

**Scientific dishonesty,
questionable research practice (QRP)
and
unethical research practice**

In Denmark

- Scientific dishonesty belongs under The "Act on Research Consulting etc"
 - Ministry of Higher Education and Science
 - Danish Committees on Scientific Dishonesty (DCSD)
 - **Anyone can refer a case!**
- Unethical research practice belongs under "The Committee Act"
 - Ministry of Health
 - **Only** biomedical research

Terminology

Scientific dishonesty as defined in Denmark

“Falsification, Fabrication, Plagiarism and other serious breaches of good scientific practice that have been committed intentionally or with gross negligence in the planning, implementation, or reporting of research results.”

Unethical practice

No very clear definition

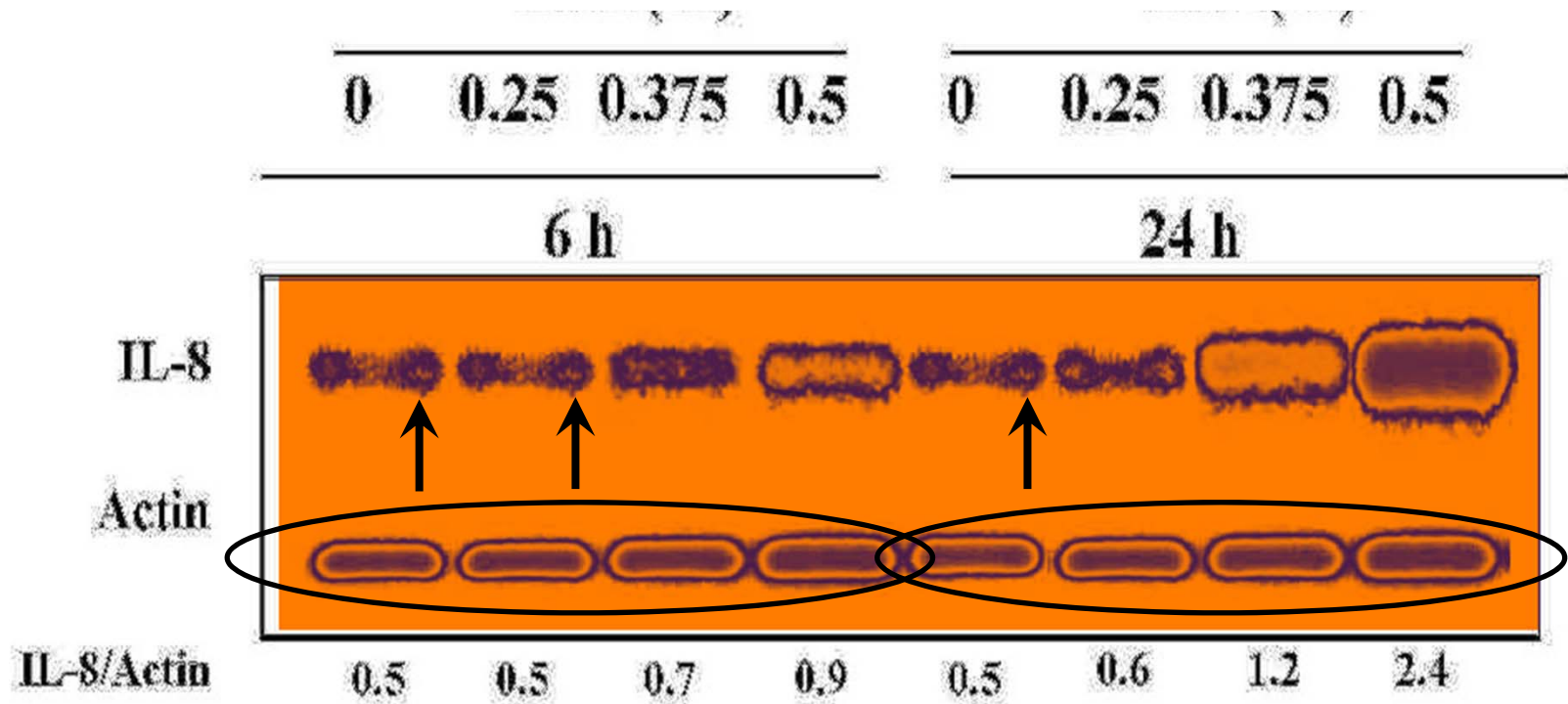
Breaking the Committee Act – definitely

Open for some discussion

Scientific dishonesty

- Falsification
- Fabrication
- Plagiarism





OSF

Scientific dishonesty

- Falsification
- Fabrication
- Plagiarism

FEW!

