When science and regulatory action meet reality: barriers and critical success factors to managing risk... ...& the salience of trust

PATRICK BROWN – ASSISTANT PROFESSOR, DEPARTMENT OF SOCIOLOGY/
CENTRE FOR SOCIAL SCIENCE AND GLOBAL HEALTH

UNIVERSITY OF AMSTERDAM

DEPUTY EDITOR, *HEALTH, RISK & SOCIETY*

The problem (at least as I understand it…)

- 'At the European Medicines Agency, we no longer use terms like "ensuring drug safety" in public communications, instead [we refer to] striving to ensure a **"positive benefit–risk profile**" — a phrase implying the concept of tolerability of risk' (Eichler et al. 2009: 1380)

- Two key questions/problems of **risk management** in this area
  - How to harness regulators' knowledge regarding (uncertain) benefits and (uncertain) dangers in order to optimise the informing of medicines-users' practices? Knowledge←→practice
  - How to collect experiences of medicine-users (via pharmacovigilence frameworks) and translate these into regulatory knowledge?

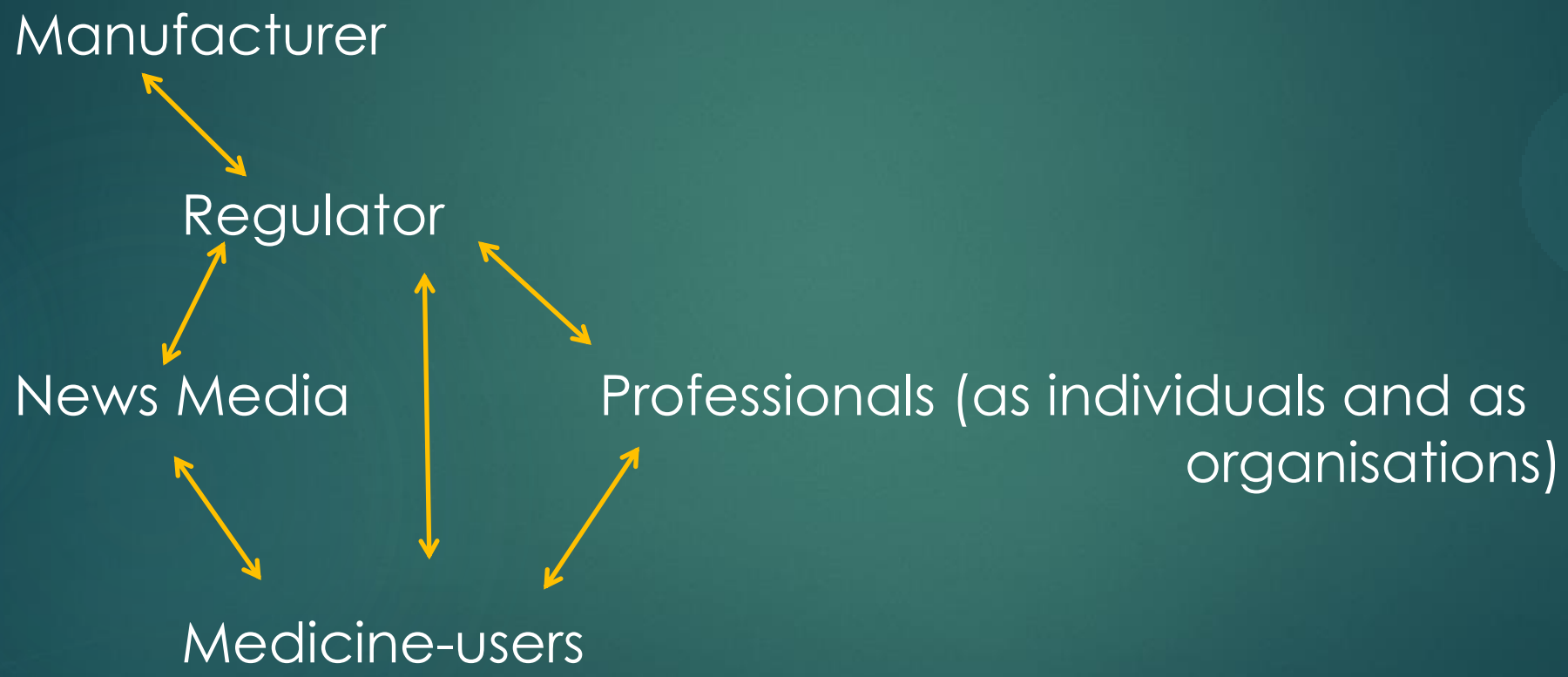
Where I am coming at this from…

- My research mainly deals with concerns of policy & administration and medical sociology; it is largely qualitative in approach

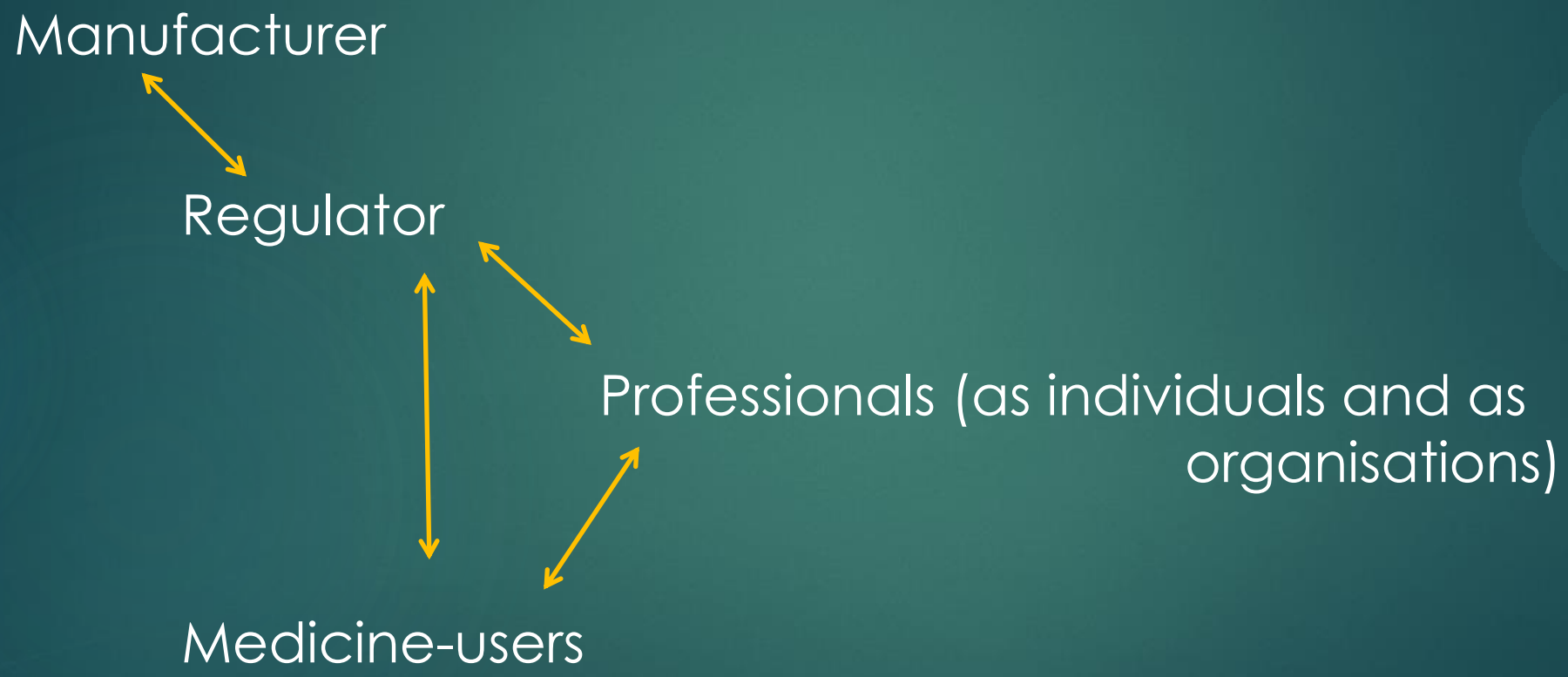
- Some of my main studies/questions informing what I say here:
  - How do **regulator**y committees arrive at decisions amidst uncertainty?
  - How do healthcare **professionals** experience working amidst clinical governance – what drives cooperation or resistance?
  - How do **professionals** and **service-users** deal with uncertainty in contexts of psychosis care? What is the role of trust in such contexts?
  - How do **patients** with advanced-cancer diagnoses understand and experience their participation in drugs trials?

