STANDARD DEVIATIONS: The Good, The Bad, and The Ugly

Greetings,

There is one engineering control that has unquestionably saved million of lives and that laboratorians have been using for decades. This engineering control has also been the source of unforeseen harm and havoc. And while sound scientific evidence has long been a hallmark of its value, there has also been centuries of a large vocal and adamant opposition to its use. Here is The Good, The Bad, and The Ugly of **vaccines**.

The Good.

{These shots never miss.}

Vaccines save lives. For HUNDREDS of years we have known that the principle provides protection from lethal infections. Our understanding has grown exponentially since and the technology and science of vaccinology is cutting-edge in the most highly regarded universities and biotechnology industry leaders.

Undeniably, millions of lives have benefitted from vaccines. From Edward Jenner's use of cowpox in 1796 to Maurice Hilleman's many vaccines still in use today all the way to the novel mRNA vaccines emerging in the coronavirus pandemic, the protection of vaccination has allowed mankind to focus on improving life rather than struggling to survive infectious disease.

The eradication of smallpox and polio (well, nearly) are evidence of vaccine success.

The Bad.

{These shots are killers.}

The road to a safe vaccine is long and difficult, travelling through unchartered territory. Intensive study, experimentation and trials are necessary and still lead down dead-end paths or fail spectacularly. The nature of this science is trial and error. As hard as they try, vaccines are not sure bets. Oversight is a crucial yet flawed mechanism to evaluate efficacy and safety. The study and trial phases of research are plagued with issues, and unexpected outcomes thwart our efforts. The balance between production and safety is affected by the severity of morbidity/mortality, competition for profit, social acceptance, time, and the quality of investigation.

In April 1955 more than 200,000 children in five Western and mid-Western US states received a polio vaccine in which the process of inactivating the live virus proved to be defective. Within days there were reports of paralysis and within a month the first mass vaccination program against polio had to be abandoned. Cutter Laboratories had caused 40,000 cases of polio, leaving 200 children with varying degrees of paralysis and killing 10.

Rotavirus is the most important cause of severe gastroenteritis and diarrheal mortality in children. In 1998, a live attenuated vaccine was approved (RotaShield, Wyeth-Ayerst Laboratories). 1.5 million infants received treatment in the next year, but 13 cases of intussusception (part of the intestine folds into the section immediately ahead of it) occurred. The vaccine was withdrawn. The studies had either failed to include proper control groups to

account for recency of wild-type rotavirus infection, consider cumulative rates of intussusception, or include sample sizes large enough to detect differences in intussusception rates. The condition had been seen but did not meet the statistical threshold to stop the approval. Another vaccine did not come into use until 2006 (Rota Teq) and 2008 (Rotarix). Worldwide, rotavirus continues to take a toll. About 450,000 children under age 5 die each year from rotavirus illness.

In 2017, the Philippines stopped a dengue fever vaccination program after reports of complications and several deaths linked to Dengvaxia. The French manufacturer, Sanofi Pasteur, later stated that the vaccine posed a risk to those without prior infection from one of the disease's four stereotypes. The result was that *it actually increased the risk* that a child would contract a more severe form of the disease.

Wild-type polio is effectively vanquished, but the vaccine strains have mutated to the point where they are problems in their own right.

And, The Ugly.

{This gun is empty!}

Then there is the age-old problem of trust. For many reasons, vaccines have been polarizing people for as long as they have been used. Science is not one of those reasons.

Many Americans (and people, world-wide) fall into the enthusiastic supporter group and accept the science of vaccines. Many others don't and back away for their own reasons.

Most hesitancy stems from worry. It isn't the vaccine but side effects, lack of knowledge, concern for children, and just plain shyness and/or social pressure. Religion and education access make the list of factors affecting hesitancy.

The number of people who distrust vaccine science is relatively small and minorities comprise a disturbingly outsized portion, citing a lack of testing among their ethnicity.

And then there is the political angle. A growing divide among ideologies is pushing rational thought to the brink. Conspiracy believers are guided by misinformation and misdirection in order to promulgate ulterior motives of political gain.

In Tennessee, Republicans legislators threatened to shut down the state health department, saying it was targeting minors for mass vaccinations without the consent of parents. In Ohio, lawmakers allowed a doctor to testify at a legislative hearing last month that coronavirus vaccines could leave people magnetized (they can't). During a hearing in the Montana Senate, a senator said he had read articles about "putting a chip in the vaccine." One in five surveyed Americans believe that the U.S. government is using the COVI-19 vaccine to plant microchip tracking devices into people. A significant number of those who reject vaccines also cite the belief that inoculation in general causes autism. Neither claim is true.