**About 2% of
researchers**



But.....

About 30% have made other dubious actions in the grey area that extends from scientific dishonesty

QRP

AND

>50% of all research cannot be reproduced!

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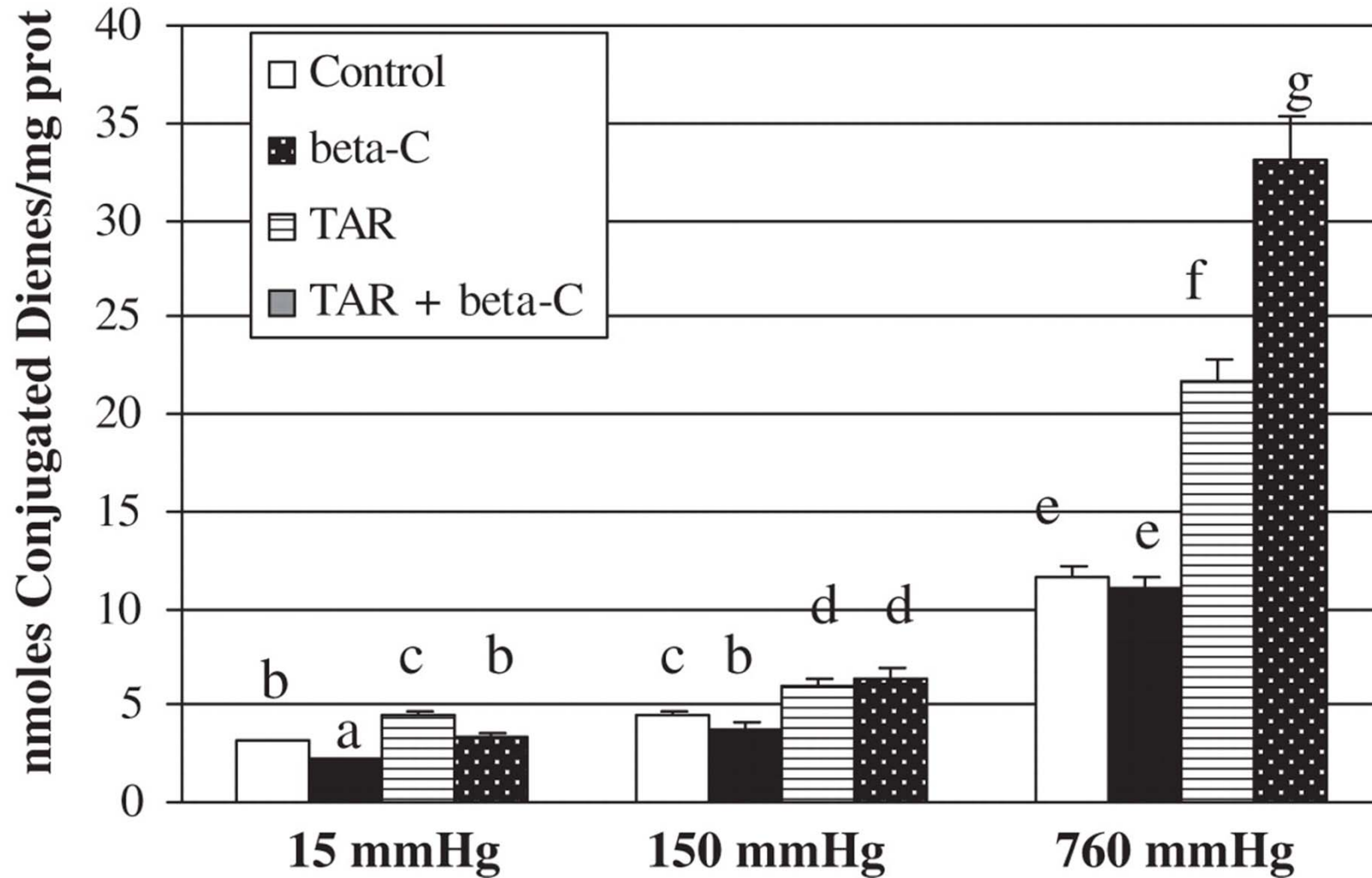
1. Martinson BC, Anderson MS, de Vries R. Scientists behaving badly. Nature 2005; 435: 737-8
2. Fanelli D. How many scientists fabricate and falsify research? PloS One 2009; 4: e5738

