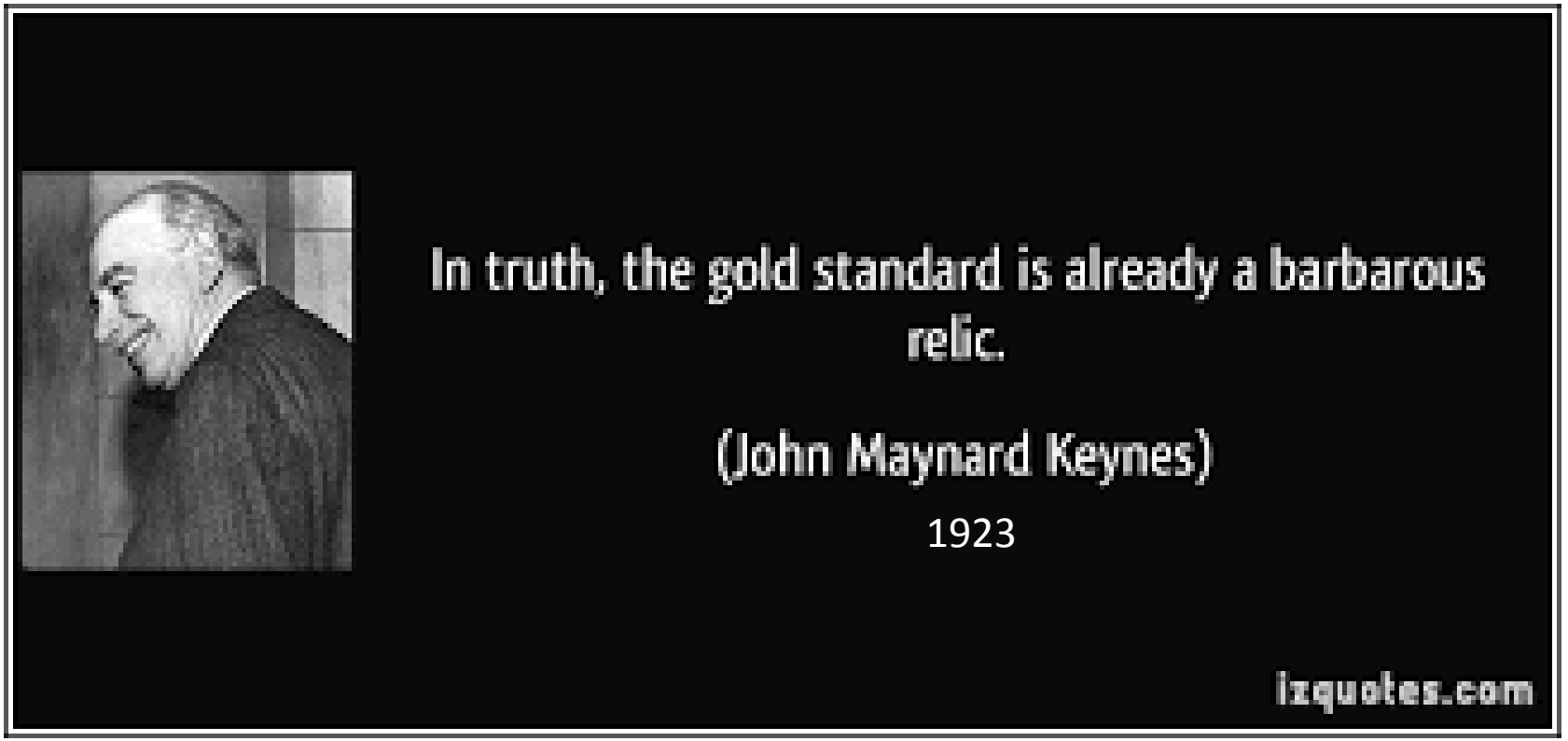
“The gold standard is already a barbarous relic”

Weighing up RCTs for depression

University of Essex

“Gold Standard” 1821



Encouraging nations to implement deflationary policies at a time when expansionary measures were needed to address rising unemployment

Abandoning the Gold Standard 1931

1929: Great Depression….. Run on the pound…. Bank foreign exchange reserves drained….1931…

"The Bank therefore feel it their duty to represent that, in their opinion, it is expedient in the national interest that they should be relieved of their obligation to sell gold under the provisions of [the Gold Standard Act 1925]."

Gold standard?

How did RCTs get pegged to gold?

- Origins of Evidence Based Medicine (EBM):
  - First RCT 1948
  - Cochrane/Sackett 1970s
- UK Policy Reforms 1989-1998
  - National Institute for Clinical Effectiveness 1998
  - Increasing link to commissioning

How did RCTs get pegged to gold?

