Comparison of side effects caused by common vaccines and Pfizer BioNTech COVID-19 (BNT162)

Douglas A. Drevets, MD, DTM&H, FIDSA

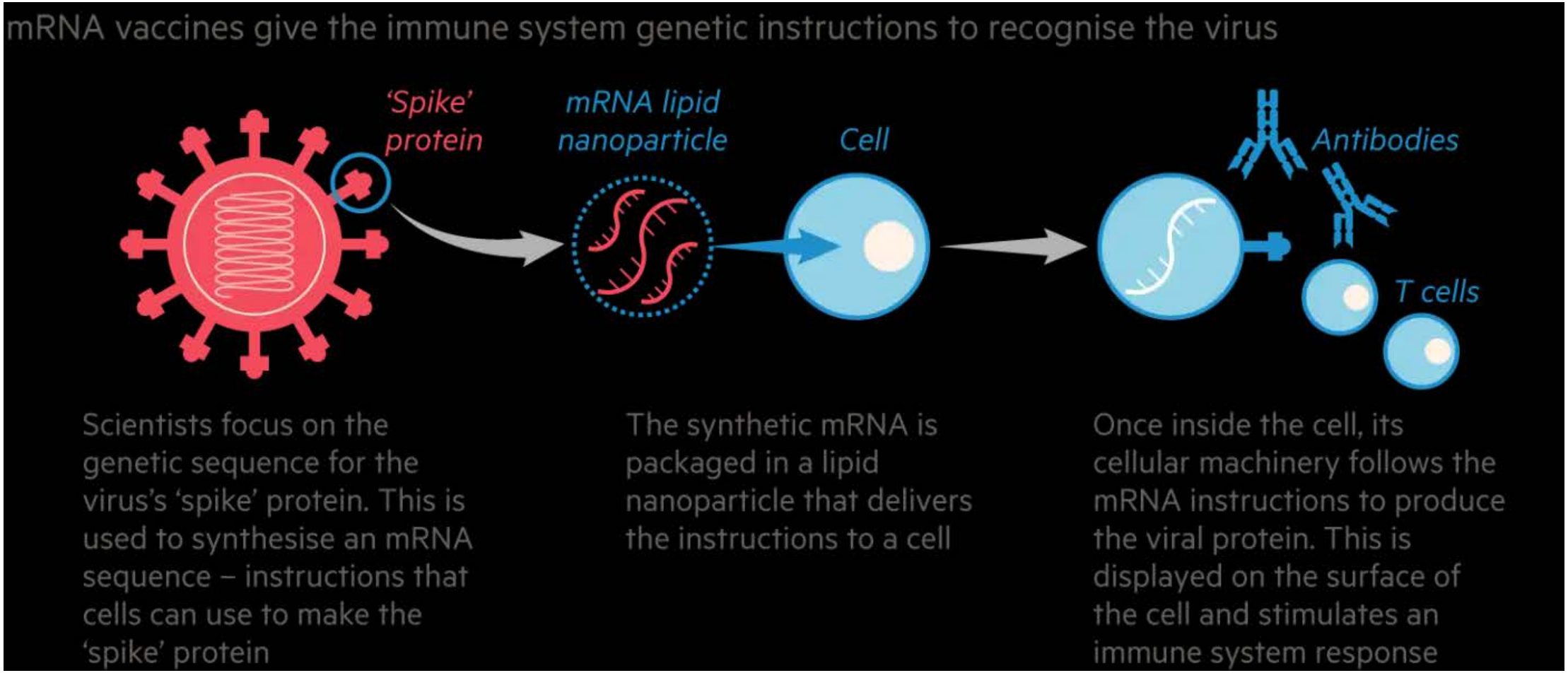
Internal Medicine/Infectious Diseases
University of Oklahoma Health Sciences Center
Oklahoma City, OK

