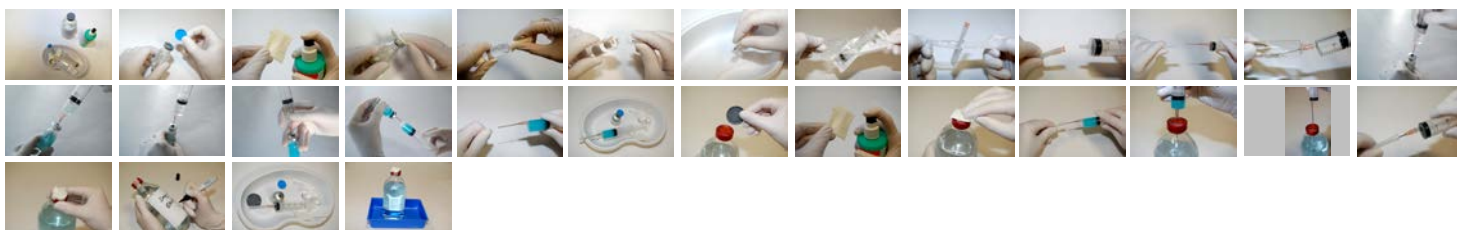
5. Drug Admixture (prepare bolus)



6. Drug Delivery (infusion)

Worst case scenario: glass bottle, needle, glass ampoule

Drug Admixture: 30 steps



Drug Delivery: 40 steps



Patient Access: 35 steps



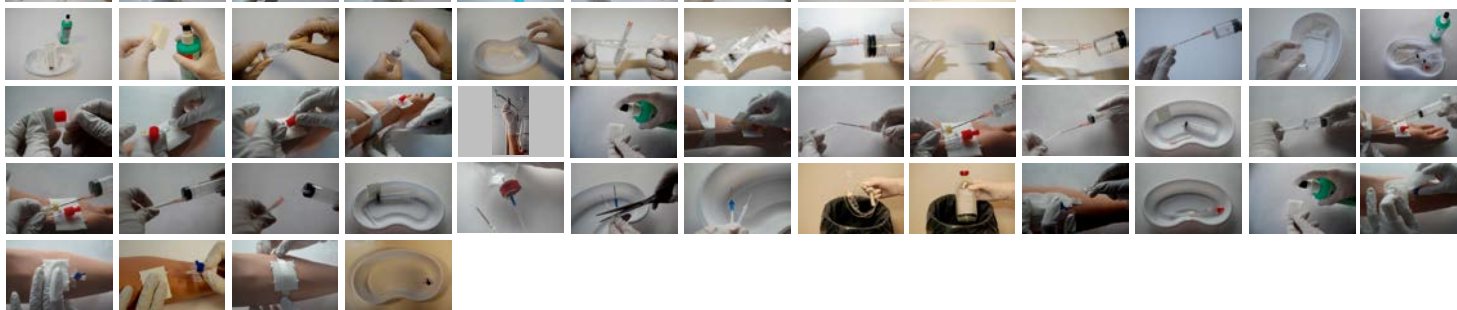
