General COVID Vaccine Plans

1. Title: "Universal Masking in Hospitals in the COVID-19 Era"

Authors: Michael Klompas, M.D., M.P.H., Charles A. Morris, M.D., M.P.H., Julia Sinclair, M.B.A., Madelyn Pearson, D.N.P., R.N., and Erica S. Shenoy, M.D., Ph.D.

Journal: The New England Journal of Medicine

Date: 4/1/2020

Summary: The article covers the utilization of universal masking in hospitals during COVID to lower transmission spread. It is an older article so some of it's statements aren't scientifically accurate (i.e. they bring up masking does not protect in general when we now know that masks are the best form of protection). They describe two possible scenarios where masks are useful in the healthcare setting. The first is with asymptomatic COVID patients; masks alone provide limited protection in this context but protection all the same. The second and more important possibility is masks reduce transmission of asymptomatic/minimally symptomatic healthcare workers which would reduce spread in vulnerable patient populations. They argue that a mask alone is simply not enough for a healthcare provider and that focusing on only masks may actually cause more transmission if it diverts attention from more fundamental infection control measures. They utilized mask modeling from Wuhan to note the importance of undiagnosed infection spread. They lastly argue that while masks have debatable importance, they do serve as a visible reminder that we are in a pandemic and thus should follow social distancing protocols and remind patients/healthcare providers of their deeply important roles.

JA opinion: Interesting to read now in November, almost December about masks. Hindsight is key and I think that their best point with the masks is the visual reminder that we are in a pandemic and should act accordingly. I like how it's formatted, it's a short and easy read, backed with evidence from other studies and from Wuhan, which was the largest source of data at this time.

Link: https://www.nejm.org/doi/full/10.1056/NEJMp2006372

 Title: Long-Term Care Policy after COVID-19- Solving the Nursing Home Crisis Authors: Rachel M. Werner, M.D., Ph.D., Allison K. Hoffman, J.D., and Norma B. Coe, Ph.D.

Journal: The New England Journal of Medicine

Date: 9/3/2020

Summary: The article begins telling the story of nursing homes in the U.S. and how they were devastated by COVID. They introduced their idea of the new crisis in NH industry in that the U.S. has failed to invest in a safe/long-term care system as regulatory policies (Federal NH Reform Act of 1987) that monitored deficiencies in quality of care/monitoring systems are not enough to protect homes from pandemics. It's highly likely that NH's will fail to be able to pay rent/forced to file for bankruptcy and displace hundreds of thousands of elderly. The authors propose that Medicaid programs need to invest considerably more in care in all settings and make sure that home-based care is paid for even if the care is provided by family members or professionals to loosen

load/strain on LTCFs. Also given that caregiving at home isn't feasible for a lot of people, investing in safe affordable smaller residential options like high quality group models or the Dutch Dementia Village models. The authors argue that a combination of funding, regulation and new strategy that supports institutional and noninstitutional care needs to be used to save NH's.

Opinion: Really loved this article, thought it brought up super valid points of the lame duck situation created by NH's and loved the policies that they used to support their conclusions. Going to look into Dutch dementia village models cuz I didn't know they were a thing.

Link: https://www.nejm.org/doi/full/10.1056/NEJMp2014811

3. **Title**: The Equitable Distribution of COVID-19 Therapeutics and Vaccines **Authors:** Thomas J. Bollyky, Lawrence O. Gostin, Margaret A. Hamburg

Journal: JAMA Date: 5/7/2020

Summary: The authors bring up past challenges to global vaccine distribution and lack of access in low to middle income countries with the H1N1 vaccines. The article argues that to have fair distribution you need flexible, trusted governance, adequate, predictable financing, open collaboration and evidence based, health driven allocation. With the trusted governance, the framework needs the WHO to play a central role, rapid action, giving any country a seat at the table conditioned by criteria relevant to pandemic control, with lack of leveraging political/financial influences and point to the G7 backed AMC funding of pneumococcal vaccines as an example. Financing needs to be well established, primarily using country/philanthropic contributions, participation of low income countries needs to be heavily subsidized, and points to the World Bank as a leader to oversee an APC fund. The last point of open collaboration with evidence-based, health-driven allocation explains success depends on countries sharing data, being transparent, and ensuring medical products are affordable and equitably accessible by marginalized groups. The main fear that authors point out is that if there is a highly competitive race for a vaccine, only losers will result as COVID has no borders and if one area is deeply infected, no area is truly safe.

Opinion: I like their opinions and I believe they do have very solid points. I like that they utilize specific groups as examples to back their opinions. This being said, I believe this approach is highly idealistic, especially the non-partisan/political trusted governance and the affordability of COVID vaccines. I think to strengthen this short article, they really need to cover how to deal with a more realistic world.

