

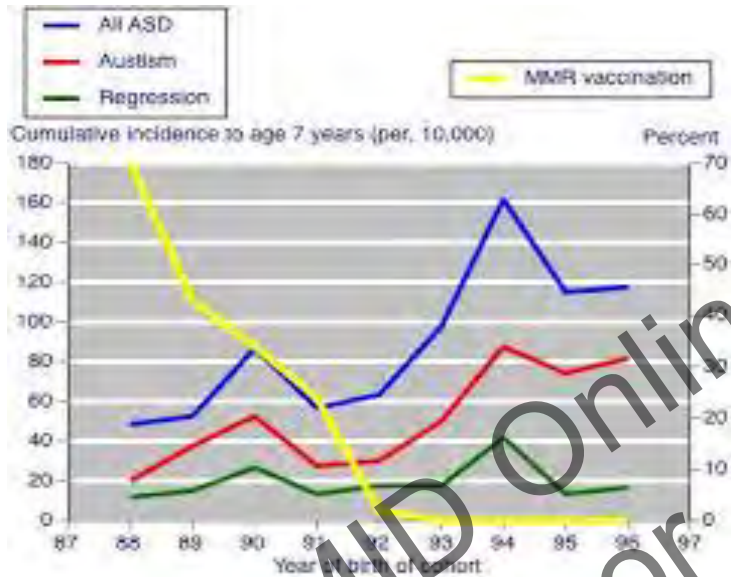
Does the unvaccinated population impact
the community they live in?

Frederic Boudier, UM TSS

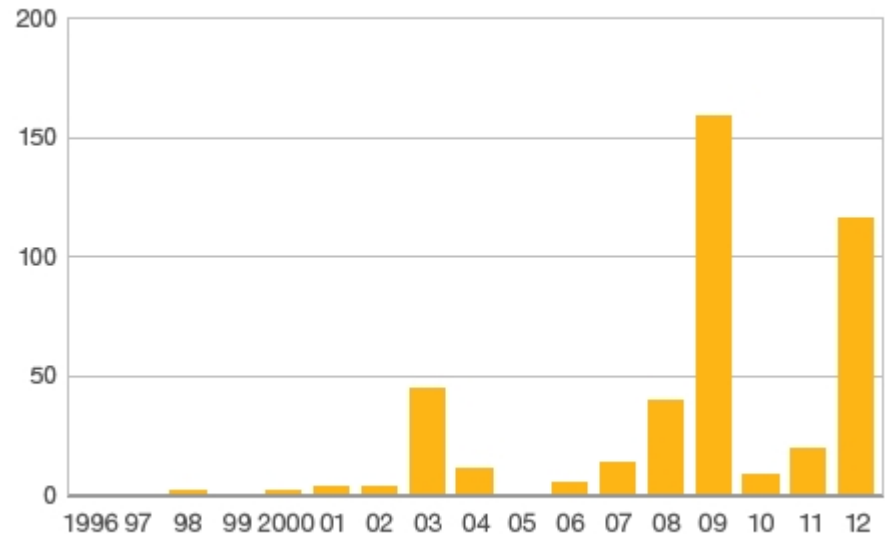
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They surely do!

MMR case



Measles in Wales 1996-2012
Number of confirmed measles cases



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Why?

Growing level of public distrust toward industry/
regulators/policy makers

Public demanding access to information

Pluralism of science: e.g. alternative medicines

Media amplifications

Pluralism of information sources: e.g. Internet

Concerns for risks increasingly small and uncertain

**Consequence: scientific communication only one
'voice'**

Who will people turn to?

