

Research in Long Term Care: Practical Issues

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Disclosures

- Janssen
- Pfizer
- Moderna
- CyanVac
- Vax Co
- BioFire Diagnostic
- Sanofi Pasteur
- GSK
- ADMA Biologics

St Ann's Community

First nursing home study-1989, first vaccine study 1992 and most recent study vaccine study 2023-2024



1980s

Outbreak attack rates
12 - 89%
1-15% in prospective
studies



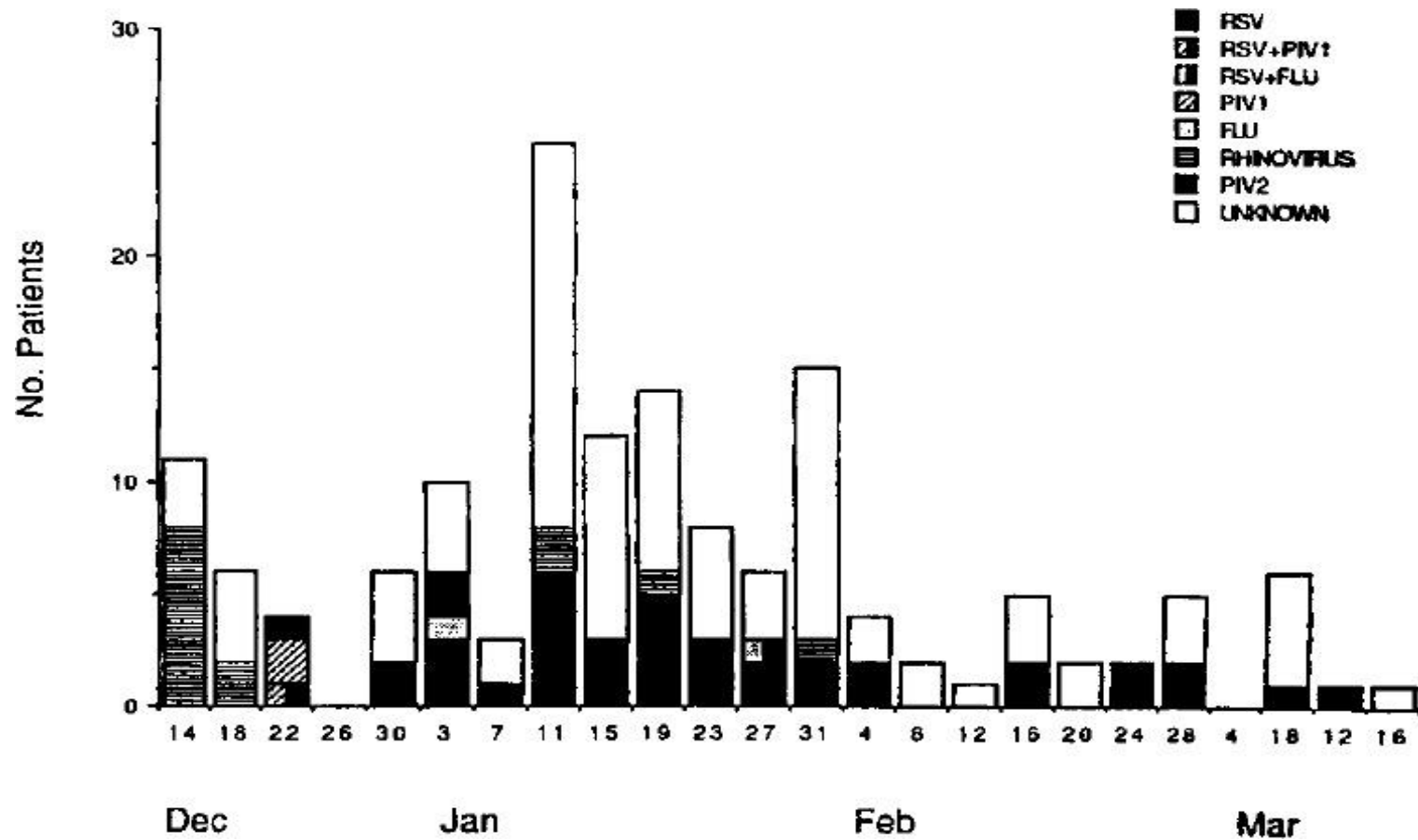
Reported severity is
variable

Pneumonia (0 - 55%)

