



Quality Culture

Misconduct and Behavioural Cues

A Cautionary Tale from Scotland

Shona Ross

CLINICAL TRIAL DATA INTEGRITY CONFERENCE

BRATISLAVA, SLOVAKIA

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Scientist Steven Eaton jailed for falsifying drug test results

🕒 17 April 2013

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A scientist who faked research data for experimental anti-cancer drugs has been jailed for three months for falsifying test results.

Steven Eaton, from Cambridgeshire, has become the first person in the UK to be jailed under scientific safety laws.

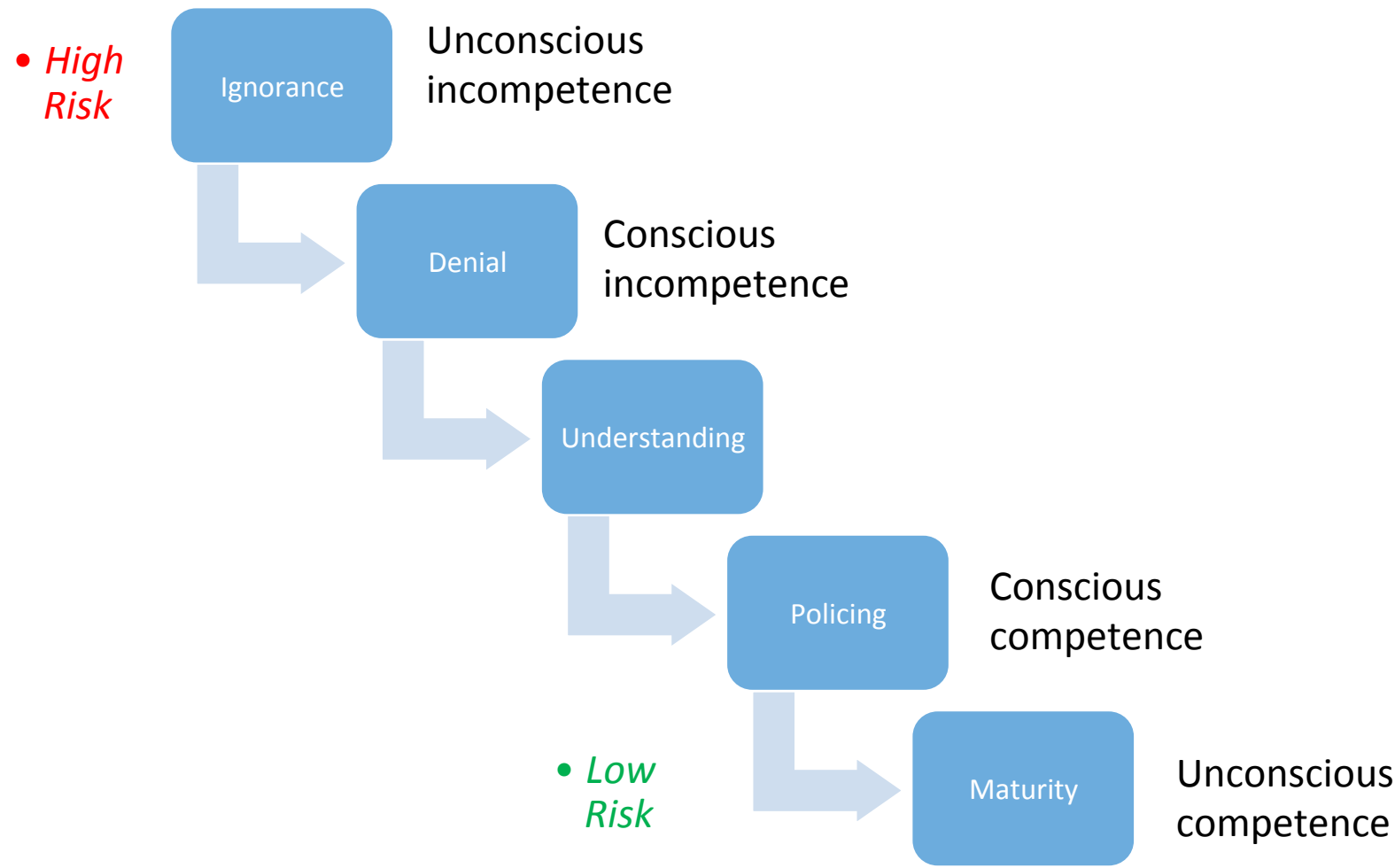
Eaton, 47, was working at the Edinburgh branch of US pharmaceutical firm Aptuit in 2009 when he came up with the scam.

