

# **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

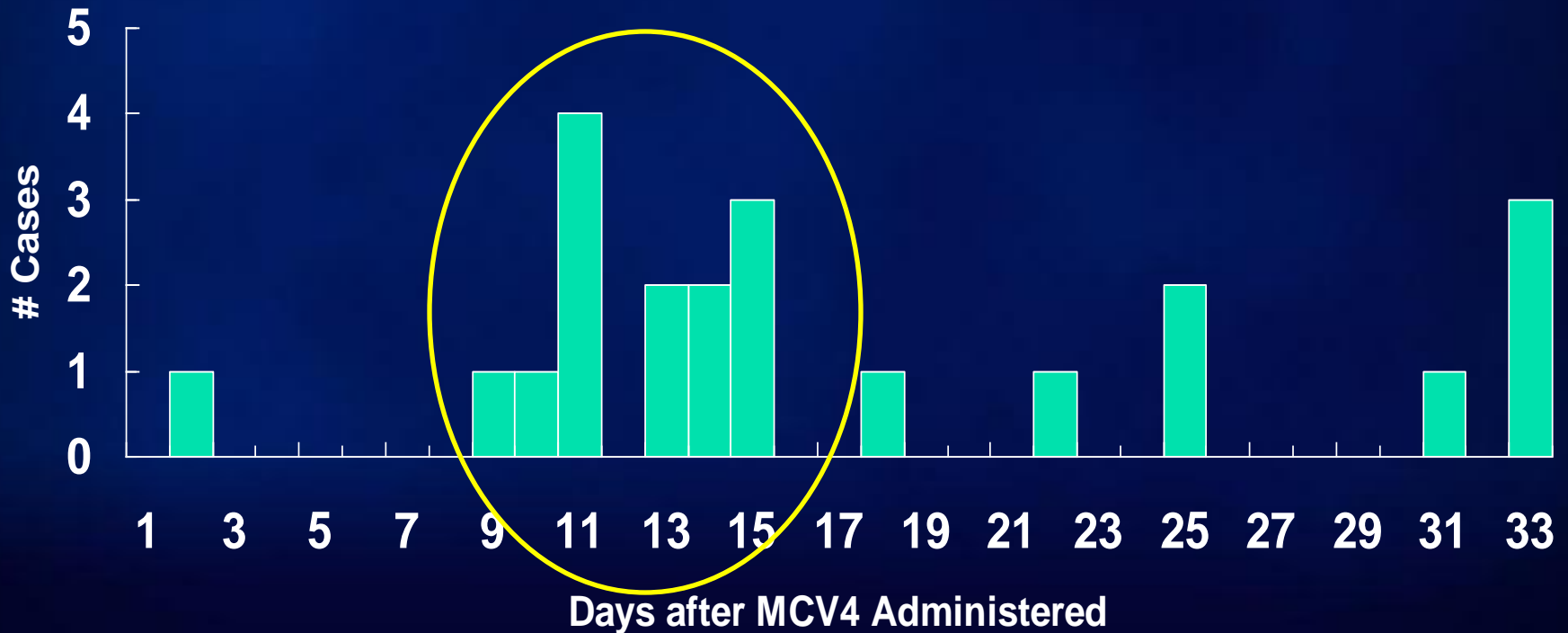
- **Brief updates on a number of current vaccine safety issues**
- **Vaccines and autism (June 2008 edition)**
- **What are parents concerned about, and how to better address those concerns**

