Alumni Exchange
Our Shared Path Forward to the Development of a Vaccine
Epidemiological Update

with Dr. Al Edwards
Slide Support & Graphics by
Alice Voiss, PMP
alicevoiss@yahoo.com
SOME SIMPLE TRUTHS ABOUT

• PPE > placing a barrier between you and the virus decreases the likelihood of infection

• FACE COVERING/FACE MASKS> think of them as barriers [bandages] for your lungs, i.e., keeping the virus out of your lungs

• Nose & throat are the most likely entry points for the virus to infect you
SOME SIMPLE TRUTHS ABOUT (cont’d)

• HANDS > the most used and therefore the most opportunity for virus contamination

• Decrease the chances of virus invasion by washing with soap & water for 20 seconds or using a hand sanitizer with minimum 60% alcohol content

• Disposable gloves also provide a barrier

https://www.ted.com/talks/alex_rosenthal_and_pall_thordarson_which_is_better_soap_or_hand_sanitizer?language=en
WE’RE ALL IN THIS TOGETHER

• Based on the highly contagious and potentially lethal nature of the virus
• Your safety depends on me, and my safety depends on you
WHY PPE VERSUS A DRUG OR VACCINE?

• Currently there are no proven, effective therapies
• Barriers, via PPE, are the best choice, at this time
KEEPING UP WITH THE NUMBERS:

• Using the reference numbers for each state can get to state statistics

https://www.worldometers.info/coronavirus/country/us/
THE BOTTOM LINE

• It is still early in the discovery life of this virus
• There are many things we do not know or do not know with certainty
• Expect health authorities to offer changes to our lifestyles
• A 2-5 year plan for changing how we live and what we do
• Is likely in order
Our Shared Path Forward to the Development of a Vaccine

DIAGNOSTICS:

A brief education on antibody and antigen testing

with Dr. Al Edwards
COVID-19 Diagnostics

A brief education on Swab & Blood testing for the coronavirus

S. Albert Edwards, PharmD LTD
Founder & President
eSubmissions University
fdaexpert@gmail.com
(847) 945-4750
www.esubmissionsuniversity.com
TESTING FOR THE CORONAVIRUS

Two types of Tests

• Swabbing, aka, Diagnostic Tests
• Blood Test, aka, Antibody Test
Swab Tests Can be Further Divided into THREE TYPES of TESTS

• All tests detect viral substances from the SARS-CoV-2 virus
• Molecular tests detect viral RNA
• PCR, aka Polymerase Chain Reaction tests detect viral DNA
• Both Molecular & PCR tests multiply viral DNA so it can be more easily detected
• Antigen tests detect the presence of viral proteins

Swab Tests (cont’d)

• They all answer the same question: *Do I have the virus, NOW?*

• When you have current virus-related symptoms, e.g.,
  
  • Fever
  • Cough
  • Shortness of breath
  • Chills
  • Muscle pain
  • Recent loss of taste or smell
  • Vomiting
  • Diarrhea and/or
  • Sore throat
Swab Tests (cont’d)

- Why a nasal swab: nose/throat are the most likely ways the virus invades the body
- How: by swabbing the nasopharyngeal passages, i.e., The upper throat area behind nose
- CAUTION: swab insertion can be uncomfortable
Body Immunity / Antibody / Serologic Testing

• Detects the body’s response to the virus and NOT viral substances
• When: well after you’ve had the virus and recovered
• Usually 1 to 3 weeks or more after all your symptoms have resolved
• How: blood sample
FDA STATUS of ALL COVID-19 TESTS

• 120 tests have received Emergency Use Authorization or an EUA
• EUAs are not the same as an FDA APPROVAL
• The majority are Swab Tests: 104 Molecular Tests & 1 Antigen Test, and
• There are 5 Antibody Tests available [on the market] through EUA
HOW EUAs DIFFER FROM FDA APPROVALS:

• APPROVALS are awarded when all required testing has been completed & verified
• They are permanent
• EUAs are temporary “passes” for manufacturers to sell and market their products
• During a defined emergency, such as a pandemic
HOW EUAs DIFFER FROM APPROVALS (cont’d)

• FDA using its best judgement, places achievable limits on tests and works with test developers
• Allowing the tests use during a public health emergency
• This was done, initially, with the EBOLA virus outbreak in 2013
HOW EUAs DIFFER FROM APPROVALS (cont’d)

