

What Immunization Providers Need to Know about Vaccine Safety

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION



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Overview of Presentation

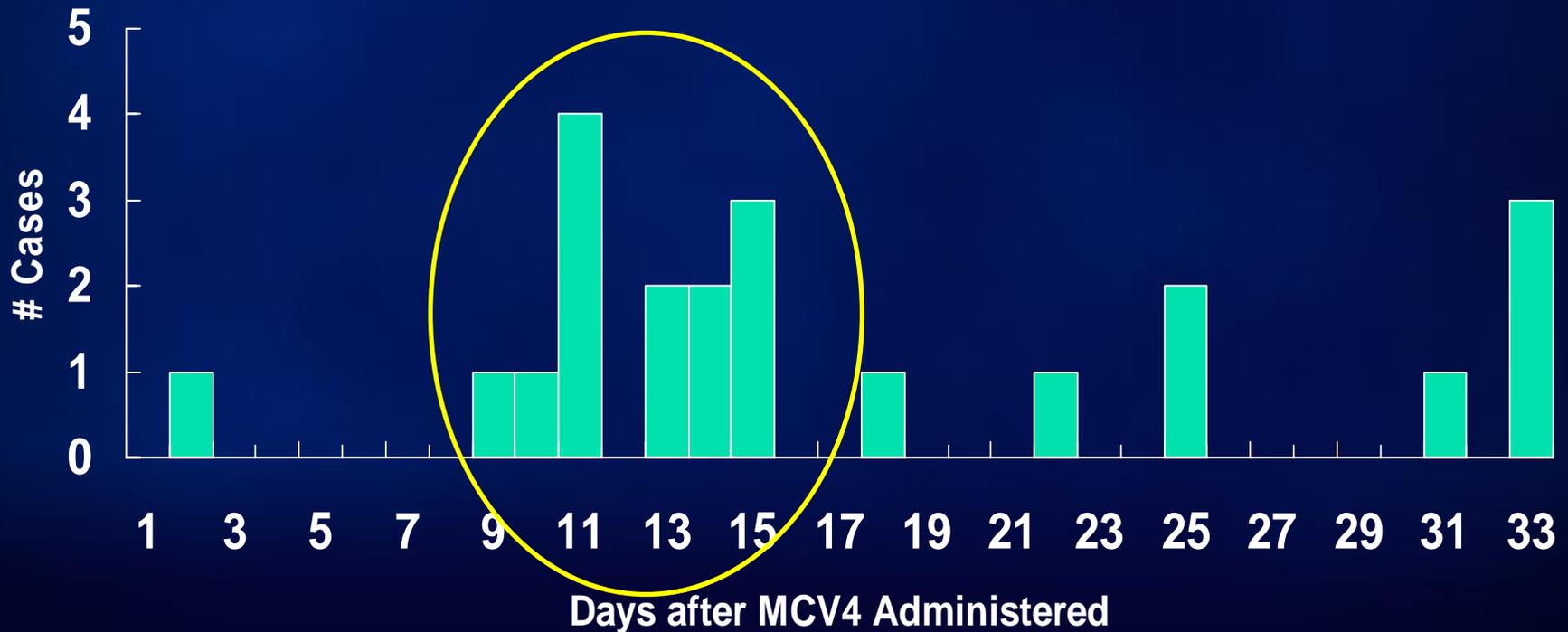
- **Brief updates on a number of current vaccine safety issues**
- **Vaccines and autism (June 2008 edition)**
- **What are parents concerned about, and how to better address those concerns**

Meningococcal Conjugate Vaccine and Guillain-Barré Syndrome

- **VAERS: 24 confirmed reports among vaccine recipients**
 - 2 among persons 11-14 years of age
 - 20 among persons 15-19 years of age
- **Observed cases > expected cases for 15-19 year olds**
 - Calculation assumes complete reporting and administration of all doses of vaccine distributed
- **Benefits of vaccination still outweigh risks, even if magnitude of risk is greater than that observed to date**

Timing of Onset of GBS following MCV4

- Onset intervals 2-33 days
 - Mean 17.4 days
 - Median 14.5 days



MACLEAN'S



**BARBARA
AMIEL:
I'm home
alone P.12**

AUG.
27th
2017

OUR GIRLS AREN'T GUINEA PIGS

A mass inoculation of Canadian girls against a sexually transmitted virus is under way. Experts say it's unnecessary—and potentially dangerous.