E·S·R·C
ECONOMIC & SOCIAL RESEARCH COUNCIL

Chains of knowledge across medicine regulation contexts



Chains of knowledge across medicine regulation contexts



Overview

- Barriers, limitations and possibilities for managing risk – amongst:
  - Medicine-users – how do they make sense of risk?
  - Professionals – how do they work re: guidelines & protocols?
  - Regulatory decision-makers – how do they reach decisions amidst complexity and uncertainty?
- The possibilities of creating chains of communication re: problematic experiences with medicines
  - Barriers to such communication
  - Trust as a vital facilitator of communication and of 'learning organisations'

Risk management is ***one*** means of handling uncertainty

- **NB** it is not the only way, other approaches are drawn upon because:
  - Risk knowledge has limited utility in everyday life
  - Risk knowledge can seem abstract and can *feel* less concrete than other approaches
- Understandings of risk are importantly mediated by trust; e.g. - in various institutions

- We need to be attentive to heterogeneity across medicine-users and how they deal with uncertainty

Medicine-users may not find *risk knowledge* useful in everyday life

- Ecological prevention paradox (Heyman, 2010)
  - Risk knowledge is far more useful for making decisions concerning populations or large groups than for individuals
  - Risk helps us frame uncertainty but does not solve it! Hence other approaches – eg hope
    - Thijs (aged in his 60s): *[The doctor] named, I think, a half-per cent [likelihood of a successful outcome], and that is of course very slim, but yeah, you want to hold on to that tightly… Such a remark gives hope!* (Brown & de Graaf 2013:551)

- Bio-medical/pharmacological understandings of risks and potential benefits are only one part of a rich social picture of medicines-use
  - Biographical and social conditions shape ways of *seeing* and *knowing* medicines and attributing to them particular 'cultural-symbolic logics' (van der Geest et al. 1996: 155; Conrad, 1985; Gardner and Dew, 2011)
  - Eg Anti-psychotics impact via stigma (reputational risk), side-effects (risks to social position) but may also be considered positively in relation to 'control' and other goals

Medicine-users may find risk knowledge rather abstract; it can *feel* less 'concrete'

- Other priorities and everyday routines can diminish the salience of risk information:
  - Bissell, Ward & Noyce (2001:15) found that the majority of participants in their study (including 94 interviews & 7 focus groups with pharmacy store customers) took the safety of OTC medicines purchased from pharmacies for granted. Moreover:

    If I had to be thinking about those things all day, I'm not gonna have time to think about my work, or my family. There's enough things to be worrying about besides them. You take them to get better anyway. It's obvious isn't it? (I 63)"
- First-hand, *embodied* knowledge of medicines-use may be far more concrete for users than more abstract information on risk
  - Robert: *So the psychiatrist is away on holiday so we get another psychiatrist in to give his opinion, one that I've had before when I was in [in-patient ward] and he's not happy with what I want to do. He's not happy with the haloperidol. He's not happy with increasing the depixol, he's not happy with putting in a benzodiazapine – just to take the edge off it.* (Unpublished data)