COLLEGE OF MEDICINE
The UNIVERSITY of OKLAHOMA

Purpose

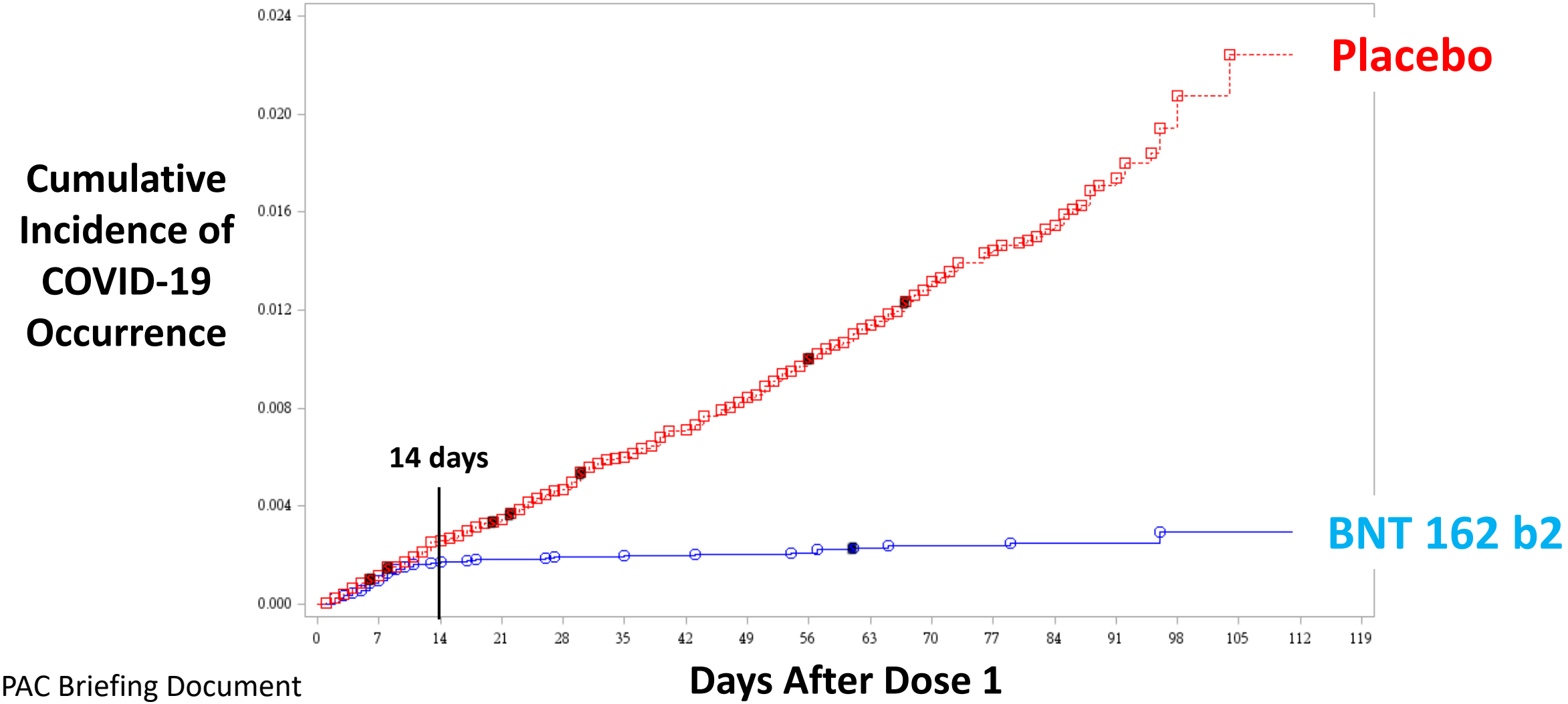
- Comparison of the reported side effects of BNT 162b2 with three, commonly used FDA approved vaccines
- Provide a quick look at the reported side effects of Pfizer's COVID-19 vaccine (BNT 162b2)

Background on BNT 162b2



https://www.ft.com/content/c4ca8496-a215-44b1-a7eb-f88568fc9de9

Cumulative Incidence Curves for the First COVID-19 Occurrence After Dose 1 – Dose 1 All-Available Efficacy Population



