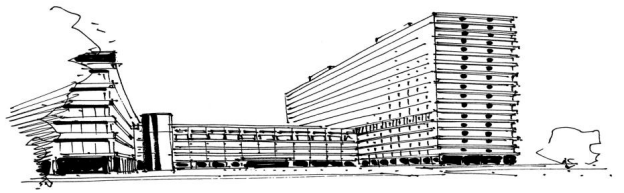
Copenhagen University Hospital - Rigshospitalet

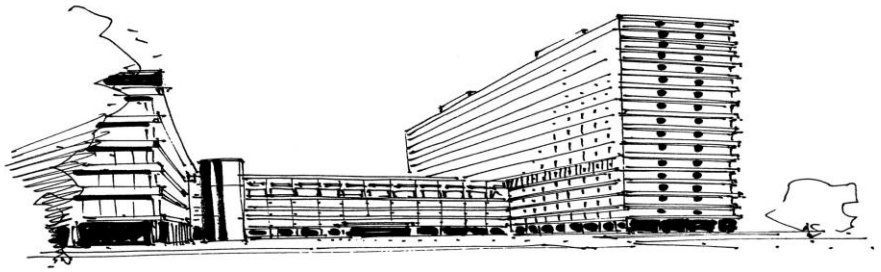
Success Factors for Nordic Clinical Trials

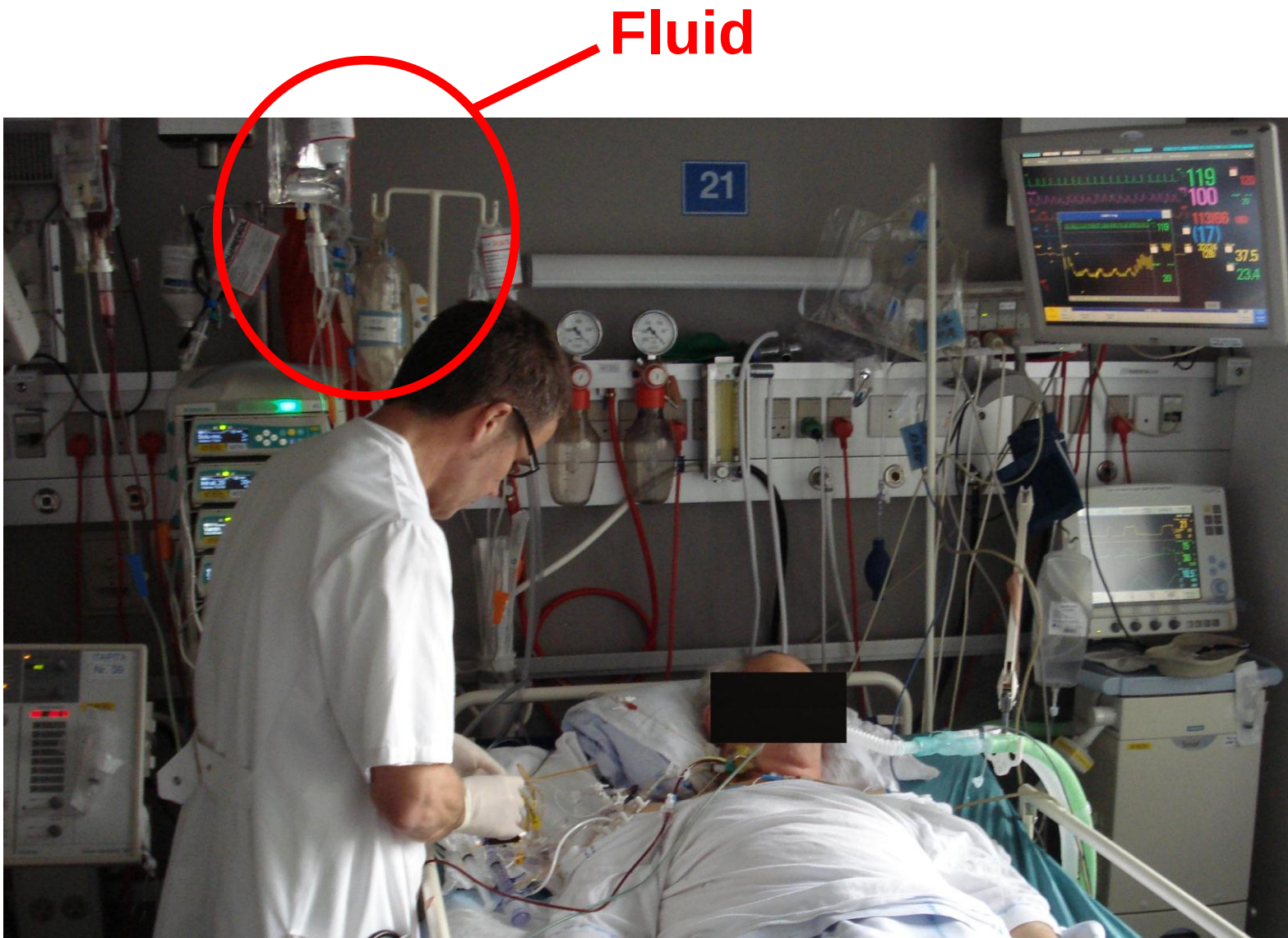
Nicolai Haase, MD, ph.d.-student, 6S-trial coordinator



