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May COVID-19 Report

FDA Grants Emergency Authorization for 1st Rapid Antibody Test for COVID-19 – April 4, 2020

- The FDA granted **Cellex** and emergency use authorization to market a rapid antibody test for COVID_19
    - This is the first antibody test released during this pandemic
- How the test works
    - A drop of serum, plasma, or whole blood is placed into a well on a small cartridge, and results are read 15-20 min later
    - Lines indicate the presence of IgM, IgG, or both antibodies against the SARS-CoV-2 virus
- During testing, 120 out of 128 samples confirmed positive by reverse transcription polymerase chain reaction in premarket testing tested positive by IgG, IgG, or both
- Alternatively, 239 out of 250 confirmed negative samples were also negative by the rapid test
- Negative results do not rule our infection. Antibodies may not have had enough time to form or the virus could have had a minor amino acid mutation in the epitope recognized by the antibodies screened for in the test
- False positives can occur due to cross-reactivity with antibodies from previous infections such as from other coronaviruses
- IgM antibodies are generally detectable several days after the initial infection
- igG antibodies can take longer
- It is not known how long COVID-19 antibodies persist after the infection has cleared
- FDA has waived good manufacturing practice requirements
    - However, they have said that advertising must state that the test has not been formally approved by the FDA
- Testing is limited to Clinical Laboratory Improvement Amendments-certified labs
- Positive results are required to be reported to public health authorities
- Tests can be ordered through Cellex distributors or directly from the company

Cincinnati, Ohio begins quest to learn if blood plasma can treat COVID-19 – April 17, 2020

- A clinical study of plasma as a treatment for the lung disease resulting from the novel coronavirus has begun in Cincinnati
- They are testing if plasma donated by people who have recovered from COVID-19 can treat those who are still ill
- Plasma has not been government approved as a treatment for COVID-19 but on April 3, the FDA allowed emergency studies of plasma for COVID-19
    - Partly due to a trial in China that showed plasma reduced the virus load in 5 patients
- A pint of blood is taken by needle from the arm of a donor → plasma is separated from the red blood cells → donor gets the red blood cells back by needle

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- This plasma treatment likely is not a cure but the treatment appears to decrease the presence of the virus
- Key value of plasma is that it can be frozen at -13 degrees Fahrenheit for up to a year
    - Means it can be stored for use for later, should another surge occur later in the year
- Early research suggests the hearts of COVID-19 patients suffer damage before they go into lung failure
    - Measuring the levels of a heart enzyme called troponin could be useful early in treatment in deciding whether to give convalescent plasma

World's largest randomized trial on COVID-19 treatments launched – April 17, 2020

- The world's largest randomized, controlled clinical trial looking at a range of potential treatment for adults hospitalized due to COVID-19 is being launched in the U.K
    - Labelled the Recovery Trial
- The trial includes more than 5400 patients from over 165 hospitals
- The trial aims to gather reliable clinical trials data on some of the more common treatments currently being used globally
    - Determine the safety and effectiveness of these treatment options
    - Treatments include Lopinavir-Ritonavir, steroid dexamethasone, anti-malarial drug hydroxychloroquine, antibiotic azithromycin
- Trial is supported by chief medical officers across the country and financially backed by a grant to the University of Oxford from the U.K, funding from the Bill and Melinda Gates Foundation + several other organizations

Home Testing – March 31, 2020

- At-home test kits have been a source of both hope and controversy
- The FDA has cracked down on unauthorized at-home COVID-19 tests and have warmed American that no such tests have received agency authorization
    - Consequently, start-ups like Everlywell, Nurx, and Carbon Health who used to offer these products have now stopped
- After years of slow uptake, telehealth platforms are surging due to COVID-19
- Accurate, scientifically validated at-home test could ease burdens on the health care system
- However, people are not experienced at collecting test samples and this can lead to false positives or false negatives
- Laboratory-developed tests can be sold in the US without going through the FDA premarket review process
    - FDA warns that these tests may overpromise and under-deliver and lead to incorrect results
- About half of U.S. consumers say they feel comfortable with at-hone testing → this may go up even more as COVID-19 drives cultural acceptance of at-home medical care