Practices towards risk are importantly shaped by medicine-users' **trust**

- Much research suggests trust shapes how we handle risks
  - Eva (70s): *Well, I had so much confidence in [the doctor], I thought he was a very nice man with whom you could have an honest conversation. And I didn't know anything about it [the trial medicine], so I left it up to the doctor.*
  - Daughter: *He said, 'I would appreciate it a lot if you would want to participate, but if you don't want to that is okay as well'. But, he had been to America, he goes to several conferences. You feel that he …* [interrupted]
  - Eva: *He is a very compassionate doctor. You can sense that right away, I can't explain it.*
- Relationship between trust and risk is further mediated by familiarity – trust more likely to be drawn upon as a heuristic tool when we are confronted with less familiar technologies (Earle et al. 2007);
- The more vulnerable we are, the more we are likely to *disregard* risk and uncertainty (Brown 2009); trust as a 'forced option' (Barbalet 2009)
  - Marcel (70s): What 'turned the scale' was, well, I have nothing to lose (Brown et al 2015:316-7)
  - See also: Conrad (1985) re epilepsy medicines; Bissell et al. (2001:20) re terfenadine;

Medicine-users are highly heterogenous – eg proactive, passive & no risk approaches

- Varying trust in a range of institutional and/or relational sources may shape how we perceive and apply risk knowledge
- Different illness experiences → levels of vulnerability → shape 'will to trust' in prescribers and/or to hope in medicines
- Different past experiences, social backgrounds, age and educational levels may shape the nature and extent of our trust, our attitudes towards scientific knowledge and managing risks
- Different approaches to risk (Ryan, 2000) – active risk management, passive risk awareness, 'no risk' approach
- But Himmelstein and colleagues (2011) found no significant relationship between various measures regarding parents social background and a) risk awareness or b) trust in MHRA

Professionals play a vital but complex role in the management of medicine risks…

- Prescribers:
  - GP partner: *When what we used to do [with regard to warfarin prescribing] is look at someone and think, oh, let's try… let's do this or let's do that. But when you've got software that's driven properly, you realise how you got away with it by the skin of your teeth. And we can do it properly now, people are seen a lot more often, the controls are tighter, a lot of people were on the wrong range – when these things are driven by protocols you get it done properly. Its all more accurate, safer – you're a little less likely to end up in court* (Brown 2008: 216)
- Other 'allied' health professionals…
  - Robert: *I can phone her [nurse/key-worker] up and tell her how I'm feeling and what's going on and I can say I want to take haloperidol because I'm … and she'll say "don't be daft…"* (Brown & Calnan 2012: 43)
- Pharmacists:
  - "[pharmacy] staff spoke of intervention in medicine sales [through giving advice] as an often contentious undertaking, in which the meaning and purpose of the interventions was open to potential challenge by consumers" (Hibbert et al. 2002: 58; see also Stevenson et al. 2008)

Professionals' interactions with patients with regard to managing medicines risk

- Cox & colleagues (2007: 777): "A total of 479 patients participated (75.7% of those approached). Thirty-nine per cent of these patients wanted their GPs to share the decision, 45% wanted the GP to be the main (28%) or only (17%) decision maker regarding their care, and 16% wanted to be the main (14%) or only (2%) decision maker themselves".
- Makoul and colleagues (1995: 1241) studied "perceived and actual communication in 271 GP-patient interactions". Some key findings:
  - "Patients were extremely passive, rarely offering their opinion or initiating discussion about…treatment"
  - "[Authors] suggest that improving patients' decision-making competencies may require more discussion of benefits and risks, as well as discussion of patients' opinions about the prescribed medications and their abilities to follow through with the treatment plans"
  - "Physicians tended to overestimate the extent to which they discussed patients' ability to follow the treatment plan, elicited patients' opinion about the prescribed medication and discussed risks of the medication"
  - "And, 24.3 % of the patients left the consultation with an "illusion of competence', a belief that important topics had been discussed when, in fact, they had not been mentioned at all".

Professionals' understanding of and cooperation with regulatory guidance

- *GP Partner:* But then I think these kind of protocols are particularly suited to general practice because so many of the patients we see – especially with chronic illnesses, are incredibly predictable, so they are very amenable to protocols. Whereas in [emergency medicine] you get a real hotchpotch of all sorts of issues which are all a lot more atypical. And in psychiatry… there are many more soft features to psychiatry which wouldn't work so well I don't think.
- *General medical SHO:* I think doctors are quite difficult people, and they like to manage themselves. And as a profession we're not very good at letting anyone else tell us what to do. But I think, NICE, we love; most doctors love it.