The biggest "sins"

Top ten behaviours
1. Falsifying or 'cooking' research data
2. Ignoring major aspects of human-subject requirements
3. Not properly disclosing involvement in firms whose products are based on one's own research
4. Relationships with students, research subjects or clients that may be interpreted as questionable
5. Using another's ideas without obtaining permission or giving due credit
6. Unauthorized use of confidential information in connection with one's own research
7. Failing to present data that contradict one's own previous research
8. Circumventing certain minor aspects of human-subject requirements
9. Overlooking others' use of flawed data or questionable interpretation of data
10. Changing the design, methodology or results of a study in response to pressure from a funding source

Other behaviours
11. Publishing the same data or results in two or more publications
12. Inappropriately assigning authorship credit
13. Withholding details of methodology or results in papers or proposals
14. Using inadequate or inappropriate research designs
15. Dropping observations or data points from analyses based on a gut feeling that they were inaccurate
16. Inadequate record keeping related to research projects

Effects of cigarette tar and β -carotene, alone and in combination, on conjugated diene production in rat lung microsomes exposed to 15 mmHg, 150 mmHg and 760 mmHg.



Case of Puk

- Puk is writing up a paper as part of her thesis work on cortisol activity, sleep and physical activity.
- In her dataset is one person with a very high morning cortisol
 - There is no explanation
 - The results are the same whether he is included or not, although statistical significance weakens
- What should she do with this "outlier"

Really big unethical studies

- WW2 Concentration camp experiments
- The Tuskegee Syphilis Study
- The Stanley Milgram experiment

- Using a whole population, e.g. the Icelandic experience – good or bad?
- Small populations? Can we guarantee anonymity? Is it wanted?
- Conducting research without letting research subjects know they are taking part?

A small detour to Sweden

The MACCHIARINI case

- 2010 Karolinska Institute hires Paolo Macchiarini to introduce stem cell research into the clinic
- Rector Harriet Wallgren a central figure in his recruitment
- No Italian hospital would hire him
- No animal studies as basis for his trachea transplant procedure, which did not undergo ethical approval
- Very good results published in Lancet

Only the rectors of the country's universities and colleges can refer cases to the Swedish "DCSD".

Where is the border?

Patients who are terminally ill may be willing to do anything to survive

Some doctors may think that in these situations they should try everything

Not research, just a doctor trying to save a patient?

Organization

- Three standing committees:
 - Health sciences
 - Science, technology and production science
 - Culture and social sciences
- 6 members (recognized scientists) in each committee
- Joint chairman (high court judge)

The committees may not consider cases concerning the validity or truth of scientific theories, or cases concerning the research quality of a scientific product

The Act on Research Consulting etc.

For scientific products prepared under private arrangements, the case may be considered only if the private company [or person] wants to be covered by the Committee's jurisdiction or wishes to contribute to resolving the case, §31, paragraph 2

Examples from practice concerning rejection

Case no. 2 (2009 Annual Report)

- Complaints about dishonesty in connection with the publication of two articles
- Complainant unhappy that the articles included an author who had not participated in the clinical trials
- The clinical trials that formed the basis for the controversial articles had been initiated and funded by a private company

Examples from practice concerning rejection

Case no. 2 (2009 Annual Report)

- Complaints about dishonesty in connection with the publication of two articles
- Complainant unhappy that the articles included an author who had not participated in the clinical trials
- The clinical trials that formed the basis for the controversial articles had been initiated and funded by a private company
- The private company did not wish to be covered by DCSD's jurisdiction, so the case was dismissed

Objective criteria for scientific misconduct: *has been falsification, fabrication, plagiarism and other serious breaches of good scientific practice*

Subjective requirements that must be satisfied for an act to be characterized as scientific misconduct: *that the act was committed intentionally or with gross negligence in the planning, implementation, or reporting of research results*

SIGH!

Neither the law and its processes nor the Notice includes a more detailed description of what is meant by "committed intentionally or with gross negligence"

This is consistent with ordinary legislative technique.

Negligence

The concept of negligence can be defined as lack of care - culpa (guilt) and is based on blameworthy conduct. There is negligence when a person has not shown due care that he or she has a duty to show in a given situation.