Bouder et al. 2014

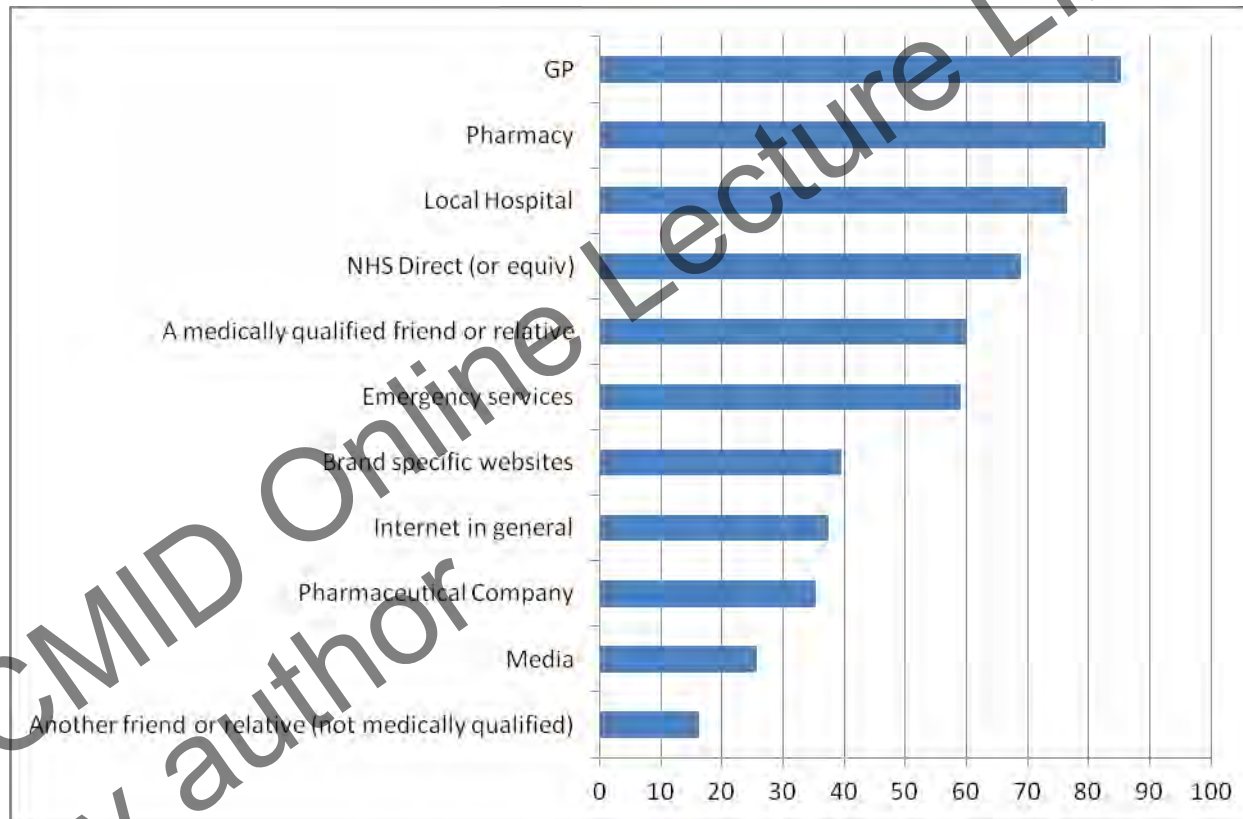


Figure: Bar Chart showing how trustworthy respondents (%) (N=5,648) felt a predetermined list of sources of information are in (a) providing them with advice about medicines or communicating health alerts (blue shading) and, (b) providing them with advice on the side effects associated with specific medicines (red shading). The bar chart represents the % of respondents that chose very or fairly trustworthy for each source of advice.

Risk communication/ decision
sciences can help

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Risk perception has been extensively studied

Scholars (e.g. Fischhoff, Renn, Slovic and White) have uncovered a series of cognitive drivers that influence risk perceptions.

Understanding these drivers is the first step towards building an effective risk communication strategy (Fischhoff 1995; Leiss 1996)

Psychometrics

Starr 1969; Fischhoff et al. 1979; Slovic 1987 etc.

Intuition and rationality

Kahneman and Tversky 1974; Slovic 2001

Trust

Renn and Levine 1991; Lofstedt 2005

Risk perception drivers

- Natural – Technological
- Voluntary – Involuntary
- Familiar – Non Familiar
- Control – Non Control
- High Frequency/Low Consequence Risk VS
Low Frequency/High Consequence Risk
- Child – no child
- Reproduction
- Trust – no trust

All jabs are not the same...



Why do people ignore expert vaccine advice?

- Vaccines are mostly uncontrolled and imposed risks and as such generate specific anxieties (Ball et al. 1998; Bostrom, 1996)
- Involuntariness: laws mandating vaccination for school entry render vaccination an involuntary risk affecting children (Evans et al. 1997).
- Vaccine acceptance is challenging when the prevalence of a disease is low (Ritvo et al 2005).

