

Regulatory transparency in Europe: more science needed



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This talk

- 1- The appeal of transparency in today's regulatory environment
- 2- How strategic is the current thinking about the impact of the new transparency policies?
- 3- Recommendations to move forward and build more evidence-based risk management

Transparency is like motherhood and apple pie...

Being honest,
and preventing
corruption (Ball 2004)



Ensuring legality,
morality and veracity (Hood 2006)



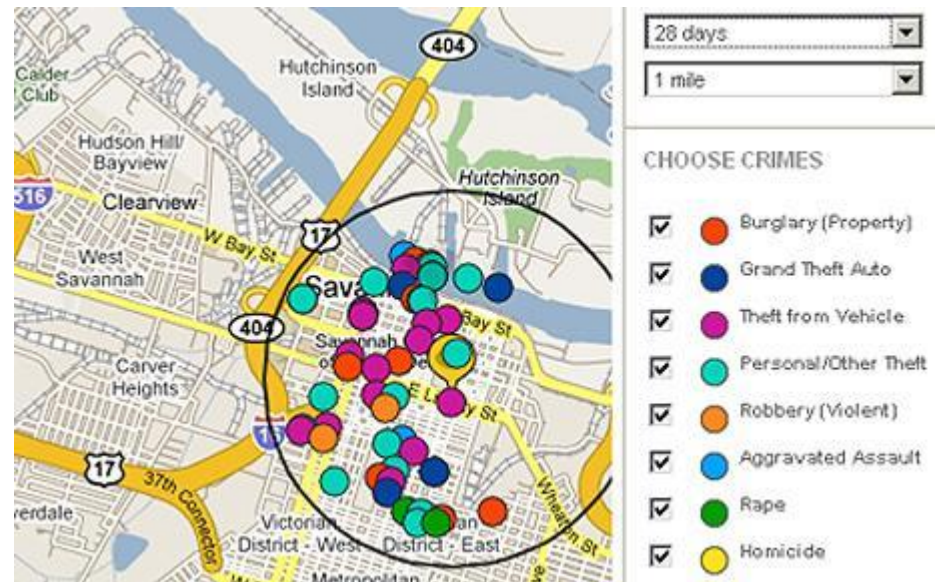
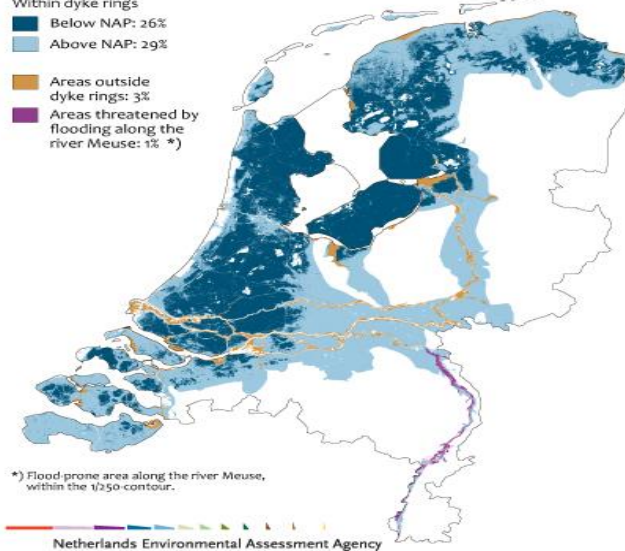
Transparency revolution?



Flood-prone area

Within dyke rings
 Below NAP: 26%
 Above NAP: 29%

Areas outside dyke rings: 3%
 Areas threatened by flooding along the river Meuse: 1% *)



Transparency's appeal

1. Lifting the veil of secrecy;
2. Looking clearly through the windows of an institution;
3. Voluntary disclosure of information by an organisation;
4. Allowing external bodies to verify the internal organisation's performance
(Grimmelikhuijsen 2010)

Critical Steps on both sides of the Atlantic

Food labelling laws in the early 20th century (e.g. the US Food and Drug Act of 1906) (Hilts 2003)

“Right to know” and disclosure (Baram 1984) Proposition 65 in California

Access to documents laws and regulations at MS and EU levels (Sabel and Zeitlin 2010)

EU Ombudsman

Aahrus convention (1998)

Defining moments

Food: Bovine Spongiform Encephalopathy (BSE)

Feeling that scientists did not update the public

Answer

Following the BSE crisis, the regulatory body established in the wake of the crisis, the UK Food Standards Agency (FSA) decided to web-stream its board meetings

(Way and Löfstedt 2015)

More transparency scandals ...