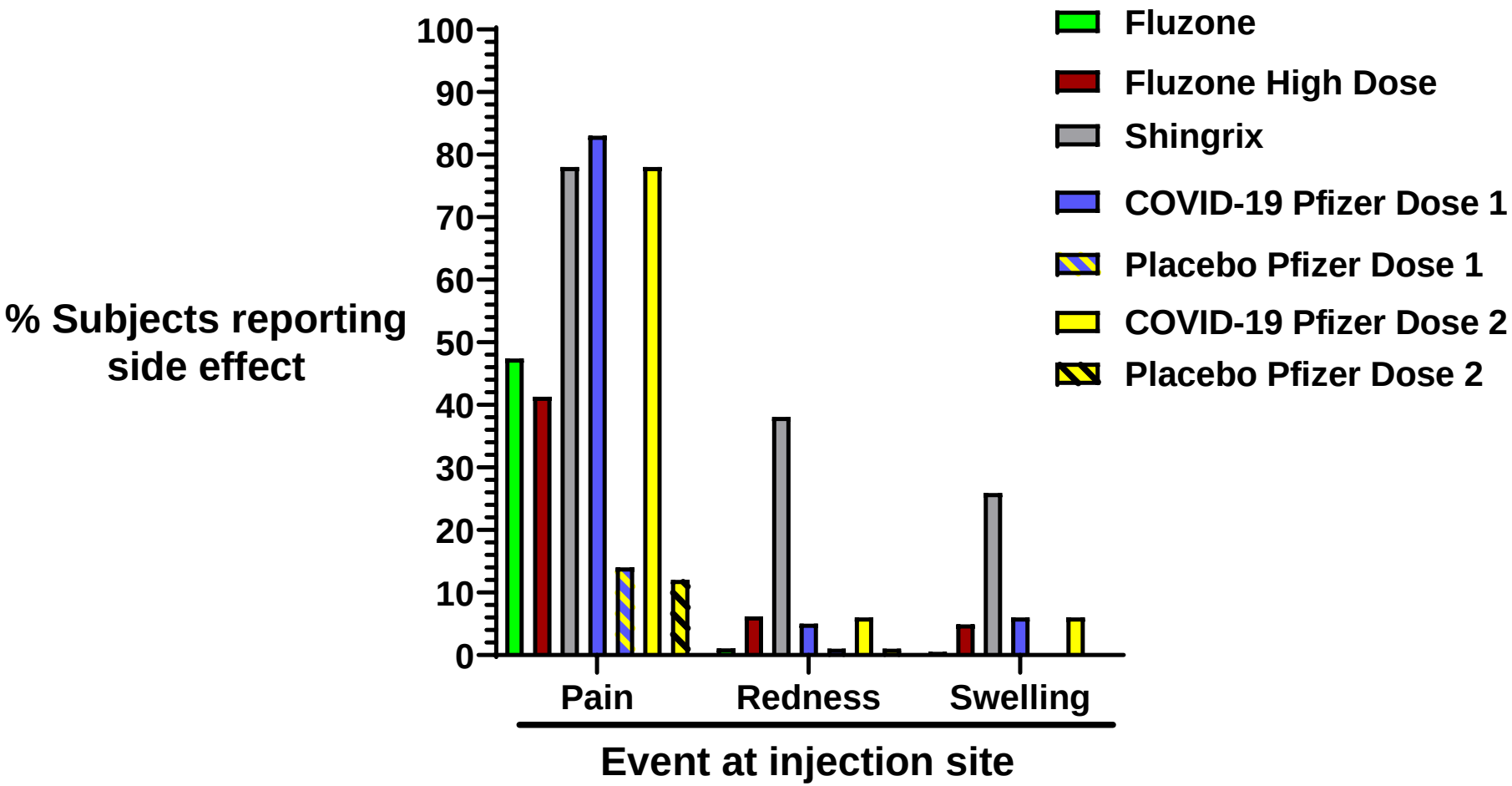
Materials

- Safety data were obtained from package inserts of 3 FDA approved vaccines
  - Seasonal Influenza
    - **Fluzone® Quadrivalet** (Sanofi Pasteur)
    - **Fluzone ® High Dose Quadrivalet** (Sanofi Pasteur)
  - Shingles (Varicella Zoster virus) reactivation
    - **Shingrix** (GlaxoSmithKline)
- COVID-19 vaccine (Pfizer-BioNTech)
  - **BNT 162b2** versus Saline placebo
  - Documents used for data collection
    - FDA VRBPAC Briefing Document released 12/09/2020
    - Clinical Protocol C4591001 (Pfizer)