Vaccine Safety and HPV Vaccine

- **As of April 30, 2008, VAERS reports of:**
 - **31 cases of Guillain-Barré syndrome; 10 have been confirmed**
 - **15 deaths, only 10 of which could be verified**
 - **1 case of lower motor neuron disease**
- **Increased reporting of syncope among vaccinees**
- **Syncope recognized to occur following vaccination, especially among adolescents and adults**

General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP)

“..., although syncopal episodes are uncommon ... vaccine providers should strongly consider observing patients for 15 minutes after they are vaccinated. If syncope develops, patients should be observed until symptoms resolve.”

MMWR 2006; 55 (No. RR-15)

Intussusception and RotaTeq®

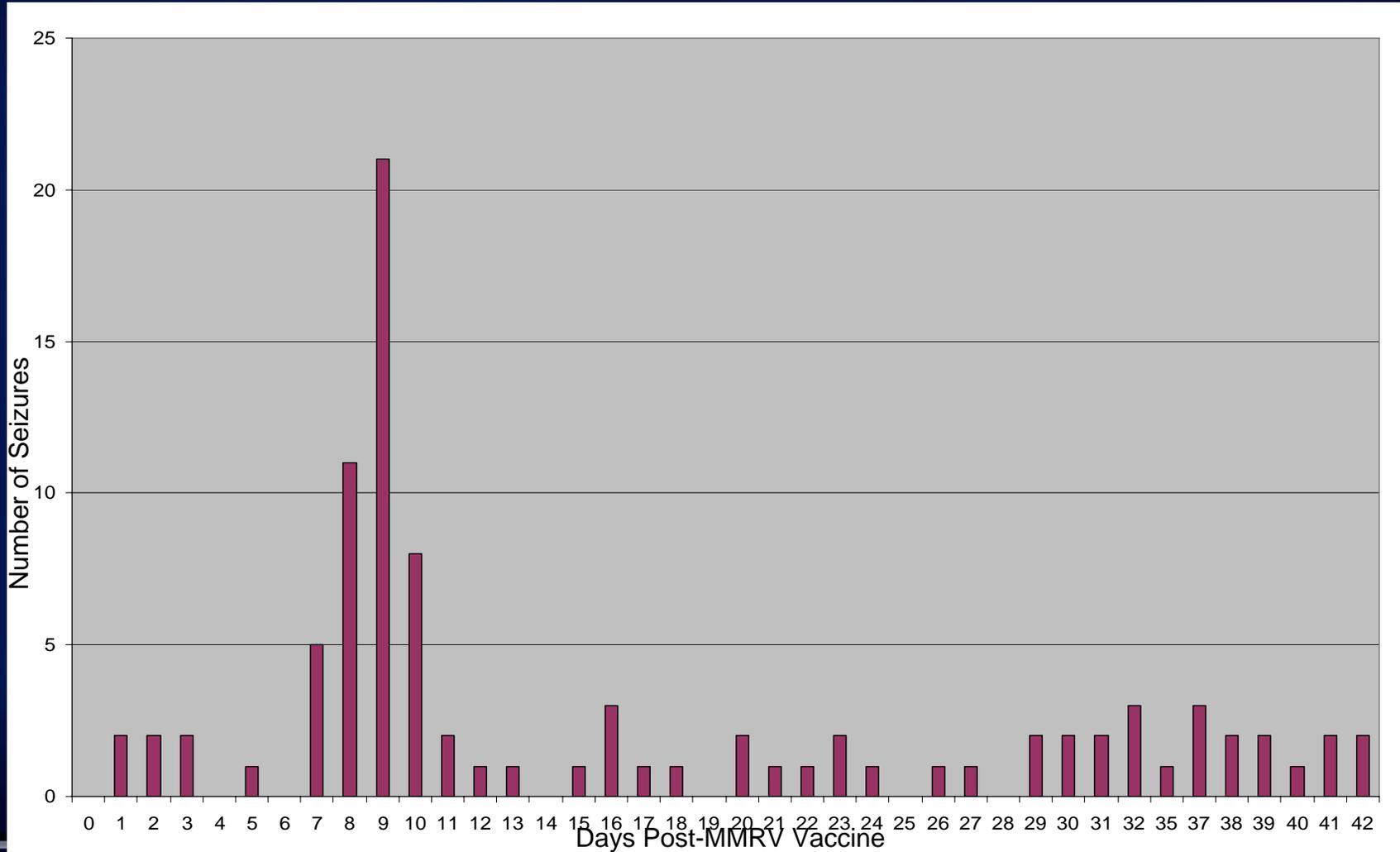
- **9.1 million doses distributed (March 2006-August 31, 2007)***
- **VAERS: 160 confirmed intussusception reports**
 - **47 reports with onset 1-21 days after vaccine**
 - **27 of 47 were within 1-7 days**
- **Observed cases < expected cases, assuming 75% of intussusception cases reported to VAERS and 75% of distributed vaccine administered**

