

COVID 19 Vaccines by Lot Number

Do all lots contain “the same” product?

Excessive lot-to-lot variability is highly unusual and must be investigated.

About the Authors – Team Enigma

- We are a group of independent researchers with experience in:
 - Pharmaceutical R&D and manufacturing
 - Clinical trials
 - Pharma industry regulations
 - Data analyses and modeling
 - Statistics
- Located worldwide, conducting independent analyses of the same data
- Financially and politically independent
- We are not afraid to think for ourselves and speak up

Why does this matter?

- All drugs are poisons, it is a matter of dosing, application and risk/benefit:
 - Warfarin (blood thinner) – its other application is rat poison
 - Chemotherapy agents for cancer are highly toxic
- Mass produced food, beverages, vitamins, supplements, homeopathic products, etc:
 - If you drank a can of beer from your favorite brand and the result was 300% different from previous time, would you drink that beer again?

That's why product consistency matters!

FDA Good Manufacturing Practices (GMP):

21CFR210.1

- High quality, consistency and purity standards for drugs/vaccines:
 - Expectation that every new lot/batch is “almost the same” as all previous lots
 - Expectation that vaccines from different manufacturers for a disease indication are “the same” or interchangeable product
- Current FDA GMP regulations were developed after several adulterated or poorly tested products poisoned and killed 100s of people (early 1900’s to 1960’s)
- “The failure to comply ...shall render such drug to be adulterated ...shall be subject to regulatory action”.

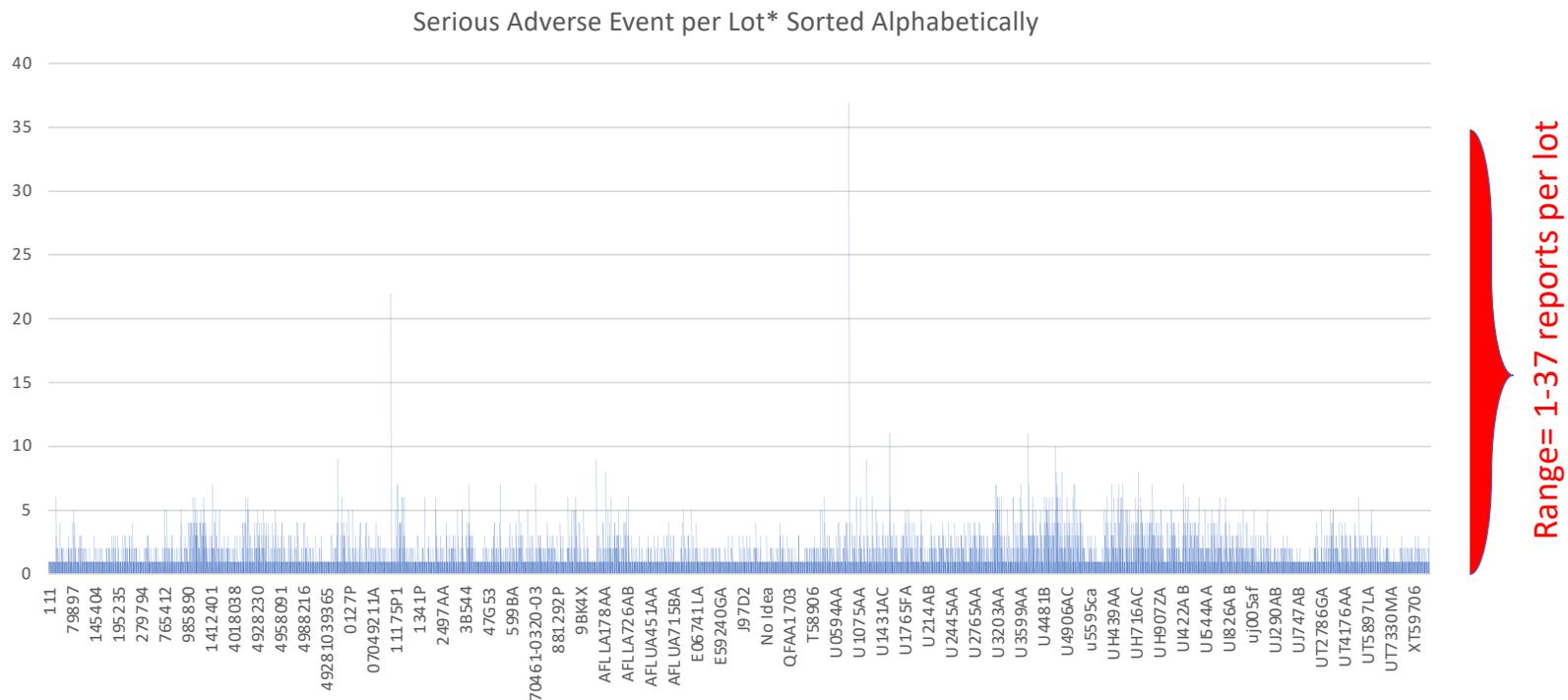
VAERS Data: Covid 19 mRNA Vaccines vs Seasonal Flu Vaccines