Death (0 - 53%)



Viral Respiratory Infections in the Institutionalized Elderly: Clinical and Epidemiologic Findings



591 bed
149 illnesses

RSV- 40 (18 culture +)
6.8% of population
27% of illnesses

HRV-14
Flu-2

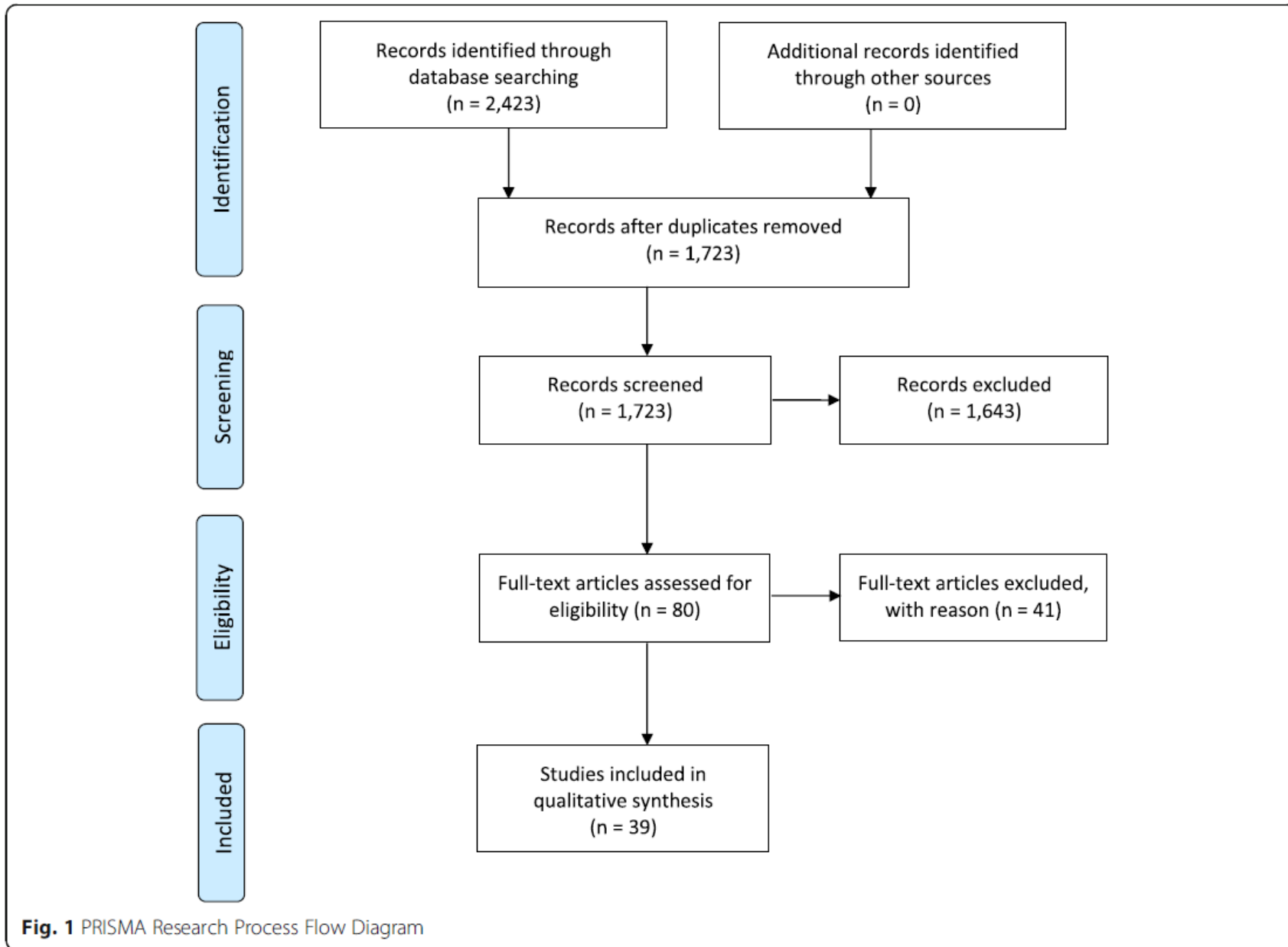
RESEARCH ARTICLE

Open Access

Challenges of conducting research in long-term care facilities: a systematic review



Helen R Lam¹, Selina Chow^{1,2}, Kate Taylor¹, Ronald Chow¹, Henry Lam¹, Katija Bonin¹, Leigha Rowbottom¹ and Nathan Herrmann^{1,2*} 



Research Challenges in LTCF – 8 Themes

- Facility/Owner/Administrative
- Resident
- Staff Caregiver
- Family
- Investigator
- Ethical/Legal
- Methodological
- Budgetary

Facility/Owner/Administrator

- Suspicion regarding motives
- Lack of Understanding of Research

- Education
- Long term partnership

Resident

- Feeling too old
 - No personal benefit
 - Fear of invasive procedures
 - Cognitive impairment
 - Lack of privacy
-
- Spend time and provide understandable explanations
 - Many residents are anxious to help
 - Ensure privacy
 - Compensation

Family

- Belief there is no benefit for loved one
- Fear of bothering loved one
- Not on site to provide consent

- Educate on the problem being studied
- Stress what would “Mom” want to do?
- Stress issue of “assent”
- Remote or verbal consent

Staff

- Time constraints
- Turnover
- Low educational level in some

- Minimize disruption
- Try to have research do most of work
- Education
- Offer some type of thankyou

Methodologic

- Difficult to do individual randomization
- Tradition outcome measure may not work

- Alternative study designs
 - Cluster randomization
 - Quasi-experimental
- Adapt outcome measurement appropriate for LTCF

Planning how to staff a study

- Partner with leadership and staff at the facility
- Try very hard to minimize the burden on an already overworked staff
- Staff can identify for you, good candidates
- Spend some time understanding facility routines
- Plan travel time
- Remember that pharmacy issues will arise with investigational drugs, vaccines, transport

Informed Consent



- Visual Impairment- Large Print
- Hearing Impairment – need quiet places
- Cognitive Issues- teach back
- Hard to email consent forms ahead of visit
- LAR may live out of town
 - Red cap consent
 - Mail consents
 - Verbal consent for minimal risk

RESEARCH CONSENT FORM

This is to certify that I _____ hereby agree to participate as a volunteer in the scientific investigation _____

The investigation and my part in the investigation have been defined and fully explained to me and I understand the explanation. A copy of the procedures of the investigation and a description of any risks and discomforts has been provided to me and has been discussed in detail with me.

- I have been given an opportunity to ask whatever questions I may have had and all such questions and inquiries have been answered to my satisfaction.
- I understand that I am free to deny any answers to specific questions in the questionnaires.
- I understand that any data or answers to questions will remain confidential with regard to my identity.
- I understand that I am free to withdraw consent and to discontinue participation in the project or activity at any time.
- I certify to the best of my knowledge and belief, I have no physical or mental illness or weakness that would increase the risk to me of participating in this investigation.
- I am participating in this project of my own free will and I have not been coerced in any way to participate.

• Signature of Subject: _____ Date: ____/____/____

I, the undersigned, was present when the study was explained to the subject's in detail and to the best of my knowledge and belief it was understood.