Drug Delivery: 7 steps



Drug Admixture: 22 steps

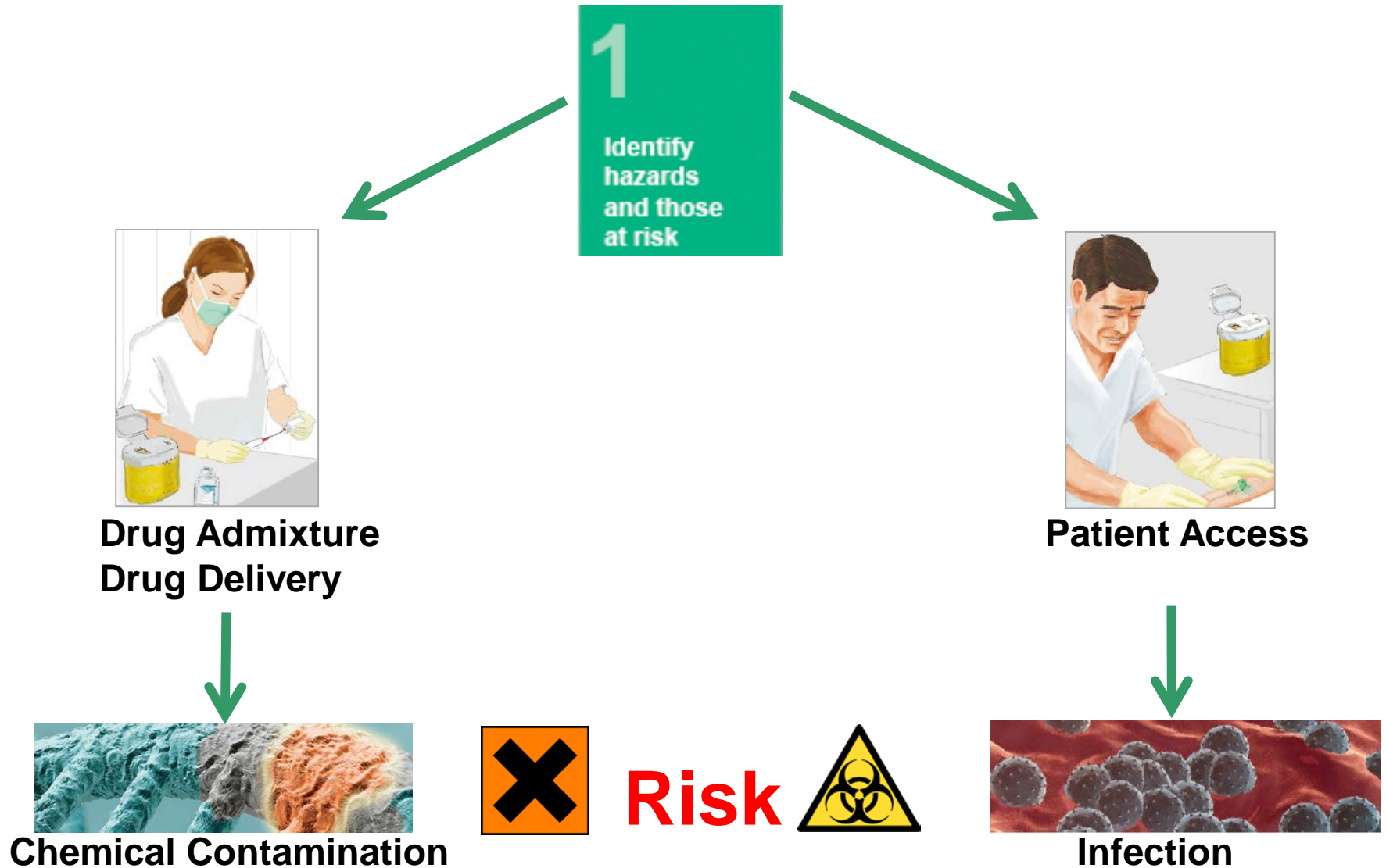


Drug Delivery: 43 steps

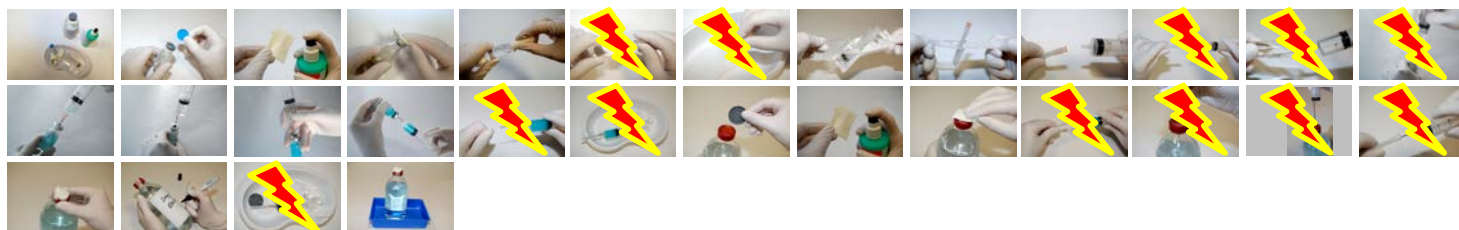


Total process: 177 steps

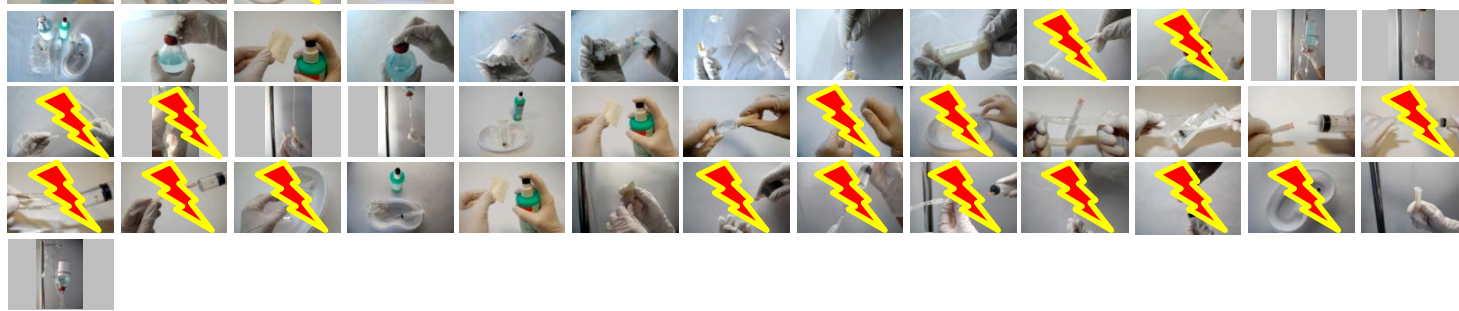
OSHA Risk Assessment = Process Analysis



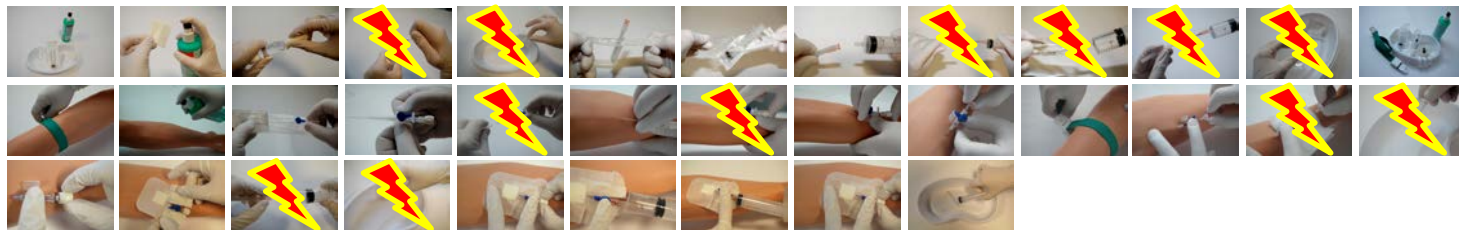