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- Shortages of testing equipment and protective gear have also made this option more appealing

Milken Institute COVID-19 Treatment and Vaccine Tracker
https://docs.google.com/spreadsheets/d/16DbPhF9OD0MHHtCR12of6yUcfiRzP_-XGkynEbnipds/edit#gid=2075421071

Updates on Experimental Coronavirus Treatments – April 27, 2020

- Remedesivir
  - In human trials
  - Most-watched antiviral being tested
- **Chloroquine and Hydroxychloroquine**
  - In human trials
  - On Marhc 30, FDA issued an Emergency Use Authorization to allow it to be used in teen and adult patients hospitalized with COVID-19
    - An April 24 they warned of heart problems in COVID-19 patients treated with the drugs
    - Therefore, it can only be given to patients participating in clinical trials or being treated in hospitals
  - Most controversial potential COVID-19 treatment
  - Data supporting efficacy remains thin
- Kevzara
  - In human trials
  - An arthritis drug that is an IL-6 inhibitor sold by Sanofi and Regeneron was being tested in 2 separate Phase 2.3 trials in hospitalized patients with sever cases
  - On April 27, Regenron and Sanofi said trial would only continue for the sickest patients as preliminary analysis of Phase 2 showed that Kevzara had no notable benefits, though there were positive trends among the sickest
- Actemra
  - In human trials
  - A Roche arthritis drug that is an IL-6 inhibitor
  - Being studied for its potential to manage COVID-19 side effects in patients who develop pneumonia
  - China's National Health Commission includes Actemra in its recommended COVID-19 treatment plan for patients with pneumonia
- Kaletra
  - In human trials
  - An HIV drug sold by AbbVie – combination of 2 antivirals called lopinavir and ritonavir
  - Produced disappointing results in trials in mid-March but more trials are being conducted
- Baricitnib
  - Human trials set to start at the end of April

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  - Being examined under the hypothesis that it could reduce inflammation in the lungs
  - Eli Lilly, the company, claim a secondary hypothesis that the drug could have an antiviral effect
  - Company expects the trial to begin at the end of April in hundreds of patients – data expected 2 months later
- Regeneron antibody program
  - Will start human trials in June
  - Various companies are working on identifying antibodies that can neutralize the virus that causes COVID-19 and turning those antibodies into a drug
  - The company used the same technique to develop an Ebola drug
  - Company plans to pick 2 of the antibodies to test as a cocktail treatment and plans to begin manufacturing in April and start clinical trials in June
- Vir Biotechnoloy antibody program
  - Human trials expected to begin in 3-5 months
  - Vir Biotechnology is working on a COVID-19 antibody therapy with GlaxoSmithKline
  - Company says the antibody it has identified can neutralize the virus that causes COVID-19 in tests in the lab
  - They predict that they could begin Phase 2 clinical trails of the drug within 3-5 months
- Vir Biotech siRNA program
  - Preclinical
  - Vir is also working with biotech firm Alnylam Pharmaceuticals to develop COVID-19 drugs that use a technique known as RNA interference to go after the virus
  - The drug would use molecules called small interfering RNA that could potentially stop messenger RNA molecules from carrying instructions to make disease-causing proteins
  - Alnylam has synthesized hundreds of siRNA molecules targeting the genomes of the virus that causes COVID-19 and Vir will now evaluate those molecules in the lab

UBC researcher claimed they have found aCOVID-19 trial drug – April 4, 2020

- UBC researchers say they found a trial drug that blocks the cellular door the virus uses to infect people with COVID-19
- Drug may soon be ready for testing
- They claim their findings hold some promise for a treatment capable of stopping early infection of COVID-19
  - That a drug called APN01 – soon to be tested in clinical trials by the European biotech company Apeiron Biologics, is useful as a antiviral therapy for COVID-19

