

# **Safety of Rubella and MMR Vaccines**

## **- Issues to be addressed**

**Jan Bonhoeffer**  
**Brighton Collaboration**



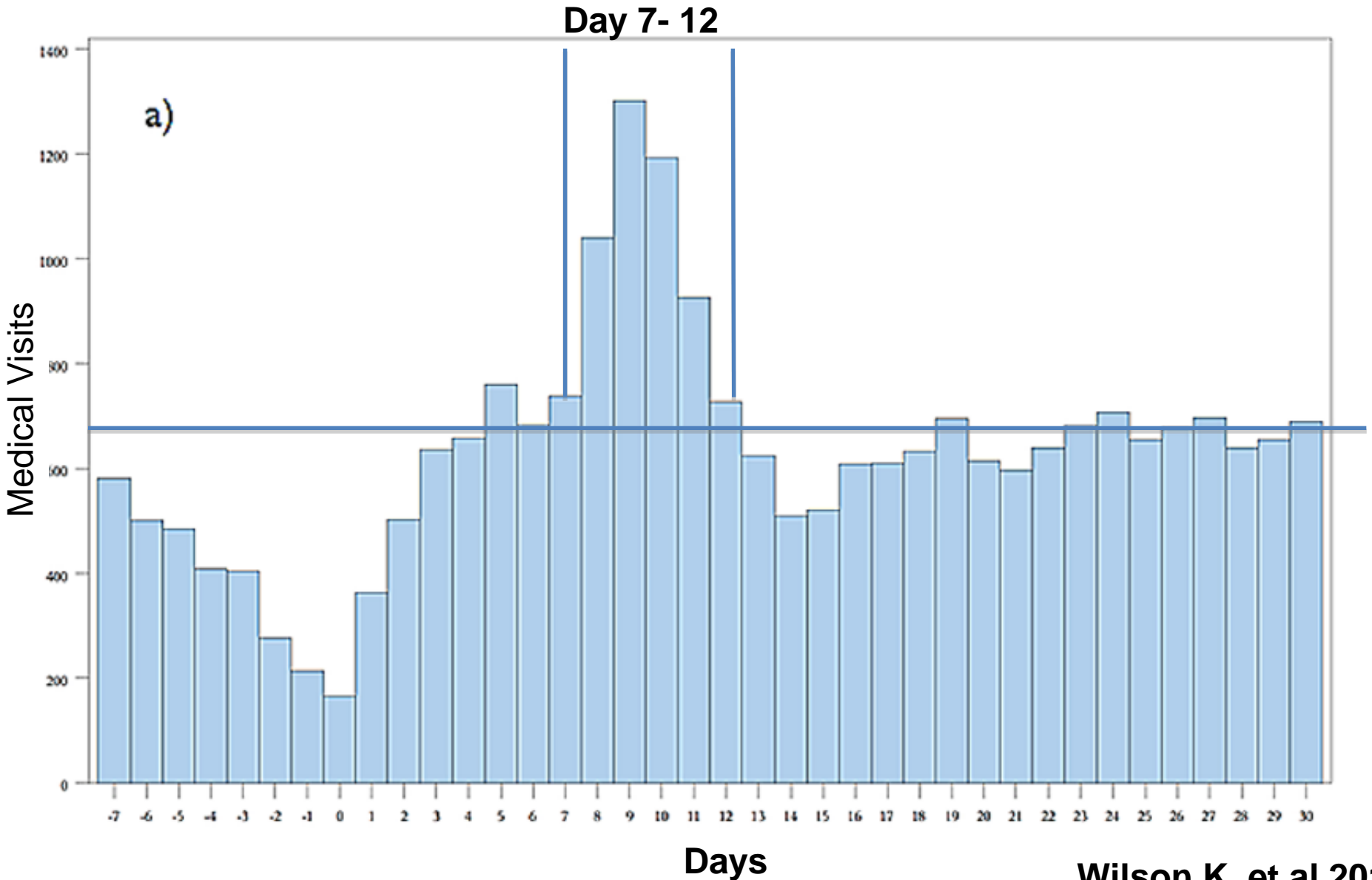
# The next 15 minutes

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- 1. What do we know about MMR safety**
- 2. Today's concerns**
- 3. Upcoming issues**
- 4. Communicating Uncertainty**
- 5. Tomorrows methods**

