Twitter Thread by Dr. Hilda Bastian



Dr. Hilda Bastian
@hildabast

Moderna data has arrived at the FDA.... I'll be tweeting about the 54-page document by the FDA https://t.co/rh3K9BvqgO The brief from Moderna is much smaller than BNT/Pfizer's - only 84 pages (+ a 7-page presentation) https://t.co/EWDYzYwf2g 1/n

..Efficacy data is for 27,817 people randomized to either vaccine or placebo; & there's safety data for 30,350 people. I'll get started with the adverse events data, because that has been a question mark for this vaccine...2/n

...The FDA raises lymphadenopathy & Bell's palsy again. More people with lymphadenopathy with Moderna's vaccine than BNT/Pfizer's: 173 in vaccine group, 95 in placebo. Bell's palsy similar. Frequency of serious adverse events (SAEs) low: 1.0% in vaccine & placebo arms...3/n

...FDA expressed no concern about any SAE: 7 SAEs were determined by FDA to be vaccine-related or potentially so (more than the sponsor deemed related) - several from nausea/vomiting. People died at the same rate as would expected for their age groups, the FDA concluded...4/n

...A developmental/reproductive toxicity study report was included: FDA identified no serious concern about adverse impact on pregnancy or perinatal/postnatal development. All up, no safety concern that would prevent emergency authorization... 5/n

Solicited adverse events (AEs) in 1st 7 days were considerably more common than for BNT/Pfizer vaccine - close to universal: 92% had local reactions, 83% systemic - severe systemic reactions were common: 17%.(Remember: BNT/Pfizer has a 30µg dose; Moderna 100µg.) ...6/n

... Frustratingly, solicited AEs are only reported here split into people under & over 65, & differently in general to the BNT/Pfizer report. So can't unpack this quickly...7/n

...Eg fatigue. After 2nd dose, was 68% for 18-64 year-olds; 58% for 65+. Severe fatigue: 11% for younger, 7% for 65+.

For BNT/Pfizer, it was 59% overall, severe was 5%. But the 2 trials have different age spread, for example. Complicated...8/n

...Bottom line, many similarities, but some types of AEs tilt to more common & severe for Moderna; some other things seem more clear, tho depends how measured etc: eg rate of pain around the injection site is higher (80-90%, severe 5% & 3%; for BNT/Pfizer, 66%, severe 0.5%)..9/n

...OK, over to the efficacy questions. Overall efficacy, after 2 doses & a week (people with no previous SARS-Cov-2 infection): that's the great news we already knew - 95% efficacy overall... 10/n

...Vaccine efficacy was similarly high for people with co-morbidities at high risk for severe Covid-19 (remembering some, as for all these trials, were excluded). 0 people out of 13,934 in this efficacy analysis got severe Covid-19 vs 11 in the placebo group. ...11/n

... There was 1 person (■■) in the vaccine group who was severely ill, but without a confirmed test result till later - so the 0 severe Covid-19 call is questionable here. (So no major difference here between the 2 vaccines) ...12/n

...Here's the corresponding incidence graph to the now-famous one for BNT/Pfizer. However, there wasn't a calculation for vaccine efficacy after 1 or 2 shots, to see if the extra week between shots makes a difference (BNT/Pfizer has 3-wk interval, Moderna 4)...13/n

..Finally, news on efficacy & age is great: similar for both vaccines. Some differences as numbers are smaller for Moderna (& there's 0 Covid-19 for 65+, while BNT/Pfizer had 1 in a larger group). But basically, great news - though one seems somewhat easier to tolerate...14/ fin

Not "fin" after all! Firstly @Nutmeg031992 pointed out my screenshot was for the interim efficacy analysis. Apologies! Here's the final vaccine efficacy: 15/16

Vaccine efficacy for both vaccines was similar for Hispanic/Latino & Black/African-American groups to overall. (BNT/Pfizer had a much larger number of Hispanic/Latino people.) ... 16/16

I checked the sponsors' document https://t.co/EWDYzYwf2g but couldn't find the modified intention-to-treat vaccine efficacy I was hoping for (1 or 2 shots, with/without previous infection). However, there was this good overview. .../ends (really!)