If it had been successful, cancer patients who took the drug could have been harmed, the court was told.

Edinburgh Sheriff Court heard how Eaton had manipulated the results of an experiment so it was deemed successful when it had actually failed.



Background

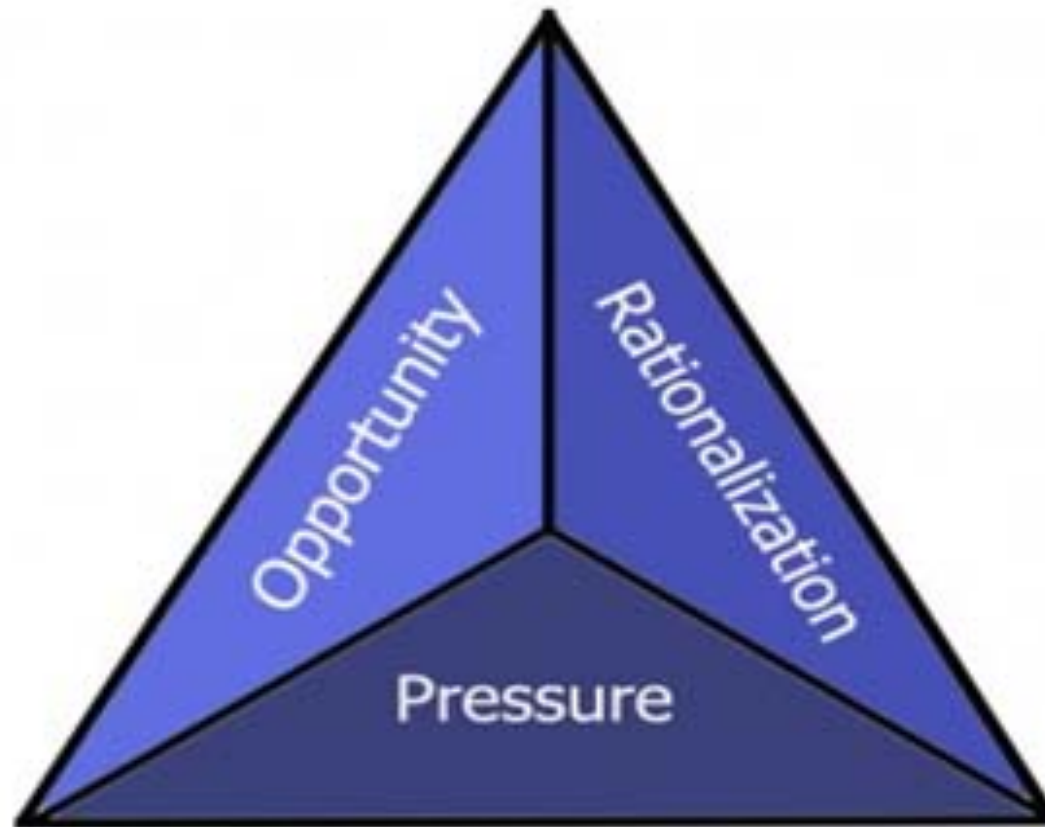




- I / He / She would not do that
- Nobody here would lie
- They are the expert – they know best
- It is just poor / bad practice

What does misconduct look like?

