The Struggle for Epistemic Superiority in Medical Research

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Introduction

We are going to illustrate the value of regime analysis for the description of conflicts in private and public medical research.

Contents

1. Science & Public Decision Making
2. Regime Analysis
3. Epistemic Regimes in Medical Research

Science & Public Decision Making

Public Decision Making: Ideal

Decision making on the individual level: Approach of maximizing expected utilities: Pick a_i with:

$$u(a_i) \cdot Pr(a_i) = max(u(a_1) \cdot Pr(a_1), \ldots, u(a_n) \cdot Pr(a_n))$$

Collective level: Maximize that of the group: $max(max(\ldots), \ldots, max(\ldots))$

Two ingredients:

- u ... utilities
- Pr ... probabilistic information/knowledge

Due to the value-neutrality postulate for science it is assumed that the tasks for public decision making should be strictly separated:

- u is provided by politics etc.
- Pr is provided by science

Public Decision Making: Problem

The account is prone to several problems:

- Feedback-loops: Normative statements within science politics retroact on scientists' core domain, the context of justification.

  E.g.: Restrictions of data gathering due to ethical reasons.

- The value-ladeness postulate: Even if scientists' role is considered only within the context of justification, they need to make value judgements in order to assess and justify hypotheses and theories.

  E.g.: $Pr(a_i) = r \quad \Rightarrow \quad Acc(a_i)/Ref(a_i)$

- Shift of epistemic/knowledge regimes: De facto public decision making transforms from applications of a separated model to an integrated model of knowledge and values.

  E.g.: # EU regulatory agencies

Public Decision Making: Ad Problem

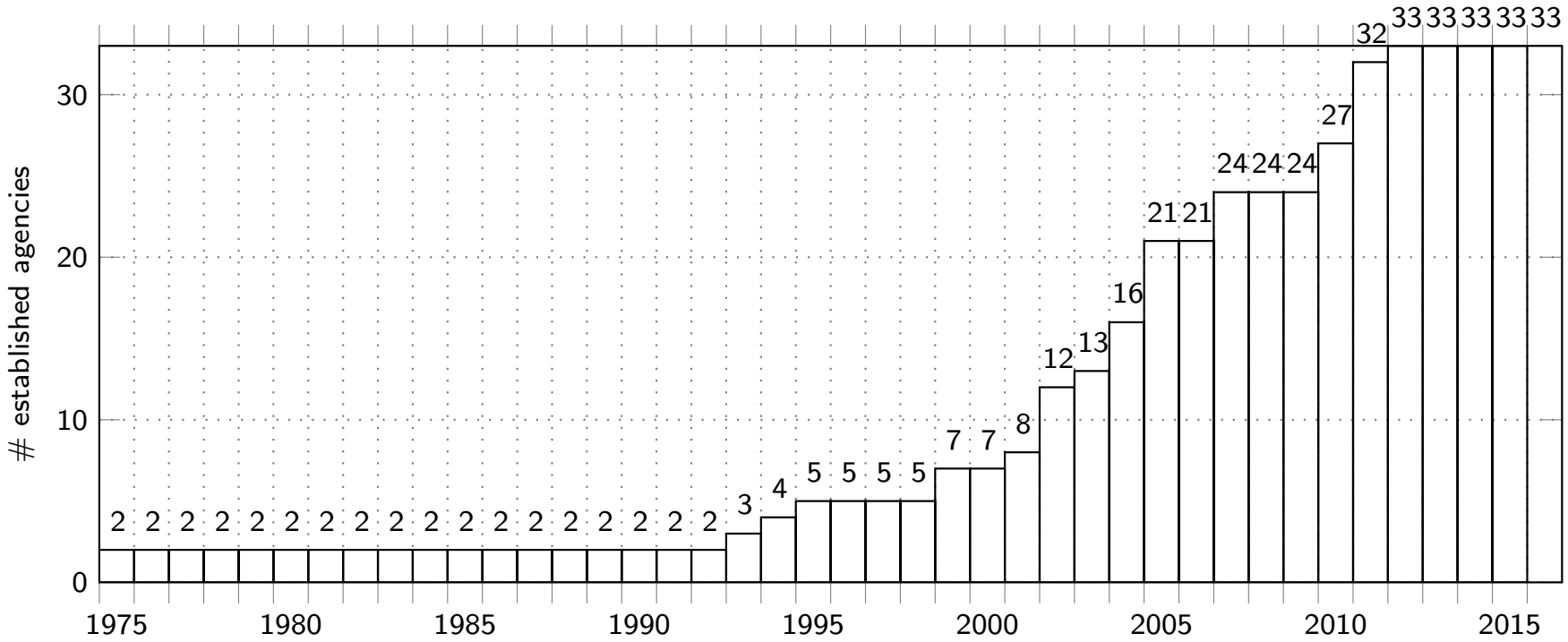


Figure: Number of decentralised agencies of the EU established between 1975 and 2016, starting with the *European Centre for the Development of Vocational Training* (1975) and ending with the *European Agency for the operational management of large-scale IT Systems in the area of freedom, security and justice* (2012). Source: `https://europa.eu/european-union/about-eu/agencies_en`, accessed 2016-08-01;

Regime Analysis

Characterisation

"Regimes can be defined as sets of implicit or explicit principles, norms, rules, and decision-making procedures around which actors' expectations converge in a given area of international relations." (Krasner 1982, p.186)

Definition (Regime)

A regime is considered to be a set of normative statements about a specific issue-area on which agents concerned with the issues of the area agree.