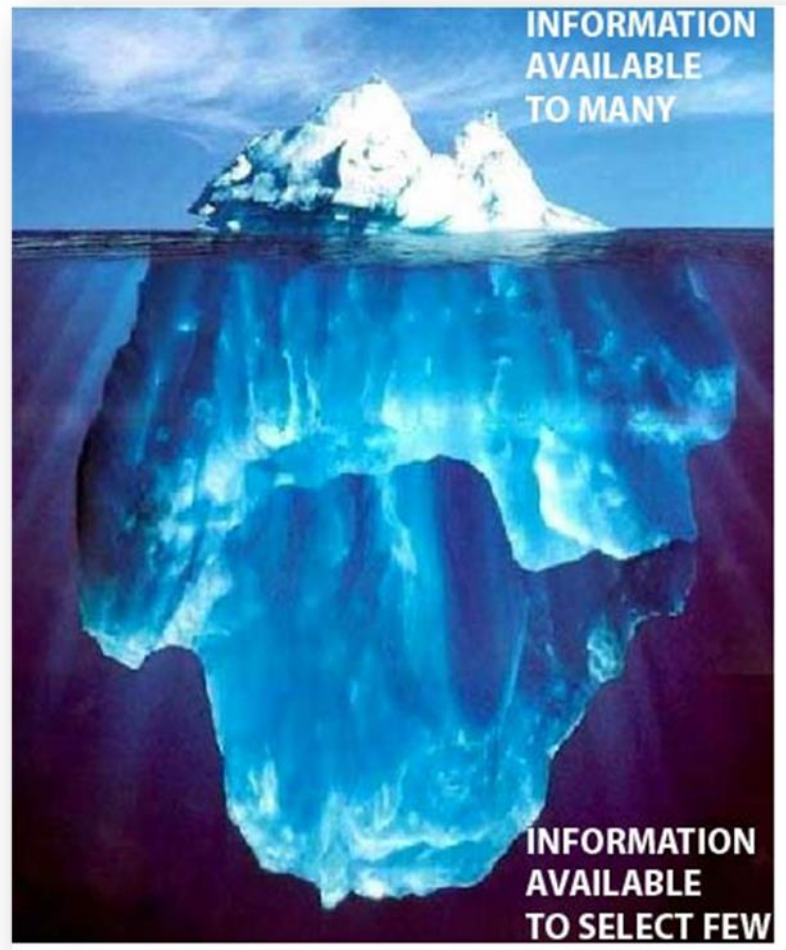
Finance: Enron

Energy: Deepwater Horizon oil spill

Food: horse meat

Medical: Vioxx, Mediator...

Key concerns...



“Common sense” suggestions

- ✓ Independent data and safety monitoring (Krumholz et al. 2007; Gøtzsche 2011 ++)
- ✓ Release as much information as possible, allow independent scrutiny : concerns for intellectual property are misplaced (Godlee and Clarke 2009; Chan 2008; Doshi et al. 2011; Goldacre 2012)
- ✓ Prohibit all free bees (Brennan et al. 2006)
- ✓ Uniform format for disclosure of competing interests. Set up internet sites with information on consulting agreements and unconditional grants(Drazen et al. 2010; Mitchell 2009)

What form of Transparency?

- **Fishbowl transparency**
 - Aims to “expand release of info” documenting how regs come to decisions (Coglianese, 2009)
 - Publishing minutes or reg input docs
- **Reasoned transparency**
 - Demands regs offer explicit explanations for actions/decisions (Coglinese, 2009)
 - Concise understandable comms (Bouder et al. 2015)



Publishing risk assessment data

- Publishing increasing quantities of raw data (fishbowl)
 - External (re)analysis
 - Cannot be seen to be 'hiding' or 'concealing' info
- ❖ EFSA: Warehouse project (Url, 2014)
- ❖ EMA: Clinical reports policy (Rasi, 2014)



Positive impact of transparency

- ❑ Rewards and encourages good behaviour , i.e. hygiene in restaurants (Fung et al 2004 and 2007)
- ❑ Secrecy destroys trust (Breakwell 2007; Löfstedt 2005)
- ❑ Being seen as open and honest (Matsumoto et al. 2005; Schutz and Wiedemann 2000)

But no panacea...