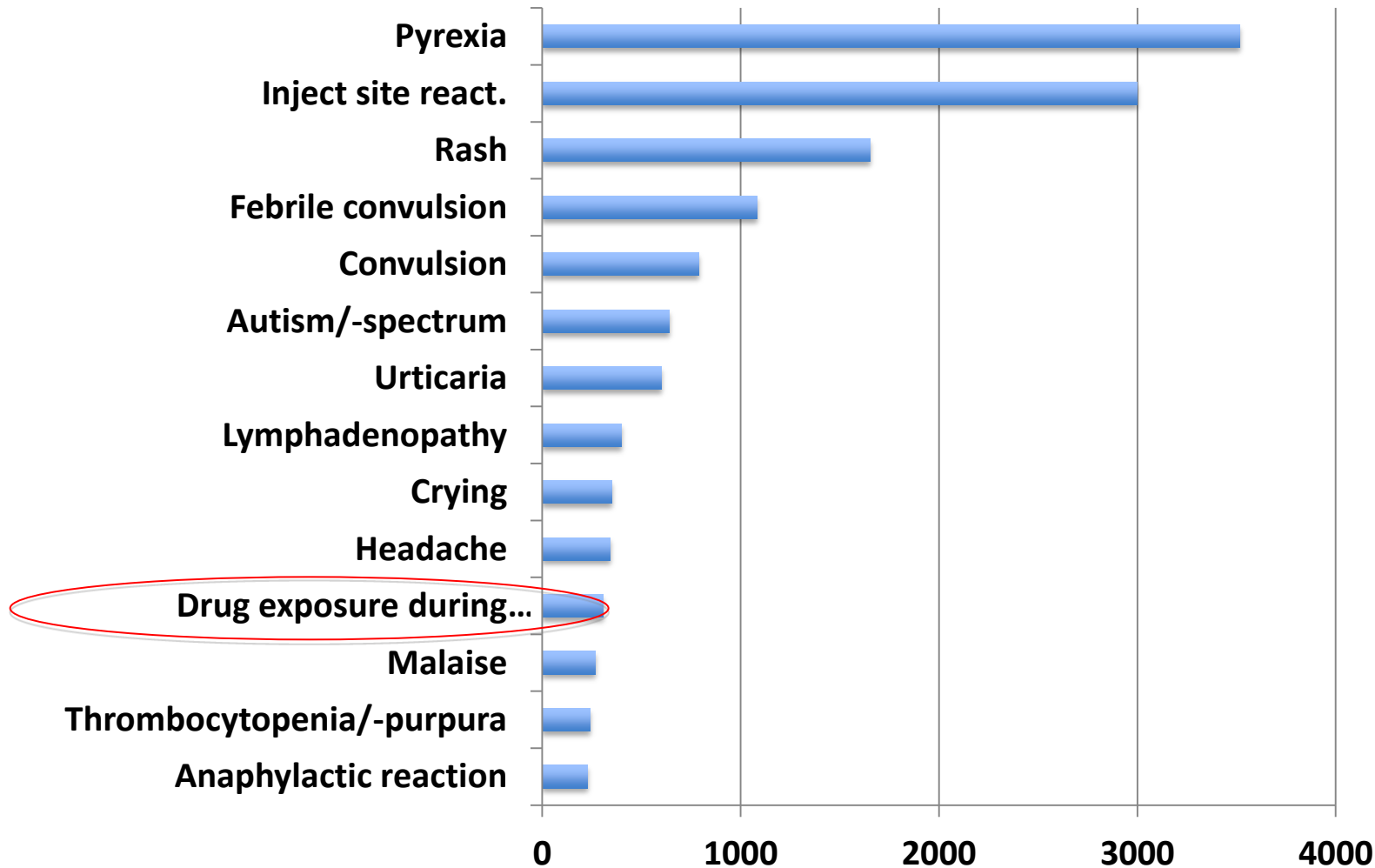


# 1<sup>st</sup> dose live virus vaccines (12 mo)





# MMR - AEFI reports to Eudra-Vigilance



 Campaigns may yield important population level effects



# MMR-AEFI by age group

Age group	Sex		Total
	M	F	
0-12 months	622	485	1107
12-24 months	1927	1756	3683
2-18 years	1949	1565	3514
Over 18	321	836	1157
<b>Total</b>	<b>4819</b>	<b>4642</b>	<b>9461*</b>

