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Session 3: Challenges and risks in innovation

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A risk: reproducibility

Continuum of misconduct in research



- There are the big three (FFP)
 - Fabrication
 - Falsification
 - Plagiarism – estimated at 4%
- And then there are questionable practices...
 - Taking other people's ideas
 - Over-selling results
 - Inappropriate co-authorship – estimated at 31 to 37%

Assuming researchers are honest...

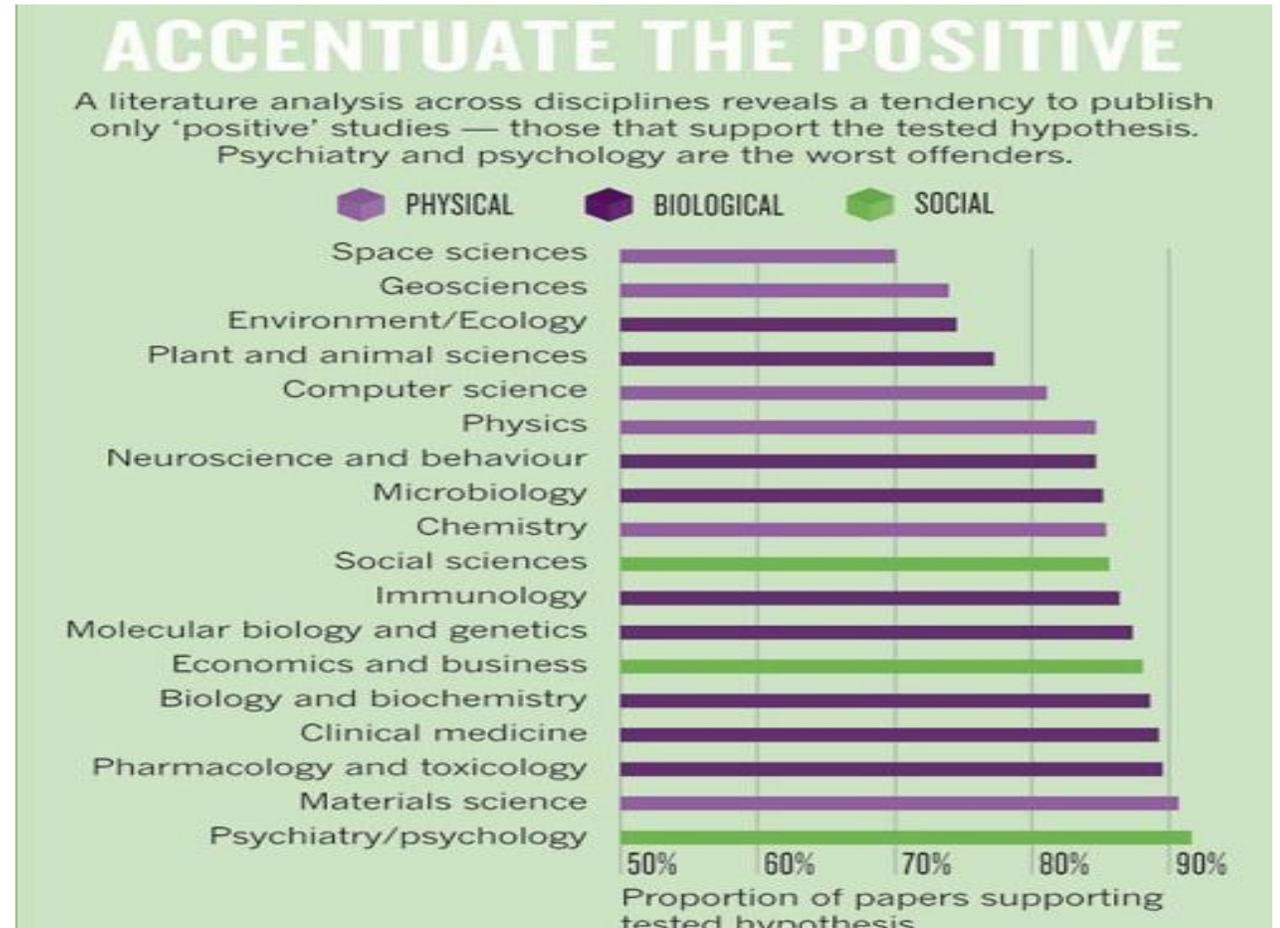


- Still major issues for commercialisation
- Questionable practices
 - Over-selling results
- As well as
 - Data selectivity and irreproducibility
 - Statistical errors

*“Too many sloppy mistakes are creeping into scientific papers.”
Nature 483, 509 (29 March 2012)*

Data selectivity and irreproducibility

- Only 6 of 53 landmark studies in preclinical oncology research were reproducible by Amgen (Begley, CG & Ellis, LM, 2012)
- In 4,600 studies across the sciences, the proportion of positive results rose by more than 22% between 1990 and 2007 (Fanelli, D, 2011)



Fanelli, 2011

Statistical errors



- Too few data points
- Tests done on too few animals or people
- Incorrect statistical methods used
- Incorrect controls
- Using statistics for identical replicates and not independent data

“The incidence of papers in cell and molecular biology that have basic statistical mistakes is alarming.” Vaux (2012)

A real risk – some solutions?