Trials in Intensive Care – why?

- Very expensive treatment
- Many common treatments are untested
- Weakest patients




Fluid
21
119
100
37.5
23.4

The 6S-trial

- Investigator-initiated Scandinavian Multicenter Trial
- Comparison of fluids with/without the additive ’hydroxyethyl starch’
- 800 patients from 26 hospitals

Challenge #1: Investigator's time is precious

DENMARK:
2 consultants (part-time)
1 trial coordinator (full-time)
1-2 research nurses (full-time)

Other Nordic Countries:
1 national investigator
(spare-time)

Local investigators (spare-time)

Challenge #2: Funding


Berlingske Tidende 29/06/12

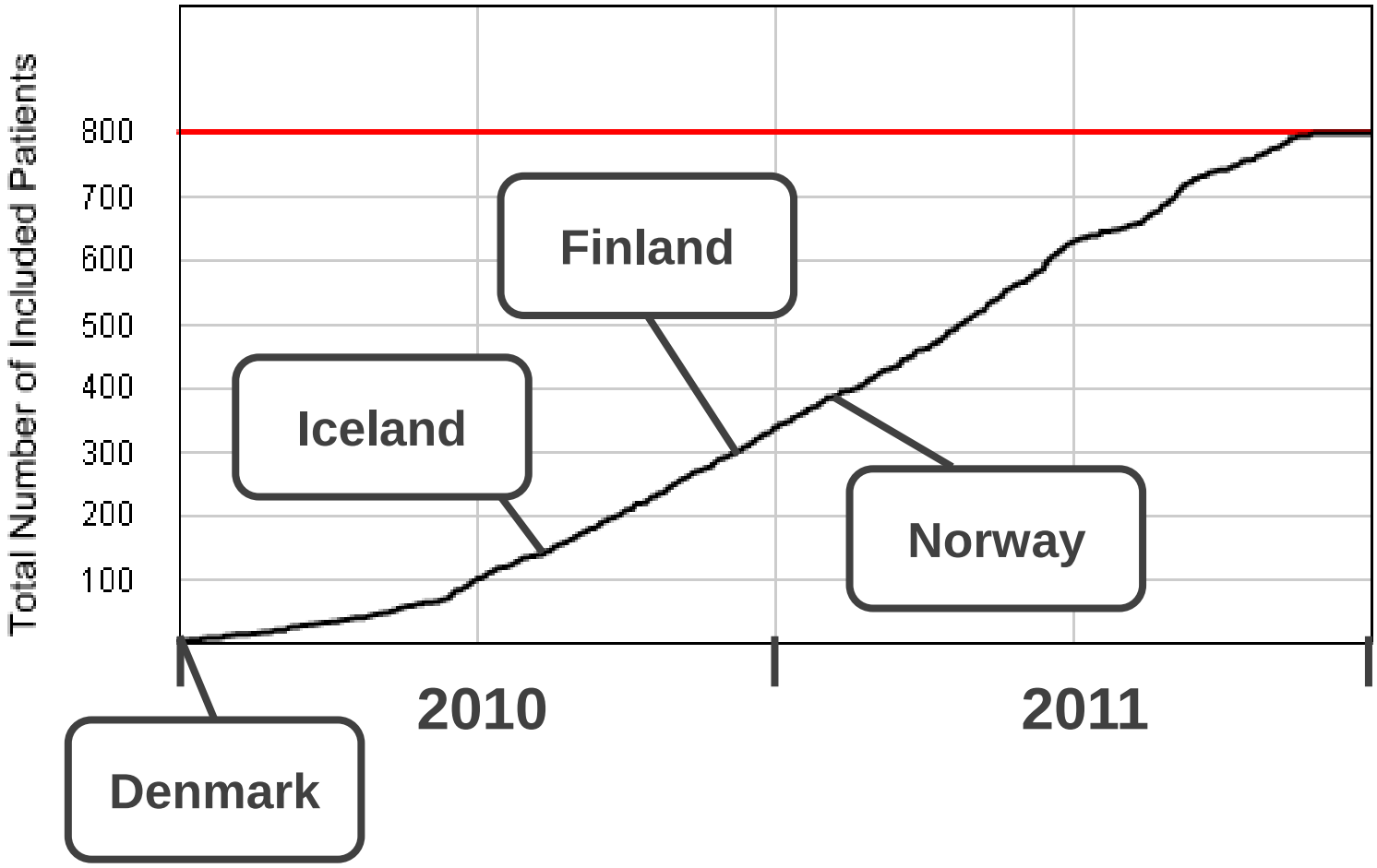
- Low budget trial: € 900,000
- Competition is hard
- Grant from the Strategic Research Council, Denmark

