Preparing to Implement a New COVID-19 Vaccine

**What is the Clinical Problem?** In 2019, a novel SARS-CoV-2 virus started a global pandemic

**What has the impact been?**

World

27.6 million infected

898,000 deaths

US

6.35 million infected

190,000 deaths

Significant racial/ethnic/economic disparities

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**What are the limitations of current mitigation and management strategies?**

Management strategies largely focus on 1) changing behavior to reduce virus transmission (masking, handwashing, social distancing) through education and public policy, and 2) testing and contact tracing

* + Economic and social disruption from social distancing measures
  + Only moderately effective
  + Political barriers to widespread and consistent implementation in the U.S.
  + Limited access to community wide testing and contact tracing

**What is a possible solution?**  A new vaccine\*

\**This is a theoretical case study, not an actual vaccine*

**How does the vaccine work?**

Messenger RNA (mRNA) supplies information that DNA uses to make proteins, which regulate cells and tissues

* mRNA in SARS-CoV-2 enables a “spoke protein” that pierces cells throughout the body

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* mRNA vaccine contains synthetic mRNA that stimulates immune system into producing antibodies to viral proteins

Limitations of traditional viral vaccines (e.g. influenza or measles)

* In rare cases it can cause disease: Vaccine activates immune system by injecting small amount of attenuated virus or inactivated virus.
* Takes a long time to develop: grow weakened form of virus in chicken eggs, test which parts of virus successfully elicit antibodies – takes 4-6 months for annual flu vaccine. For a totally new virus like SARS-CoV-2, this process could take years or decades

Advantages of mRNA vaccine

* Does not contain any live or inactivated virus
* Faster to develop: researchers determine mRNA that results in SARS-CoV-2 producing proteins, create synthetic mRNA that is basis of new vaccine
* In early animal studies in the 1990s, mRNA vaccine delivery was dangerous – created an innate immune response (widespread inflammation), however, in mid-2000s, addition of carbon atoms to mRNA reduced inflammatory risk while preserving antigenicity function

**Is the mRNA vaccine for SARS-CoV-2 safe and effective?**

* ***In Clinical Trials, there is evidence that 50% of people who receive the vaccination series are protected. The rate of protective immunity is lower in children <5 and older adults (greater than 65).***
* ***10% of vaccine recipients experience a minor adverse event (e.g. arm discomfort)***
* ***0.1% of vaccine recipients experience a major adverse event (e.g. Guillane Barre Syndrome)***
* ***Vaccine was co-developed by investigators at UW/Fred Hutch and a biotech company, and is FDA approved. Currently 100million 2-dose vaccines available for distribution in the U.S. An additional 200million 2-dose vaccines will be available by January 2021.***
* ***2-dose vaccine for ages 6mos and up, 4 weeks between doses***

***IMPLEMENTATION CHALLENGES***

* Nation-wide pandemic – many people in need of vaccine!
* Single companies have insufficient production and delivery capacity to meet potential demand
* Not everyone is willing to get the vaccine, resistance not necessarily related to cost
* Vaccine cost is covered by most commercial and government insurances. Cost for self-pay is $250 for 2-dose series
* Think about where it should be administered and by whom – healthcare providers, public health staff, others

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