# **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®**

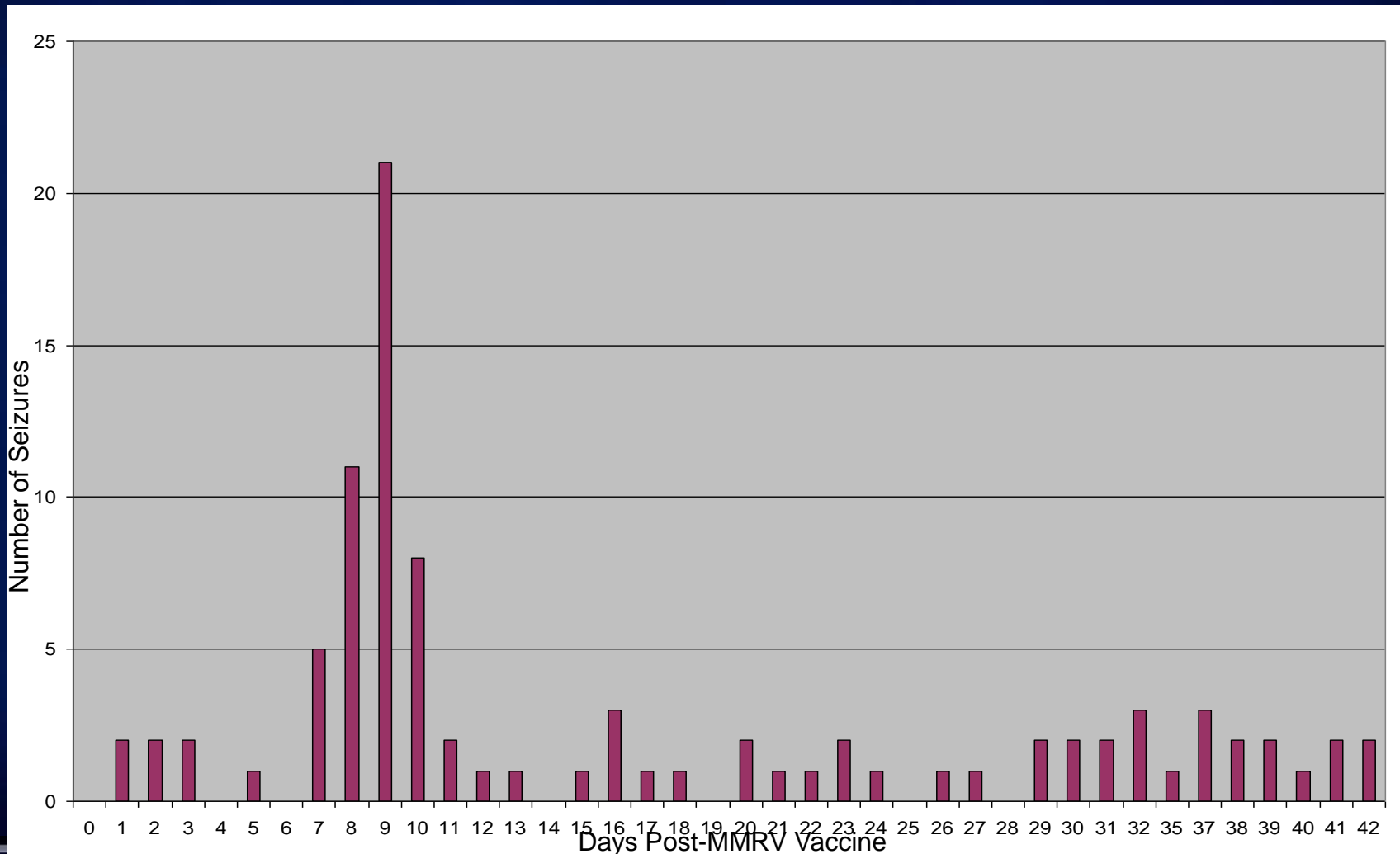
- **9.1 million doses distributed (March 2006-August 31, 2007)\***
- **VAERS: 160 confirmed intussusception reports**
  - **47 reports with onset 1-21 days after vaccine**
  - **27 of 47 were within 1-7 days**
- **Observed cases < expected cases, assuming 75% of intussusception cases reported to VAERS 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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12/06-9/07 after 47,137 vaccine visits)

