



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Evidence-based guidance for risk communication planning

PCWP-HCPWP Workshop on Benefit-Risk Communication

Presented by Priya Bahri on 17 September 2014
Lead for Pharmacovigilance Guidelines and Risk Communication

An agency of the European Union



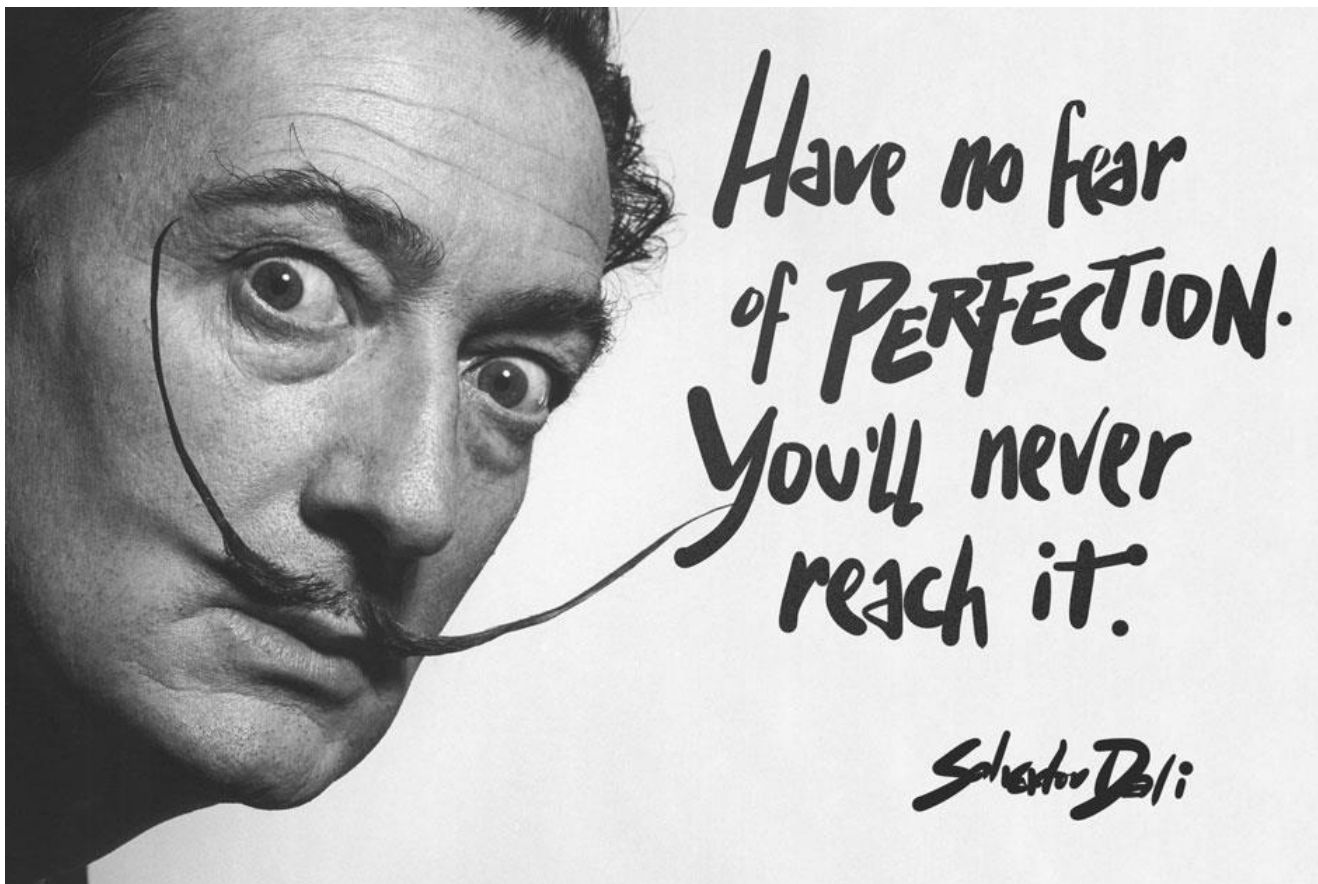


Evidence

Empirical evidence is information that is acquired by observation or experimentation. This data is recorded and analyzed by scientists and is a central process as part of the scientific method.

[www.lifescience.com]





Improvements through evidence?

Applying communication research in practice - Example of influenza vaccines

- (H1N1) influenza pandemic in 2009/10
- Crisis management plan for pandemic influenza had been developed a priori in 2006
- Lessons learnt a posteriori

→ Question: How would a literature review have looked like on 31 August 2009?

= “Historical simulation”



Improvements through evidence!

Applying communication research in practice - Example of influenza vaccines

Comparison of simulated a priori literature review versus lessons learnt a posteriori:

- Finding: Congruence of issues identified
- Conclusion: Applying research findings (knowledge, attitudes, perceptions, concerns, preferences, controversies, values, behaviour, voices, media coverage) to communication has the potential to support proactive planning of communication interventions



EU good pharmacovigilance practices (GVP) on vaccines includes guidance on communication

- Integrate communication process with risk assessment and communication evaluation, and prepare for public information needs
- Address concerns raised by the public proactively by communicating
- Explain concepts: coincidental event, temporal association, single case, safety monitoring need \neq identified risk, mock-up
- Advise healthcare professionals on management of vaccination/needle anxiety and concerns e.g. in pregnancy, puberty, immunosensitive conditions, general anxiety/mood disorders, epilepsy
- Plan for communication on excipients, residues, individuals with special conditions...
- Monitor the media



PDCO guideline on pharmacovigilance for medicines used in paediatrics will include guidance on communication

- Especially important medicines: Vaccines, neurological and neuropsychiatric medicines, antibiotic (resistance development!), contraceptives, chronic medications
- Special concerns of adolescents (e.g. dependency, loss of self-healing capacity) and parents
- Need for autonomy and hence ensure correct autonomous use
- Specific vulnerability and need for boundaries (-> e.g. on choice of words, fill information needs)
- Specific information needs: Impact on school and sports, risks of diversion
- Different communication channel / media preferences, but also: need for confidentiality
- Paediatric patients in the Paediatric Committee to consult on communication too

An initiative at the EMA for applying communication evidence – Next steps

- Communication guidance for biologicals, medicines used in pregnancy, in geriatrics...
- Through GVP module on continuous pharmacovigilance: Implementation of processes for communication planning and evaluation – includes collaboration with patient and healthcare professional organisations and use of participation mechanisms

→ Learning cycle and continued evidence development





Conclusions

- Practical guidance for communication planning and evaluation should be informed by research.
- Application of guidance and evaluation of communication effectiveness provides for learning, evidence development and, in future, for informed option analyses.
- We need to use and further develop combined methods from pharmacoepidemiology and the social/communication/cognitive sciences.
- Research advocacy and stakeholder collaborations!



Thank you for your attention

Further information

Priya Bahri

Lead for Pharmacovigilance Guidelines and Risk Communication

Telephone: +44-(0)20 3660 8454 **Email:** priya.bahri@ema.europa.eu

European Medicines Agency | Office Best Evidence Development

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom

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