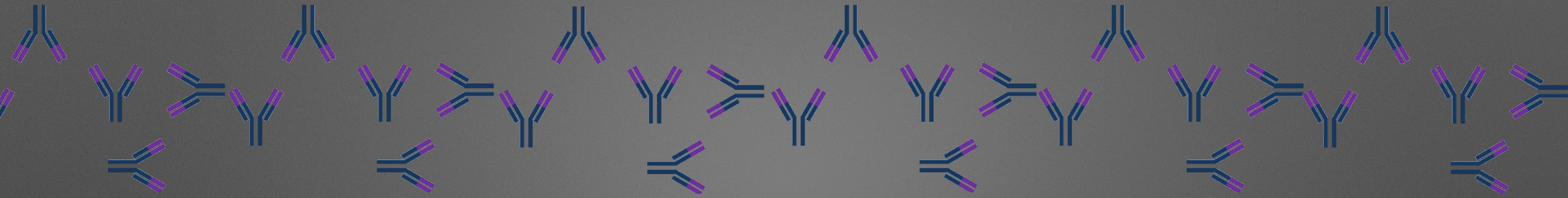


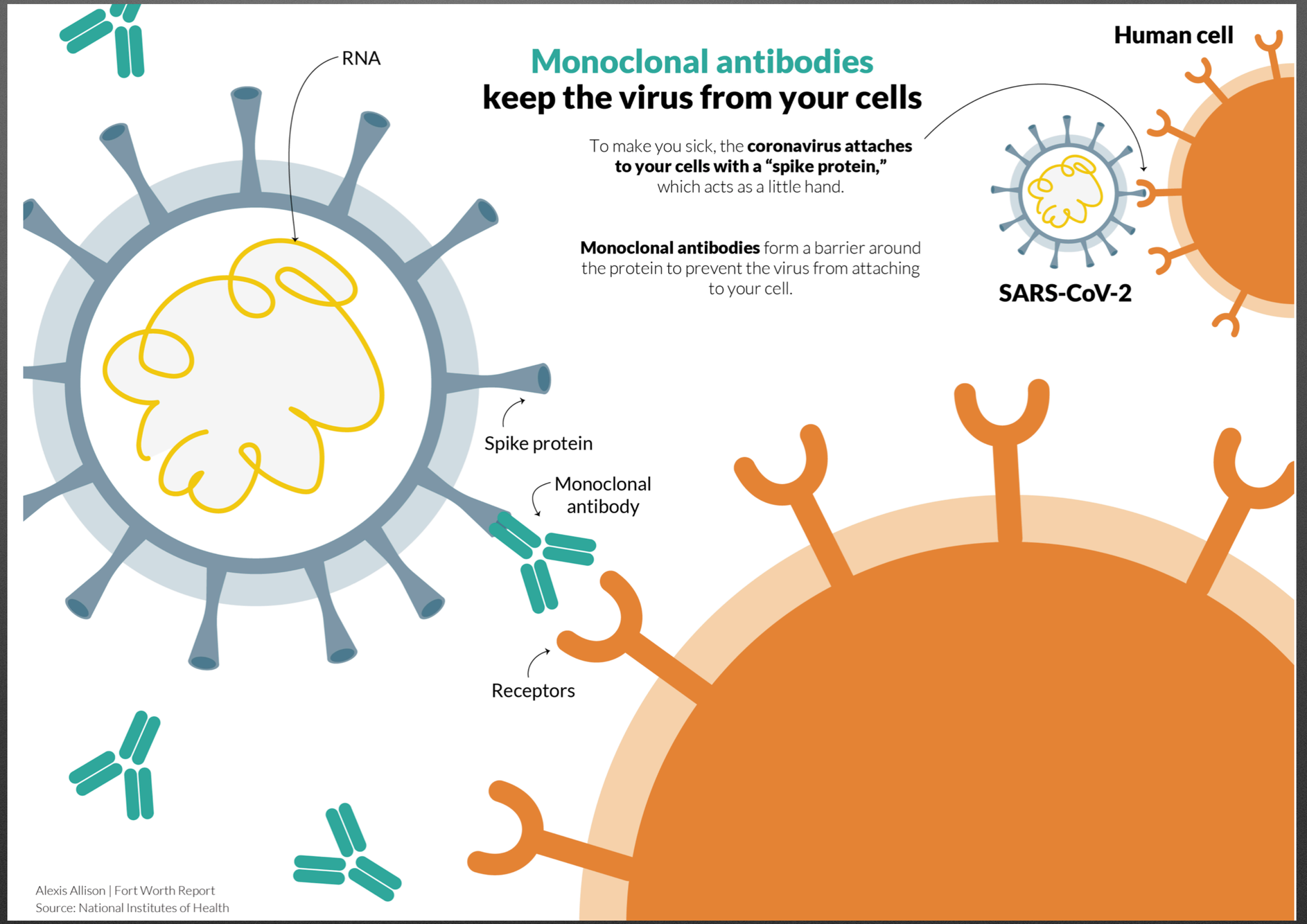
Monoclonal Ab Treatment for COVID-19

(Casirivimab/imdevimab)