- Evidence Based Mental Health (EBMH)
  - 1950s-1990s: monoamine hypothesis/drug research
  - Overthrowing psychoanalysis: archaic, clinical inference, political influence

Already a barbarous relic

Early critics of RCTs for EBMH e.g. Healy, Harari

- permissive influence of the pharmaceutical industry
- Problems in empiricism (Husserl, Galileo, Einstein… observer cannot be neutral)
- Loss of fidelity (Dixon & Goldman)
- Suspect observer rating scales
- Convenience samples for marketing

Barbarous relic: lay views of an RCT

…that questionnaire is just the most depressing thing you've only got, I started reading that, someone gave me that and I felt like shit… I mean, do you feel miserable, blah, blah do you want to kill yourself and… I get to about half way through it and I cannot bear to complete it. (service user)

Barbarous relic: lay views of an RCT

…how we know or how we cannot review or establish without the result in psychotherapy improvement in treatment is due to the psychotherapy itself, to the psychotherapy variables, to their interactions, with their relationship with the psychotherapist all the techniques… I'm not sure that even if the RCT is considered the gold standard for effectiveness of treatment, we can easily establish that and pin point exactly the variable the elements that make that different psychoanalytic treatment versus treatment… (Carer)

Barbarous relic: lay views of an RCT

it goes hand in hand with trust… I very, very openly, when I first went into any sort of therapy, have said very sceptical and I don't trust you and until I can trust you I can't talk to you about the things that I don't even know are there, that I do know are there, but I don't know what they are because they're so suppressed… and until I trust you I can't do that (service user)

Barbarous relic: lay views of an RCT

They keep pushing me back into a template… I said please can you listen to what I'm saying, I don't fit into that profile, can you try to offer me kind of alternative therapy… so at the moment they're not really listening to me at the moment. (Service user)

Clinging to the gold standard

Jonathan Shedler: "Selling Bad Therapy to Trauma Victims" 2017

APA trauma guidelines are *unethical* and *dangerous*

No RCT has ever shown that the sun causes sunburn, sex causes pregnancy, or food deprivation leads to starvation. We know these things because we can observe cause and effect relationships and because we understand the mechanisms of action…

Copernicus, Galileo, Darwin, Einstein, Niels Bohr, Marie Curie, Stephen Hawking. What do they have in common? None of them ever conducted an RCT.

Most scientific knowledge does not come from RCTs…

The guidelines are by researchers for researchers. The interests of patients and therapists are secondary….. 675 pages of complex minutia….537 pages of tables and forms. Therapies are designated as 'highly recommended' because of the research methods used to study them, not because patients get well…

The Great Depression guideline

NICE update….

- Jul17 – 8 week consultation opened (over August!)
- Sept17 – first consultation responses submitted
- Oct17 – joint letter to NICE requesting 2nd consultation
- Jan-Mar18 – briefing MPs; cross party letter; EDM
- Mar18 – publication postponed (last minute)
- Apr18 – meeting with NICE (SPR, BACP, UKCP etc)
- May18 – second 4 week consultation granted and launched with 1 week notice
- June18 – joint response submitted – now including BPS, Royal college of Psychiatrists and others
- July18 – meeting of NICE committee
- 3 Oct 18 – stakeholders informed of 3rd revision: ‘new evidence, shared decision making, patient choice’

Stakeholder position statement

Stakeholder position statement on the NICE guideline for depression in adults

Organisational signatories

Association for Family Therapy and Systemic Practice (AFT): Shan Tate, Chair
British Association for Counselling and Psychotherapy (BACP): Dr Andrew Reeves, Chair
British Psychoanalytic Council (BPC): Gary Fereday, CEO
British Psychological Society (BPS): Alison Clarke, Chair, Professional Practice Board
British Psychotherapy Foundation (BPF): Mike Owen, CEO
MIND: Paul Famer CBE, CEO
National Survivor User Network (NSUN): Sarah Yiannoullou, Managing Director
Psychotherapy Foundation: Dr Stephen Buller, Chair
Royal College of Psychiatrists: Professor Wendy Burn, President
Society for Psychotherapy Research UK (SPRUK): Dr Felicitas Rost, President
South London and Maudsley NHS Foundation Trust (SLAM): Dr Matthew Patrick, CEO
Tavistock and Portman NHS Foundation Trust: Paul Jenkins, CEO
Tavistock Relationships: Andrew Balfour, CEO
UK Council for Psychotherapy (UKCP): Professor Sarah Niblock, CEO

Stakeholder position statement

- Methodological not modalogical critique
- Role of stakeholder consultation
- Key asks
  - Analysis of follow-up data 1-2 years
  - Systematic review and metasynthesis of service user experience research
  - Grouping CD/TRD/complex as ‘persistent’
  - Re-categorise severity and take account of partial recovery for severe depression
  - NMA de-prioritised as supplementary only
  - Examine non-symptom outcomes

Why won't NICE abandon the Gold Standard?