  Interviewer: And why's that?

  General medical SHO: I think it's because the clinicians tend to agree with it. And it comes up with really good, well researched, good evidence for why you should implement a certain thing. And it's also reasonably flexible in that it recognises that not all trusts can meet all the standards due to whatever. (all quotes on this slide from Brown 2008)

- NB Spyridonidis & Calnan (2011) – role of local organisational, managerial & identity factors

Regulators also struggle with uncertainty…

- Uncertainty is tackled by modelling probable future outcomes
  - But these models are highly complex and riven with both explicit and implicit uncertainties.
  - Any one aspect can offer up 'vast fractal complexity if probed deep enough' (Downer 2010: 85).
- Dealing with complexity and uncertainty is made more problematic by market forces and political pressures:
  - Committee member: *[the manufacturer's] job is to try and put their best foot forward in whatever model they have produced, to make their drug look as cost effective as possible and, as long as you understand that and…then just get on with it…* (Brown et al., In press)
  - Committee member: *I think some of the companies produce much better open and transparent models than others.* (Brown et al. forthcoming)
  - Time pressures on regulatory decisions (Davis and Abraham 2011)

The story so far: Chains of more questionning or more trusting relations influencing one another…

Manufacturers ← → regulators
Regulators ← → professionals
Professionals ← → medicines-users
Regulators← → medicines-users
Medicines-users ← → medicines

- Regulator needs to ensure/build its legitimacy and trust
- Regulator needs to engage other links in the chain
- Problems of uncertainty in regulation may be partially attended to via other forms of **knowledge aggregation**…