Drug Admixture: 30 steps



Drug Delivery: 40 steps



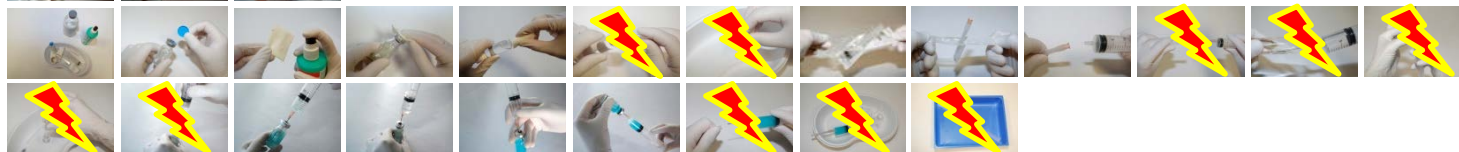
Patient Access: 35 steps



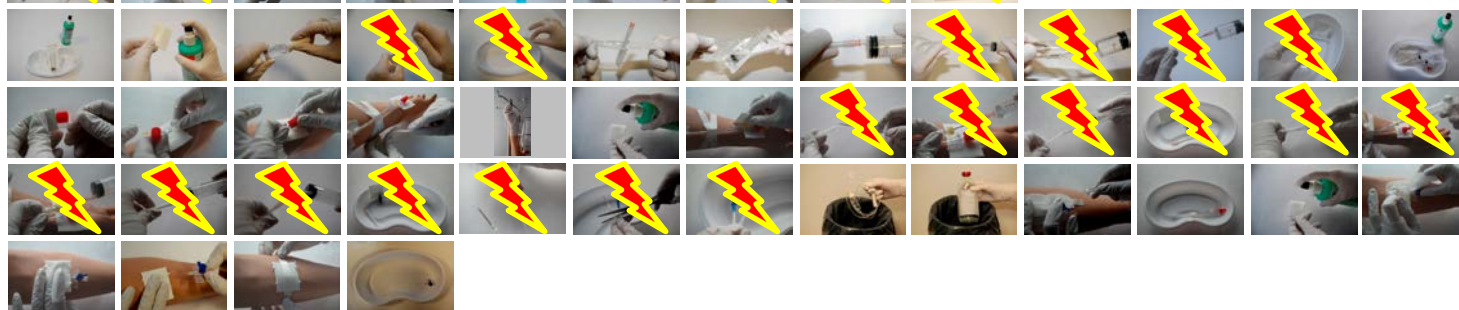
Drug Delivery: 7 steps



Drug Admixture: 22 steps



Drug Delivery: 43 steps



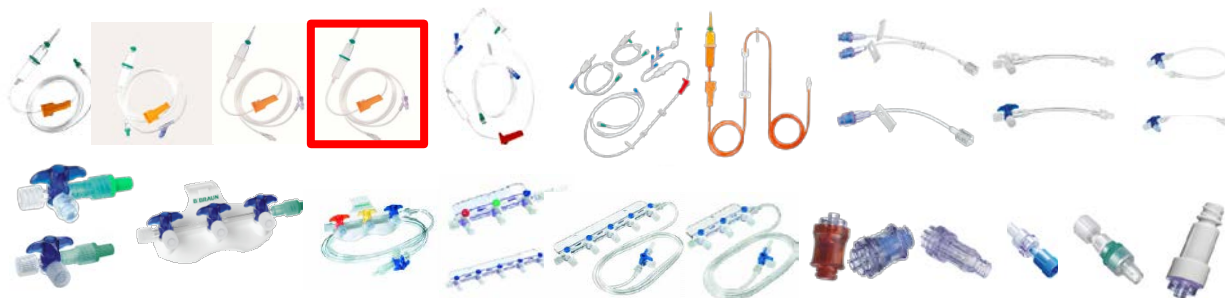
Total: 177 steps. Sharps Injury risk: in 69 steps

>60 products to choose from:

Drug Admixture



Drug Delivery



Patient Access



Ecoflac +
Ecoflac Connect



30 -17 = 13 steps

Safeset
w. Caresite



40 -17 = 23 steps

Introcan Safety +
Omniflush



35 -12 = 23 steps

Safeset w.Caresite: 7 st.