- ❑ Muddling and bickering exposed (Lindbloom 1959; Stone 2001)
- ❑ Disenchantment (Bovens and Willie 2008; Grimmelikhuijsen 2010)
- ❑ Trustworthiness framed by pre-existing views (van de Walle 2004)
- ❑ More knowledge = more criticism (Mandak et al. 2009)
- ❑ Take evasions, tell half truths and become hypocrites (O'Neill 2002) e.g. financial sector.

Have transparency policies been tested?

Challenges:

People don't admit that they are ignorant (Fischer 1993)

Information requires interpretation (Tsoukas, 1997)

Unintended consequences: e.g. sex offenders registries

Impact?

Evidence from recent pharma research points to the impact of negative information on compliance (Löfstedt et al. 2012; Boudier et al. 2015; Way et al. 2015)

Online surveys

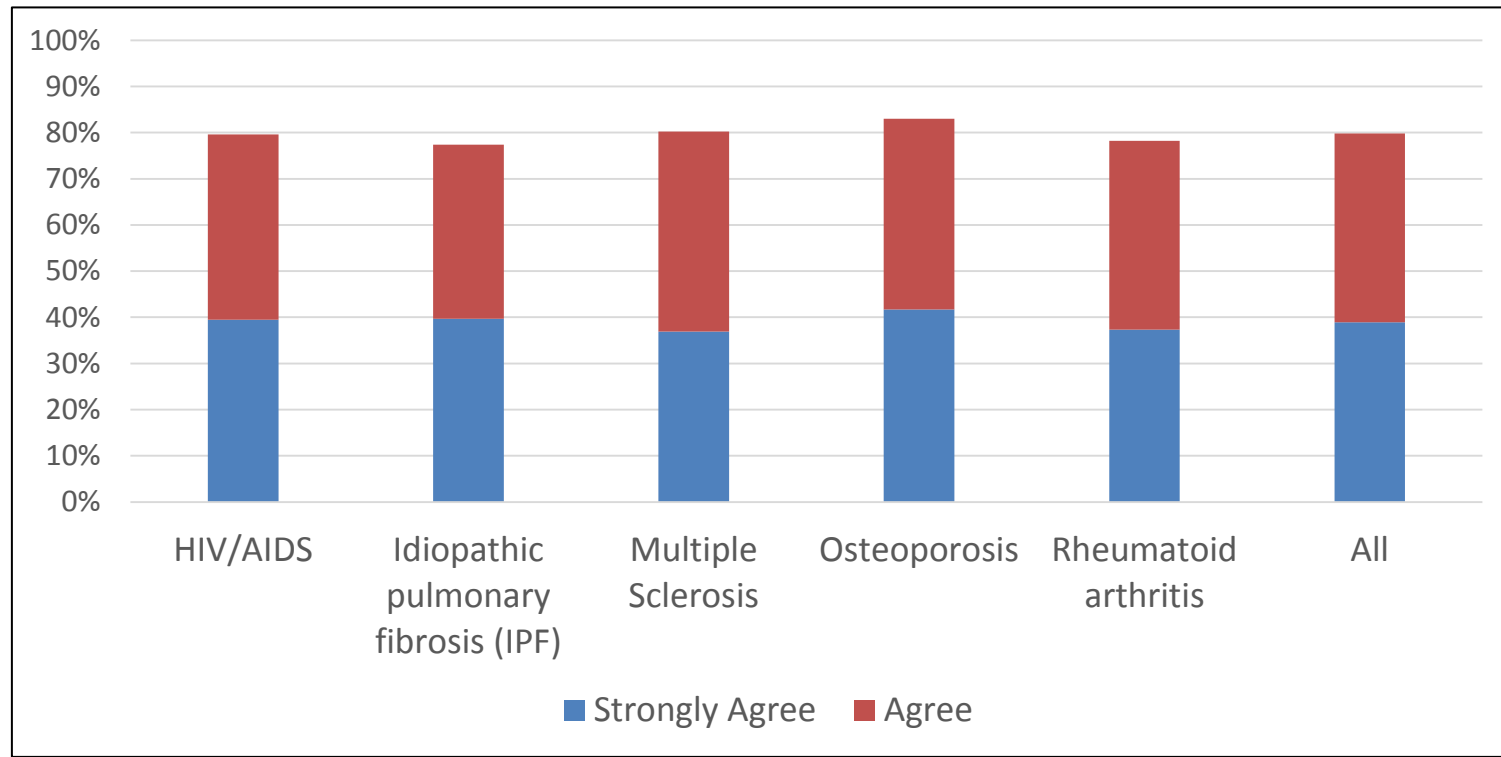


	General public	Patients	Doctors
Dates (year)	2013	2014/2015	2014/2015
Size	5,648	1,010	1,005
Type	European adults	HIV/AIDS, IPF, MS, Osteoporosis, RA	GPs (50%) + Specialists (HIV/AIDS, IPF, MS, Osteoporosis, RA)
Countries	Fr, De, Sp, UK, Swe, NL	Fr, De, Sp, UK	Fr, De, Sp, UK
Questions	32	30	36
Authors	Bouder <i>et al.</i>	Way <i>et al.</i>	Lofstedt <i>et al.</i>
Response rate		4.5%	5%

*Not for circulation

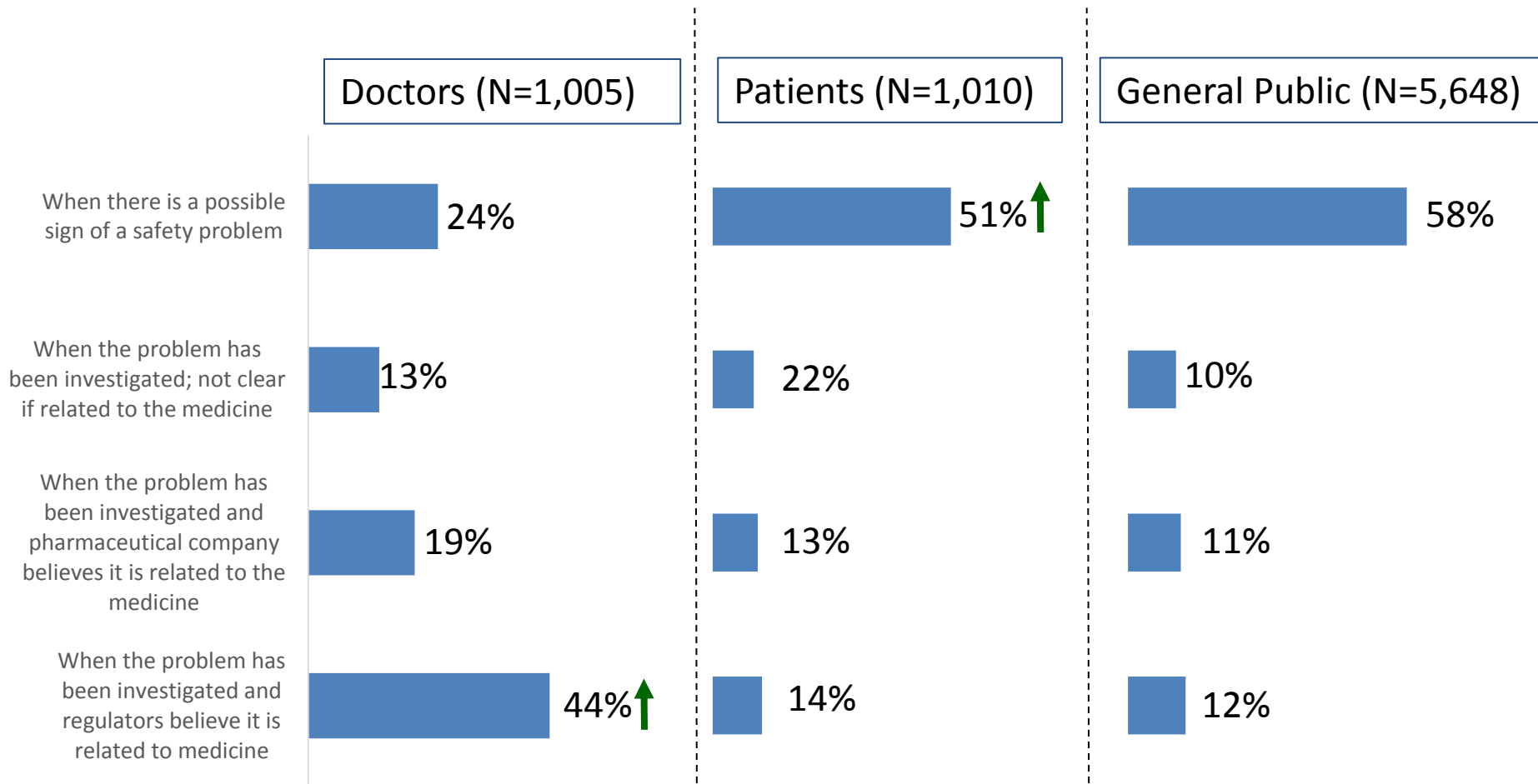
Patients desire more info

➤ Supports Löfstedt and Way (2014a, b)