Signature of Researcher: _____ Date: ____/____/____

You need really good phlebotomists



- Fragile skin
 - Tiny veins
 - Contractures
 - Awkward blood drawing positions
-
- Pediatric Nurses
 - NICU Nurses
 - Contract with the facility
 - Combine with SOC as much as possible

Be Careful with Impressionable Young Coordinators



Dress lightly or in layers

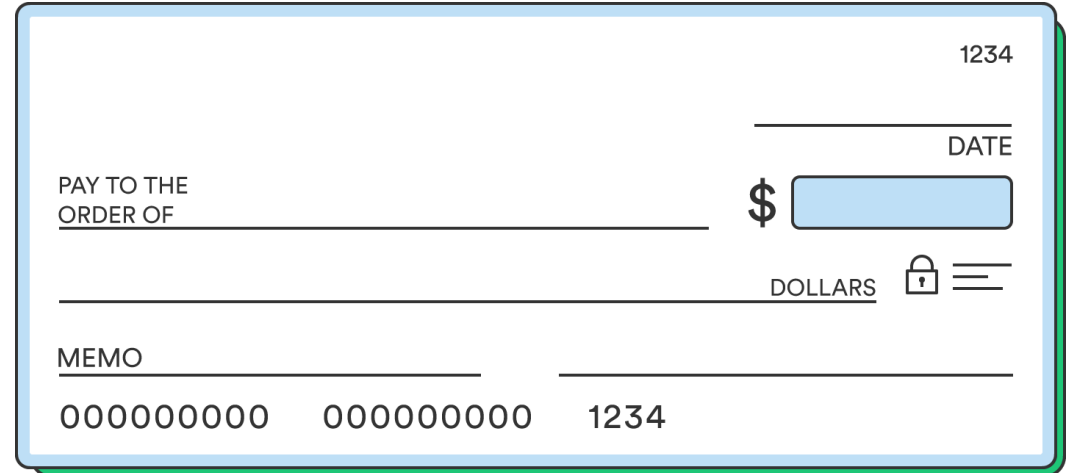


Be prepared to spend a lot of time



How to pay honorarium?