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    - Through cell cultures, researchers found that the drug inhibited the coronavirus load
    - Using engineered replicas of human blood vessel and kidney, they demonstrated the virus can directly infect and duplicate itself in such tissues
    - This finding was published in the science journal Cell Friday
- WHO announced on March 20 that Thailand, Argentina, Bahrain, Canada, France, Iran, Norway, South Africa, Spain, and Switzerland will be involved in a multi-country clinical study for potential treatments for COVID-19
    - Part of a rapid global search for drugs to treat COVID-19
- WHO's work will test 4 different drugs or combinations and will compare their effectiveness to standard care (regular support hospitals treating COVID-10 patients)
    - Remdesivir
    - Combination of lopinavir and ritonavir
    - lopinavir and ritonavir plus interferon beta
    - chloroquine

Emergency doctors urged to avoid drugs used to ventilate COVID-19 patients

- Placing patients on an artificial breathing machine usually requires a sedative such as propofol, and painkillers such as fentanyl and morphine
- The Canadian Association of Emergency Physicians wrote a statement to members, warning them of potential shortages of those drugs and a need to conserve them
- Propofol and morphine shortages have also been reported to Health Canada by manufacturers

COVID-19 drugs trials start April 9, 2020

- Clinical trials on a drug to block the COVID-19 virus will start April 9, at 10 centers in Europe
- A University of BC researcher, Dr Josef Penniger, will be leading the work
    - He warned a vaccine could be a year to 18 months away
- Penniger's team stated that last week, they found a trial drug that blocks the cellular door the virus uses to infect people with COVID-19
- Their research identified ACE2 as the entry gate for SARS-CoV-2
- Using engineered replicas of human blood vessels and kidneys (organoids grown from human stem cells) the researchers demonstrated the virus can directly infect and duplicate itself in such tissues
    - This was published in the science journal Cell April 13
- Clinical trials will start in Germany, Denmark, and Austria
- It will include 200 patients with severe cases (but not late stage) and last for 7 days
- Cell membrane-surface protein ACE2 plays a key role in the outbreak according to Penniger
- Earlier in 2003, Penniger, colleagues at the University of Toronto, and the Institute of Molecular Biology in Vienna identified ACE2 as the key receptor of SARS
- It is still unknown why the virus only affects some and not others

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- Penniger's team was supported in part by the Canadian federal government through emergency funding focused on accelerating the development, testing and implementation of measures to deal with the COVID-19 outbreak

Utah's mistake with chloroquine and hydroxychloroquine as COVID-19 treatments

- The state of Utah pursued a policy that would have let pharmacies dispense chloroquine and hydroxychloroquine to patients with COVID-19 without a prescription although there is no rigorous evidence showing the drugs work
- The state put in an order of $800,000 worth of chloroquine and hydroxychloroquine to build a stockpile
- While clinical trials that test the efficacy of these drugs are ongoing, recent observational studies have caste doubt on an effect
- In the weeks since Utah's efforts to promote and procure the drugs, the Food and Drug Administration has warned they should not be taken for COVID-19 outside a hospital or a clinical trial due to reports of serious heart rhythm problems
- With this, Utah eventually abandoned its plans to make the drugs available without prescriptions and cancelled its order

European Medicines Agency urged to release full clinical trial data - May 18, 2020

- The European Medicines Agency is being urged by several international clinical evidence experts to publish all trial data on the same day any product is authorized for use against COVID-19
- In a letter, 4 country directors from the independent watchdog Cochrane and leaders from Germany's Institute for Quality and Efficiency in Health Care argued that it is critical to promptly release clinical study reports to support further research and proper medical care
    - The state that to assess products further and to accelerate the development of additional products, the fast and full public availability of the information submitted to regulators is important
- The EMA is currently on the verge of issuing a conditional marketing authorization for remdesivir
- Last month, U.S. officials issued a press release indicating the intravenous medicine helped seriously ill patients recover faster, although complete results of the story are not yet available (the study was also sponsored by the U.S. government
- Nonetheless, the FDA acted on the information by issuing an emergency use authorization for hospitals
- Many physicians criticized this call as there was a lack of available study data
    - They argued for complete data to male fully informed decisions about patient care
- This has also brought up concerns about clinical trial data transparency
- The pandemic has fueled a surge of study postings on pre-print servers and experts caution the reports may contain selective outcomes , underreport side effects, or research inappropriate conclusions