Q10A: Please indicate the extent to which you 'agree' or 'disagree' with each of the following statements: "Patients receiving more information on the safety of medicines would increase their confidence in taking medicines" (strongly agree, agree, neither agree nor disagree, disagree, strongly disagree).
Not for consultation

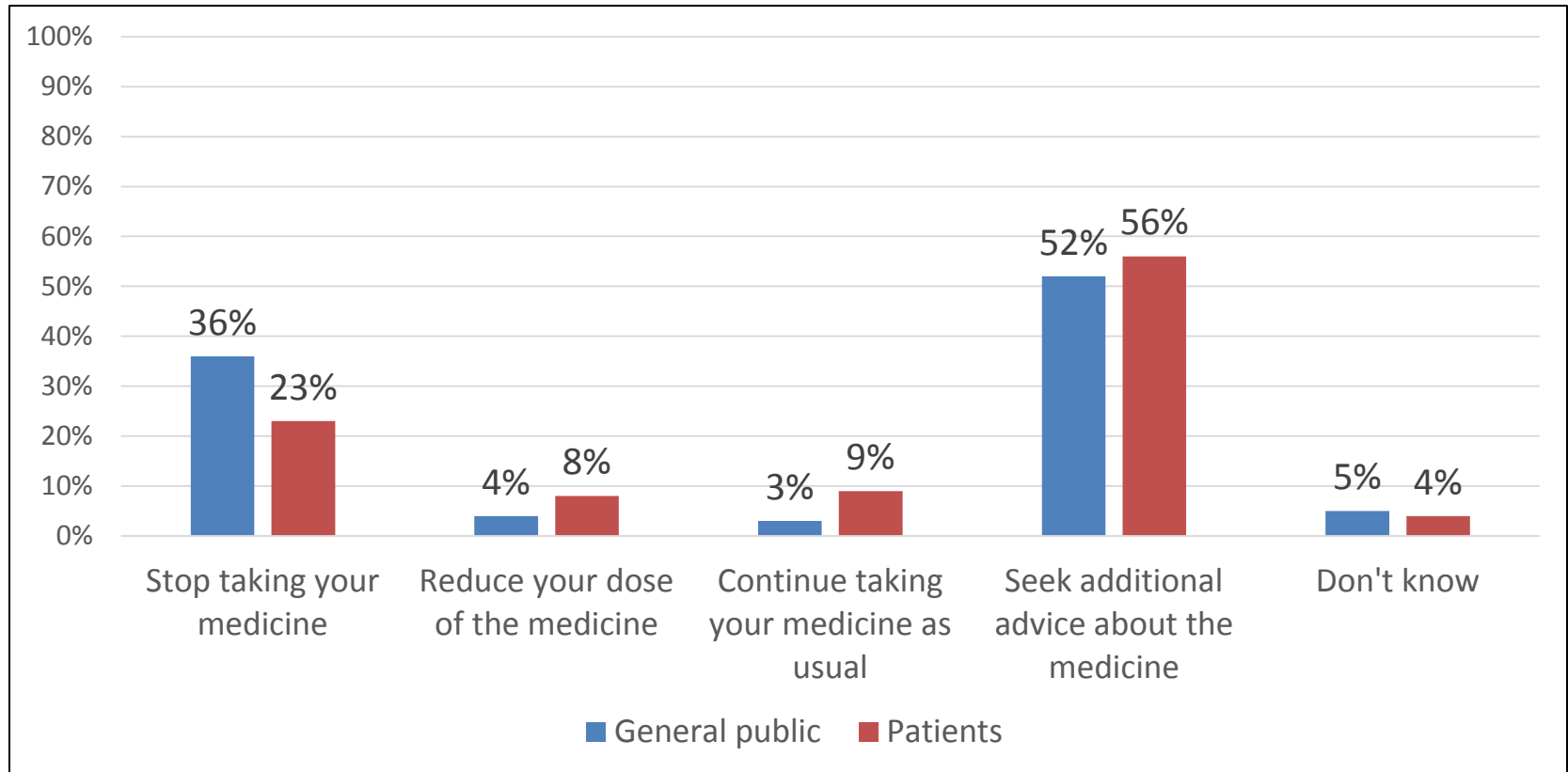
But...when should this info be communicated?