- Checks
- Cash
- Gift Cards
- Bank account at LTCF
- Relatives



1234

PAY TO THE ORDER OF _____

DATE _____

\$

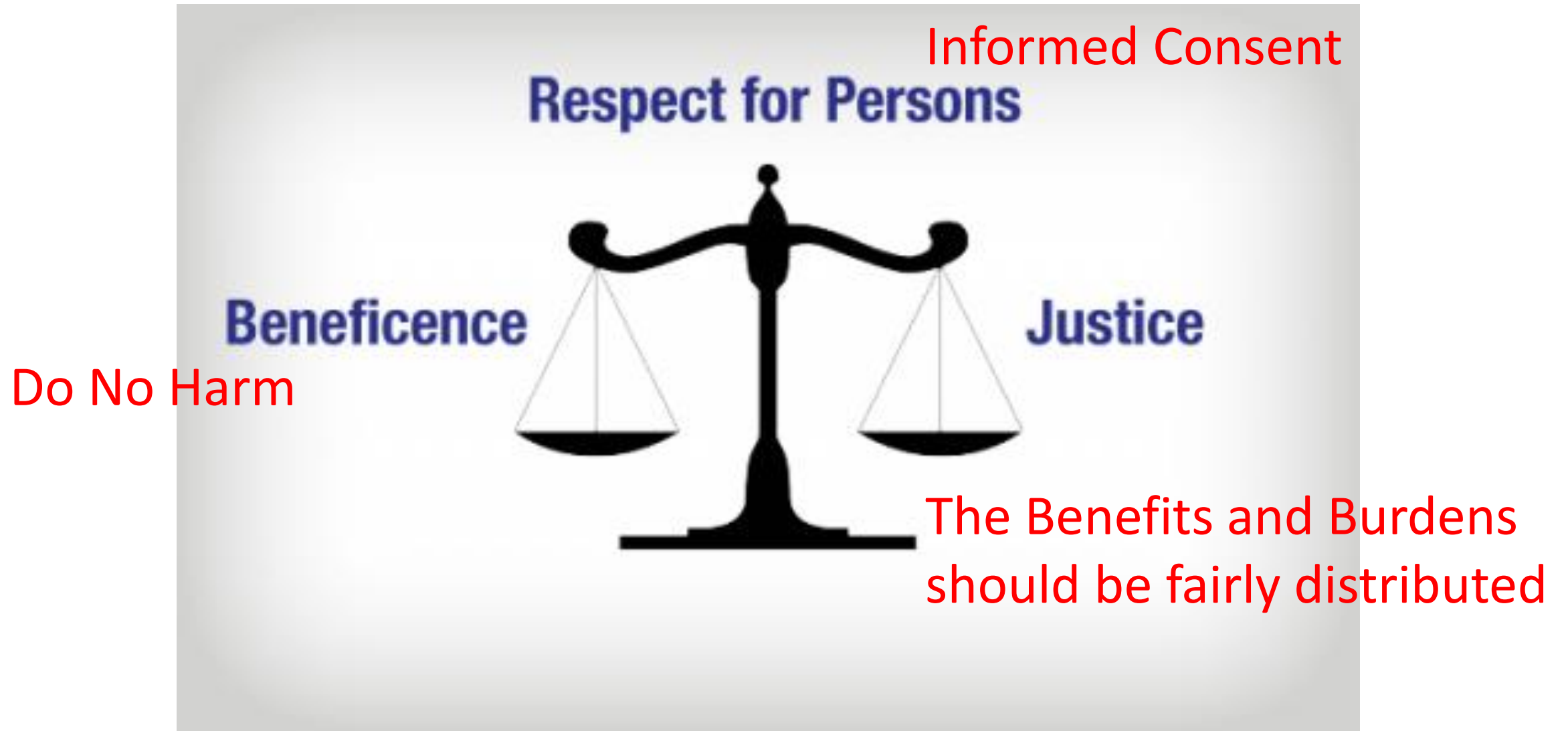
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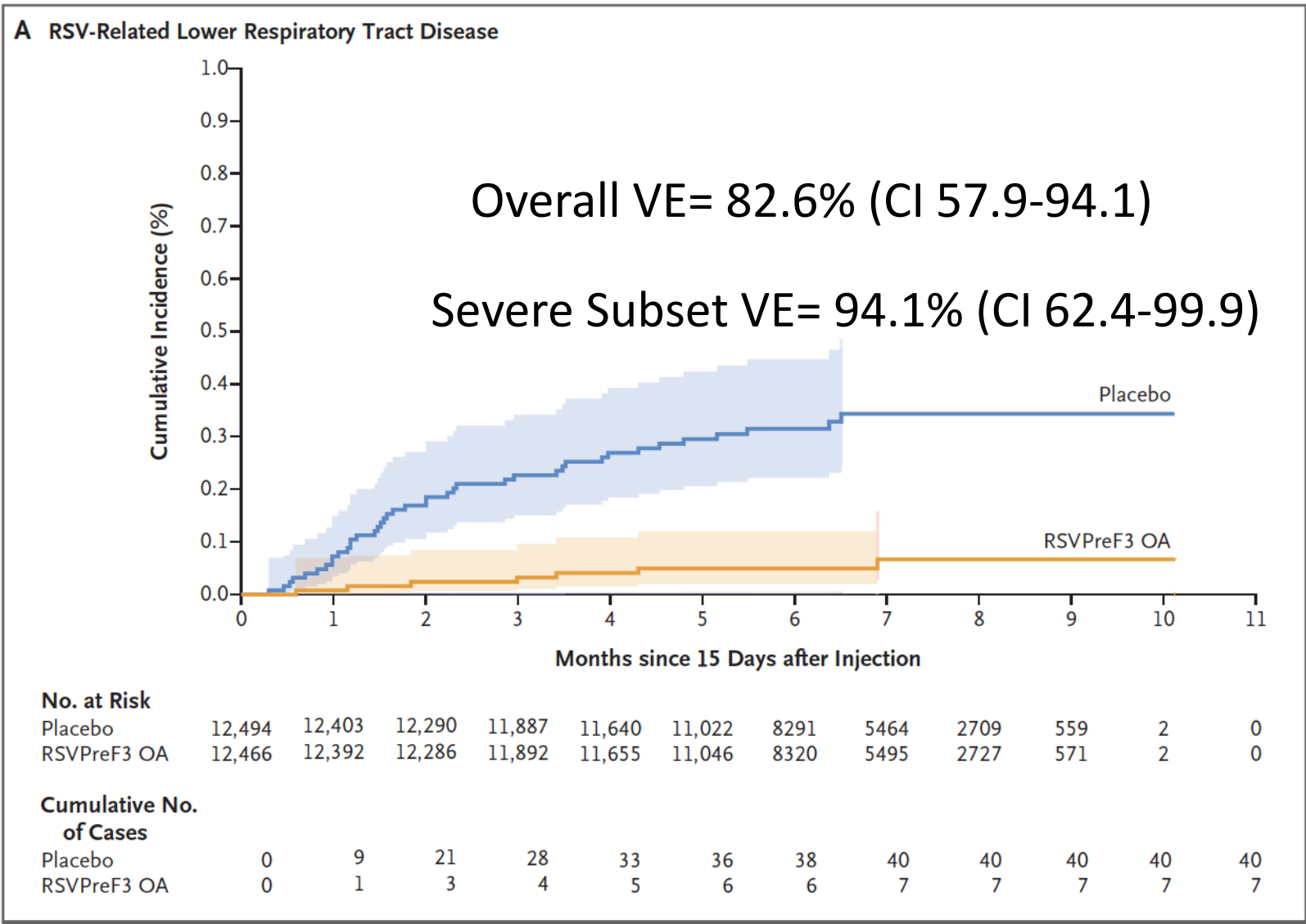


