

The *engagement* of patients and healthcare professionals in regulatory pharmacovigilance: developing a conceptualisation

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 - (1) to develop a widely applicable conceptualisation of engagement;
 - (2) to consider various methodological challenges to researching engagement, alongside solutions; and
 - (3) to outline a basis of operationalisation for regular engagement of MUs and HCPs in regulatory pharmacovigilance.

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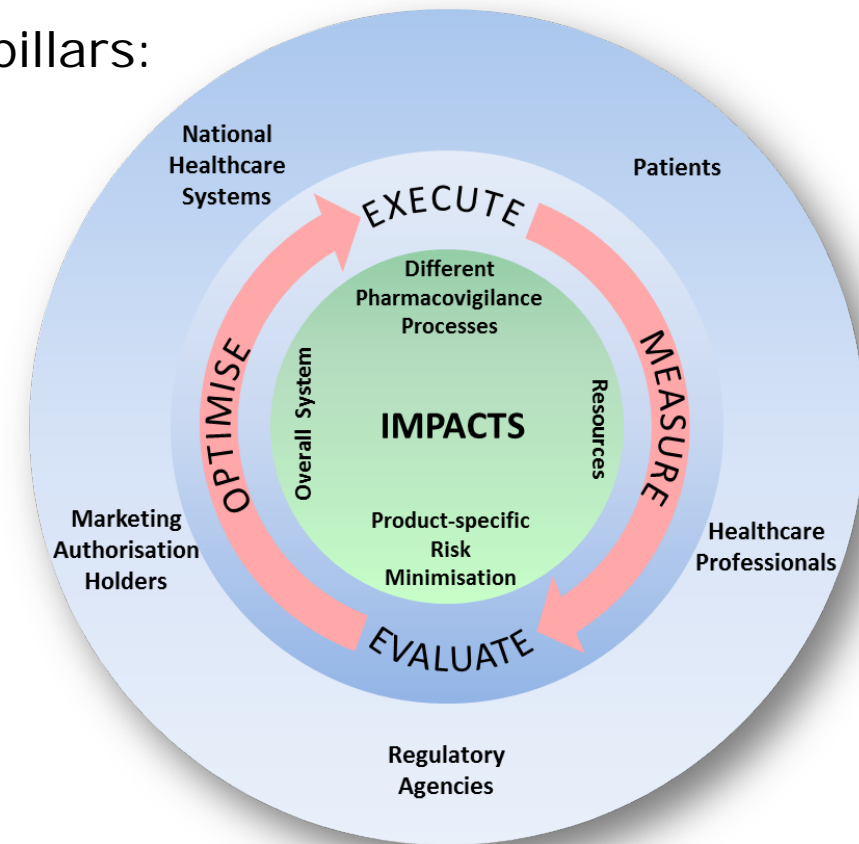
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- ▶ Aim of next 10 minutes:
 - ▶ Sketch a conceptualisation of engagement in three dimensions
 - ▶ Draw out some implications of each of the dimension for patient engagement

Measuring Pharmacovigilance Impact: The PRAC Strategy

The PRAC Strategy Rev 1 ([EMA/165407/2017](https://www.ema.europa.eu/en/press/news/2017/07/17_072017)) focusses on 4 pillars:

- I. Effectiveness of **product-specific risk minimisation** (e.g. measures following major referrals)
- II. Effectiveness of **pharmacovigilance processes** (e.g. post-authorisation studies)
- III. Enablers of effective pharmacovigilance and **stakeholder engagement**;
- IV. Identification and development of **analytical methods** (e.g. for modelling impact on health outcomes);

→ Leverage of ongoing work by regulators, industry and academia;



Underlying basis of conceptual work

- ▶ Review of all articles published in *Drug Safety* using the terms 'engagement', 'engage', or 'engaging' in 8 years between 2010 and 2017.
 - ▶ Engagement is much discussed in relation to pharmacovigilance and drug safety
 - ▶ Yet seldom defined
 - ▶ This lack of conceptual precision impedes effective measurement, analysis and critique
 - limiting possibilities for evidence-based interventions

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- ▶ Consideration of how engagement is (implicitly) considered within existing empirical studies in wider drug safety and pharmacovigilance literatures
- ▶ Synthesis of conceptual work on engagement in medical and public health literatures, but also in 'public understanding of science' and 'risk governance' literatures

Conceptualising engagement

- ▶ 'An ongoing process of knowledge exchange and knowledge adoption among pharmacovigilance stakeholders'.
- ▶ We elaborate this process in terms of 3 dimensions – breadth, depth and texture:

← **Breadth** (how many?) →



Depth (what level of engagement?)

Information-giving

Consultation

Participation

Texture (what does engagement 'feel' like?)

Interactive dynamics

Feeling and meaning

Motivation, confidence and trust

Breadth

- ▶ How many people?
- ▶ Breadth and depth inextricably linked...
- ▶ But also 'how diverse?'
- ▶ Key issue from wider literature: tension around engaging the most appropriate patients – 'typical' *versus* 'expert'
 - ▶ Hashem, F., Calnan, M. and Brown, P. (2018) Decision-making in NICE single technological appraisals (STAs): How does NICE incorporate patient perspectives? *Health Expectations*, 21(1):128-137

Depth



- ▶ Importance of participation – for quality of knowledge and for legitimacy
- ▶ Difference between depth of intervention (as it is designed) and depth of outcome (as it functions in reality)
- ▶ Key issue from wider literature: 'Inclusion has deep implications'
 - ▶ Van Asselt M, Renn O. (2011) Risk governance. *Journal of Risk Research*, 14(4):431-449.

Texture

- ▶ What does engagement 'feel' like?
- ▶ Texture is not vital to assessing if engagement works but fundamental to capturing **how** it works – **process** (rather than outcomes)
- ▶ Key issue from the wider literature: Texture can, however, be an outcome when considered over time
 - ▶ "trust is created when citizens are emotionally involved, take part, have a say, and in some sense are able to recognize themselves in the recipient of their trust"
 - ▶ Engdahl, E., Lidskog, R. (2014) Risk, communication and trust: Towards an emotional understanding of trust. *Public Understanding of Science*, 23(6):703-717.

Conclusion – thinking about *engagement* in 3D

- ▶ Engagement is fundamental yet seldom defined or conceptualised
- ▶ Being more precise assists the design of effective evidence-based engagement processes
 - ▶ through measurement, evaluation, critical reflection
- ▶ The three dimensions are hopefully a useful basis for:
 - ▶ conceptualising the design of initiatives
 - ▶ measuring impact/outcomes
 - ▶ understanding process

Acknowledgements

- ▶ This presentation draws on an article –
'Engagement' of patients and healthcare professionals in regulatory
pharmacovigilance: establishing a conceptual and methodological framework
– which I have been writing with Priya Bahri.

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