Q9. At what stage do you think information should be conveyed to the public about a possible safety issue of a medicine that they use or may use? (Please choose one answer only)

Not for circulation

And...how will patients react?

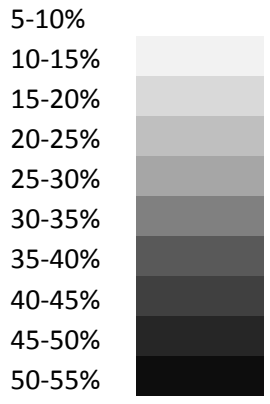


Q9B If the information you personally receive (via letter, telephone, email etc...) points to safety problems with a [Insert specialty group] medicine you are currently taking, do you think you are more likely to...

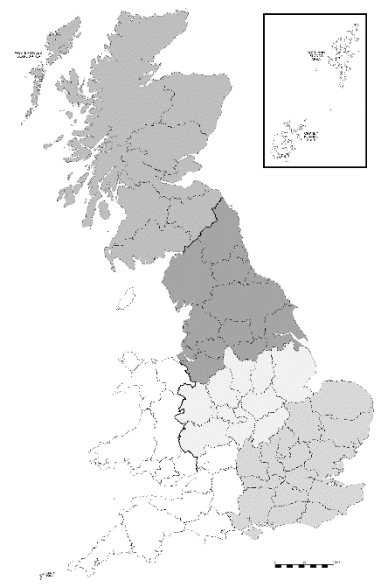
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Regional variations for stop and reduce combined (draft).

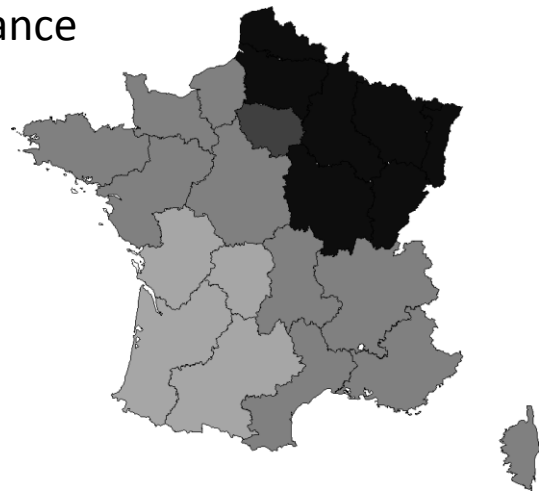
KEY



UK



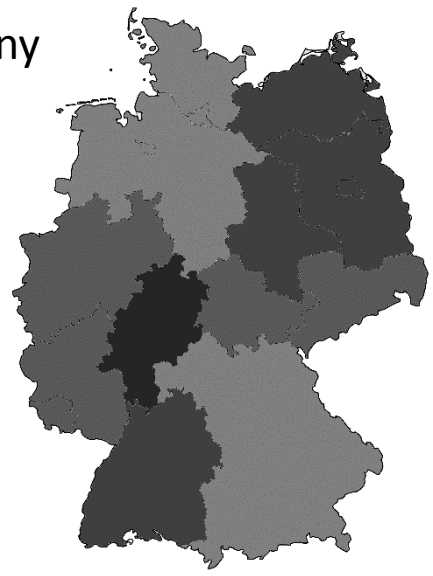
France



Spain



Germany



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Some reflections

1. Transparency is here to stay
2. Many potential (but unclear) benefits (e.g. scientific progress)
3. We must clarify different aims/types of transparency (e.g. CoI vs. external re-analysis)
4. Policies designed to enhance transparency will not necessarily do so and can have severe unwanted effects (Hood, 2001)
5. Transparency deserves measurement + evaluation (Coglianese, 2012)
6. Regulators need to become stronger to deal with the new environment (e.g. in the media)
7. Should we be separating or combining transparency and risk communication?
8. What impacts are there on resources?

Listen to the people

“ I think a lot of us are advocating a lot of transparency, a lot of disclosure early in the process but saying that there needs to be public education. There needs to be a more developed context to accountability that so you don't have the sort of whiplash panic and then overdose”.

Ms Mayer, a breast cancer survivor