• EUAs were started on January 31, 2020, for the SARS-CoV-2 virus pandemic
• EUAs will cease end when the pandemic is no longer an emergency
• With all EUA-marketed tests being withdrawn

Helpful FDA Video on Tests

https://www.youtube.com/watch?v=5hu7_xlsCRg

https://www.ted.com/talks/cella_wright_-_how_do_virus_tests_actually_work
Sars-Cov-2/Covid-19 Therapeutics and Vaccines

by

Thomas Kanyok, BS Pharm, PharmD, RPh
Therapeutics

Anti-virals and Anti-inflammatories

There are currently no FDA approved therapeutics but a number of products have been made available through EUA

Clinical Trials

- Operation Warp Speed (OWS)
- https://www.recoverytrial.net/
  - Chloroquine/Hydroxychloroquine
  - Dexamethasone
- National COVID-19 Convalescent Plasma Project
- SOLIDARITY World Health Organization (WHO).
  - > 100 countries have joined SOLIDARITY to evaluate high-profile treatment candidates for COVID-19 including hydroxychloroquine
- Interleukins cytokine storm: Tocilizumab and sarilumab IL-6 inhibitors, anakinra IL-1 inhibitor.

Other countries

- Avigan (favilavir) in China, Italy and Russia
- Veklury (remdesivir) in Japan.
Collaboration of several US federal government departments including the Department of Defense, Health and Human Services and its subagencies, Agriculture, Energy and Veterans Affairs and the private sector.

Within OWS, the US National Institutes of Health (NIH) has partnered with more than 18 biopharmaceutical companies to accelerate development of drug and vaccine candidates for COVID-19 in a collaboration dubbed Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV).

So far, the effort has yielded 14 vaccine candidates from more than 100 that are in development. Some of those are in clinical trials now.

Those 14 will be further narrowed down to seven candidates, and the most promising of those will get further testing and clinical trials.

Operation Warp Speed has also been working with multiple companies to quickly manufacture a vaccine and to develop solutions for distribution of that vaccine once it is ready. This includes tools such as pre-filled syringes, vials and containers.

May 21: HHS announced up to $1.2 billion in support for AstraZeneca’s candidate vaccine, developed in conjunction with the University of Oxford. The agreement is to make available at least 300 million doses of the vaccine for the United States, with the first doses delivered as early as October 2020 and Phase 3 clinical studies beginning this summer with approximately 30,000 volunteers in the United States.
This United Kingdom based national clinical trial aims to identify treatments that may be beneficial for people hospitalised with suspected or confirmed COVID-19

Principle Investigator - Peter Horby, Professor of Emerging Infectious Diseases and Global Health

A range of potential treatments have been suggested for COVID-19 but nobody knows if any of them will turn out to be more effective in helping people recover than the usual standard of hospital care which all patients will receive. The RECOVERY Trial is currently testing some of these suggested treatments:

- Lopinavir-Ritonavir (commonly used to treat HIV)
- Low-dose Dexamethasone (now only recruiting children)
- Azithromycin (a commonly used antibiotic)
- Tocilizumab (an anti-inflammatory treatment given by injection)
- Convalescent plasma (collected from donors who have recovered from COVID-19 and contains antibodies against the SARS-CoV-2 virus).

Data from the trial are regularly reviewed so that any effective treatment can be identified quickly and made available to all patients. Please see our news page for results that RECOVERY has already found. The RECOVERY Trial team will constantly review information on new drugs and include promising ones in the trial.

Tom Kanyok, BS Pharm, PharmD, RPh
• ‘We have concluded that there is no beneficial effect of hydroxychloroquine in patients hospitalised with COVID-19. We have therefore decided to stop enrolling participants to the hydroxychloroquine arm of the RECOVERY Trial with immediate effect. We are now releasing the preliminary results as they have important implications for patient care and public health.

• ‘A total of 1542 patients were randomised to hydroxychloroquine and compared with 3132 patients randomised to usual care alone. There was no significant difference in the primary endpoint of 28-day mortality (25.7% hydroxychloroquine vs. 23.5% usual care; hazard ratio 1.11 [95% confidence interval 0.98-1.26]; p=0.10). There was also no evidence of beneficial effects on hospital stay duration or other outcomes.

• ‘These data convincingly rule out any meaningful mortality benefit of hydroxychloroquine in patients hospitalised with COVID-19. Full results will be made available as soon as possible.