Belmont Report



Real Life Impact of Not Including Residents of LTCF in Pivotal Efficacy Studies

GSK RSV Vaccine Trial – Primary Outcome LRTD



Pfizer, GSK RSV shots get tepid recommendations from CDC advisory panel

By Kevin Dunleavy · Jun 22, 2023 8:40am

CDC

ACIP

Pfizer

RSV



- Few persons with high risk conditions
- Few persons > 80 yo
- Few Frail
- Residents of LTCF nearly absent
- Not enough events to prove efficacy against hospitalization, death
- Concern about rare but serious adverse events (GBS)
- Questions about durability
- Cost

ACIP Recommendations

June 21, 2023

- Adults \geq 60 years old
- May receive single dose of RSV vaccine using shared decision making.

Chronic underlying medical conditions associated with increased risk

- Lung disease (such as chronic obstructive pulmonary disease and asthma)
- Cardiovascular diseases (such as congestive heart failure and coronary artery disease)
- Moderate or severe immune compromise*
- Diabetes mellitus
- Neurologic or neuromuscular conditions
- Kidney disorders
- Liver disorders
- Hematologic disorders
- Other underlying conditions that a health care provider determines might increase the risk for severe respiratory disease

Other factors associated with increased risk

- Frailty[†]
- Advanced age[§]
- Residence in a nursing home or other long-term care facility
- Other underlying factors that a health care provider determines might increase the risk for severe respiratory disease

AMDA –PALTC (Post Acute Long Term Care)

Findings Task Force June 9 2023

- Neither vaccine has been adequately evaluated in the PALTC population.
- Limited or no data on vaccine response in frail individuals.
- Duration of immunity is unknown.
- More follow-up data on safety is needed.

Recommendations

1. Recommend use of the licensed RSV vaccines through a shared-decision making process.
2. Continuation of clinical trials of the RSV vaccines across several vaccine seasons
3. Recommend studies of PALTC residents, frail individuals, individuals at >80 years of age
4. No for support quality metrics targeting uptake of RSV vaccine
5. It is premature to consider clear support for vaccination across the 60+ age group.