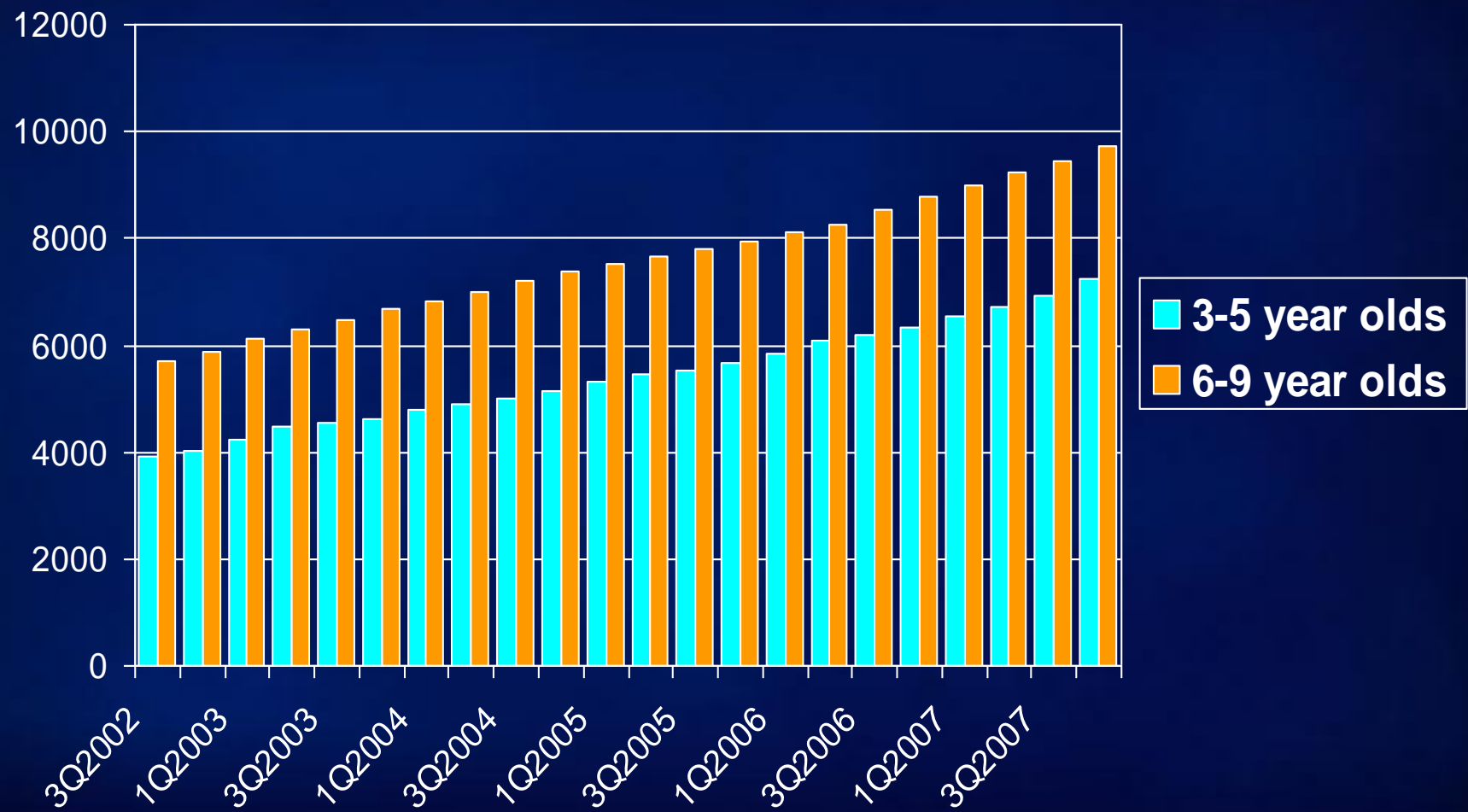


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# **Thimerosal and Autism: What Does the Science Show?**

- **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**

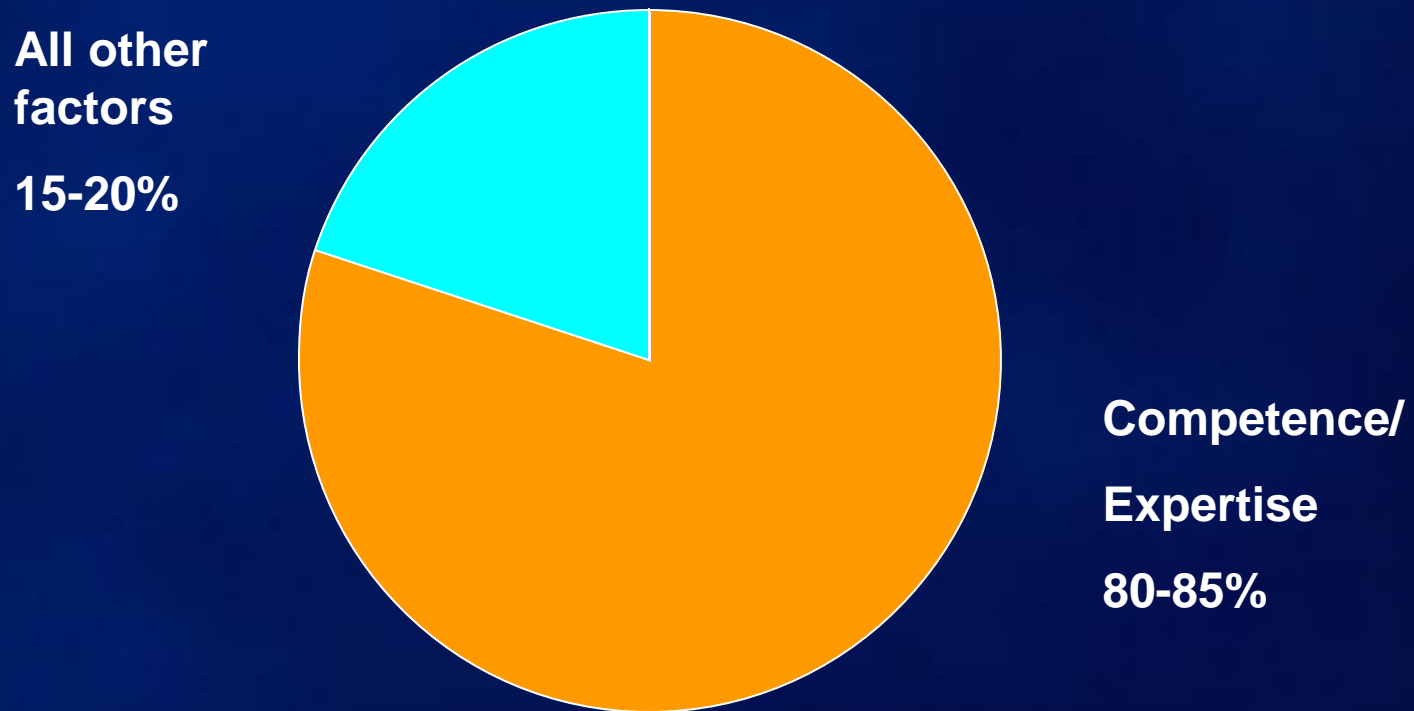
# **What Parents Are Concerned About (2003)**