It can be difficult to persuasively present evidence to refute these types of ideas, especially because experts are often seen as part of the conspiracy, and new pieces of contrary evidence can be rationalized into an existing narrative.

With vaccines, as in the lab, we are big on skepticism. Proof is required and confidence is based on evidence, reproducibility, and validation. The lens that used for observation is one of clarity and accuracy; putting bias aside and examining the facts with reason. Proving vaccine safety is the result of serious and diligent oversight.

Vaccines are an **engineering control** that makes our work safer. As a biosafety strategy, vaccines make sense. On the bench it is common to see 100% compliance with Hep B vaccination and flu vaccines are mandated yearly; and we're probably all current on tetanus. But take a closer look and you find that many technologists are vaccinated against rabies, anthrax, *Haemophilus influenzae t*ype b (Hib), and/or meningococcus. And let's not forget that we've been inoculated for mumps, measles, rubella, varicella, diphtheria, and pertussis as children.

The **ugly** truth is that vaccine hesitancy is justified. A history of **bad** outcomes reminds us that the science of vaccines is neither fool-proof nor fully understood. **Good** science and good stewardship are necessary to ensure that vaccines provide protection.

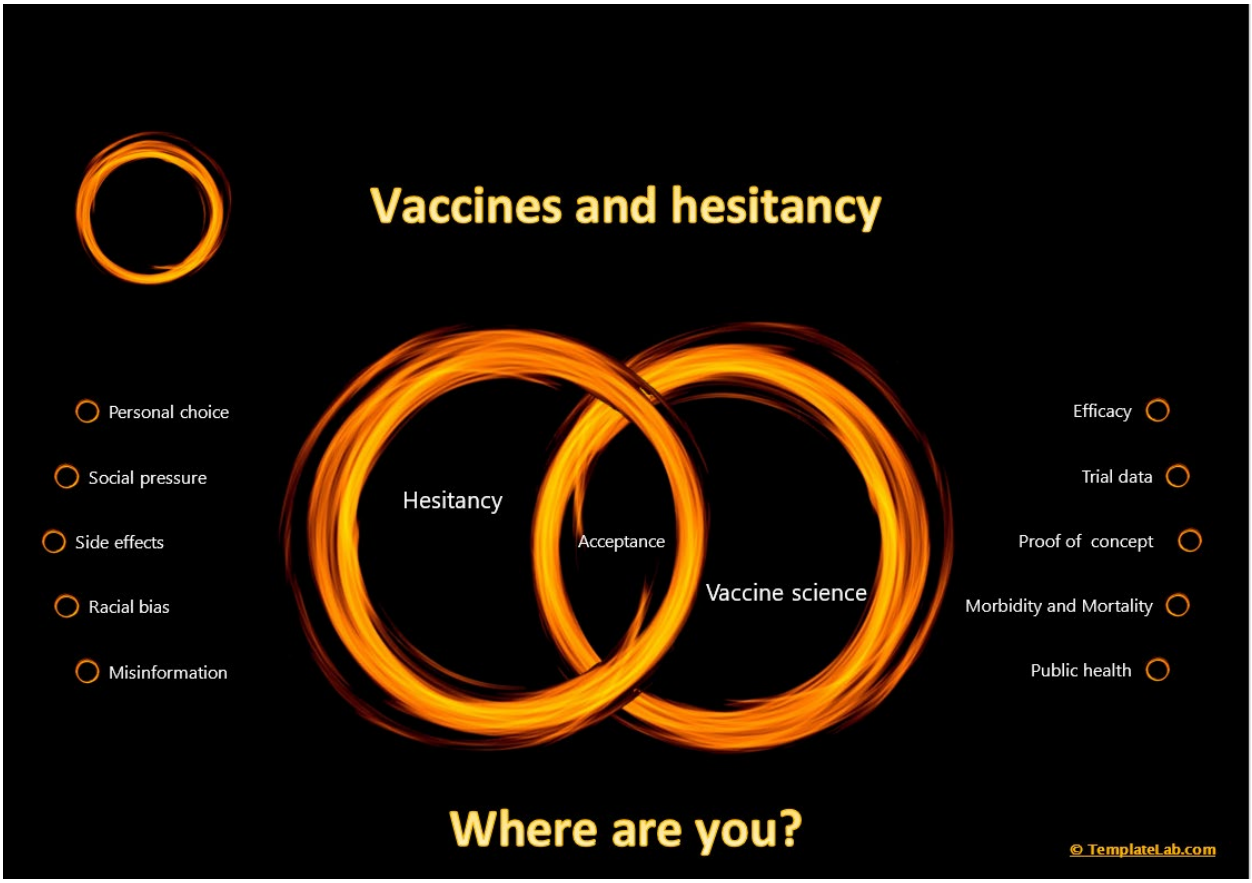
Health workers are the most trusted sources of guidance about COVID-19, and all, vaccines. As stewards of public health, it is our obligation to ensure efficacy and promote safe practices in preventing disease. Despite the bad and the ugly, vaccines are an engineering control that protects the scientist on the bench and billions of people around the world, and that's good.

