



# Enablers and barriers to measuring impact – patient and healthcare professional engagement

3.1 BREAKOUT SESSION – PART OF:

**MEASURING THE IMPACT OF PHARMACOVIGILANCE ACTIVITIES**

# Starting points for this session

- ▶ 09.00 Defining engagement – awareness and perception of public health measures  
Patrick Brown - University of Amsterdam, Netherlands
  - ▶ **Do we know what we are measuring? Is there (broad) agreement around concepts?**
- ▶ 09.20 ISPE paper “Evaluating the Effectiveness of Additional Risk Minimisation Measures via Surveys in Europe: Challenges and Recommendations”  
Rachel Sobel - Pfizer Inc.; ISPE BRACE SIG  
Terri Madison - Mapi; ISPE BRACE SIG
  - ▶ **Do we have the data to understand engagement and do these have useful measures?**
- ▶ 09.40 Patient reporting in EudraVigilance – a measure of patient engagement?  
Marin Banovac - European Medicines Agency, EU
  - ▶ **How much do available measures tell us much about engagement?**
- ▶ As a basis for wider and deeper discussions...



# 'Defining engagement - awareness and perception of public health measures'

- ▶ What is engagement?
- ▶ Who is being engaged – and does this matter for our understandings of *engagement*?
- ▶ Can we measure engagement? And if not, what are the most useful proxies? And what are the problems/dangers with such proxies?