Link: https://jamanetwork.com/journals/jama/article-abstract/2765944

4. **Title:** Fairly Prioritizing Groups for Access to COVID-19 Vaccines **Authors:** Govind Persad, Monica E. Peek, Ezekiel J. Emanuel

Journal: JAMA Date: 9/10/20

Summary: The authors discuss how to fairly distribute COVID19 vaccines in the beginning of vaccine distribution. They combine the framework from the US National

Academy of Medicine (NAM) to more global perspective and apply ethical values to explain how the vaccine can be distributed in a fair manner. The 3 ethical values relevant to COVID vaccine distribution are: to benefit people and limit harm, prioritize disadvantaged populations, and provide equal concern for all individuals despite differneces. The 3 ethical values favor prioritizing 3 groups: health care workers; other essential workers and people in high-transmission settings; and people with medical vulnerabilities as- sociated with poorer COVID-19 outcomes. This prioritization uses a combination of direct and indirect benefit. They also cover challenges with priority for COVID research participants which risks exacerbating disadvantages due to lack of diversity in research participant populations and also the danger of lottery vaccine systems. While the lottery vaccine system seems fair, it only works in situations where all considerations are equal and thus can't apply to COVID. They lastly discuss the benefits of taking a tiered approach with evidence based categorized backgrounds that gives preference to priority groups that promotes equitable treatment and limits harm. **Opinion:** Really great short read! Probably the best paper so far on vaccine distribution. It focuses on the U.S. and provides evidence based support and ethical concerns for vaccine distribution. It also points out flaws in the NAM framework and how approaches that seem ethical are not (i.e. lottery system) through social/health disparities and how this would perpetuate harm.

Link: https://jamanetwork.com/journals/jama/article-abstract/2770684

5. **Title:** Older Adults May Be Left Out of Some Covid-19 Trials

Author: Paula Span

Journal/News: New York Times

Date: 6/19/2020

Summary: Dr. Sharon Inouye and her team has reviewed 241 interventional Covid-19 studies undertaken in the United States. 37 of these trials — testing drugs, vaccines and devices — set specific age limits and would not enroll participants older than 75, 80 or 85. A few even excluded those over 65. Another group of 27 trials set no maximum age but used study designs that could nevertheless disqualify many older adults. In conclusion, she found that about one-quarter of interventional trials in the United States could exclude or underrepresented older adults. In response to similar concerns, the N.I.H. began last year to require the studies it funds to include individuals of all ages unless the investigators provided acceptable justification for exclusion or NIH won't grant awards. The struggle here is that a) most clinical trials are privately funded/don't need NIH grants and b) there are still loopholes in policies due to exclusion criteria. Inclusion is vital as the elderly will be some of the first to receive the vaccines and elderly typically face more severe symptoms. If not represented properly in clinical trials/rushed processes, the fear is that there may be severe consequences.

Opinion: Interesting article, brings up a lot of scary points on lack of representation in COVID studies. It falters in that it points out a lot of the drawbacks of lack of representation but it does not propose as many solutions

Link: https://www.nytimes.com/2020/06/19/health/vaccine-trials-elderly.html

6. **Title:** Covid vaccine: Pfizer says '94% effective in over-65s'

Authors: BBC

Journal: BBC News: Health

Date: 11/18/2020

Summary: This article covers the preliminary data released by Pfizer on their COVID19 vaccine. The trial involved 41,000 people worldwide. Half were given the vaccine, and half a placebo. Wednesday's data from Pfizer and BioNTech, which builds on last week's data, suggests the vaccine is 95% effective based on 170 cases of Covid-19 developing in volunteers. In the trial, 42% of all participants are from diverse ethnic backgrounds and 41% are aged between 56 and 85 years old. Just eight were in the group given the vaccine, suggesting it offers good protection. In older adults, who are most at risk from the virus and have weaker immune systems, the vaccine worked as well as it did in younger people. There is also evidence that the vaccine protects against severe Covidbut this is based on only 10 cases. The companies behind it expect to produce up to 50 million doses of the vaccine this year and up to 1.3 billion doses by the end of 2021.

Opinion: Good that they are using 41% of those aged 56-85, I would like to know more about the breakdown of representation of the age groups in this category as this is a large age range and also specific count numbers as it's slightly confusing that 41,000 were tested and there were only 170 covid cases to trial on.

Link: https://www.bbc.com/news/health-54986208

7. **Title:** From the Factory to the Frontlines: The Operation Warp Speed Strategy for Distributing a COVID-19 Vaccine

Authors: Department of Defense and Department of Health and Human Services

Journal: DoD and HHS report

Date: ?

Summary: This is a policy plan/brief form the U.S. Department of Health and Human Services. Once a vaccine has received approval or authorization from the FDA, the four key tasks to achieve the primary objective of ensuring vaccine access for every American who wants it are to: engage with state, tribal, territorial, local, stakeholders, and the public around vaccine, vaccine confidence and uptake, distributing vaccing using emergency use authorization in a developed phase allocations, ensure safe administration and availability of administration supplies, and monitor IT for supporting and tracking vaccine distribution. A multi-agency federal team has worked with five pilot jurisdictions—California, Florida, Minnesota, North Dakota, and Philadelphia—to utilize a basic plan for administration and adapt it to create jurisdiction-specific plans that will serve as models for other jurisdictions. Proposed phase structure is in 3 phases: phase 1-limited dosage, focuses on maximizing vaccine efficacy and protecting vulnerable groups, phase 2-larger quantities of vaccines, focus on widespread access to vaccines and high uptake in target population, phase 3- continued vaccination that is universally available.

Opinion: Well thought out plan, interesting to see the changes as time goes on/as we get closer to a vaccine

US NAM framework covid 19 vaccine allocation <- https://www.nap.edu/read/25917/chapter/1, it costs \$60
Look into dutch dementia village