- **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”?

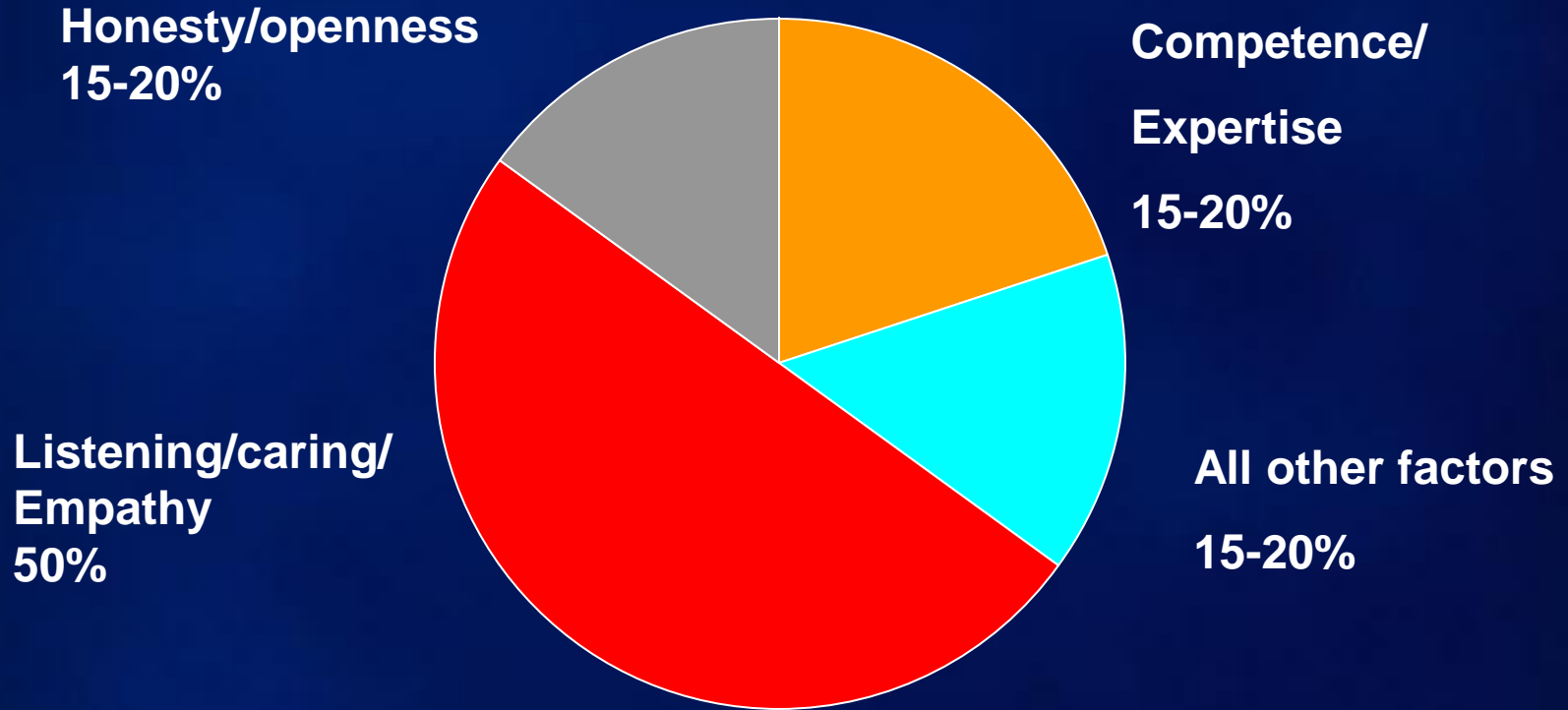
- **Contraindications and precautions do provide guidance for decision-making**
- **Flexibility in timing within the recommended schedule**
- **Some children *are* vulnerable, and screening usually not possible**
- **Vulnerable children *can* be protected -- with safer vaccines for everyone**

# 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**