Adverse Reactions Following MMRV and MMR+V

- Fever is more common in the 5-12 days after vaccination following MMRV (22%) than following MMR+V (15%)
- Data from CDC Vaccine Safety Datalink sites indicate the rate of febrile seizures following MMRV (9 per 10,000 vaccinated) was approximately 2 times higher than among those receiving MMR+V at the same visit (4 per 10,000 vaccinated)
- Merck postlicensure surveillance has identified a similar trend



Temporal Distribution of Seizures after MMRV Vaccination



Klein, ACIP presentation, February 2008

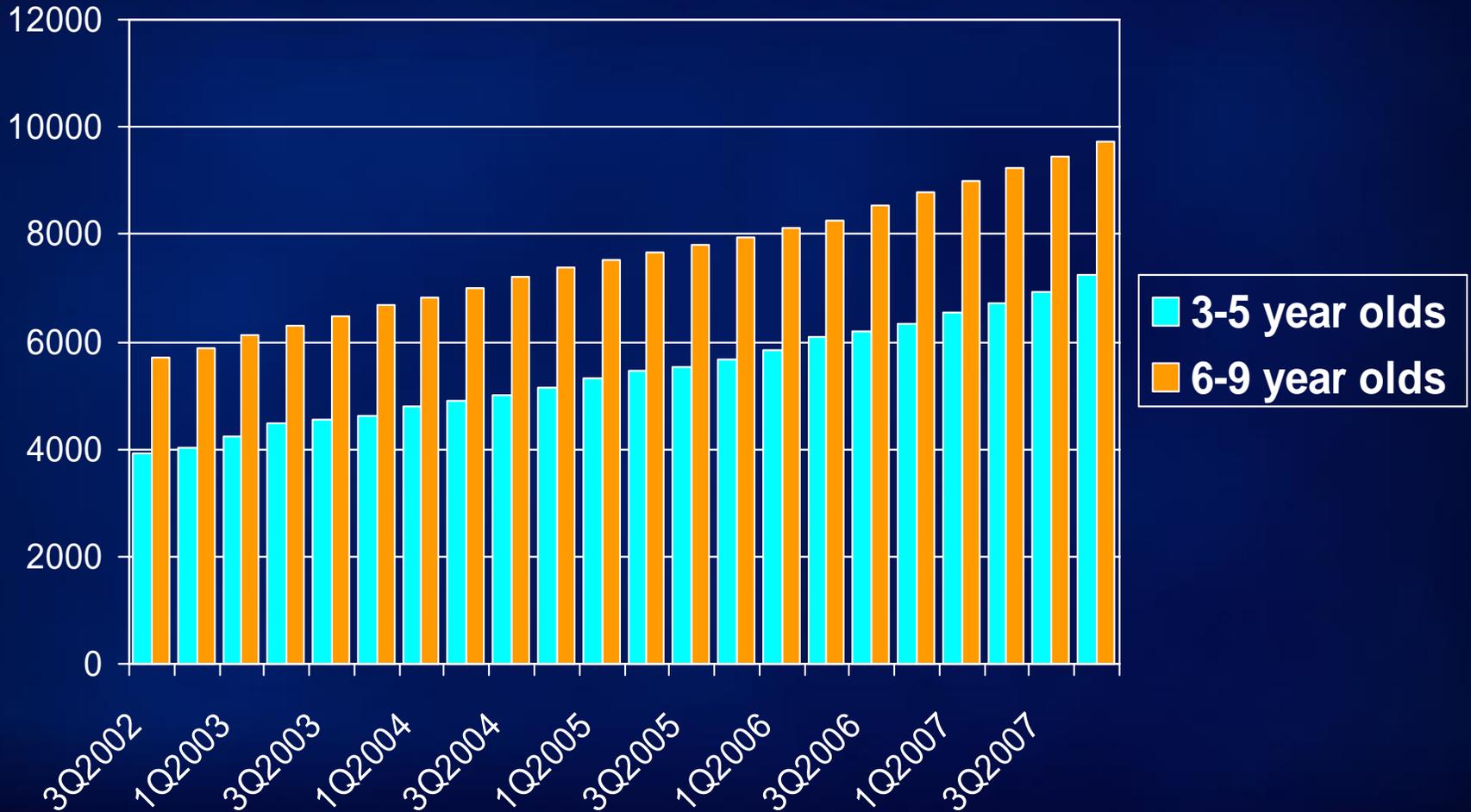
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Thimerosal and Autism: What Does the Science Show?