Challenge #3: Approvals

- Medicines Agencies
  - Separate application in each country
- Ethics Committees:
  - Separate application in each country (per region in Sweden)
- Data Protection Agency
  - Separate application in each country

Paper work done in investigator's spare time!!

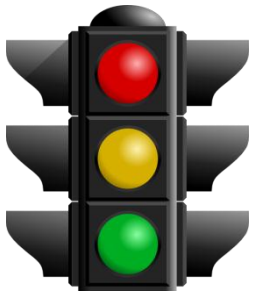
Delayed trial initiation in other countries



710 of 800 patients were Danish

Challenge #4: Informed consent

- One EU-directive → varying procedures in Scandinavian countries
- Fast procedure needed to resemble clinical practice
- Severely sick patients cannot consent!
- Legal substitutes:
  - Sweden: Legal substitutes not allowed in drug trials!!!
  - Finland & Iceland: Relatives must sign first (slow)
  - Denmark & Norway: Independent doctors (fast)



Some additional burdens

- GCP-monitoring
  - 'New' demand to ensure quality
  - Same requirements as those for industry
  - Increases costs (> € 200,000 = 20-25% of total)
- Local administrative burdens
- During trial conduct
  - Eg. adding a new t… …col amendment to medicine
  - Fee: €
  - Wait 6 weeks for approval

No longer needed

Our key to success

- Important clinical question
- Motivated investigators
- **We took work load off local investigators**
- Luck

Does it matter?

- Patients treated with hydroxyethyl starch had
  - Increased mortality
  - Kidney failure
  - Spontaneous bleedings

Does it matter?

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Treatment for blood poisoning can be fatal

July 5, 2012 - 05:00

A widespread treatment of severe blood poisoning can provoke life-threatening kidney failure and haemorrhages. The researchers behind a new study recommend that this treatment should be stopped.

Keywords: Diseases, Medicine, The Body

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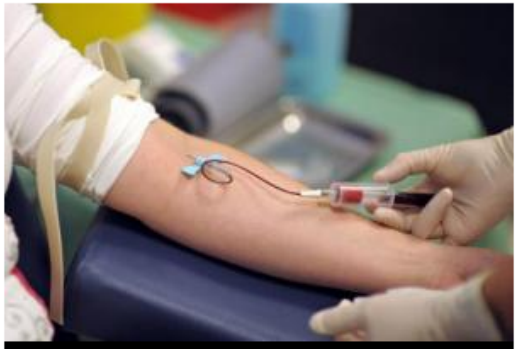
By: Sybille Hildebrandt

Patients suffering from severe blood poisoning (sepsis) are usually treated with a drug called hydroxyethyl starch (HES).

A new study now shows that there is a significant risk associated with the drug. It can induce kidney failure and haemorrhages, which in the worst case can kill the patient.

The findings have been published in *The New England Journal of Medicine*.



In 2007, the Danish government introduced a

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Jobs

PhD Research Fellow in Marie Curie Initial Training Network NanoS3
University of Oslo

2 Professorships
Greenland Institute of Natural Resources

Managing Director

Does it matter?

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Hydroxyethyl Starch 130/0.42 versus Ringer's Acetate in Severe Sepsis

N Engl J Med 2012;367:124-34.
DOI: 10.1056/NEJMoa1204242

Does it matter?