• 16 June 2020 FDA pulls EUA for hydroxychloroquine/chloroquine
In March 2020, the RECOVERY (Randomised Evaluation of COVid-19 thERapY) trial was established as a randomised clinical trial to test a range of potential treatments for COVID-19, including low-dose dexamethasone (a steroid treatment). Over 11,500 patients have been enrolled from over 175 NHS hospitals in the UK.

On 8 June, recruitment to the dexamethasone arm was halted since, in the view of the trial Steering Committee, sufficient patients had been enrolled to establish whether or not the drug had a meaningful benefit.

A total of 2104 patients were randomised to receive dexamethasone 6 mg once per day (either by mouth or by intravenous injection) for ten days and were compared with 4321 patients randomised to usual care alone. Among the patients who received usual care alone, 28-day mortality was highest in those who required ventilation (41%), intermediate in those patients who required oxygen only (25%), and lowest among those who did not require any respiratory intervention (13%).

Dexamethasone reduced deaths by one-third in ventilated patients (rate ratio 0.65 [95% confidence interval 0.48 to 0.88]; p=0.0003) and by one fifth in other patients receiving oxygen only (0.80 [0.67 to 0.96]; p=0.0021). There was no benefit among those patients who did not require respiratory support (1.22 [0.86 to 1.75]; p=0.14).

Based on these results, 1 death would be prevented by treatment of around 8 ventilated patients or around 25 patients requiring oxygen alone.
Convalescent Plasma – Mayo Clinic


• Background: Convalescent plasma is the only antibody based therapy currently available for COVID 19 patients. It has robust historical precedence and sound biological plausibility. Although promising, convalescent plasma has not yet been shown to be safe as a treatment for COVID-19.

• Methods: Thus, we analyzed key safety metrics after transfusion of ABO compatible human COVID-19 convalescent plasma in 5,000 hospitalized adults with severe or life threatening COVID-19, with 66% in the intensive care unit, as part of the US FDA Expanded Access Program for COVID-19 convalescent plasma.

• Results: The incidence of all serious adverse events (SAEs) in the first four hours after transfusion was <1%, including mortality rate (0.3%). Of the 36 reported SAEs, there were 25 reported incidences of related SAEs, including mortality (n = 4), transfusion-associated circulatory overload (TACO; n = 7), transfusion-related acute lung injury (TRALI; n = 11), and severe allergic transfusion reactions (n = 3). However, only 2 (of 36) SAEs were judged as definitely related to the convalescent plasma transfusion by the treating physician. The seven-day mortality rate was 14.9%.

• Conclusion: Given the deadly nature of COVID 19 and the large population of critically-ill patients included in these analyses, the mortality rate does not appear excessive. These early indicators suggest that transfusion of convalescent plasma is safe in hospitalized patients with COVID-19.

Tom Kanyok, BS Pharm, PharmD, RPh
Avigan (favilavir)

15 March 2020, the drug was approved in China for SARS-CoV-2

Zhejiang Hisun Pharmaceutical

Toyama Chemical (Fujifilm group) approved in Japan for influenza in 2014

Broad spectrum anti-viral mechanism of its actions is thought to be related to the selective inhibition of viral RNA-dependent RNA polymerase.

Has reportedly shown efficacy in treating the disease with minimal side effects in a clinical trial involving 70 patients. The clinical trial is being conducted in Shenzhen, Guangdong province.

US Department of Defense developed favipiravir in partnership with MediVector, Inc. as a broad-spectrum antiviral and sponsored it through FDA Phase II and Phase III clinical trials, where it demonstrated safety in humans and efficacy against the influenza virus. Was developed to replace Tamiflu (oseltamivir). However, animal experiments show the potential for teratogenic effects.

Tom Kanyok, BS Pharm, PharmD, RPh
Veklury (remdesivir)

Preliminary Report NEJM May 22, 2020 John H. Beigel, M.D. et al., ACTT-1 Study Group Members*

Tom Kanyok, BS Pharm, PharmD, RPh
### Table 2: Outcomes Overall and According to Score on the Ordinal Scale in the Intention-to-Treat Population.