\* Missing Age Information = 6560

 Prepare for catch up campaign in adolescents & adults

Source data kindly provided by J. Slattery, EMA



# Safety of currently licensed MMR vaccines

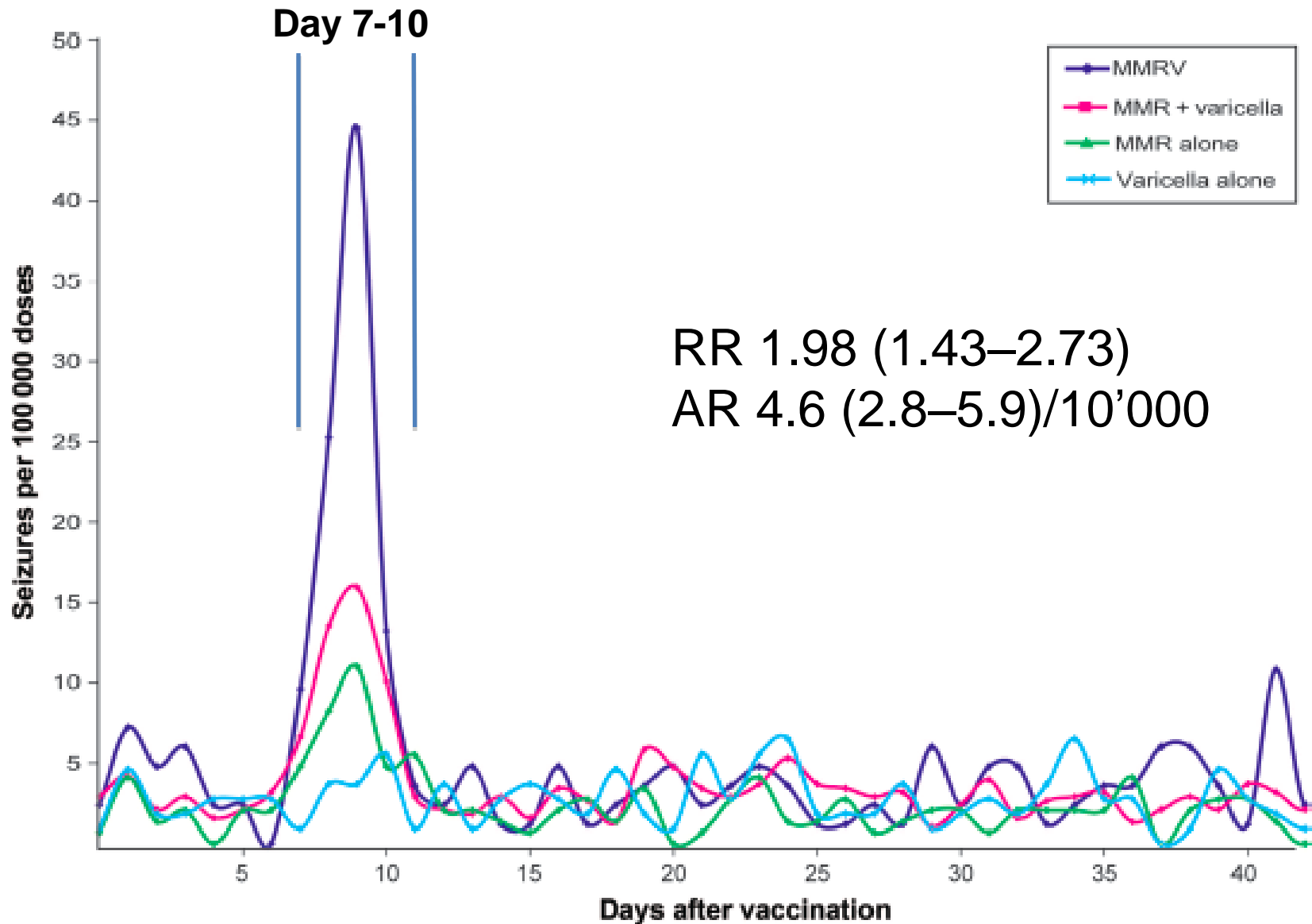
Evidence for causal association	Evidence against Causal association
Fever	Arthropathy
Febrile seizures	Fetal abnormalities
Rash	CRS
Allergic Reaction	Encephalitis
Thrombocytopenia	Autism