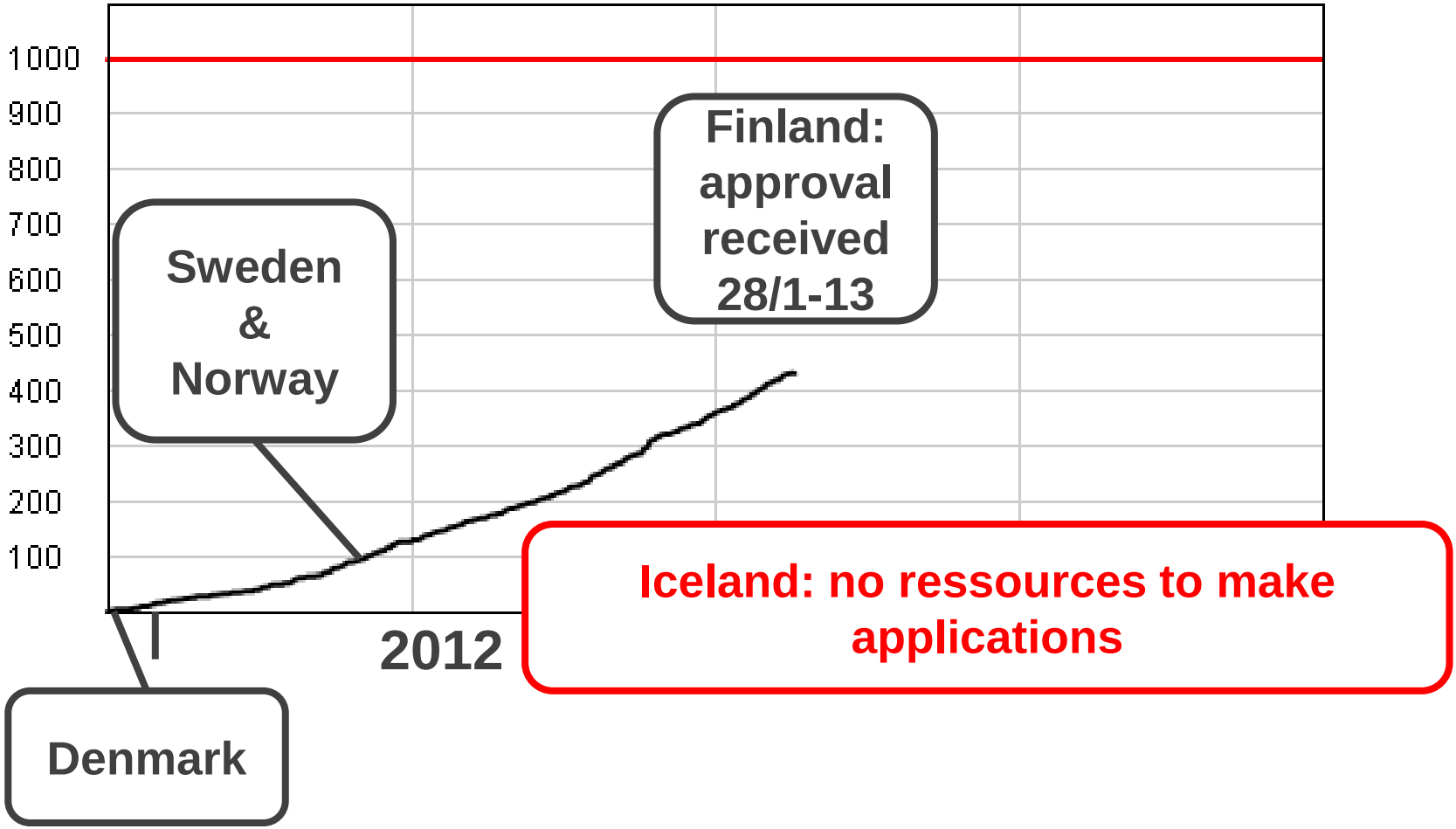
- January 2013: International guidelines changed:

  ’Hydroxyethyl starch should not be used’

- EMEA and FDA are now reassessing the benefit-risk balance of hydroxyethyl starch

The TRISS Trial

TRISS trial


1000
900
800
700
600
500
400
300
200
100
2012
Finland: approval received 28/1-13
Sweden & Norway
Denmark
Iceland: no ressources to make applications

Final Remarks

Barriers and burdens

↓

Delays
Increased costs
Investigators will loose motivation

↓

Risk of trial failure
Fewer trials

Final Remarks

- Trials are life-saving and reduce the burden and cost of disease
- All burdens must actively be minimised for investigator-initiated trials