<table>
<thead>
<tr>
<th>Recovery</th>
<th>Overall&lt;sup&gt;a&lt;/sup&gt;</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remission (N=130)</td>
<td>273</td>
<td>64</td>
<td>47</td>
<td>123</td>
<td>52</td>
</tr>
<tr>
<td>Placebo (N=122)</td>
<td>233</td>
<td>64</td>
<td>47</td>
<td>121</td>
<td>51</td>
</tr>
<tr>
<td>Remission (N=127)</td>
<td>288</td>
<td>64</td>
<td>47</td>
<td>127</td>
<td>51</td>
</tr>
<tr>
<td>Placebo (N=126)</td>
<td>244</td>
<td>64</td>
<td>47</td>
<td>122</td>
<td>49</td>
</tr>
</tbody>
</table>

| Median in days to recovery (95% CI) — (days) | 11 (9–12) | 15 (13–19) | 5 (4–6) | 6 (4–8) | 7 (6–8) | 9 (7–11) |
| Rate ratio (95% CI) | 1.52 (1.23–1.88) | 1.38 (1.04–1.86) | 1.47 (1.17–1.84) | 1.20 (0.99–1.46) | 0.95 (0.64–1.42) |

<table>
<thead>
<tr>
<th>Overall Ordinal Score at Baseline</th>
<th>1.2</th>
<th>1.3</th>
<th>1.4</th>
<th>1.5</th>
<th>1.6</th>
<th>1.7</th>
</tr>
</thead>
<tbody>
<tr>
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<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Race</th>
<th>White</th>
<th>Black</th>
<th>Asian</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazard rate (95% CI)</td>
<td>1.39 (1.12–1.73)</td>
<td>2.12 (0.81–5.61)</td>
<td>1.04 (0.28–3.77)</td>
<td>1.83 (1.08–3.09)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Kaplan-Meier estimate</th>
<th>0.98 (95% CI)</th>
<th>0.92 (95% CI)</th>
<th>0.85 (95% CI)</th>
<th>0.75 (95% CI)</th>
</tr>
</thead>
</table>

| Ordinal score at day 15 (or day —) — (no. [%]) |
|-----------------------------------------------|---|---|---|---|---|
| Patients with baseline and day 15 score data — no. | 434 | 410 | 157 | 119 | 58 |
| 1 | 39 (20.7) | 47 (11.7) | 12 (7.5) | 2 (1.0) | 0 |
| 2 | 158 (16.1) | 127 (10.9) | 28 (17.7) | 2 (1.0) | 0 |
| 3 | 17 (11.5) | 14 (11.7) | 1 (0.7) | 0 | 0 |
| 4 | 21 (19.2) | 20 (17.4) | 1 (0.7) | 0 | 0 |
| 5 | 30 (27.3) | 40 (34.8) | 3 (2.6) | 0 | 0 |
| 6 | 11 (10.7) | 14 (12.9) | 1 (0.7) | 0 | 0 |
| 7 | 65 (29.3) | 72 (42.7) | 0 (0) | 0 | 0 |
| Odds ratio (95% CI) | 1.16 (0.17–8.81) | 0.00 (0.00–0.00) | 1.31 (1.09–5.42) | 1.60 (0.89–2.66) | 1.64 (0.66–4.48) |

*P values and confidence intervals have not been adjusted for multiple comparisons. NE denotes not possible to estimate.

1. Recovery rates and hazard ratios were calculated from the stratified Cox model. P values and 95% CI ratios were calculated with the stratified log-rank test. Recovery rate ratio estimates were based on the following criteria: recovery rate ratios of 1.0 indicate no benefit or harm, recovery rate ratios less than 1.0 indicate a benefit, and recovery rate ratios greater than 1.0 indicate harm.

2. The ordinal score at day 15 is the patient’s worst score on the ordinal scale during the previous 3 days. In the remission group, 103 patients did not have ordinal scale scores for the day 15 visit. In the placebo group, 309 patients did not have ordinal scale scores for the day 15 visit. At the time of the data freeze (11 with mild-to-moderate illness and 50 with severe illness). In the placebo group, 209 patients did not have ordinal scale scores for the day 15 visit. Two patients died within 15 days after randomization and are included in the ordinal scale scores but not in the estimate of mortality by day 15. Scores on the ordinal scale are as follows: 1, no treatment; 2, mild treatment; 3, no treatment; 4, hospitalization, not requiring supplemental oxygen and no longer requiring ongoing medical care (used if hospitalization was extended for infection control reasons); or 4, hospitalization, not requiring supplemental oxygen but requiring ongoing medical care (used if related to unrelated medical condition(s)); or 5, hospitalization, requiring any supplemental oxygen; or 6, hospitalization, requiring no supplemental oxygen but use of high-flow oxygen devices; or 7, hospitalization, requiring mechanical ventilation or extracorporeal membrane oxygenation (ECMO). A and B, death. Odds ratios and P values were calculated with the use of a proportional odds model. Odds ratio values greater than 1.0 indicate a benefit for remission.
Recommendation for Hospitalized Patients with Severe COVID-19:

- The COVID-19 Treatment Guidelines Panel (the Panel) recommends the investigational antiviral agent remdesivir for treatment of COVID-19 in hospitalized patients with \( \text{SpO}_2 \leq 94\% \) on ambient air (at sea level) or those who require supplemental oxygen (AI).

- The Panel recommends remdesivir for treatment of COVID-19 in patients who are on mechanical ventilation or extracorporeal membrane oxygenation (ECMO) (B1).

Recommendation for Duration of Therapy in Patients with Severe COVID-19 Who Are Not Intubated:

- The Panel recommends that hospitalized patients with severe COVID-19 who are not intubated receive 5 days of remdesivir (AI).

Recommendation for Duration of Therapy for Mechanically Ventilated Patients, Patients on ECMO, or Patients Who Have Not Shown Adequate Improvement After 5 Days of Therapy:

- There are insufficient data on the optimal duration of therapy for mechanically ventilated patients, patients on ECMO, or patients who have not shown adequate improvement after 5 days of therapy. In these groups, some experts extend the total remdesivir treatment duration to up to 10 days (CIII).

Recommendation for Patients with Mild or Moderate COVID-19:

- There are insufficient data for the Panel to recommend for or against remdesivir for the treatment of patients with mild or moderate COVID-19.
<table>
<thead>
<tr>
<th>Developer</th>
<th>Properties</th>
<th>Development status</th>
</tr>
</thead>
<tbody>
<tr>
<td>mRNA-1273 Moderna and NIAID</td>
<td>mRNA vaccine</td>
<td>Phase 2</td>
</tr>
<tr>
<td>BNT162 BioNTech and Pfizer</td>
<td>mRNA vaccine</td>
<td>Phase 1/2</td>
</tr>
<tr>
<td>INO-4800 Inovio Pharmaceuticals</td>
<td>DNA vaccine</td>
<td>Phase 1</td>
</tr>
<tr>
<td>AZD1222 University of Oxford and AstraZeneca</td>
<td>Adenovirus vaccine</td>
<td>Phase 2b/3</td>
</tr>
<tr>
<td>Ad5-nCoV CanSino Biologics</td>
<td>Adenovirus vaccine</td>
<td>Phase 2</td>
</tr>
<tr>
<td>Unnamed Wuhan Institute of Biological Products and Sinopharm</td>
<td>Inactivated virus</td>
<td>Phase 1/2</td>
</tr>
<tr>
<td>Unnamed Beijing Institute of Biological Products and SinoPharm</td>
<td>Inactivated virus</td>
<td>Phase 1/2</td>
</tr>
<tr>
<td>PiCoVacc Sinovac</td>
<td>Inactivated virus, plus adjuvant</td>
<td>Phase 1/2</td>
</tr>
<tr>
<td>Unnamed Institute of Medical Biology and Chinese Academy of Medical Sciences</td>
<td>Inactivated virus</td>
<td>Phase 1</td>
</tr>
<tr>
<td>NVX-CoV2373 Novavax J&amp;J, Merck and Pfizer</td>
<td>Protein subunit</td>
<td>Phase ½</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pre-clinical</td>
</tr>
</tbody>
</table>
History of Vaccines and the Importance of the FDA Process
Can a vaccine for SARS-Cov-2 be produced and approved in record time?


In the history of medicine, rarely has a vaccine been developed in less than five years. Among the fastest to be developed was the current mumps vaccine.

Currently there are no approved DNA vaccines or RNA vaccines.

Vaccine development for a new pathogen traditionally takes many years or even decades.

The process includes:
- Small-scale manufacturing
- Phase 1
- Phase 2
- Phase 3 clinical trials
- Regulatory approval and large-scale manufacturing

Goal is to compress these timelines considerably without compromising safety

Tom Kanyok, BS Pharm, PharmD, RPh
What Can We Learn from the Shingrix Vaccine Development Timeline?