- **Ecologic studies: autism does not go down when thimerosal is removed from childhood vaccines**
- **Epidemiologic studies: well-designed studies demonstrate no association between thimerosal exposure from vaccines and autism**
- **Biochemical studies and animal models interesting but uninformative**

Children Receiving Autism Services by Quarter, California, 2002-2007



Vaccines and Autism, Still

- **MMR and autism (1998)**
- **Thimerosal and autism (2001)**
- **Simultaneous administration of multiple vaccines and the “one size fits all” immunization schedule (2007)**
- **Mitochondrial disorders (2008)**

“Why doesn’t CDC do a study autism rates in unvaccinated children?”

- **Almost all children in the U.S. have received at least some vaccines; only 3 per 1000 children have received no vaccines**
- **Unvaccinated children probably very different from other children in terms of:**
 - **Health care utilization**
 - **Other exposures**
- **Although recognized autism spectrum disorders more common than previously reported (2-6 per 1000), disease is infrequent enough that a large population needed to identify sufficient cases for a study**

Vaccines and Autism: Context

- Heuristics and biases
- Distrust of government
- Unanswered questions about autism and real needs of families
- Advocacy
- Litigation
- The Internet

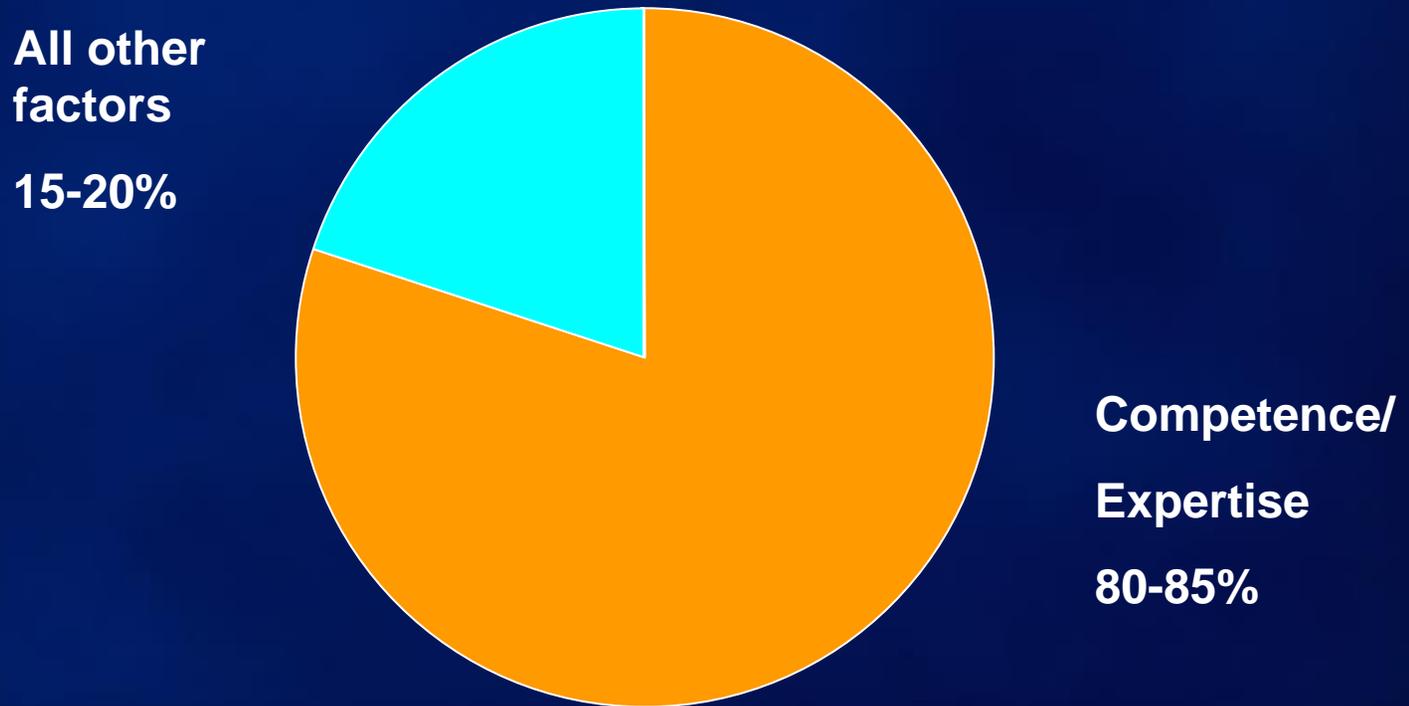
What Parents Are Concerned About (2003)

- **It is painful for children to get so many shots during one doctors visit (31%)**
- **The ingredients in vaccines are unsafe (24%)**
- **Vaccines are not tested enough for safety (21%)**
- **Children get too many vaccines (21%)**
- **Vaccines may cause learning disabilities (17%)**

Is Our Immunization Schedule “One Size Fits All”?