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- The IQWIG and the Cochrane researchers argue that only clinical study reports can provide sufficient confidence in the safety and effectiveness of a medicine or vaccine

WHO sees 'potentially positive data' on COVID-19 treatments - May 12, 2020

- WHO is leading a global initiative to develop safe and effective drugs, tests, and vaccines to prevent, diagnose, and treat COVID 19
- On May 12, they announced that some treatments appear to be limiting the severity or length of the COVID-19 disease
- They are no focusing on learning more about 4-5 of the most promising ones
- They have however disclosed that while some treatments seem to be in very early studies, limiting the severity or the length of the illness, they do not have anything that can kill or stop the virus
- They are not disclosing specifics until they have more results
- In April, a WHO official sounded a note of caution around expectations of a vaccine and stated that it would take at least 12 months for a vaccine
- There are currently more than 100 potential COVID-19 vaccines being developed

COVID-19 New drug candidate updates - May 15, 2020

A team of Chinese-based researchers found a new candidate drug against SARS-CoV-2

- A type of enzyme without which the virus cannot survive was the starting point of the scientist' efforts
- Using 2 compounds, 11a and 11b, the team managed to inhibit this protease
- They then monitored the antiviral activity of these 2 compounds and found that the substances successfully fought the infection
- Experiments in mice suggested that scientists could safely administer the 2 compounds via several routes, including an IV drip
- Final animal tests in rats and Beagle dogs revealed that 11a is less toxic, so the scientists focused on this one compound
- There is no human equivalent to the enzyme that the compound targets – this minimizes the likelihood of severe side effects in humans

Researchers led by Professor Nevan J. Krogan, from the University of San Francisco used a special technique that helped them map all the human proteins that the new COVID-19 virus needs to interact with to survive

- They then looked at existing drugs that already target these proteins
- This interactive mapping method yielded a promising anticancer drug called PB28
- They say that PB28, which is an experimental drug, was 20 times more potent than hydroxychloroquine at deactivating SARS-CoV-2 and that it may be a lot safer at higher doses
- However, the team stress the importance of testing these compounds in animals and then in extensive clinical studies
- They also note that their study has limitations due to the fact that they confused in cell cultures

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A phase 2 clinical trial has found a combination of 2 drugs that can successfully treat mild to moderate cases of COVID-19

- The drugs include:
  - Interferon beta-1b
  - Lopinavir-ritonavir (an HIV drug)
  - Ribavirin (an oral hepatitis C drug)
- In the study, for the 14-day duration of the treatment, the scientists have 86 participants 400 mg of lopinavir and 100mg of ritonavir, every 12 hours, 400 mg of ribavirin every 12 hours, and 3 doses of 8 million international units of interferon beta-1b on alternate days
- The control group consisted of 41 partiicpants who took lopinavir 400 mg and ritonavir 100 mg every 12 hours
- Participants in the intervention group saw a viral clearance after 7 days, on average, compared with the average of 12 days in the control group
- Participants seemed to tolerate the drug combination well and experienced no serious side effects
- This suggests that interferon beta 1-b may be a key component of the combination treatment that is worth further investigation for the treatment of COVID-19

Remdesivir gets EUA

- Recently, there are mixed results on the efficacy of Remedesivir in fighting COVID-19
- A trial publicized by the WHO, in particular, showed that the drug did not have statistically significant benefits and its side effect were roughly the same as for the group that took a placebo
- Other studies however continue to showcase remedesivir's benefits
  - That it led to a 31% faster recovery time than a placebo
- Consequently, the drug has now received emergency authorization from the FDA
- Researchers however are cautious and state that Remdesivir is NOT a cure for COVID-19