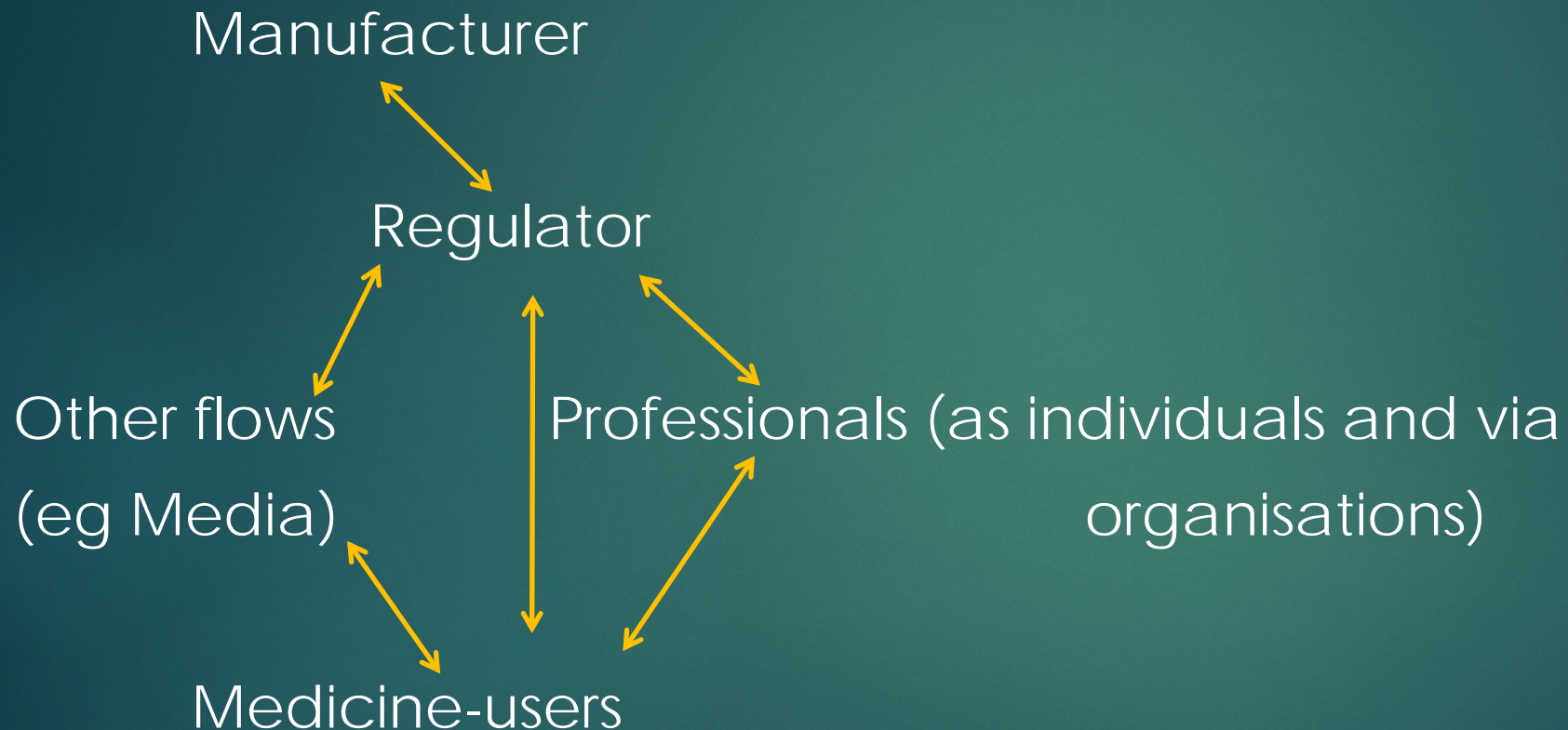


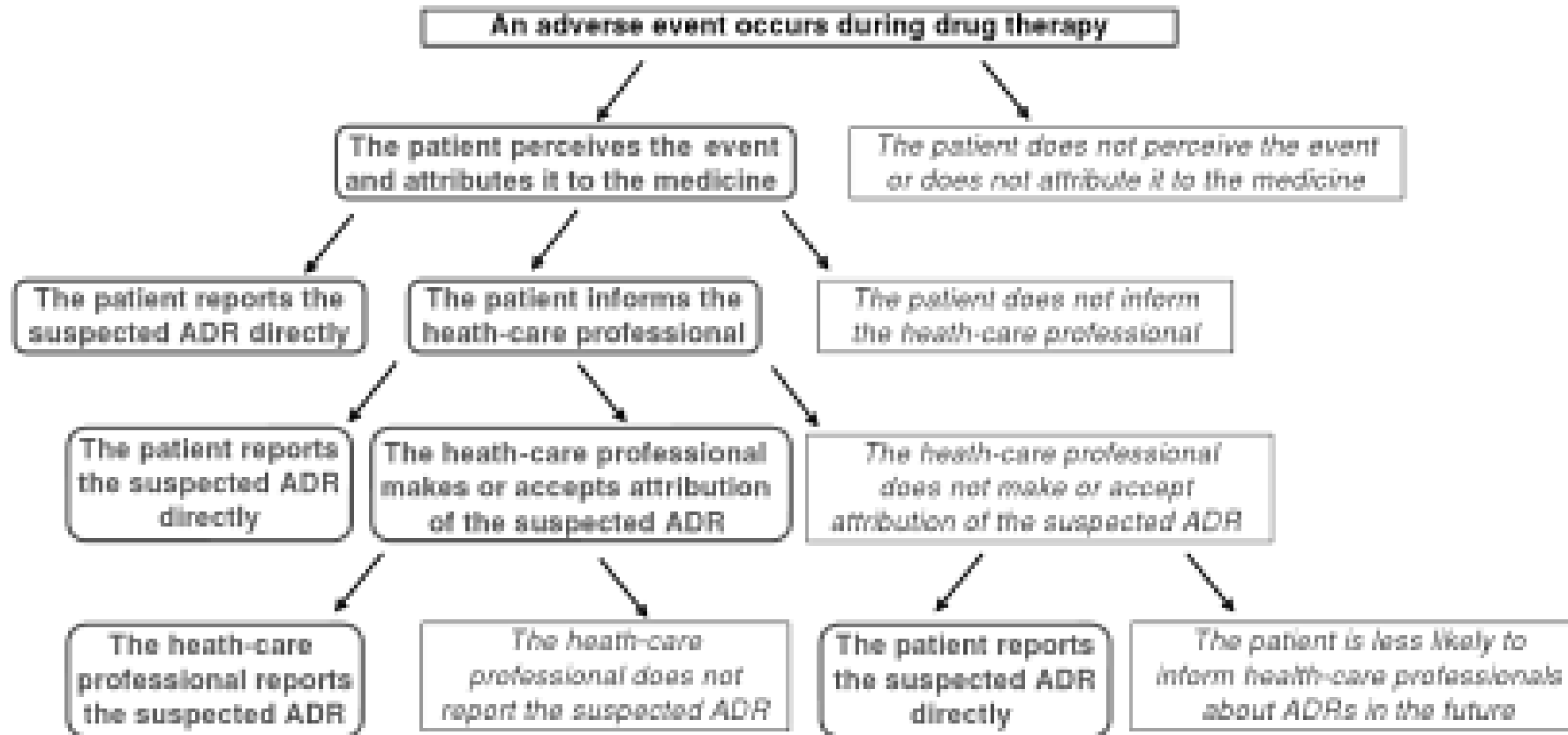
# Different conceptualisations of engagement?