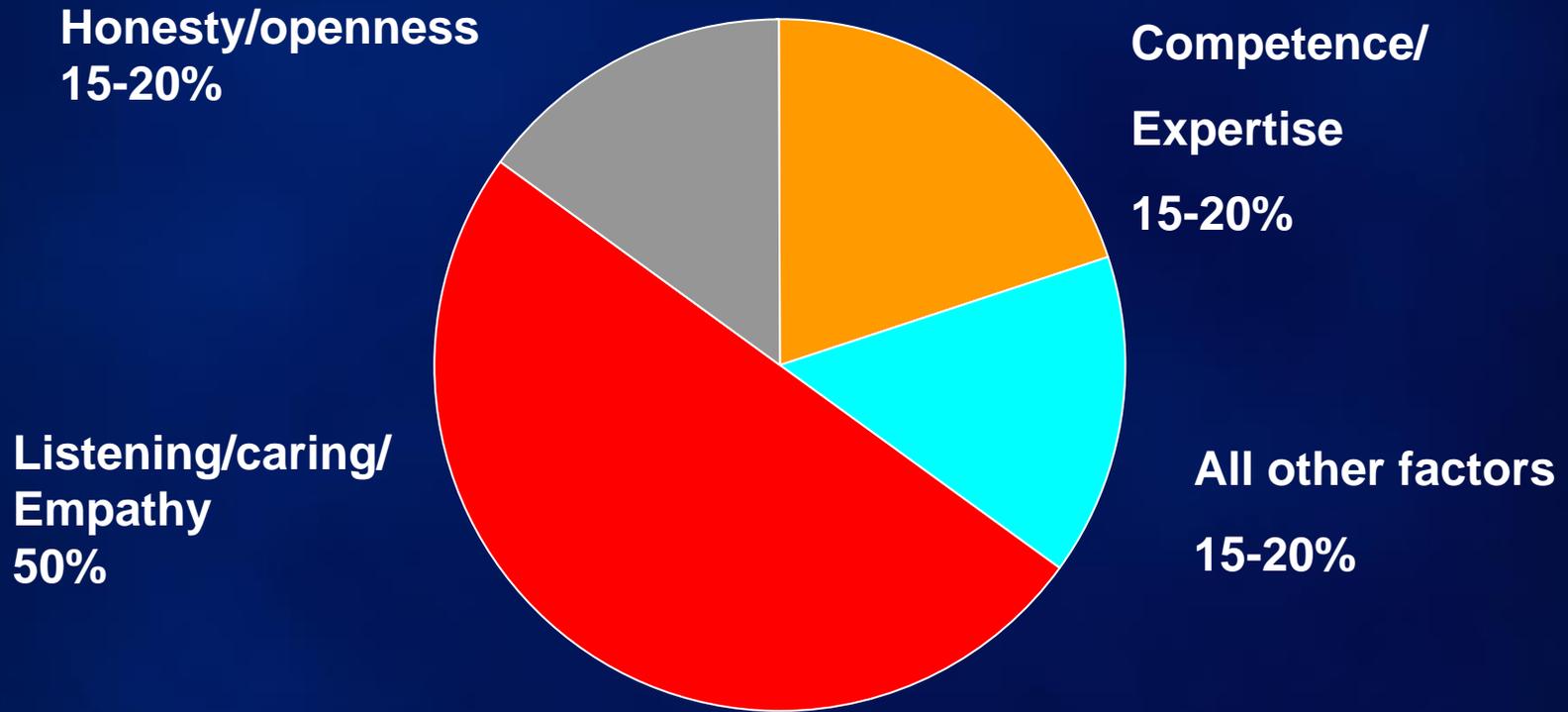
- **Contraindications and precautions do provide guidance for decision-making**
- **Flexibility in timing within the recommended schedule**
- **Some children *are* vulnerable, and screening usually not possible**
- **Vulnerable children *can* be protected -- with safer vaccines for everyone**

What Determines Credibility? Low Concern Settings



Randall Hyer, NIC, 2005

What Determines Credibility? High Concern Settings



Randall Hyer, NIC, 2005

Three Take Home Messages

- **Vaccination is the best way to protect children from 16 vaccine-preventable diseases**
- **Science does not support a relationship between vaccines and autism**
- **Science, and scientific communications, are insufficient to address current concerns**