Minispike 2 +
Combistopper
22 -5 = 18 steps



Safeset
w. Caresite



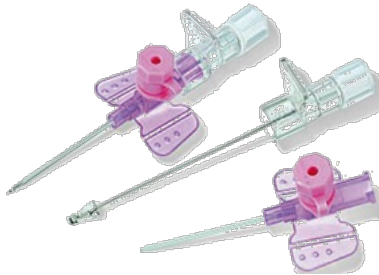
43 -21 = 22 steps



Eliminated: all potential Sharps Injuries & 72 steps

Needle Stick Injuries in spite of a „Safety Device“

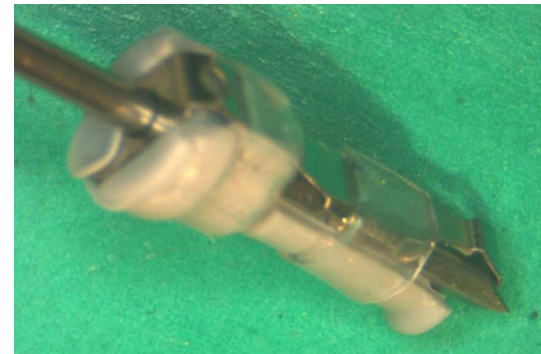
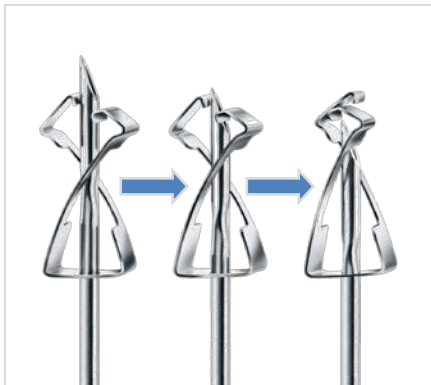
Is



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- **Example:** „Safety “ IV cannula
- **Cause:** mechanical failures due to inappropriate product design and component material
- **Consequence:** needle stick injuries may occur in spite of a safety mechanism

Patient harm due to IV fluid container quality

Is



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source: Krankenhauspharmazie, Nr. 3, 2010



- **Example:** incompatibility of IV fluid container port with IV Set spike
- **Cause:** insufficient holding force of IV fluid container port
- **Consequence:** IV Set fell out of IV container when patient moved during sleep. Patient almost died from blood loss. ADKA issued warning letter.

Medication Error due to IV fluid container material

Comparison: drug losses in PVC and polyolefin (eg. Poliethilene, Polipropilene) containers:

Drug	In PVC	In polyolefin
Calcitriol	50% loss/24 h	Stable
Carmustine	65% loss/2 h	Insignificant loss/2h
Chlordiazepoxide	10-20% loss/2 h	Stable
Diazepam	80-90% loss/24 h	Stable
Heparin	15-25% loss/1-3 h	Stable
Isosorbide dinitrate	15-30% loss/24 h	Insignificant loss/24h
Nitroglycerin	70% loss/24 h	Stable
Thiopental	25% loss/8 h	Stable
Warfarin	29% loss/8 h	Stable



example: PVC bag

source: L. A. Trissel, Handbook on Injectable Drugs, 9th edition, 1996

- **Example:** Drug incompatibility of IV fluid container material
- **Cause:** PVC is a material leading to drug adsorption.
- **Consequence:** dosage error, patient harm, additional length of stay and additional medication cost to reach therapy result.