Known misconceptions

- **Natural vs. Unnatural**

- People tend to think that immunity acquired after **natural** infection is preferable to vaccines (Howe and Johnston, 1996)

- **Control vs. No control**

- Several parents refused vaccination due to feeling in **control** and able to prevent the dramatic consequences of the disease (Meszaros et al. 1996)

Vaccination heuristics

Working for...

- **Altruism:** “I want to protect my child”
- **Bandwagoning:** “I do it because everyone else is doing it”

Working against...

- **Compression:** Overestimating frequency: Rare vs. common risks
- **Availability:** Media information overwhelmingly negative
- **Omission bias:** Higher sense of responsibility for the death of a child after vaccination than after a vaccine-preventable disease (Asch et al. 1994; Ritov and Baron, 1990)

Fairness, competence, efficiency

(Renn and Levine 1992)

“Well I would rather have a med approved then not, but they are definitely in cahoots with the drug companies.”

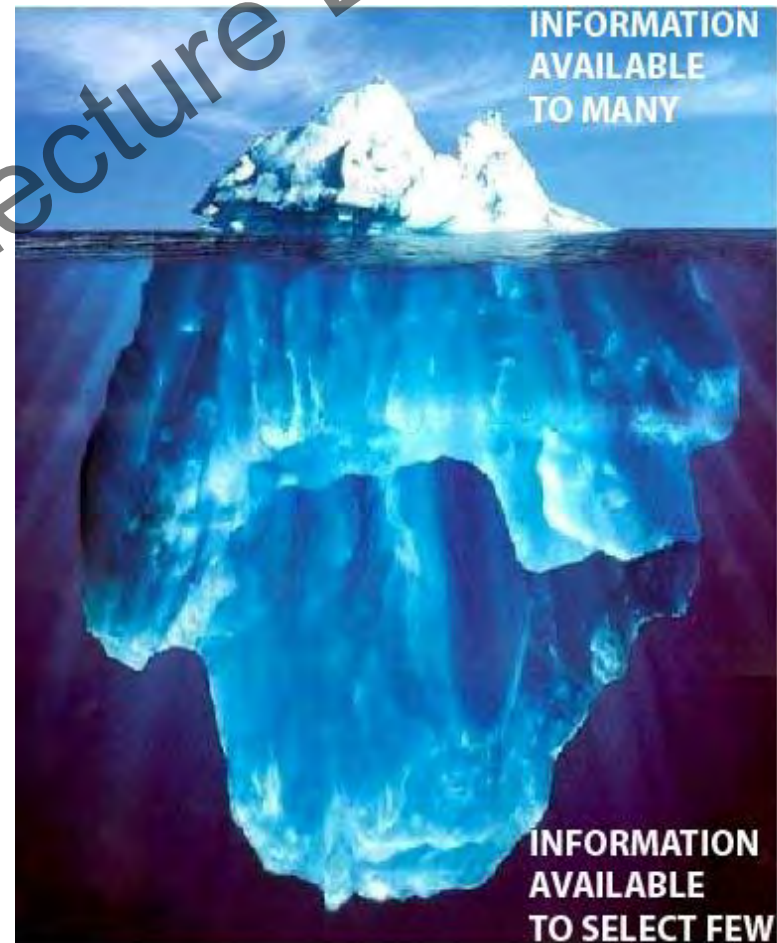


**FDA
Approved**

“They try to do a good job but I don’t think they have enough resources to take care of all of it.”

“Who calls the shots” (Bostrom 1999)?

- Distrustful environment (e.g. Swine flu)
- Pressures on regulators
 - Data miners (Gøtzsche 2011 ++)
 - Opinion leaders (Goldacre 2012)
 - Journal Editors (Godlee; Hampton)
- EU involvement
 - EU Ombudsman decision 2010
 - Legislation changes (ENVI, 2014)



Media and perception

Risk amplification/attenuation

(Kasperson & Kasperson 1988; Pidgeon et al. 2003)

Information passes from sender to receiver

Intermediate stations of a communication chain (individuals; medias; NGOs etc.) change the message

Ripple effects, may amplify (or attenuate) perceptions



From risk perception

to risk communication



Trust-building risk communication

(Löfstedt 2005; Boudier and Löfstedt 2008)

- Frequent dialogues
- Confrontation between key parties is destructive
- Lawyers likely to inject more disputes
- Neutral third parties play a positive role
- The opinion of local policy makers is important
- NGOs may shape policy outcomes

Case analysis - Gardasil scare in Spain

Gardasil, from Sanofi Pasteur MSD SNC, is a vaccine for the prevention of cervical cancer and other pre-cancerous diseases caused by human papillomavirus (HPV). It has been authorised in the European Union (EU) since September 2006. In January 2009, around three million girls in Europe had been vaccinated with this vaccine since it was first authorised.