**Health professionals and parents: different priorities**

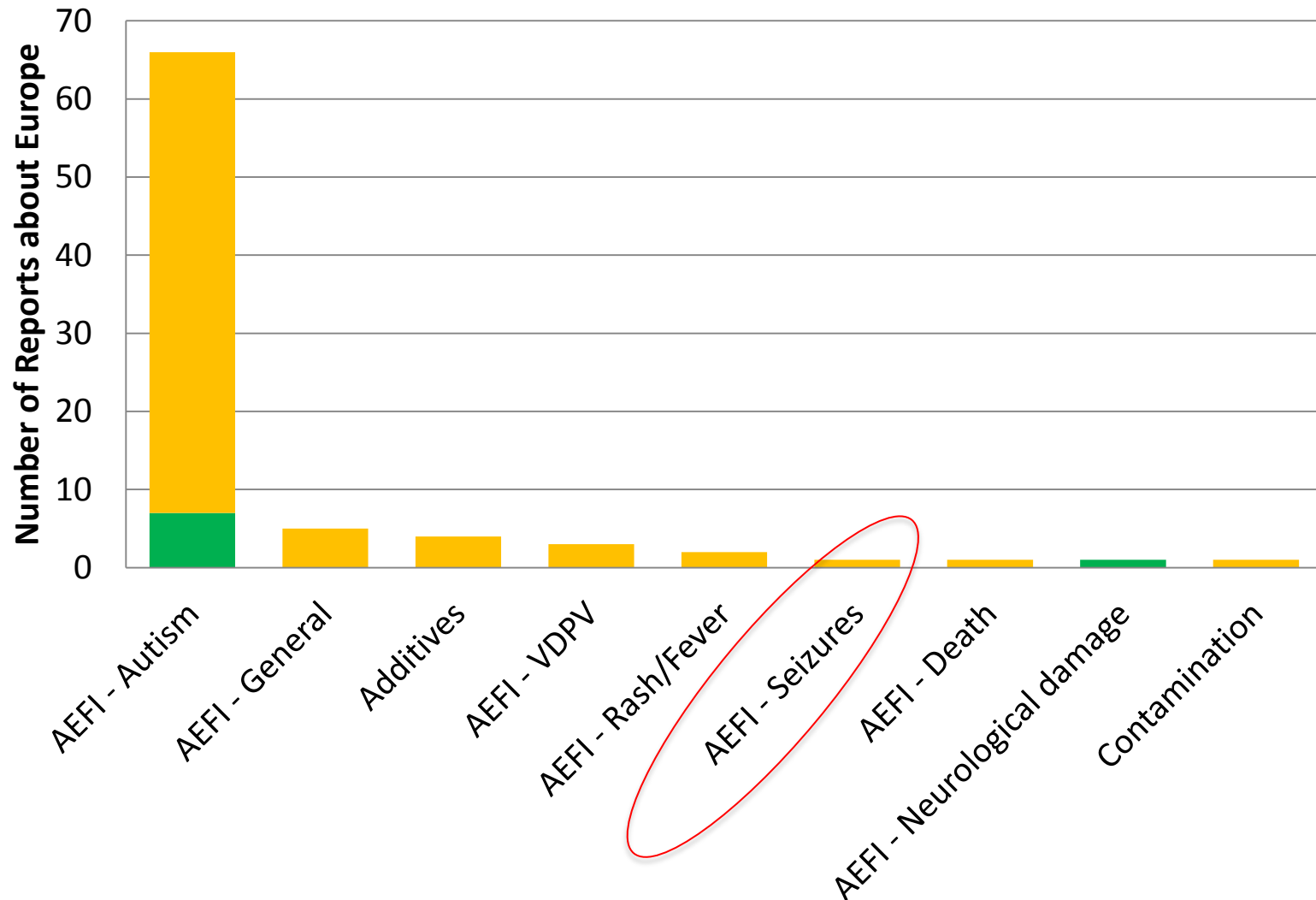


# First dose MMR-V and febrile seizures



# Reports about MMR in Europe by data categories of concern (May 2011 – Feb 2012)

*(red-negative; yellow-medium risk; green-low risk)*







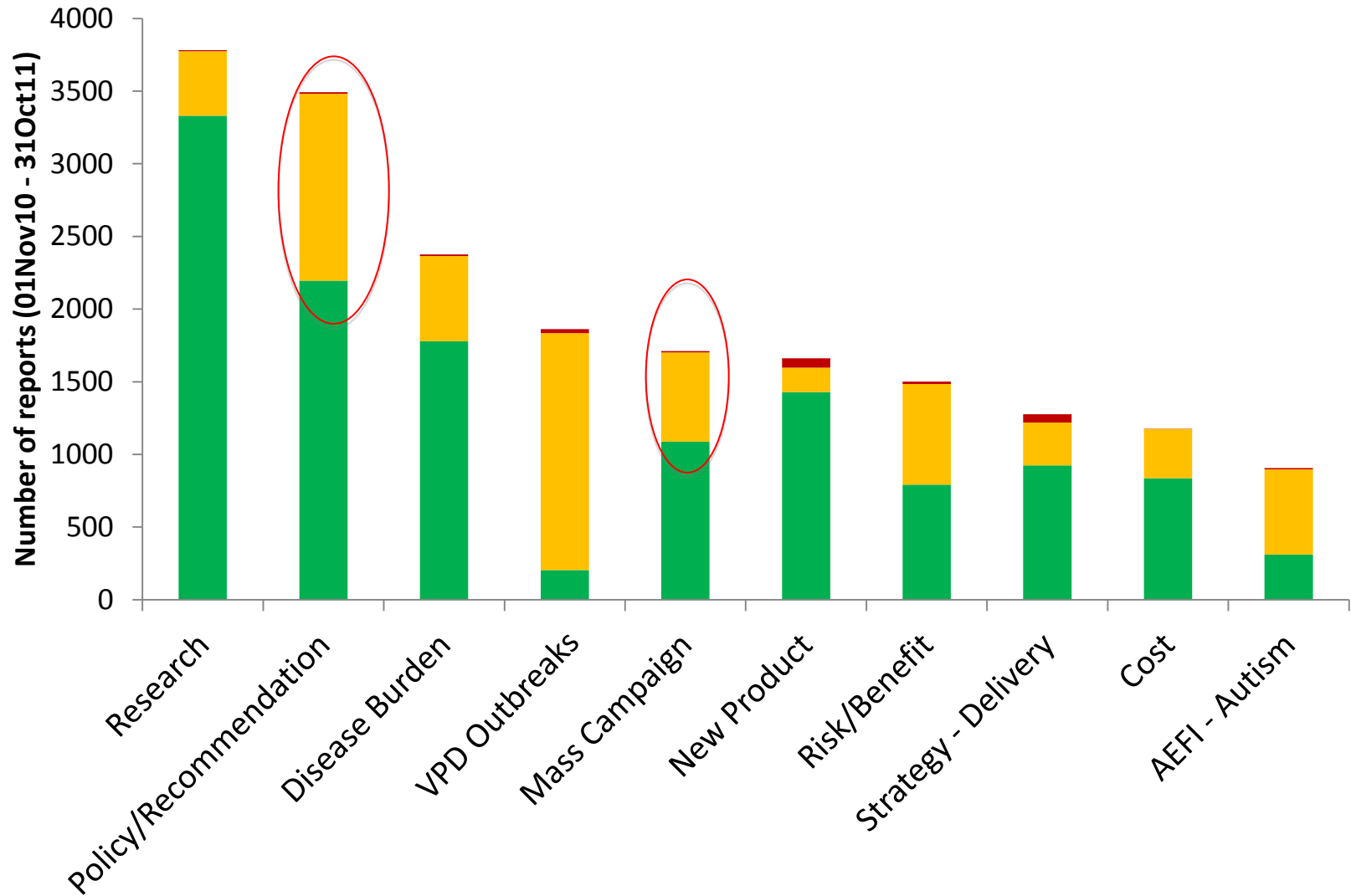
# Drivers of MMR vaccine questioning

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- **No experience of disease and its complications**
- **Second hand information about autism**
- **Fear of wrong decision making related to vaccination**
- **Distrust in policy /procurement/manufacturers**