- Kirsch (2008) meta-analysis
  - Antidepressants vs placebo Effect Size 0.32
  - NICE threshold of 0.5 (medium)
  - Cipriani et al (2018): ES=0.3
- Kirsch uses 'within paradigm' principles to critique the paradigm
- **This further reifies the paradigm and its principles**.

It is the very methodological weaknesses of RCTs that imbues them with the authority they hold: for to deny the reliability of a particular study, one must reach for more data, more studies, larger RCTs, in order to justify the validity of one's objections. Of course, individuals are free to suggest that RCTs themselves are incapable of arbitrating in the debate before them. But what data do they possess, what representation, what visuals, what inscriptions … does such a dissenter have at hand to convince others of the value of her or his interpretation over others'? The problem is not that individuals are incapable of or restrained from challenging RCTs, but that, unless they have the resources to defend the scientific rigour of their objections, preferably through RCT evidence, their interlocutors are equally free to remain deaf. (McGoey, 2010: p71)

Never before…

- **Strategic ignorance**: the behaviour of key players in which they are aware of the faults within the methodology and yet in order to make their case and appear authoritative on the matter, they must also appear ignorant of those very faults.
- **Paradox of EBMH**: “never before have the inadequacies of RCTs been so apparent to so many. Yet, equally, never before have those in positions of authority – from regulators, to NICE policy-makers, to doctors – relied so extensively on RCT evidence.” (McGoey, 2010)

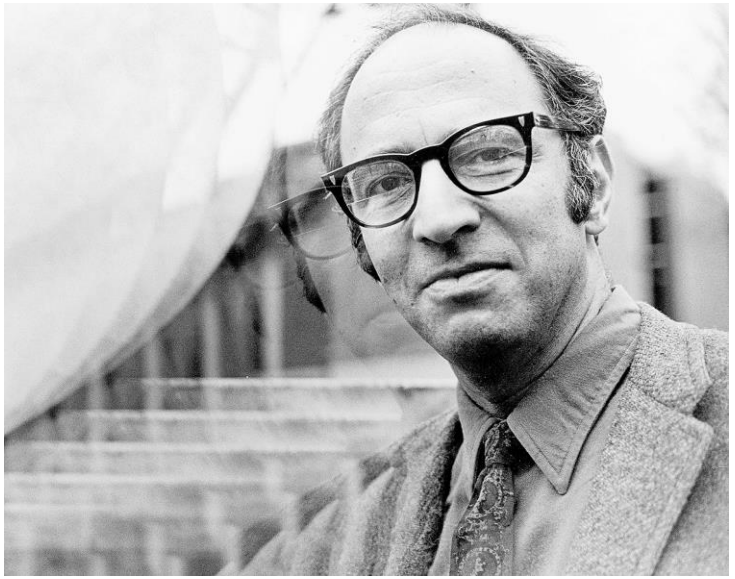
Public and Patient Involvement

- ‘New’ EBM – ‘moving beyond its modernist roots’ (Wieringa et al, 2017)
- Recognising limits of scientific evidence?
- Taking into account patient views and individual context?
- But is PPI often largely tokenistic?

Normal Science

Though they may begin to lose faith and then to consider alternatives, they do not renounce the paradigm that has led them into crisis.

Thomas Kuhn
"The Structure of
Scientific Revolutions"



Time to abandon the gold standard

- Paradigm shift?
- Need for a more democratic and less technocratic approach to PPI in which populations are ‘critically involved’ and engaged in decision making (Madden & Speed, 2017)
- A paradigm in which valued knowledge comes from outside positions of power, policy and commissioning

A Fiat System

(currency value not fixed to a commodity – fluctuates dynamically)

- Up to date review of client experience data including experience of treatments and experience of depression - including under-represented groups in relevant social and economic contexts
- Employ methodologically sound qualitative review approaches (e.g. metaethnography, metasummary etc)
- Develop more democratic approaches to involving service users and carers in service development, commissioning, research and guideline development
- Enable these dynamic forms of knowledge to genuinely influence recommendations
- How do we ‘take back’ our guideline development process?... (are NICE and Cochrane now too corrupted…?)

McPherson, SJ., Rost, F., Sidhu, S. and Dennis, M., (2018). Non-strategic ignorance: Considering the potential for a paradigm shift in evidence-based mental health. Health, 136345931878572-136345931878572

McPherson, SJ., Rost, F., Town, J. and Abbass, A., (2018). Epistemological flaws in NICE review methodology and its impact on recommendations for psychodynamic psychotherapies for complex and persistent depression. Psychoanalytic Psychotherapy. 32 (2), 102-121

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