September 15, 2021

Cody Takenaka, MD, MS, CMD
University Of Hawaii Dept of Geriatrics

Mechanism of Action



FDA Emergency Use Authorization

Nov 2020

- Treatment of mild to moderate COVID-19 for patients who are at high risk for severe COVID-19, including hospitalization or death. (Age 65 and up)

July 2021

- Post-exposure prophylaxis of COVID-19 for individuals who are at high risk for progression to severe COVID-19, including hospitalization or death, and are:
  - At high risk for exposure to COVID-19, including in the same Nursing Home
  - Not fully vaccinated or immunocompromised

Evidence

Double-blind, Phase 3 Randomized Controlled Trial: Treatment

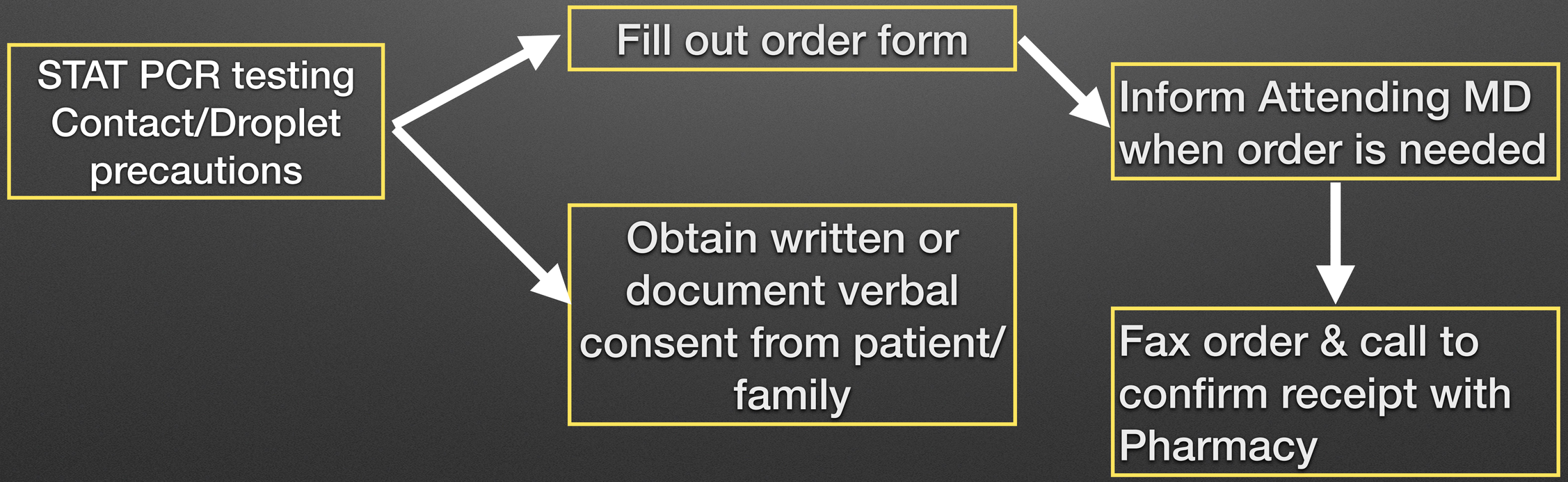
Patients: PCR+ for COVID, onset of Sx ≤7d (n=3867)

Intervention: placebo, 600mg, or 1200mg of casirivimab/imdevimab IV

Outcomes: 2.2% absolute reduction and a 70% relative risk reduction in COVID-19-related hospitalizations or all-cause deaths in patients who received CAS 600 mg plus IMD 600 mg compared to those who received placebo (p=0.0024).