How to Assess Risk - Benefit

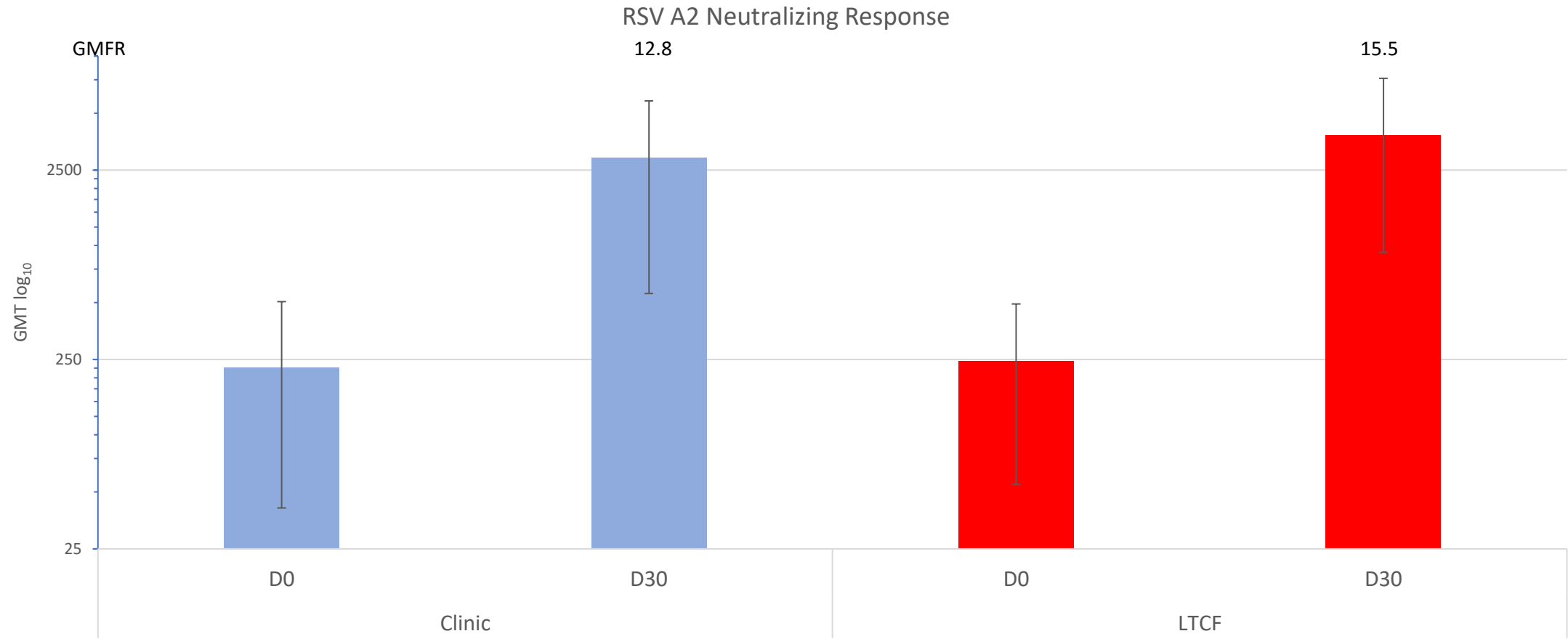
- Benefits- protection against lower respiratory tract RSV illness and serious illness
- Risk of serious disease increases with age, comorbidities, frailty
- Issues/Risk
 - Cost - \$250- should be covered under Medicare part D
 - Harm
 - Possible increase rate of Afib
 - Possible increase in GBS – 10-20 per million doses

Population based rates of RSV Infection in LTCF

- 2017-18 650/100,000 (95% CI; 331-968)
- 2018-19 540/100,000 (95%CI; 234-845)
- 2019-20 456/100,000 (95% CI; 186-725)

- 3 years combined 550/100,000 (95% CI; 377-722)

Immunologic Response to RSV vaccine



Enrolled

Community -76

St Ann's Community -38

Highlands of Brighton -38

Conclusions

- It is hard to do research and especially interventional trials in LTCF
- Residents of LTCF should be involved in trials if the disease affects LTCF residents
- It is the right thing to do
 - Ethically
 - Practically- a great product may not be adopted
- Although challenging the rewards of doing research in this population are great!

Thank you!

Questions?