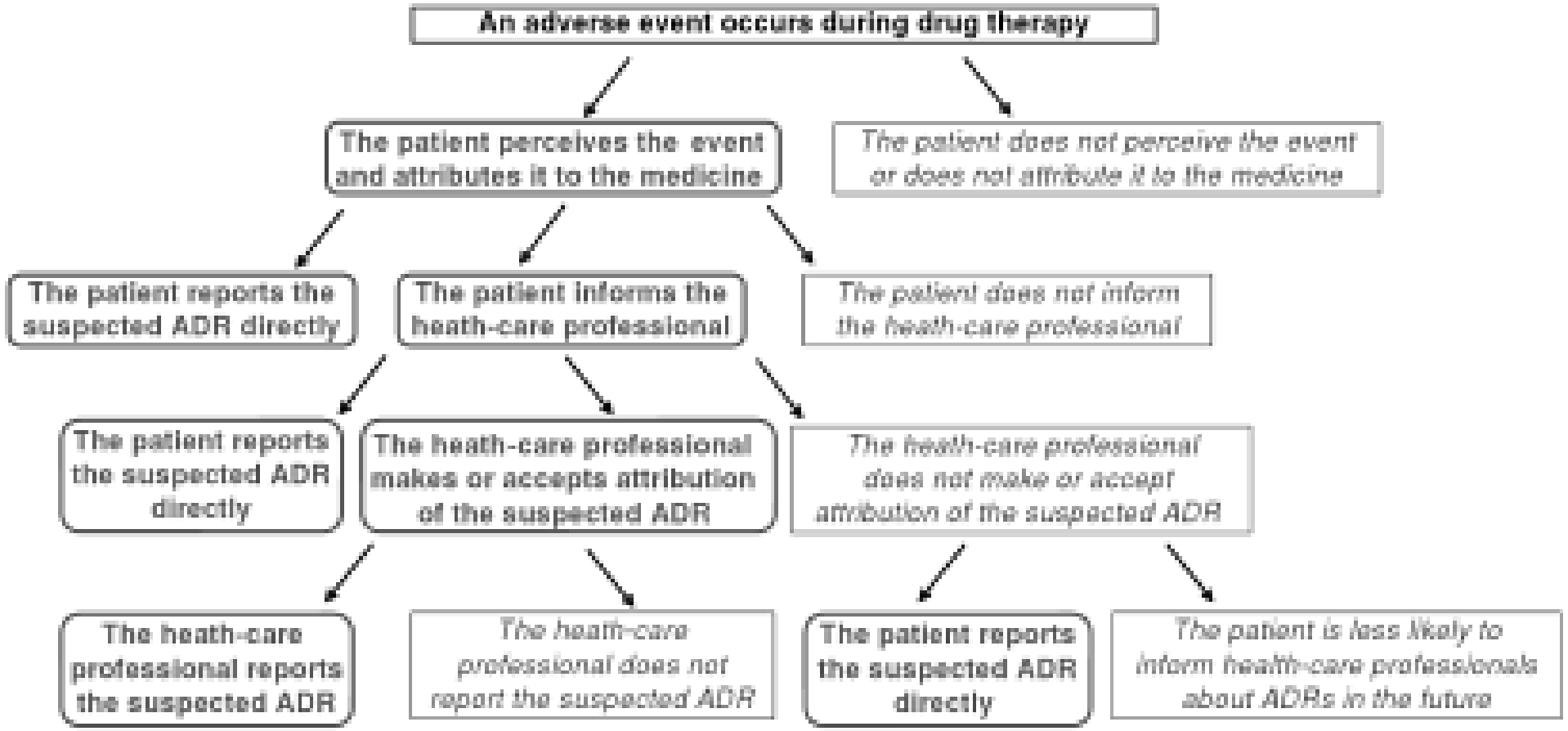


Figure 11.1 Pathways for reporting adverse drug reactions (ADRs)
italics, rectangular boxes = negative outcomes
roman, rounded boxes = positive outcomes

Source: 'Adverse Drug Reactions: Social Considerations' - Britten 2012:578 - in: *Stephens' Detection and Evaluation of Adverse Drug Reactions*

Understanding breaks in the ADR reporting chain 1

- Medicine-users do not attribute their 'harmful' or 'unpleasant' (Britten 2012: 574) reaction to the medicine
- Medicine-users see no need/responsibility to report experience or are unaware of possibility for doing so
- Medicine-users are keen to mention something to their prescriber or pharmacist but are not given the opportunity

- How to create an atmosphere of risk awareness without undermining trust? (Eichler et al. 2009)
- Possibilities for cultivating active 'critical trust'? (Walls et al. 2004)

Understanding breaks in the ADR reporting chain 2

- Patient does say something but is not taken seriously or the incident is briefly mentioned but gets 'lost' amidst the fleeting encounter with the pharmacist or prescriber
- Ways of standardising ADR protocols within encounters to ensure these are not lost? But cadence…
- But problems of lack of ownership of protocols/guidelines…
- Need for protocol/guideline development which is local & professional-led – thus enhancing legitimacy (Brown & Calnan 2011)
- ADR system highly 'abstract' (Britten, 2012); professionals and patients need 'access points' in order to develop trust & see a difference