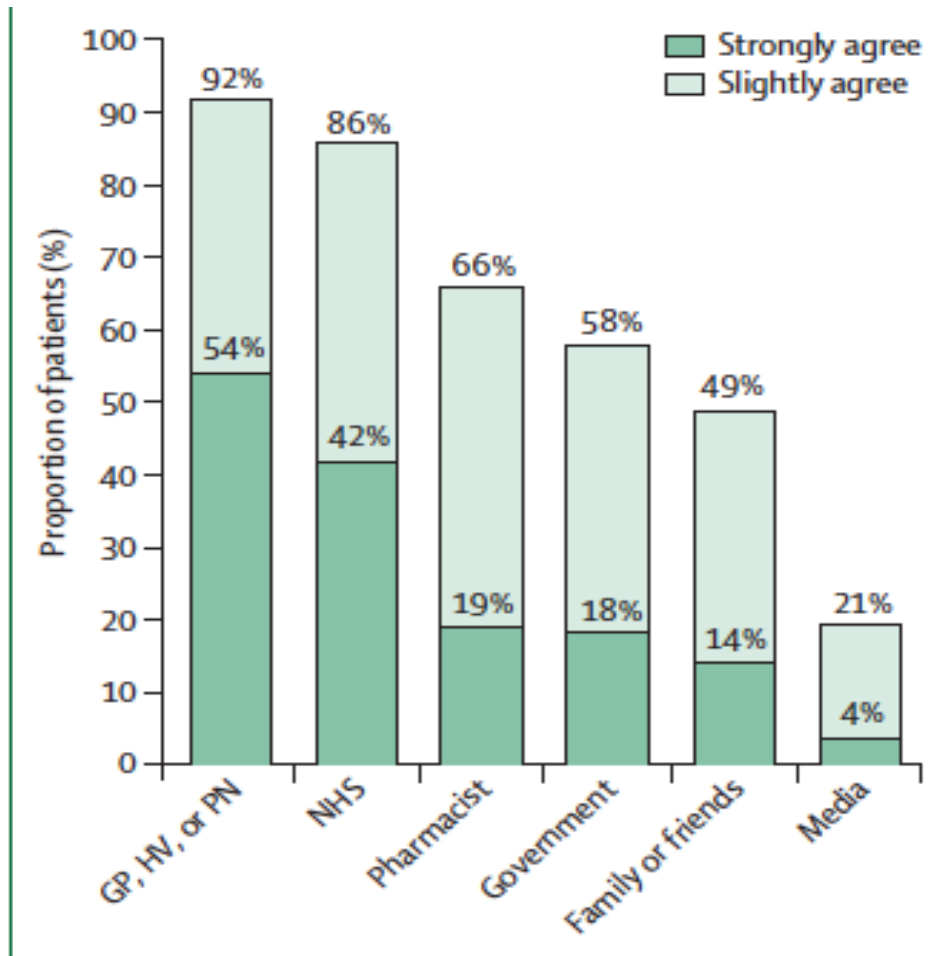
# Global media reports by data categories

(red-negative; yellow-medium risk; green-low risk)





# Drivers of public trust



**Target health care professionals**



# Target the uncertain and the opinionated



- ➡ **Outbreaks have major impact on immunization rates**
- ➡ **Failure to communicate change in parental mind set**

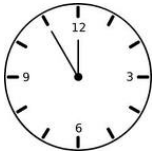


# Lessons learned from MMR Vaccine

- Large scale public concerns often unpredicted  
➡ **Anticipate public concerns**
- Public concerns unnecessarily derailed programs  
➡ **Understand dynamics of “threshold events”**
- Communication alone will not stop public distrust  
➡ **Strong evidence to speak with confidence**
- Post-hoc investigation may take 10-20 years  
➡ **Rapid, reliable investigation of concerns**
- Small scale and fragmented research  
➡ **International collaboration and data sharing**



# Communicate uncertainty during learning curve

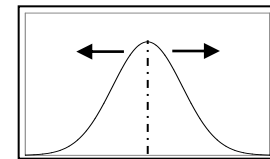


## International Collaboration & Shared Methods



**Causality**

Mechanistic Studies



**Large Linked Populationbased Databases**



# Issues to be addressed

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- **Public concerns have derailed MMR programs**
  - **Mass exposure is risk for public concern**
  - **Policy changes are risk for public concern**
  - **Build confidence in “being a good parent” with MMR**
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- ➔ **Structured monitoring of public trust**
  - ➔ **Hypothesis testing of MMR in adults/pregnancy**
  - ➔ **Strengthen international linkage of large databases**