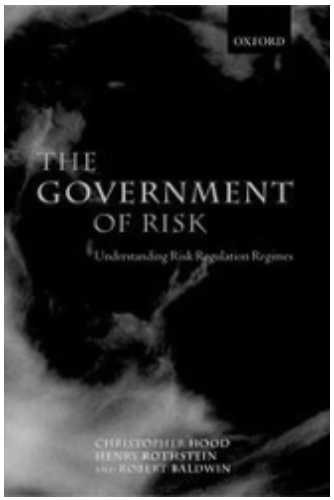
E.g.: WTO: Rules regulating trading of about 160 member states.

Specification & Purpose

Definition (Epistemic Regime)

Regime with normative statements regulating:

- what counts as acceptable knowledge and what not,
- knowledge assessment and distribution of epistemic authority,
- crediting, but also blaming of epistemic misdemeanour.



"[Regime analysis is a] 'middle way' approach to institutional analysis. It is designed to capture the variety that is left out of macroscopic [...] approaches [...]. At the same time, it is designed to achieve a broader and more general perspective than is yielded by microscopic approaches." (Hood, Rothstein, and Baldwin 2001, p.14)

Comparison with PoS

There are also other frameworks relevant for connecting science studies and philosophy of science:

- Ludwik Flecks's thought collectives
- Thomas Kuhn's paradigms
- Imre Lakatos' scientific research programmes

Regime analysis allows embedding these, but is broader in an important sense: It

- relates directly science and politics, and it
- allows to relate science and economy.

This supports our purpose, since the upper frameworks are mainly intended to relate scientific paradigms/research programmes.

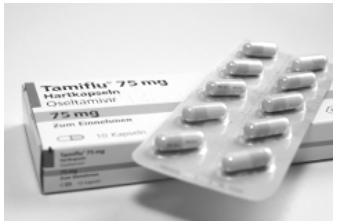
Whereas we are interested in relating scientific and economic programmes.

Epistemic Regimes in Medical Research

ER in Medical Research

Case study: Oseltamivir (Tamiflu®)

- Tamiflu is an antiviral medication used for treatment and prophylaxis of influenza type A and type B.
- Smith et al. (2002), 2207–2212
- Gubareva (2004), 199–203



Detailed timeline: `www.bmj.com/tamiflu`, received August 26, 2016

- 1997: First observations of human cases of avian influenza H5N1, Hong Kong
- 1999: WHO publishes its first pandemic influenza plan in collaboration with the European Scientific Working Group on Influenza (ESWI), a group funded entirely by Roche and other influenza drug manufacturers
- 1999: FDA issued warning letter to Roche
- 2003: Meta study by Kaiser et al

ER in Medical Research

- 2009: Kejii Hayashi critizises Kaiser et al (2003): 8/10 un-, 2/10 published
- 2009: Roche denied access ⇒ Cochrane Collaboration
- 2009: Roche offered data under the condition that the Cochrane Collaboration signs legal agreement promising confidentiality about data and agreement (Cochrane declined offer ⇒ excluded data contained in Kaiser et al (2003)).
- 2009: Roche promised to release so called 'full study reports' ⇒ incomplete
- 2011: EMA changes its policy on access to documents and provided the Cochrane group with 25.453 pages of clinical study reports for 19 trials.
- 2012: BMJ changes publication policy: Only registered clinical studies are published (also authors must agree to provide detailed patient level data when requested); Open Data campaign (`http://www.bmj.com/open-data/`, Juli 7, 2015)
- 2011/12: CC change in methodology – away from journal articles and towards unaltered clinical data

ER in Medical Research

2014: Cochrane report on Tamiflu case:

- one day reduction to first alleviation of influenza symptoms
- no decrease in risk of hospitalization
- no evidence it can stop the spread of the virus
- evidence it interferes with natural influenza antibody production

The Tamiflu case illustrates interesting shifts between and within epistemic regimes.

ER in Medical Research

Roche used three strategies to maintain epistemic authority:

- denied access to research data
- exerted legal pressure on independent researchers
- initially provided incomplete data

Reactions from scientific community and professional institutions:

- changes in policies on various levels (publication standards, open data)
- changes in methodology (meta-analysis with unaltered data)

Financial damages:

- USA ($ 1,3bn), GB (£ 424m), Germany (€ 500m) (Bartens, 2014)
- Worldwide € 10bn (Bartens, 2014), $ 20bn (Abasi, 2014)

Conclusion

- Regime analysis provides valuable theoretical framework for the description of antagonizing value spheres and their struggle for epistemic superiority
- Allows to bridge a gap between science studies in philosophy of science as well as research ethics

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