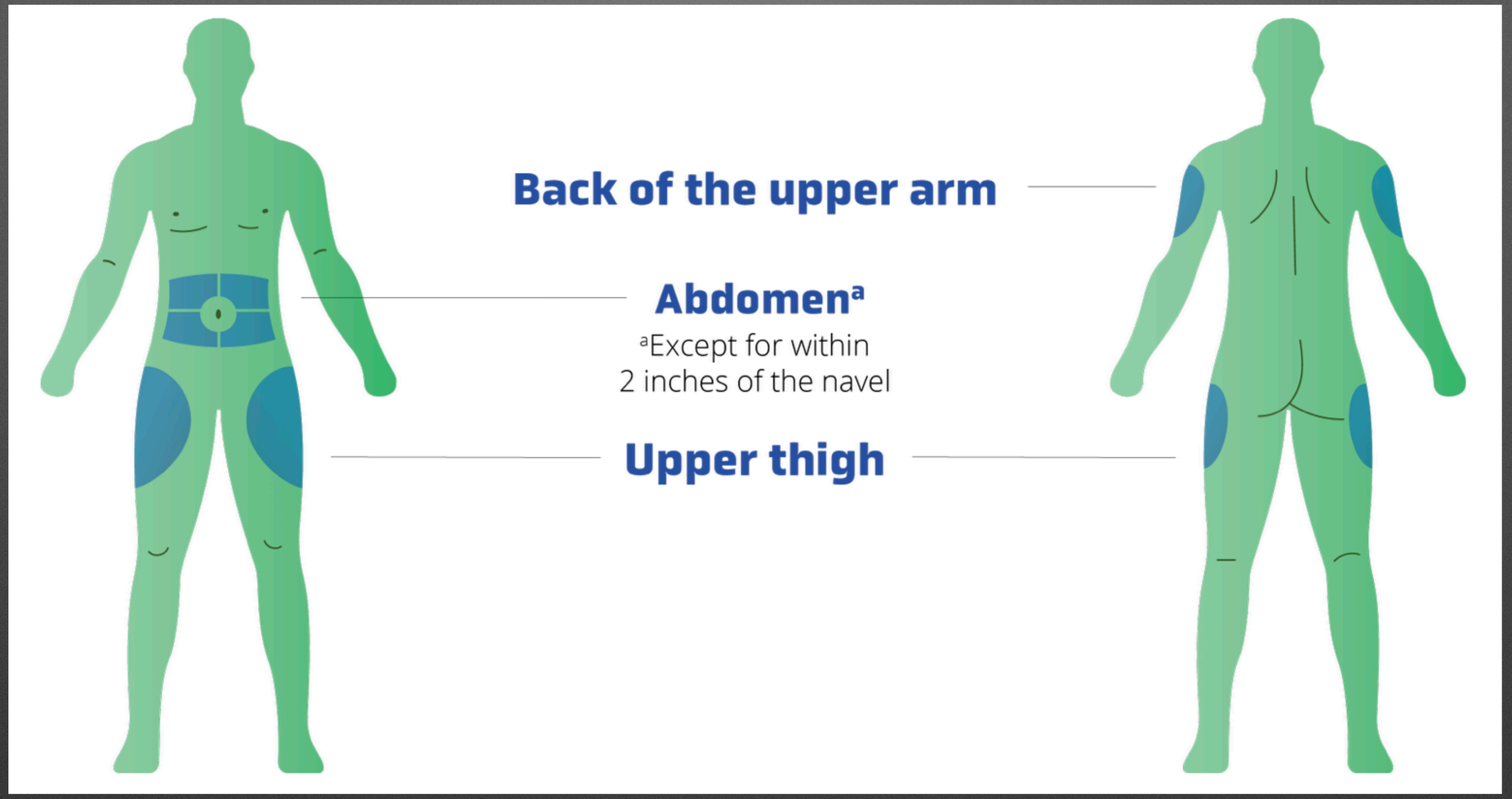
Workflow

Review/update facility policy, prepare consent form, order templates & fact sheets



Administration: Casirivimab 600mg/ Imdevimab 600mg co-formulated vial

- 5ml syringes (4), 21g needles to draw, 25/27g needle for SQ injection
- Allow vial to reach room temp (20 min from refrigerator)
- DO NOT SHAKE VIAL
- Draw 2.5ml into 4 syringes for a total 10ml dose & administer SQ ASAP (<4hrs at 77degF)
- If IV access is available w/0.2-micron polyethersulfone (PES) filter: Administer the 10ml dose in NS (50ml/20min or slower). Flush line with 25cc NS afterwards.
- Document lot# of vial, date/time & sites of administration



Avoid bruised or tender skin, waistline & 2 inches around navel & waistline

Monitoring

Monitor for at least 1 hr after treatment

- 0.2% study participants had moderate to severe adverse events
- Hypersensitivity: fever, chills, nausea, headache, shortness of breath, low/high blood pressure, rapid/low heart rate, chest pain, weakness, confusion, feeling tired, wheezing, swelling of your lips, face, or throat, hives, itching, muscle aches, feeling faint, dizziness and sweating.

Mandatory reporting within 7 days to www.fda.gov/medwatch/report.htm

- life-threatening adverse event
- inpatient hospitalization or prolongation of existing hospitalization
- persistent or significant incapacity or substantial disruption of ADLs
- congenital anomaly/birth defect
- medical or surgical intervention to prevent death, a life-threatening event,

hospitalization, disability, or congenital anomaly.

References & Resources

Fact sheet for patients, parents & caregivers
https://www.fda.gov/media/143893/download

Fact sheet for Health Care Providers
https://www.fda.gov/media/145611/download

RegenCov website Instructions for Dosing & Administration
https://www.regencov.com/hcp/dosing/dosing-administration

HHS Combat COVID Monoclonal Ab video for patients : “Monoclonal Ab What is it and how does it work?”
https://youtu.be/a9ZdqAub0zA

Combat Covid Monoclonal Ab Call Center 1-877-332-6585