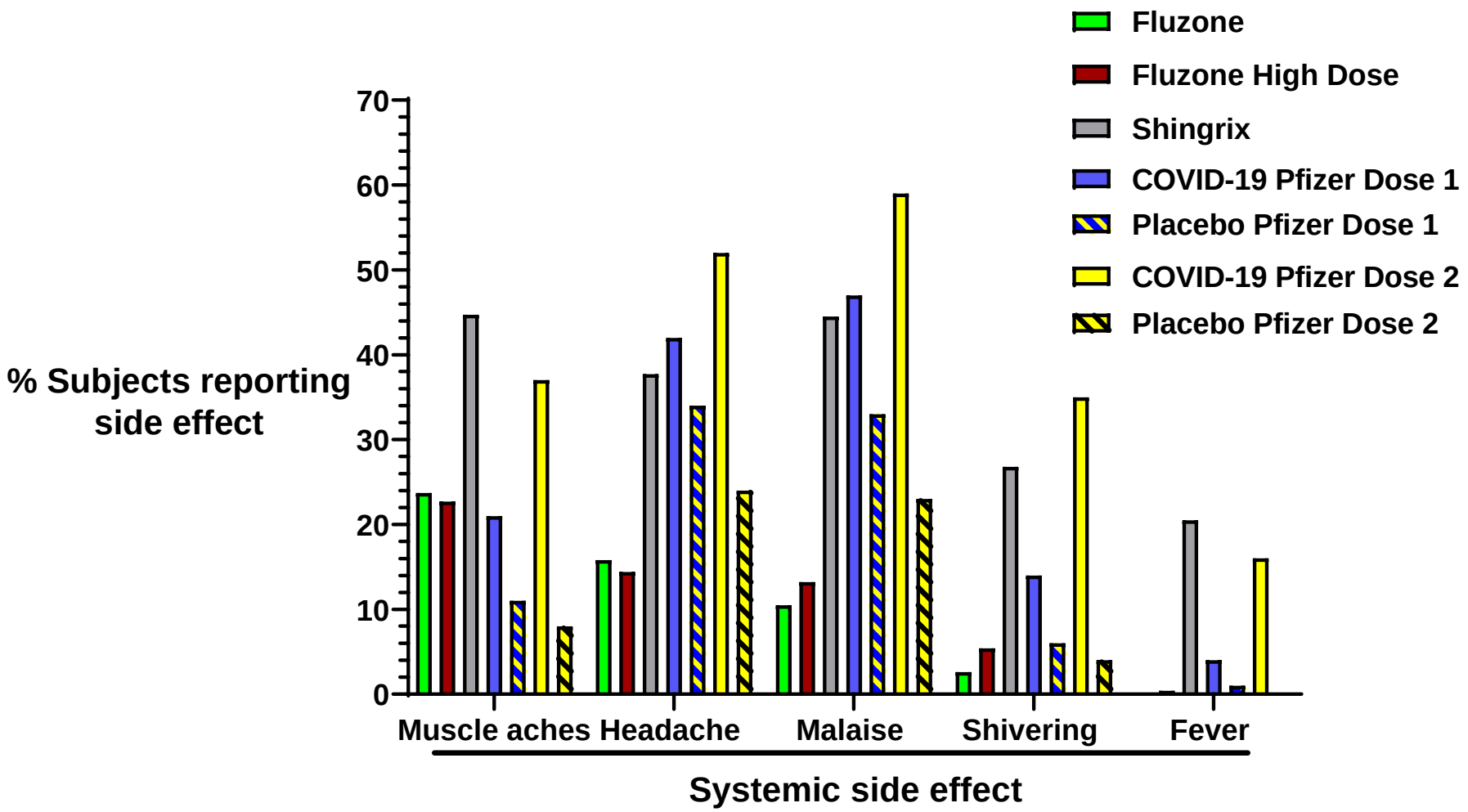
Methods

- Comparisons were made on data on adverse reactions in adult populations, but not all populations were of the same age.
  - Fluzone® Quadrivalet
    - Adults aged 18 and over
      - Half-aged 18-60 and half aged >61
  - Fluzone ® High Dose Quadrivalet
    - Adults aged 65 and over
  - Shingrix (GlaxoSmithKline)
    - Adults aged 50 and over
  - BNT162b2
    - Adults aged 16-55
      - Data comparing reactions in separate age groups are included separately