Antibody as a start for new treatment

- An international team of researchers has identified a new antibody that could become an effective treatment for COVID-19 by stopping SARS-CoV-2 from infecting healthy cells by targeting spike proteins (proteins that can be found on the virus' surface and that help it penetrate health host cells)
- Usually, researchers develop antibodies in animals and then make then effective in humans, however, in this case, the antibody used is "fully human"
  - This allows development to proceed more rapidly and reduces the potential for immune-related side effects
- Researchers found that the antibody neutralized the new coronavirus in infected cells
- However, much more work is needed to assess whether this antibody can protect or reduce the severity of disease in humans

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Antibodies in testing

- Antibodies can also be useful for testing
- The EU has validated an antibody test that determines whether a person has had COVID-19
- Public Health England has now approved an antibody test for the U.K
    - The test boasts a specificity greater than 99.8%, meaning it can distinguish SARS-CoV-2 from other coronaviruses and will detect all the antibodies that are present

Other Testing developments

    - The test can yield results in about 18 minutes
- In the U.S., the FDA has approved a test for SARS-CoV-2 that uses CRISPR technology
    - The test uses CRISPR enzyme that starts glowing when SARS-CoV-2 is detected in swabs form the mouth, throat, or nose
    - The test yields results in an hour
- Scientists from Germany has come up with a solution to fast track the testing process
    - The approach consists of pooling, or combining samples, and testing the group first
    - If the scientists find a positive result in the group, then they proceed to individual tests
    - This prevents numerous unnecessary individual tests and is useful when a large number of asymptomatic people need to be screened
    - The initial group test allowed the researchers to combine as many as 30 samples from 30 individuals in a single test tube

Taiwan uses Big Data to counter Coronavirus – May 21, 2020

- A professor from National Tsing Hua University in Taiwan is collaborating with Facebook and Harvard University in using big data to study the potential spread of COVID-19 in Taiwan
- Preliminary results indicate that the risk of local transmission is higher than long-distance transmission between countries and cities]
- The team has also been using mathematical modeling to simulate the impact of wearing masks
    - There is a clearer correlation between the widespread and correct use of masks and lower infection numbers

Study that tracked COVID=19 spread with big data – April 29, 2020

- Dr. Jayson Jia from the University of Hong Kong and his team used nation-wide data provided by a major national carrier in China to track population movement out of Wuhan between January 1-24.
    - The movement of over 11 million people travelling through Wuhan to 296 prefectures in 31 provinces and regions in China were tracked

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- The team used real-time data about actual movements focusing on aggregate population flow rather than individual tracking
- The data included any mobile phone users who had spent at least 2 hours in Wuhan during the study period
- Their study found that relative quantity of human movement from the disease epicenter directly predicted the relative frequency and geographic distribution of the number of COVID-19 cases across China
- They found that their model could explain 96% of the distribution and intensity of the spread of COVID-19 across China
- They then used this empirical relationship to build a new risk detection toolkit with an "expected growth pattern" based on the number of people arriving from the risk source
    - More confirmed cases than expected ones = higher risk of community spread
    - Fewer expected cases than reported = city's preventive measures are effective or that further investigation by central authorities is needed to eliminate possible risks from inaccurate measurement
- What makes their approach unique is that they use misprediction to assess the level of community risk
- This requires no assumptions or knowledge of how or why the virus spreads, is robust to data reporting inaccuracies, and only requires knowledge of relative distribution of human movement
- The team is currently exploring the feasibility of applying this toolkit to other countries where there are multiple COVID-19 epicentres.

Big Data Analytics and COVID-19 - May 7, 2020

- Several organizations have started to utilize AI technologies to accelerate COVID-19 drug discovery and better understand how the immune system fights the virus
- In early April, pharmaceutical companies GlaxoSmithKline and Vir Biotechnology partnered to advance coronavirus treatment development using AI and CRISPR
- Harvard T. Chan School of Public Health recently joined forces with the Human Vaccines Project to launch the Human Immunomics Initiative which uses AI models to accelerate vaccines for a range of diseases, including COVID-19
- The US believes that as they consider reopening the economy, data analytics tools will be essential for preventing a second wave of infections
- A team from Southern Illinois University recently developed a data visualization tool that leverages GPS information to show users the locations of known COVID-19 cases
- Google and Apple have also partnered to develop a contact tracing app powered by Bluetooth technology
- While helpful, these tools do come with privacy risks
- 2 weeks after announcing their partnership, Google and Apple updated their initial contact tracing app proposal to address feedback and privacy concerns from industry stakeholders