S. Albert Edwards, PharmD LTD
Founder & President
eSubmissions University
fdaexpert@gmail.com
(847) 945-4750
www.esubmissionsuniversity.com
SHINGRIX VACCINE DISCOVERY:

• Dr. Abbas Vafai, University of Illinois College of Medicine at Rockford, 1990-97
• Discovered glycoprotein on the surface of the virus/causes shingles/confers immunity
• Along with Dr. R. J. Cohrs, University of Colorado, Denver, co-discoverer
• But, next-what I think we all want from a coronavirus vaccine.....
WHAT I THINK - we all want from a vaccine

• SAFE, i.e., free of major health-related side effects, and safe for the old and the young
• POTENT, i.e., giving us immunity for a number [4-6?] years
• EASY to take, i.e., a small, quick shot, just below the skin or a drop under the tongue
WHAT I THINK - we all want from a vaccine (cont’d)

• INEXPENSIVE & EASY to manufacture, so that everyone [including other nations & populations in the world] can get it, quickly, and finally

• Heat-stable [most vaccines require refrigeration or other temperature controls]
WHAT I THINK - we all want from a vaccine (cont’d)

• **Honestly, this is a 'tall order'**
• Even for the industrialized, highly science-oriented countries of our planet
• There are many virus details that we still need to discover!
• Ed Yong, “Why the Coronavirus Is So Confusing”, The Atlantic, 4/29/2020

Vaccine Development Timelines:

Are impossible to locate – Why?

Both manufacturers/developers and FDA [by regulation]
Keep the early research dates and filings confidential
1983: Abbas begins VZV research with Nature paper

1985: Affinity purified VZV gE stimulates neutralizing antibody (J Gen Virology)

1986: Move from University of Pennsylvania to University of Colorado, School of Medicine

1987: Induction of antibody response to in vitro translated VZV gE (Virus Research)

1988: Expression of VZV glycoproteins in cells from vaccinia virus recombinant (Virus Research)

1990: Move to Rockford

1991: Research Corporation Technology (RCT) files application at US patent office

1990 (Dec) – 91 (Jan): Call from SKB; visit from 2 scientist from Belgium

1992: Discuss monoclonal antibodies to VZV glycoproteins with SKB

1993: SKB donates $8000 to further work and will wait for follow-up work

1995: Antigenicity of a candidate varicella-zoster virus glycoprotein subunit vaccine (Vaccine)

1998: Boosting immune response with a candidate varicella-zoster virus glycoprotein E subunit vaccine (Vaccine)

2000: Patent approved (modified antigen)

2002: Patent approved (modified antigen)


2016: Finish phase III clinical trial

2017: Oct. - Submit to FDA

2017: Oct. – FDA Approval

2017: Dec. - Shingrix Released
Patent filed for varicella-zoster virus glycoprotein subunit of chicken pox vaccine

Booster applied to glycoprotein E subunit portion creating best immunity

Patent approvals for the original & modified vaccines

Phase I human trials begin

Phase II begins

Phase III begins

Phase III trials complete

Submission of all data for FDA review & potential approval

Oct. – FDA Approval

Dec. - Shingrix available in pharmacies, clinics, physician's offices

At this point, I do not want you to be turned off by this 26 year timeline!

FURTHER INFO ON THE PHASES OF CLINICAL TRIALS: https://www.fda.gov/patients/drug-development-process/step-3-clinical-research#The_Investigational_New_Drug_Process
ASSUMPTIONS TO SHORTEN THE VACCINE TIMELINE

• NO coronavirus patents, since it is needed on a world-wide, urgent basis
• Save approximately 9 years from Shringrix timeline
• The immunity producing virus segment will be found & perfected in 1 year
• Time from Phase I to II human trials can be compressed to 2 years
• Phase III trials will then begin at year 3.5, assuming no issues with SAFETY
ASSUMPTIONS TO SHORTEN THE VACCINE TIMELINE (cont’d)

• Knowing that the vaccine will be used world-wide populations
• Phase III trials will likely take 4 years to complete
• Why: widely divergent populations in various countries will need testing
• US is mix of many of the world’s populations-SAFETY
• Phase III Trial data will also depend on the availability of not only the test vaccine but also the various patient populations throughout the world
ASSUMPTIONS TO SHORTEN THE VACCINE TIMELINE (cont’d)