Local Reactions

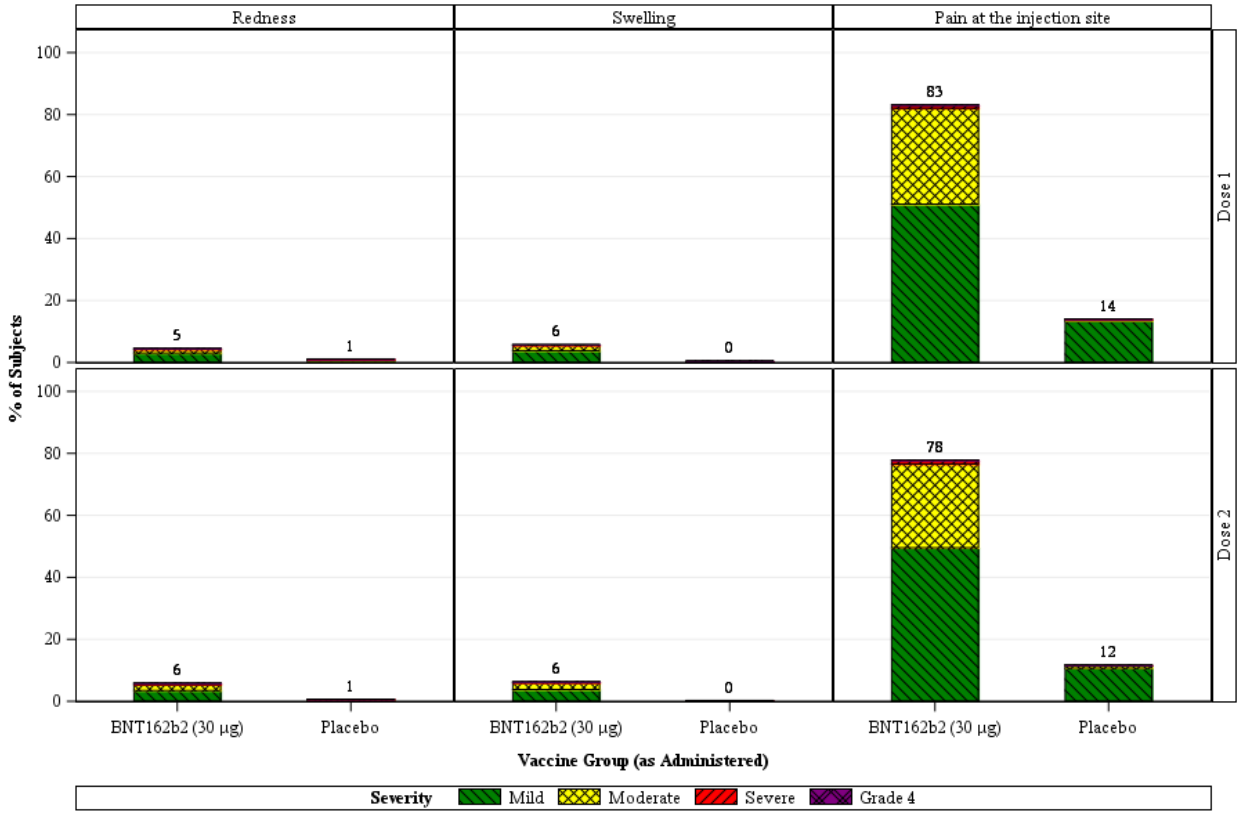


Systemic Reactions



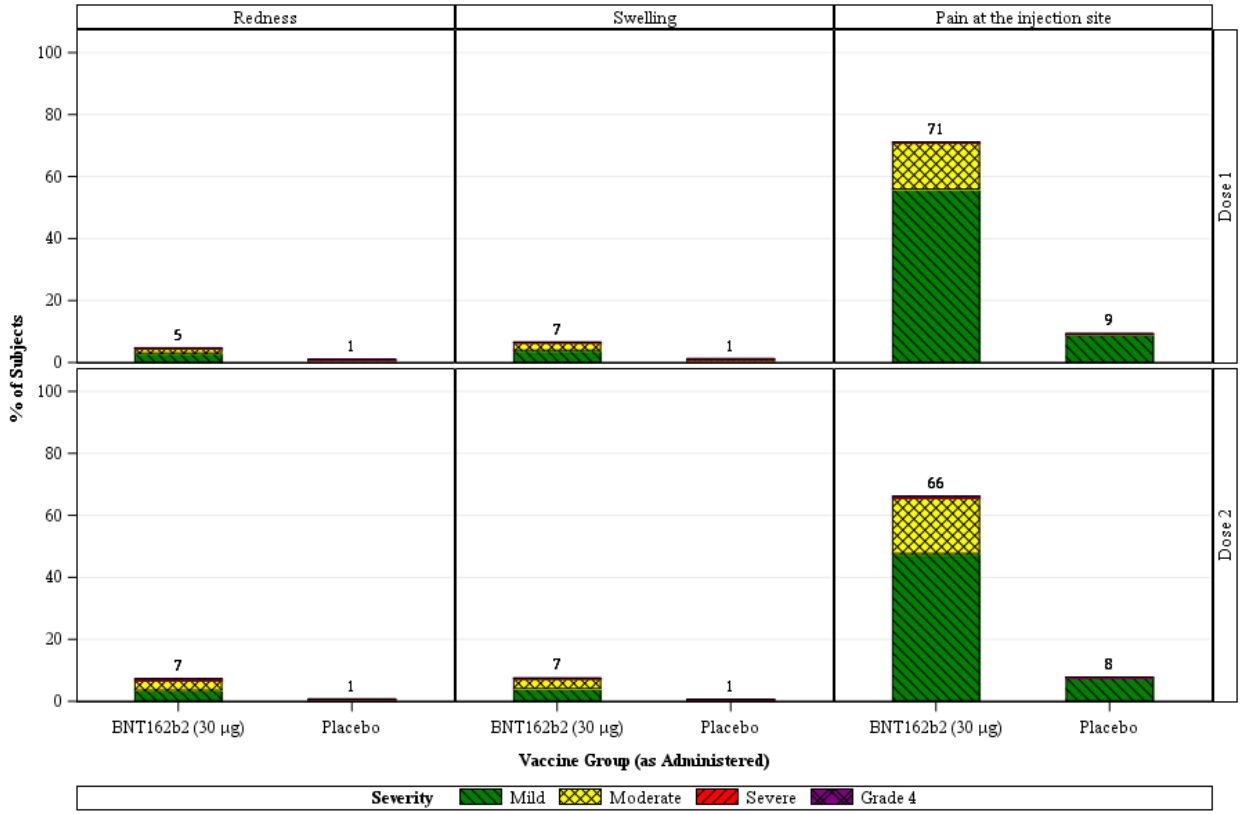
Participants Reporting Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Age Group