- External review of data
 - Could include peer-reviewed publications (but this can be a problem)
 - Use of independent consultants or academics
- Independent statistical review
 - Pay particular attention to statistical significance for potential licensee
 - Are you asking the right questions?

Need to formalise into the process so not seen as a witch hunt



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A challenge: conflicts of interest

(With thanks to Jeff Skinner, London Business School, for agreeing to let me use his material)

Anything wrong?



Prof A

- Prof A develops a prototype polishing instrument
- Prof A creates a company to manufacture it
- Prof A applies for project funding as an academic and wins it...
 - ...with his company as industrial partner
- The project requires purchase of a polishing instrument

Prof B

- Prof B is a shareholder and a director of a spin out company
- The spin out company wishes to sponsor students under the supervision of Prof B

Anything wrong?



Prof C

- Prof C is a consultant to BigCo
- A student in Prof C's lab comes up with technology of major interest to BigCo
- Prof C advises the student to take a vacation job at BigCo

Prof D

- Prof D is the inventor of a new drug
- BigPharma companies tell her it's too early to license
- She forms a spin out company and raises money to carry out pre-clinical trials
- She publishes (glowing) results

Anything wrong?



Prof E

- Prof E forms a spin out company and she is
 - A shareholder
 - A director and
 - A consultant
- Inside the university she:
 - Supervises students and staff
 - Carries out research, publishes
 - Manages her own time
 - Orders things



The problem



- In all cases the academic's loyalty is split between:
 - private interests
 - those of university
- Even if he/she acts with complete integrity motives for actions are open to question
- Problem is that academics have enormous freedom and discretion:
 - Usually there are in-built checks and balances
 - But these can break down if personal incentives are too great
- University can be (or appear to be) conflicted
- And there may be 'personal' conflicts

What can happen?



Financial loss to university

- Decisions not made in sole interests of university
- IP can 'leak' (who owns the inventions?)

Reputational damage

- Tainted research
- Financial 'scandals'

Injustices to students and young staff

- Do they get correct research direction, advice?
- How is IP treated?

Distraction

- Academic spends less time worrying and sweating for university.

All often gradual, an imperceptible slide...

If the facts came to light...

Would they

- be embarrassed?
- be able to explain themselves under questioning on TV from the most aggressive of interviewers? (The “Carte Blanche” test)
- Sound reasonable to an ordinary “man on the street” (and tax payer)?

If not then they are

- conflicted
- Exposed
- And the university could suffer

Conflicts in...



Educational mission

- Academics have a duty of care for Research students, young post-doc researchers

Research mission

- Public and university trusts that research funds are not used for private gain

Use of facilities, people

- Entrust resources are used (efficiently?) for educational and research missions

Commitment, use of time

- Universities don't manage minutes

What to do about it?



 Nothing

 Ban problem activities

 Micromanage activity

 Encourage full disclosure

 Change way activity is managed

 Manage (by policy?)

What to do about it?



- **Nothing**

- To do nothing at all could be a major reputational risk
- To wait is often the default (how bad can it be?)
- Policy often follows bad experience
- Sometimes need to find examples (yours or others)
- There may not be the political will to do anything besides waiting

- **Ban problem activities**

- Maybe OK at some institutions
- But for most, will kill all academic-led “commercial” activity.
- Not an option except for the most unmanageable conflicts

What to do about it?



- **Micromanage activity**

- When university has TTO, this is often the strategy
- TTO plays a role in all initial spin out companies - know where the conflicts are and ensure that they are managed
- As activity grows, this becomes impossible

- **Encourage full disclosure**

- 'Sunlight is the best disinfectant'
- Should certainly be encouraged (part of any policy)
- But what to do with the disclosures?
- Does it do any more than shift risk to the institution?
- Vital part of any solution, but not the only answer

What to do about it?



- **Change way activity is managed**

- Put in additional checks and balances such as Second supervisors, Research oversight
- Ban academics from being part of negotiations
- Does it work?
 - Can provide for worst excesses
 - But will the other academics take seriously or understand issues?
- Again, part of policy, but not all of it

- **Manage (by policy?)**

- Best way is a mixture of above:
 - Ban some activity
 - Seek disclosure
 - Manage where possible
- Need to be specific and provide examples
- Needs to be fast-moving and decisive

So



Acknowledge
conflicts will occur



Put policies and
practices into
place



Manage conflicts,
don't try and avoid
them

Questions for discussion



- What are the main **conflicts** that you see in your ecosystem if you grow innovation activities? How can you overcome them?
- How does your university deal with the **time** required of academics to be more involved in innovation? What policies have you got / do you need? Do you / should you be offering secondments? What are the challenges and risks of doing this?
- What type of conflicts do you see arising as **students** start developing more enterprises? How do you think these should be managed?

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Thank you!

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