Gross negligence is a particularly blameworthy deviation from normal behaviour and can be either intentional or unintentional.

The person carrying out the action must therefore have failed to an **unreasonable** extent to exercise due care.

Some numbers

Normally:

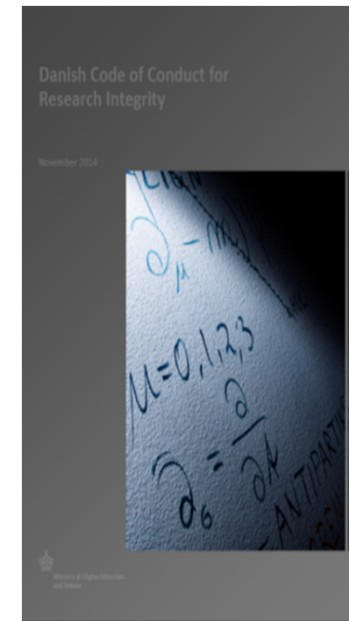
- 10-15 referrals for scientific dishonesty each year
- Of which scientific dishonesty found in 1-2 cases
- Each case takes about 6-12 months, when things go well ...

Promotion of good scientific practice

- Prevention is not part of the DCSD's responsibilities
- Nevertheless, the DCSD has published a set of guidelines for good scientific practice (www.fi.dk)
- Teaching of good scientific practice is incumbent on the research institutions (praksisudvalg)
- The area is not regulated by law
- **Danish Code of Conduct!**

The Danish code of conduct for research integrity

- The Code is divided into four main chapters reflecting best practice:
 - I. Principles of Research Integrity (**Honesty, Transparency, Accountability**)
 - II. Responsible Conduct of Research
 - III. Research integrity teaching, training, and mentoring
 - IV. Research misconduct and breaches of the responsible conduct of research



An abundance of statements

- **Singapore Statement on Research Integrity**

Honesty in all aspects of research

Accountability in the conduct of research

Professional courtesy and fairness in working with others

Good stewardship of research on behalf of others

An abundance of statements

The European Code of Conduct for Research Integrity Concept of Responsibility

All research subjects (..) should be treated with respect and care

Health, safety or welfare of a community (..) should not be compromised

Researchers should be sensitive to their research subjects

After the Klarlund and Penkowa cases, the "Oddershede report"



- 12 recommendations
- 3 Special recommendations
 - Narrower definition of scientific misconduct: FFP and severe QRP
 - DCSD only FFP and Universities only QRP (arms length principle)
 - Separation of P from FFP, thus DCSD only FF and Universities QRP and P

"Public Hearing"

Mainly:

- ✓ OK – with cases handled according to the "arm's length principle" (from management)
- ✓ No – to the separation of FF and P. Hold FFP together, otherwise signal confusion
- ✓ The definition has not become more clear

Recommended procedure - Oddershede



Recommended procedure – majority



We return to Sweden

The MACCHIARINI case

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- Rector Harriet Wallgren a central figure in his recruitment
- No Italian hospital would hire him
- No animal studies as basis for his trachea transplant procedure, which did not undergo ethical approval
- Very good results published in Lancet
- 2013 Karolinska Hospital stops transplants, which continue abroad
- Whistleblowers start expressing doubts but are stopped by Rector Anders Hamsten
- 2015 – the case explodes on TV and in written press

- Lancet expressed "concern", but the article is still on line in Spring 2016
- The same day the journal announced it was tagging the controversial paper with an expression of concern, it issued a new erratum about the paper, removing three author names (one had already asked previously to be removed).

What do you think?

- It's not surprising that a few of Macchiarini's co-authors would want to distance themselves from this ever-expanding scandal, **but should authors who originally signed on to a paper be able to change their minds?**

Consequences of Macchiarini case

- Six **patient** deaths
- Forced resignations from the Karolinska:
 - Rector
 - Rector's academic advisor
 - Dean of Research
- The Minister of Research has replaced Karolinska's Board
- Two reports from Sept. 2016 blame Wallgren, Hamsten, KI, the hospital and the culture in these organizations
- Wallgren and Hamsten thrown out of the Nobel Committee for Medicine and Physiology

Recommended procedure – Danish Universities (management)



Some tips here at the last minute?

- Agree on expectations - in advance
- Make agreements - and keep them
- Don't cheat others for authorship
- Read and use the Danish Code of Conduct

No one has to produce above their abilities, but there are limits to how stupid you are allowed to be ...