The Fraud Triangle



- A difficult test is passed to the department “expert”
 - Management praise their knowledge, expertise and work ethic and hold them up as the perfect example
 - Manager makes sure the team know that failures and missed deadlines cost the company money and business
 - Staff want to be worthy of the position / praise

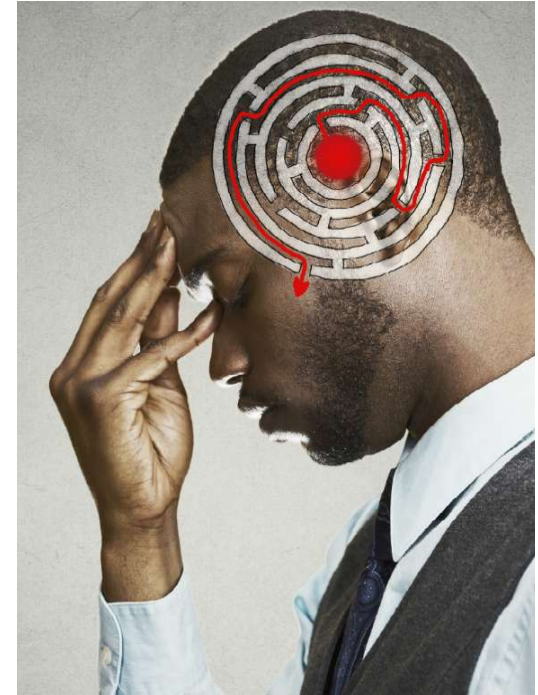


- Analyst came in early mornings / evenings / weekends
- Computer System administrator rights / training
- Checking is only for select individuals – control
- Checking is explicitly defined
- Blank records freely available



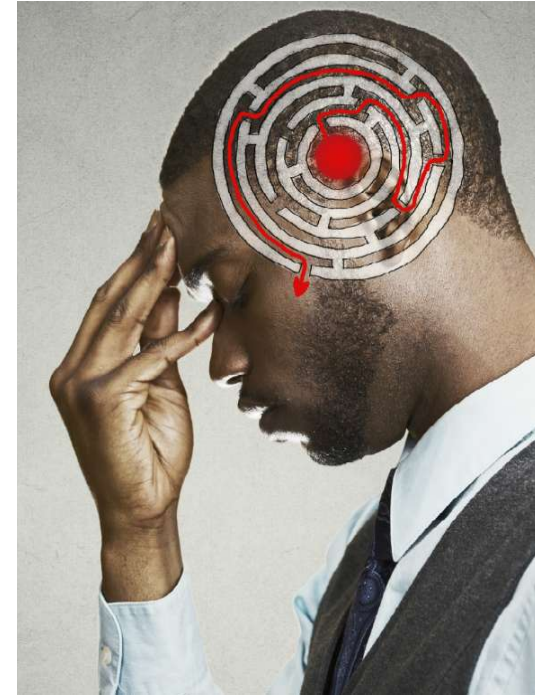
Rationalization

- Repeat work until it passes
- “Proves the test does pass – only the passed one was reported – not a lie”...
- Testing something 8 times and achieving 1 acceptable result – do you believe the results are ok?



Rationalization

- In order to make the test pass, the system was cleaned while performing the test
- The response - “Extra cleaning is not prohibited”
- Cleaning was only performed sometimes
- Cleaning was not reported
- If it is not prohibited, why hide it?



Rationalization

- The client and managers are happy
- A difficult test is fixed and the project is finished
- Clients were not happy when they were told data was fraudulent
- Management were not happy when work had to be repeated / refunded
- Test was not “fixed” for anyone following the method in future



- Everyone has different ways of working
 - This is no excuse for poor practices
 - Split shifts / overtime / no holidays can work for some but can indicate work overload
- Results and timelines were king
 - Senior Management and project management were focussed on getting results out the door
 - Setting of timelines was done at initiation without input from analytical staff and not reviewed
 - Quality was considered a drain on resources

- Asking questions was seen as an attack on professionalism
 - No focus on quality culture or continual improvement
- Reporting layout was not clear
 - All the information was available
 - QA, MHRA, clients all looked at the data and didn't notice
- Set way of checking & check the same thing
 - Checking was defined to minimise the amount of "non-billable" time
 - Checking was seen as a waste of time
 - It was predictable so hiding was easy

- Have to have a level of trust
- Operate an open and honest culture
- Keep it simple
- Hope for the best and plan for the worst



Thanks for your time

Questions?