- ▶ Communication, consultation, participation (all three?)  
(Rowe and Frewer 2005:255)
- ▶ The most appropriate level of engagement depends on nature of risk – simple/linear, complex, uncertainty, ambiguity (Renn et al 2011)
- ▶ ‘...more inclusion does not equal better risk governance. The degree and type of inclusion may vary depending on the phase and context. In each phase and context, it has to be thought through what kind and degree of inclusion is needed. So differentiation is not an exception, but rather the rule’  
(van Asselt & Renn 2011: p. 441)



# Chains of knowledge flow across medicine regulation contexts





**Figure 11.1** Pathways for reporting adverse drug reactions (ADRs)

*italics, rectangular boxes = negative outcomes*

*roman, rounded boxes = positive outcomes*

Source: Britten N (2012) 'Adverse Drug Reactions: Social Considerations' in: *Stephens' Detection and Evaluation of Adverse Drug Reactions*; p. 578



# Some dimensions of effective engagement with publics

- ▶ Maximise relevant participants (Rowe and Frewer 2005: 265)
  - ▶ Knowledge, motivation, trust in regulatory authority
- ▶ Maximise relevant information from participants
  - ▶ Competence, confidence and 'training'
- ▶ Maximise transfer, processing and aggregating of information
  - ▶ Effectiveness of tools of engagement/systematic use of info?
- ▶ 'Inclusion has deep implications. Contrary to the current state of affairs in which risk topics are usually identified by experts, public values, and social concerns may act as the driving agents for identifying risk topics. Inclusion does not just mean that various actors are included, but that they play a key role in framing (or pre-assessing) the risk' (van Asselt and Renn 2011)



# Insights into effective professional engagement

- ▶ 'The spontaneous reporting system relies on vigilant physicians who generate a suspicion that a particular drug has caused an adverse reaction and who report it' (Hasford et al 2002: 945)
- ▶ Key common factors in non-reporting (Lopez-Gonzalez et al 2009:19):
  - ▶ **ignorance** (only severe ADRs need to be reported) in 95% of studies;
  - ▶ **diffidence** (fear of appearing ridiculous for reporting merely suspected ADRs) in 72%;
  - ▶ **confidence** - 'will it make a difference' and uncertainty in 67% of studies;
  - ▶ **complacency** (only safe drugs are allowed on the market) in 47% of studies.
  - ▶ time pressure factors in 77% of studies;
- ▶ 'Almost 20% of the physicians admitted to not know[ing] the spontaneous reporting system and 30% to not know how to report;' 54% would report to a therapeutic advice service (Hasford et al 2002: 945)



# If *engagement* is hard to operationalise and measure – what are useful proxies?

Engagement 'effectiveness may be ascertained by the efficiency with which full, relevant information is elicited from all appropriate sources' (Rowe & Frewer 2005:251)

Knowledge of (the existence of) regulators and reporting mechanisms

(Hasford et al 2002: 525; Himmelstein et al 2011)

Overall levels of ADR reporting (various sources)

Measures of the quality of reporting (Figueiras et al 2006)

Measures of under-reporting (Hazel & Shakir 2006)

Trust in regulators and in reporting processes (Walls et al 2004; Engdahl & Lidskog 2014)



# References

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