Have a great week and be safe,

Bryan

p.s.

Where do the concepts of personal freedoms and public health intersect?



Links to clinical info about U.S. vaccines:

(https://www.cdc.gov/vaccines/vpd/vaccines-list.html)

- Adenovirus
- Anthrax
  - AVA (BioThrax)
- Cholera
  - Vaxchora
- Diphtheria

    - DTaP (Daptacel, Infanrix)
    - Td (Tenivac, generic)
    - DT (-generic-)
    - Tdap (Adacel, Boostrix)
    - DTaP-IPV (Kinrix, Quadracel)
    - DTaP-HepB-IPV (Pediarix)
    - DTaP-IPV/Hib (Pentacel)
- Hepatitis A
    - HepA (Havrix, Vaqta)
    - HepA-HepB (Twinrix)
- Hepatitis B
    - HepB (Engerix-B, Recombivax HB, Heplisav-B)
    - DTaP-HepB-IPV (Pediarix)
    - HepA-HepB (Twinrix)
- *Haemophilus influenzae* type b (Hib)
    - Hib (ActHIB, PedvaxHIB, Hiberix)
    - DTaP-IPV/Hib (Pentacel)
- Human Papillomavirus (HPV)
    - HPV9 (Gardasil 9) (For scientific papers, the preferred abbreviation is 9vHPV)
- Seasonal Influenza (Flu) only
    - IIV* (Afluria, Fluad, Flublok, Flucelvax, FluLaval, Fluarix, Fluvirin, Fluzone, Fluzone High-Dose, Fluzone Intradermal)
      *There are various acronyms for inactivated flu vaccines – IIV3, IIV4, RIV3, RIV4 and ccIIV4.
    - LAIV (FluMist)
- Japanese Encephalitis
    - JE (Ixiaro)
- Measles
    - MMR (M-M-R II)
    - MMRV (ProQuad)
- Meningococcal
    - MenACWY (Menactra, Menveo)
    - MenB (Bexsero, Trumenba)

- Mumps
    - MMR (M-M-R II)
    - MMRV (ProQuad)

- Pertussis
    - DTaP (Daptacel, Infanrix)
    - Tdap (Adacel, Boostrix)
    - DTaP-IPV (Kinrix, Quadracel)
    - DTaP-HepB-IPV (Pediarix)
    - DTaP-IPV/Hib (Pentacel)
- Pneumococcal
    - PCV13 (Prevnar13)
    - PPSV23 (Pneumovax 23)
- Polio
    - Polio (Ipol)
    - DTaP-IPV (Kinrix, Quadracel)
    - DTaP-HepB-IPV (Pediarix)
    - DTaP-IPV/Hib (Pentacel)
- Rabies
    - Rabies (Imovax Rabies, RabAvert)
- Rotavirus
    - RV1 (Rotarix)
    - RV5 (RotaTeq)
- Rubella
    - MMR (M-M-R II)
    - MMRV (ProQuad)
- Shingles
    - RZV (Shingrix)
- Smallpox
    - Vaccinia (ACAM2000):
- Tetanus
    - DTaP (Daptacel, Infanrix)
    - Td (Tenivac, generic)
    - DT (-generic-)

    - Tdap (Adacel, Boostrix)
    - DTaP-IPV (Kinrix, Quadracel)
    - DTaP-HepB-IPV (Pediarix)
    - DTaP-IPV/Hib (Pentacel)
- Tuberculosis
- Typhoid Fever
    - Typhoid Oral (Vivotif)
    - Typhoid Polysaccharide (Typhim Vi)
- Varicella
    - VAR (Varivax)
    - MMRV (ProQuad):
- Yellow Fever
    - YF (YF-Vax)