“It is a real breakthrough in medical history. The first vaccine that works against cancer” (Patient)

Safety

“There were no major concerns for immunologic reactions and disorders such as Guillain-Barre syndrome. But we received a number of spontaneous reports. Usually you would expect some cases of multiple sclerosis. Recently this issue of vaccine-induced multiple sclerosis has triggered concerns in scientific circles, for example in Austria”. (Regulator)

'Outbreak' in Spain

Friday 6 February 2009:

2 teenage girls after second dose

Girls put into the same room in Valencia Hospital (Spain)

Very agitated

Doctors diagnose “status epilepticus” and decide to induce coma.

Communicating precautionary measures

AEMPS immediately in touch with the Sanofi Pasteur

Monday 9 Feb: Ministry of Health and Valencia province decided to suspend the batch (against views of AEMPS experts).

Immediately (10 am) the company withdrew the batch, which represented 75.582 doses. Other Member States stop the batch

Monday 16 Feb. Spanish Ministry of Health official communication. Ref: 2009/02. “**enforcing the precautionary principle**”. Informed all EU countries, requested an investigation.

19 February: Press release

Sorted?

“Based on the current data, [CHMP] has concluded that the cases are unlikely to be related to vaccination with Gardasil and that the benefits of Gardasil continue to outweigh its risks. Therefore the Committee is recommending that vaccination with Gardasil should continue in accordance with national vaccination programmes **in Member States.**”

EMA/CHMP/103339/2009

The shadow of a doubt?

“The CHMP and its Pharmacovigilance Working Party **are investigating this situation further.** The marketing authorisation holder has been requested to provide a **full analysis of the batch**, as well as **further information on the vaccine’s side effects, any similar cases, and possible ways in which Gardasil could be linked to the cases seen in Spain.** Following assessment of all of the available data, the CHMP will **determine whether further action is needed.**”

Or?

“As part of its continuous monitoring of medicines, the CHMP recommended an update of the Product Information for Gardasil in January 2009, to **reinforce information on syncope** (fainting) as a side effect of vaccination with Gardasil, indicating that it is sometimes accompanied by tonic-clonic movements (movements resembling a seizure). This opinion has been forwarded to the European Commission, for the adoption of an EU-wide decision.”

Negative results followed

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Why the debate was so intense...

Social Amplification of Risk:

Intense media coverage in Spain about the vaccination campaign, which was never consensual (alternatives, costs)

Debate politicised

Little support from third parties (e.g. OCU) concerned about aggressive marketing

Intense media coverage of the two cases

...and how it was solved

Spanish authorities successfully solved the crisis, using an independent scientific committee with reputable experts from various disciplines (neurology, immunology, virology, epidemiology etc.)

Full report presented to Health Ministry (April 09)

Careful conclusions: “a close relationship with the vaccination but no evidence of biological relationship”

But: the legal suit continues

Key Findings from case

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One-way communication model in post trust environment...

Deficit model: top-down communication

Non-expert messages confusing

Little was done to understand and adapt communication to “perceived risks” and society’s worries.

... undermines trust even more

Multiple actors maintained multiple and often **conflicting 'voices'**

Delays due to co-ordination issues created communication vacuums

National dynamics & risk amplification

Take home lessons

1. Need to take RP/RC science on board : more **evidence-based** RP/RC . Risk communication advisory boards needed (e.g. FDA).
2. Need to **test for trust and continually evaluate** impact of RCs. More best practice sharing (Bouder 2015).
3. Must recognise significant **variations** (perceptions, context, 'cultural' differences) and **incorporate them** into RCs
4. **Role of RC 'ambassadors'** and **RC training** within vaccine community.
5. Foster **alignment** between different key parties not confrontation. Role of **neutral third parties**.