Age Group 16-55 years



Note: Number above each bar denotes percentage of subjects reporting the reaction with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adfacevd Table Generation: 17NOV2020 (16:40)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/adce_f001_lr_max_age_p3

Age Group >55 years



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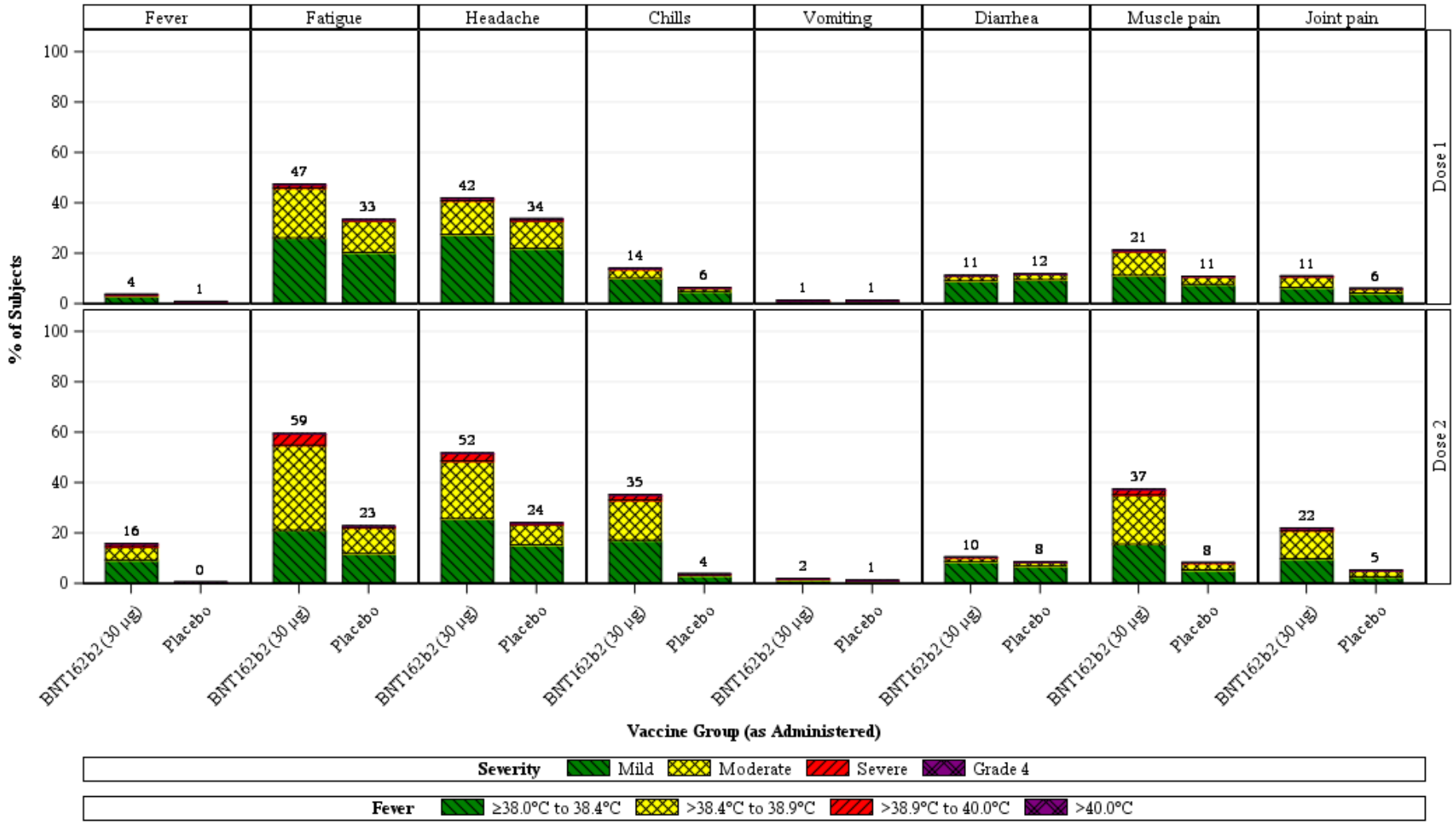
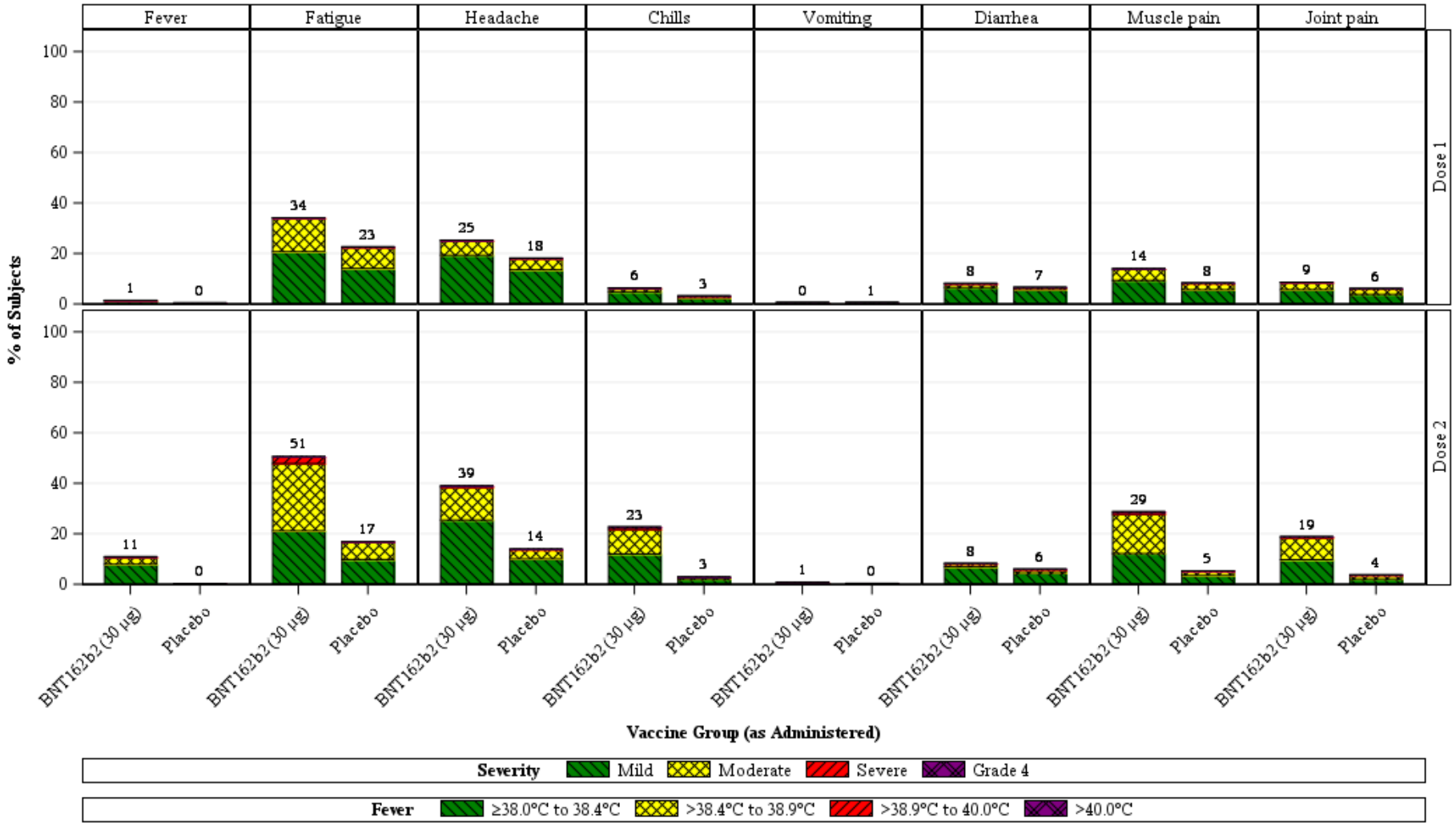
Participants Reporting Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, Age Group 16-55 years



Participants Reporting Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, Age Group >55 years



Observations

- Local side effects
  - BNT 162b2 hurts after administration.
  - Pain is similar to Shingrix (greater than flu vaccines), but evokes less swelling & redness than does Shingrix (comparable to HD flu vaccine)
- Systemic side effects
  - Are common with BNT 162b2 and are more common after the second dose than the first dose
  - Are a bit less common with BNT 162b2 in older than in younger age groups
  - Headache and malaise were the most common side effects, but were also fairly common in placebo
  - ~20-40% of adult subjects used anti-pyretics