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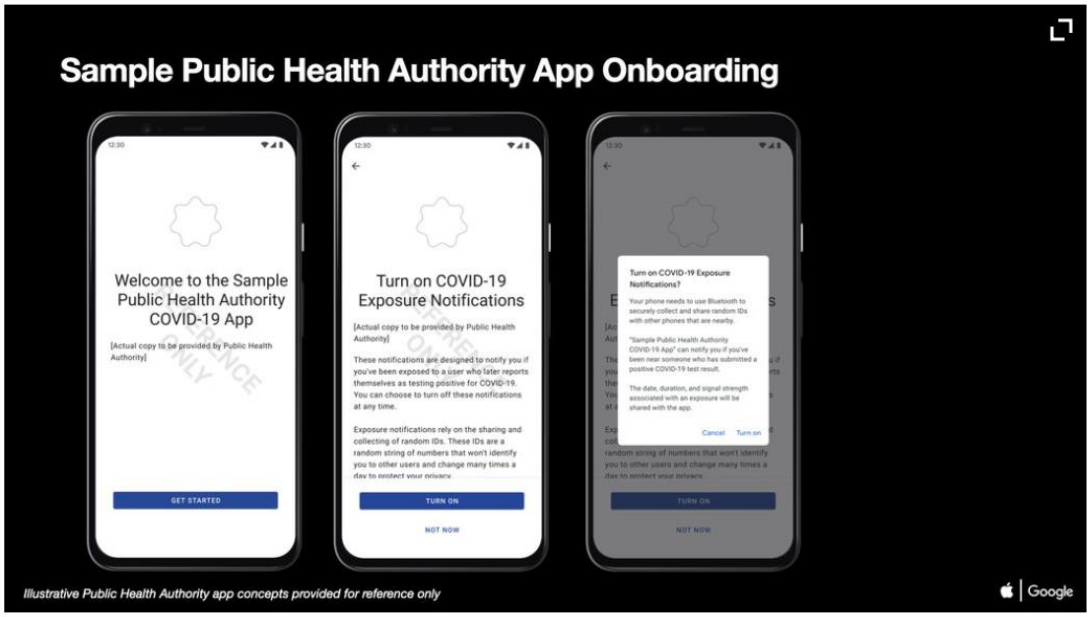
- Australia and the UK faces similar criticism when they released their own coronavirus contact tracing apps

Apple and Google's COVID-19 contact tracing app – May 7, 2020

- Apple and Google are not building an app themselves. Instead, they are providing the technical foundations for public health organizations to build their own apps for exposure notifications
- The week of May 7th, they companies released sample user interfaces and sample code for iOS and Android to support app developers
- The companies are requiring app developers to adhere to some conditions
    - That apps must require users to consent before the app can use the API
    - App would require users to consent before sharing a positive test results with the public health authority
    - App would use Bluetooth to tell users who have enabled notifications if they've been in contact with a possible exposure
    - Apps are prohibited from using location serves, or even asking for permission
- They also specify that apps should only be collect the minimum amount of data necessary and can only use that data for COVID-19 response efforts
- The prime minister of Canada has stated that the country is looking at potentially using digital technology to track and fight the virus but has not shared any specifics

Sample pictures of what the interface will look like:



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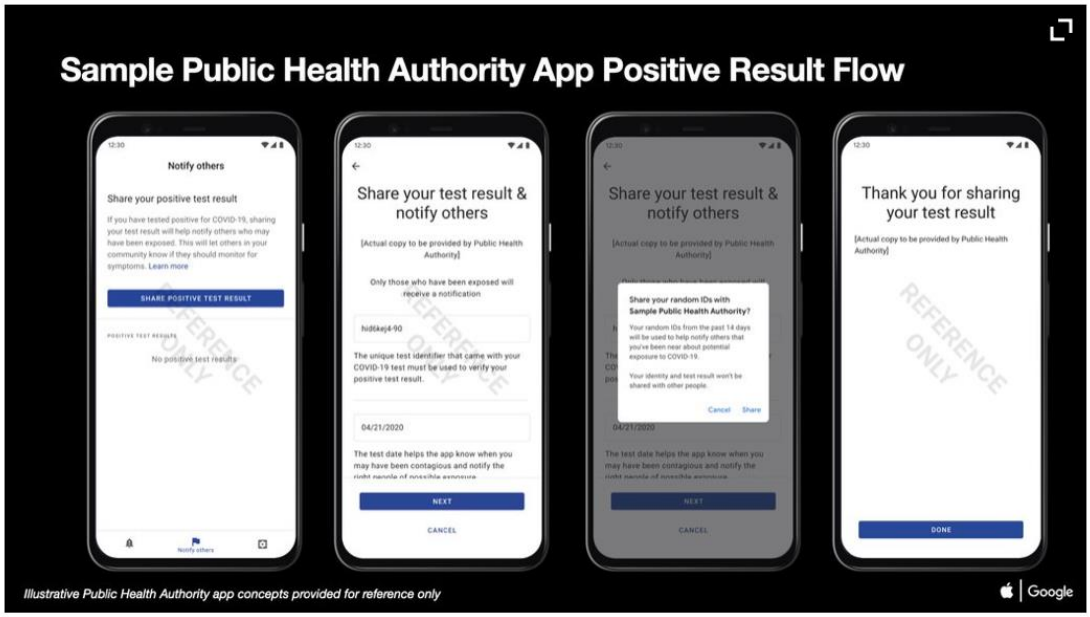

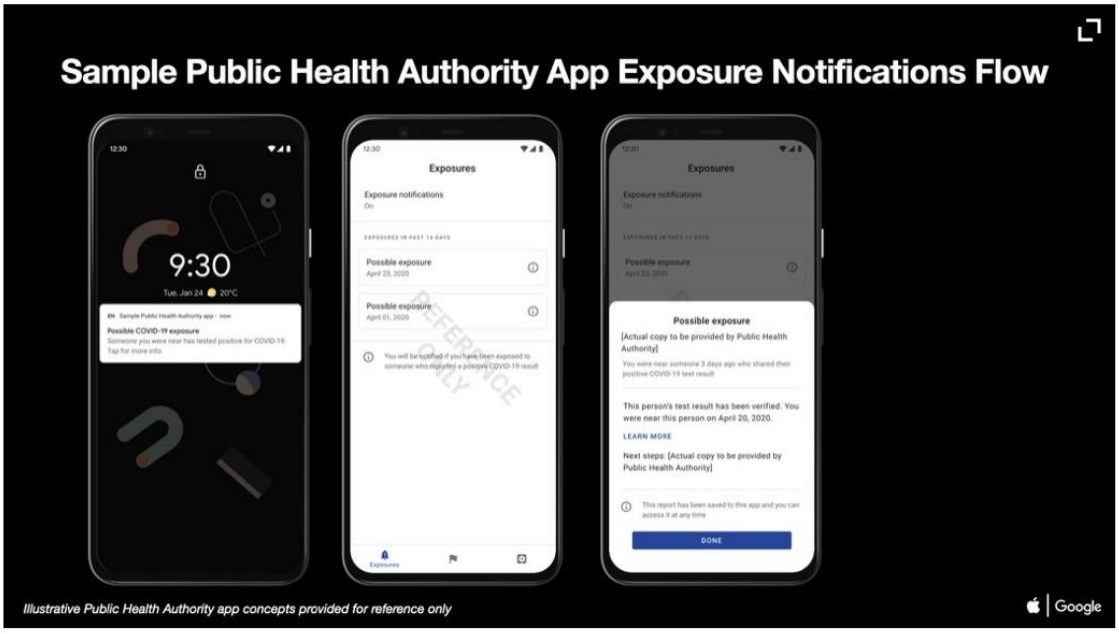

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