Patient harm due to damaged medical device material

Is





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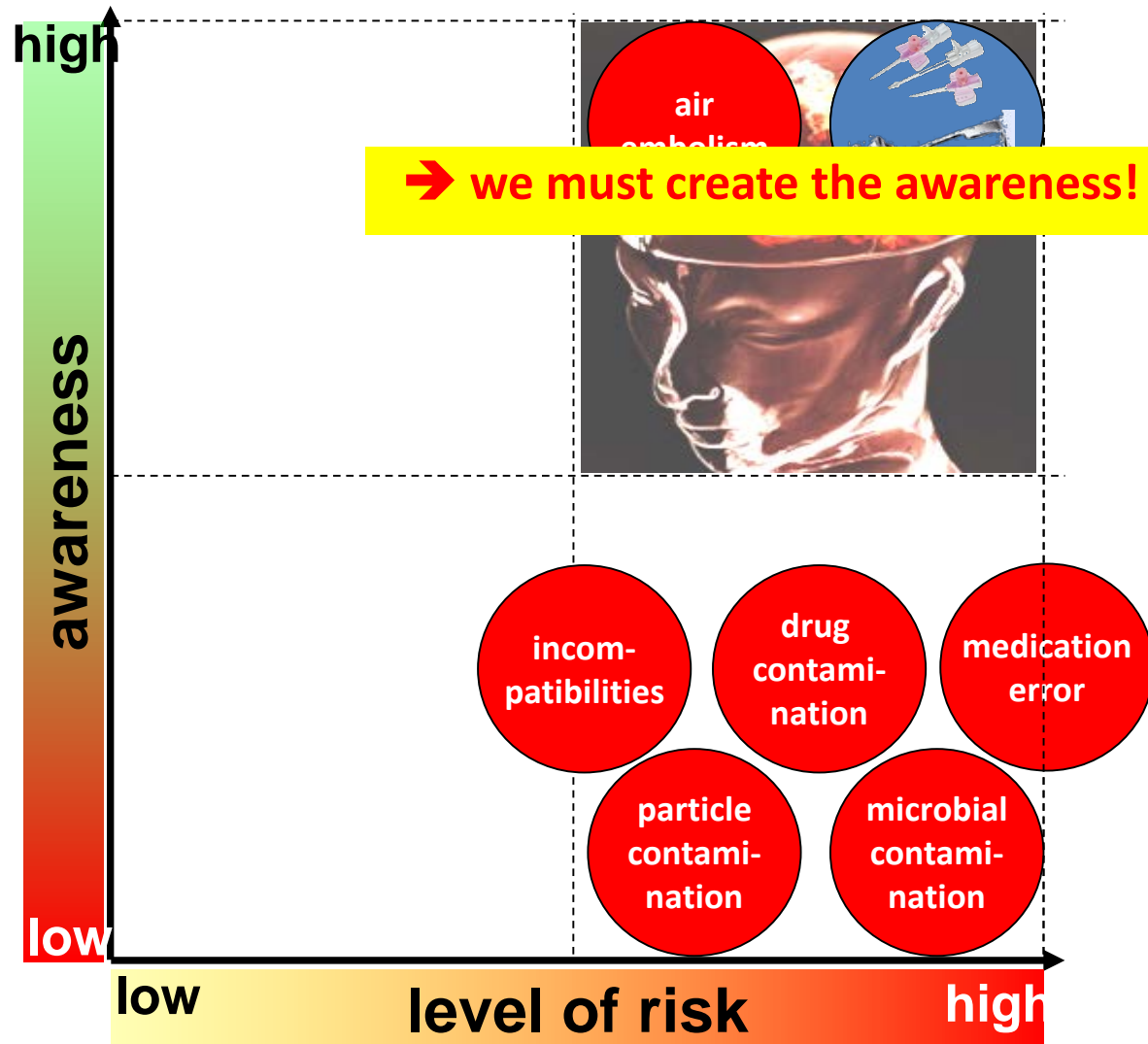
stress cracks due to material/drug incompatibility

[illegible]

list of drugs incompatible with Polycarbonate

- **Example:** Drug incompatibility of 3 way stop cock material
- **Cause:** Various drugs might caus stress cracks in polycarbonate material.
- **Consequence:** air infusion, chemical contamination due to leakages, blood loss, drug loss (medication error), infections due to microbial contamination

Challenge and solution: create awareness!



Five principles of HROs

Preoccupations with failure

Reluctance to simplify

Sensitivity to processes

Anticipation

Reliability

Commitment to resilience

Deference to expertise

Resilience



THANK YOU
FOR LISTENING!

The background of the entire image is a close-up photograph of a rugged, layered rock face, likely a quarry or cliff. The rock is composed of various shades of grey, brown, and tan, with visible horizontal and vertical fissures and textures.

**SHIFT
HAPPENS**

www.grb.de