• Assuming efficacy, i.e., lasting immunity to SARS-CoV-2, 4-6 years?
• Results would be ready for review by FDA and other world-wide Regulatory Authorities at year 8
• A vaccine would then likely be available in about 9 years
• Yes, this at odds with media predictions and speculations
ASSUMPTIONS TO SHORTEN THE VACCINE TIMELINE (cont’d)

• Can the timeline be further shortened?
• Testing fewer of the world’s populations
• Going with a much shorter “lasting immunity” time, e.g., 1-2 years
• This would necessitate more frequent, REPEAT, vaccinations
• Testing smaller numbers of patients > SAFETY?
• One cannot ‘rush the science’ and come out with a premiere vaccine!
Where are we going?

Prevention and Contact tracing best tools we have until there is a vaccine

Tom Kanyok, BS Pharm, PharmD, RPh
Planning for the future – the new normal
THANK YOU

- To our pharmacists/colleagues in retail pharmacy, outpatient clinics, emergency rooms, and ICUs who are on the ‘front lines’ of this pandemic

- As well as, ALL ‘FRONT LINERS’ who are doing their daily jobs with exposure to the coronavirus!
### Phase 1
A phase of research to describe clinical trials that focus on the safety of a drug. Usually conducted with healthy volunteers, and the goal is to determine the drug’s most frequent and serious events and, often, how the drug is broken down and excreted by the body.

<table>
<thead>
<tr>
<th>Sample size</th>
<th>Objectives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small sample size (healthy volunteers)</td>
<td>Test the safety of a new medicine</td>
</tr>
<tr>
<td></td>
<td>Test for side effects</td>
</tr>
<tr>
<td></td>
<td>Define the right dose</td>
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</tbody>
</table>

### Phase 2
A phase of research to describe clinical trials that gather preliminary data on whether a drug works in people who have a certain condition/disease (that is, the drug’s effectiveness). For example, participants receiving the drug may be compared to similar participants receiving a different treatment, usually an inactive substance (called a placebo) or a different drug. Safety continues to be evaluated, and short term adverse events are studied.

<table>
<thead>
<tr>
<th>Sample size</th>
<th>Objectives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Larger sample size (including those with the condition or disease)</td>
<td>Test for its effects in the short term</td>
</tr>
<tr>
<td></td>
<td>Compare a new medicine against an existing treatment/placebo</td>
</tr>
<tr>
<td></td>
<td>Monitor side effects</td>
</tr>
</tbody>
</table>

### Phase 3
A phase of research to describe clinical trials that gather more information about a drug’s safety and effectiveness by studying different populations and different dosage and by using the drug in combination with other drugs. These studies typically involve more participants.

<table>
<thead>
<tr>
<th>Sample size</th>
<th>Objectives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Larger sample size (including those with the condition or disease)</td>
<td>Compare a new medicine against an existing treatment/placebo</td>
</tr>
<tr>
<td></td>
<td>Test for side effects</td>
</tr>
<tr>
<td></td>
<td>See if it’s better</td>
</tr>
</tbody>
</table>
HOW DO I STAY INFORMED?

CR.org/covid19


footnote: Consumer Reports, page 11, June, 2020
IS TAKEOUT FOOD SAFE?

In general, yes, assuming prevention of food borne contamination by

• Gloves, masks, hairnets, and hand-washing by restaurant staff
• Pickup food best; avoid proximity to other people
• Transfer food to a plate, reheat it, wash hands before eating

footnote: Consumer Reports, page 19, June, 2020
YOUR CAR & THE CORONAVIRUS

• Most car interiors can be disinfected with 70+% isopropyl alcohol
• Recondition leather surfaces with a conditioner after alcohol use
• Fabric surfaces can be scrubbed with a small amount of water & laundry detergent
• NO bleach, peroxide, or ammonia-may damage non-glare coatings

footnote: Consumer Reports, page 53, June, 2020
AT THE GAS PUMP

• Gloves or a paper towel for any key pressing and using the pump/handle
• After the fill-up, wash hands or use hand sanitizer

footnote: Consumer Reports, page 53, June, 2020
GOING TO THE DENTIST

• Only urgent or emergency dental procedures
• For example: pain, bleeding, swelling
COVID-19 TESTING COSTS

• Cost of actual test is -0-

• Cost of any work-up, e.g., chest X-ray, office visit, are determined by your routine health insurance coverage
Thank You

Questions?