Understanding breaks in the ADR reporting/reception chain 3

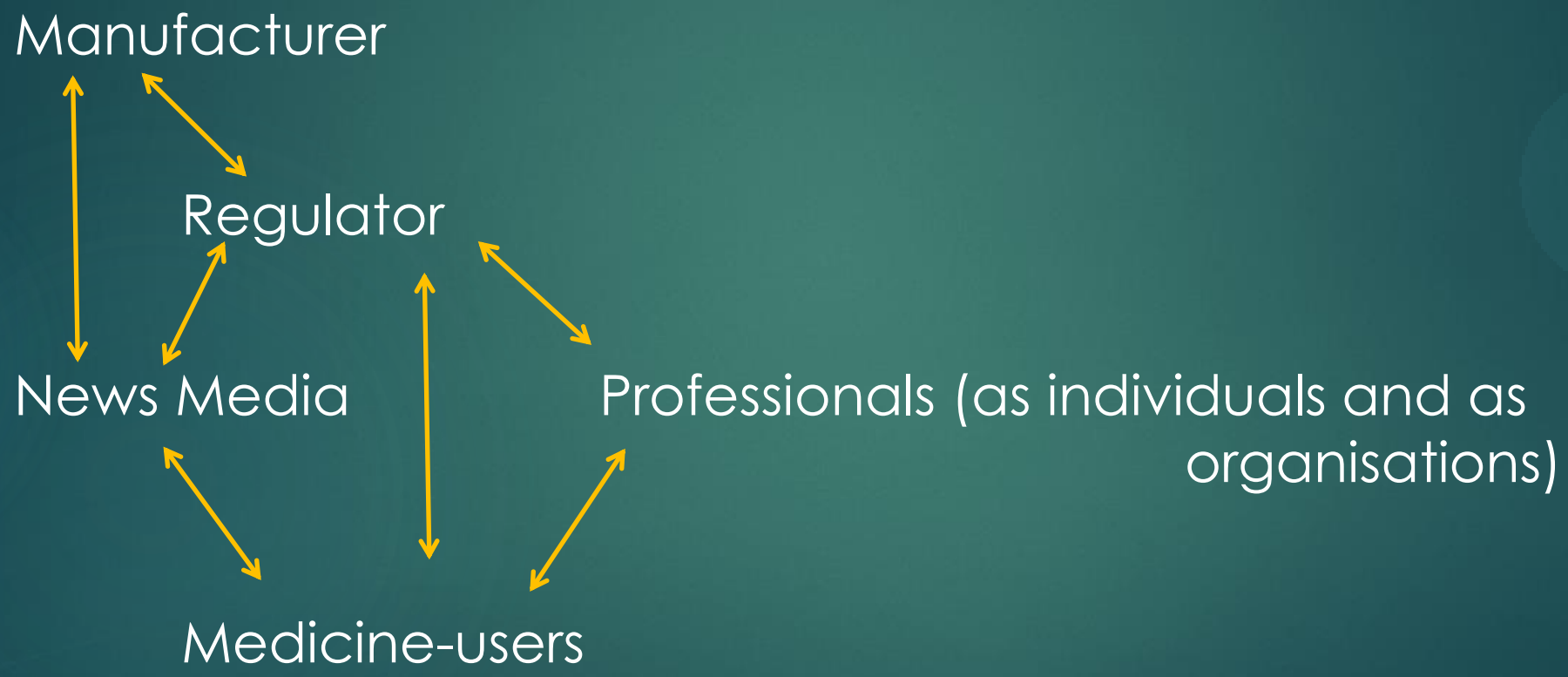
- How to deal with incidental-anecdotal report (qualitative) narratives and to **integrate** them with larger quantitative data sets at regulatory level?

- Difficulties in combining different forms of information & developing norms/standards of how to do this…and then how to act on this?

Concluding comments

- Two main processes pertaining to risk management: knowledge **implementation** and **aggregation**
- Both these processes require the effective flow of legitimate knowledge along chains of actors – i.e. *within* 'organisations' (in the looser sense of the term)
- Knowledge-intensive organisations function much more effectively when trust facilitates communication (Adler, 2001)
- The type of trust relation which exists within one relationship has knock-on effects for trust relations elsewhere in the chain
- Regulators need to find ways of influencing different links/stakeholders
- NB – different forms of trust – more active critical forms of trust may be more useful within regulatory contexts

Chains of knowledge across medicines regulation contexts – facilated by trust?