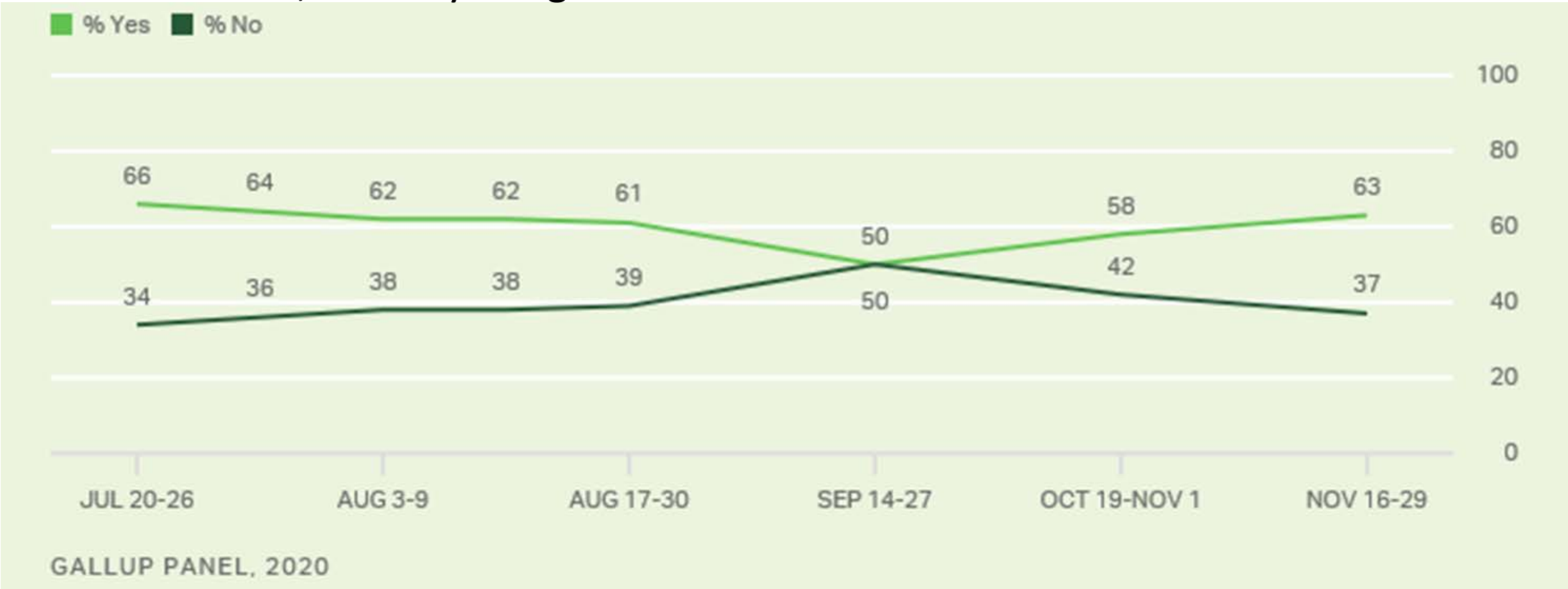
Observations

- No one developed “Cows”
- There were 2 “anaphlyactiod” reactions in the UK, successfully treated with self-administered epi-pen.

James Gillray lampooning Edward Jenner, 1802

Vaccine uptake: American's willingness to Receive COVID-19 Vaccination

If an FDA-approved vaccine to prevent coronavirus/COVID-19 was available right now at no cost, would you agree to be vaccinated?



https://news.gallup.com/poll/327425/willingness-covid-vaccine-ticks.aspx

Willingness to Be Vaccinated Against COVID-19, by Subgroup

		Jul 20-26	Sep 14-27	Nov 16-29
	Total U.S. adults	66	50	63
Gender	**Men**	65	56	66
	Women	67	44	60
Age	**18-44**	68	60	68
	45-64	62	36	52
	65+	68	54	74
Education	**No college degree**	62	45	61
	College degree	75	60	68
Race/ethnicity	**White adults**	64	54	67
	Non-White adults	72	40	53

https://news.gallup.com/poll/327425/willingness-covid-vaccine-ticks.aspx

Looking ahead

- Distribution plans and logistics
- Uptake
- Safety data
  - Reactions not seen in 10,000 vaccinations will be found after >10,000,000 vaccinations
- Impact on educational programs and workforce
- Safety and Efficacy in special populations
  - Pregnant women
  - Children (<12)
  - Groups not included in the trials

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