References

- Adler, P. (2001) Market, hierarchy and trust: the knowledge economy and the future of capitalism. *Organization Science* 12(2): 215-234.
- Barbalet, J. (2009) A characterisation of trust, and its consequences. *Theory and Society* 38(4): 367–82.
- Bissell, P., Ward, P. & Noyce, P. (2001) The dependent consumer: reflections on accounts of the risks of non-prescribed medicines. *Health* 5(1):5-30.
- Britten, N. (2012) Adverse Drug Reactions: Social Considerations, in: Talbot, J. & Aronson, J.(eds.) *Stephens' Detection and Evaluation of Adverse Drug Reactions*
- Brown, P. (2008) *The Impact of Clinical Governance and the Audit Culture on Patient Trust: The Opportunity Cost of Instrumental Rationality*. PhD Thesis, University of Kent, Canterbury.
- Brown, P. (2009) The phenomenology of trust: a Schutzian analysis of the social construction of knowledge by gynae-oncology patients. *Health, Risk and Society* 11(5): 391–407.
- Brown, P. and Calnan, M. (2011) The civilizing process of trust: developing quality mechanisms which are local, professional-led and thus legitimate. *Social Policy & Administration* 45(1): 19–34.
- Brown, P. & Calnan, M. (2012) *Trusting on the Edge: managing uncertainty and vulnerability in the midst of serious mental health problems*. Bristol: Policy Press.
- Brown, P. & de Graaf, S. (2013) Considering a future which might not exist: the construction of time and expectations amidst advanced-stage cancer. *Health, Risk & Society* 15(6):543-560.
- Brown, P., de Graaf, S., Hillen, M., Smets, E., Laarhoven, H.W. (2015) The interweaving of pharmaceutical and medical expectations as dynamics of micro-pharmaceuticalisation: advanced-stage cancer patients' hope in medicines alongside trust in professionals. *Social Science & Medicine* 131: 313-21.

References cont…

- Brown, P., Hashem, F. and Calnan, M. (In press) Trust, regulatory processes and NICE decision-making: Appraising cost-effectiveness models through appraising people and systems. *Social Studies of Science*
- Conrad, P. (1985) The meaning of medications: another look at compliance. *Social Science & Medicine* 20(1):29-37.
- Cox, K., Britten, N., Hooper, R. and White, P. (2007) Patients involvement in decisions about medicines: GP's perceptions of their preferences. *British Journal of General Practice* 57:777-84.
- Davis, C. and Abraham, J. (2011) The socio-political roots of pharmaceutical uncertainty in the evaluation of 'innovative' diabetes drugs in the European Union and the US. *Social Science & Medicine* 72(9):1574-1581.
- Downer J (2010) Trust and technology: the social foundations of aviation regulation. *British Journal of Sociology* 61(1): 83-106.
- Earle, T., Siegrist, M. & Gutscher, H. (2007) 'Trust, risk perception and the TCC model of cooperation', in: M. Siegrist, T. Earle & H. Gutscher (eds.) *Trust in Cooperative Risk Management*. London: Earthscan, pp. 1-50.
- Eichler, H-G., Abadie, E., Raine, J., Salmonsson, T. (2009) Safe drugs and the cost of good intentions. *New England Journal of Medicine*
- Gardner, J. and Dew, K. (2011) The Eltroxin controversy: risk and how actors construct their world. *Health, Risk & Society* 13(5): 397-411

References cont…

- Hibbert, D., Bissell, P. and Ward, P. (2002) Consumerism and professional work in the community pharmacy. *Sociology of Health & Illness* 24(1):46-65.
- Himmelstein, M., Miron-Shatz, T., Hanoch, Y. (2011) Over-the-counter cough and cold medicines for children: A comparison of UK and US parents' parental usage, perception and trust in governmental health organization. *Health, Risk & Society* 13(5):451-68.
- Makoul, G., Arntson, P. and Schofield, T. (1995) Health promotion in primary care: Physician-patient communication and decision making about prescription medications. *Social Science & Medicine* 41(9):1241-45.
- Ryan, T. (2000) Exploring the risk management strategies of mental health service users. *Health, Risk & Society* 2(3): 267-82.
- Spyridonidis, D. & Calnan, M. (2011) Opening the black box: A study of the process of NICE guidelines implementation. *Health Policy* 102(2):117-125.
- Stevenson, F., Leontowitsch, M., Duggan, C. (2008) Over-the-counter medicines: professional expertise and consumer discourses. *Sociology of Health & Illness* 30(6):913-28.
- van der Geest, S., Whyte, S. and Hardon, A. (1996) The anthropology of pharmaceuticals: a biographical approach. *Annual Review of Anthropology* 25:153-178
- Walls J, Pidgeon N, Weyman A and Horlick-Jones T (2004) Critical trust: understanding lay perceptions of health and safety risk regulation. *Health, Risk & Society* 6(2): 133-50.