Seasonal Flu Vaccines	Covid 19 mRNA Vaccines
9 injectable products	3 injectable products
10+ manufacturers	3 manufacturers (Pfizer, Moderna, Janssen)
10+ years of data	<12 months of data
22,334 manufacturing lots*	24,945 manufacturing lots*
9,429 Serious Adverse Events**	47,239 Serious Adverse Events**
906 deaths**	7,335 deaths**

*Unvalidated – i.e. lots that are present in VAERS database, not complete list, contains typos. This does not matter when comparing two datasets that have the same error-prone data.

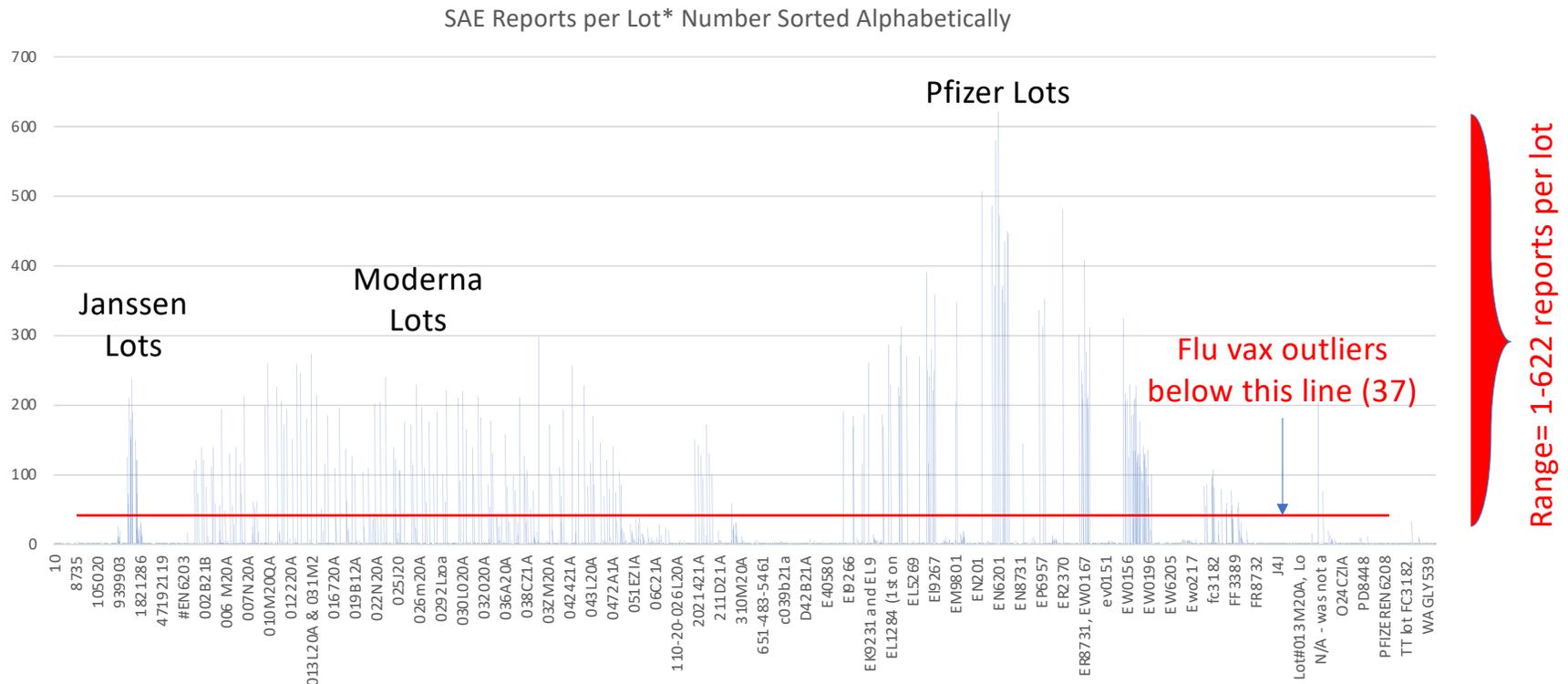
**Numbers of events reported to VAERS in each category

Flu Vaccines: Consistent product across many manufacturers, lots, years, only 2 outliers



*Includes lots with non-zero SAE Reports only, N= 5,797 Lot Numbers

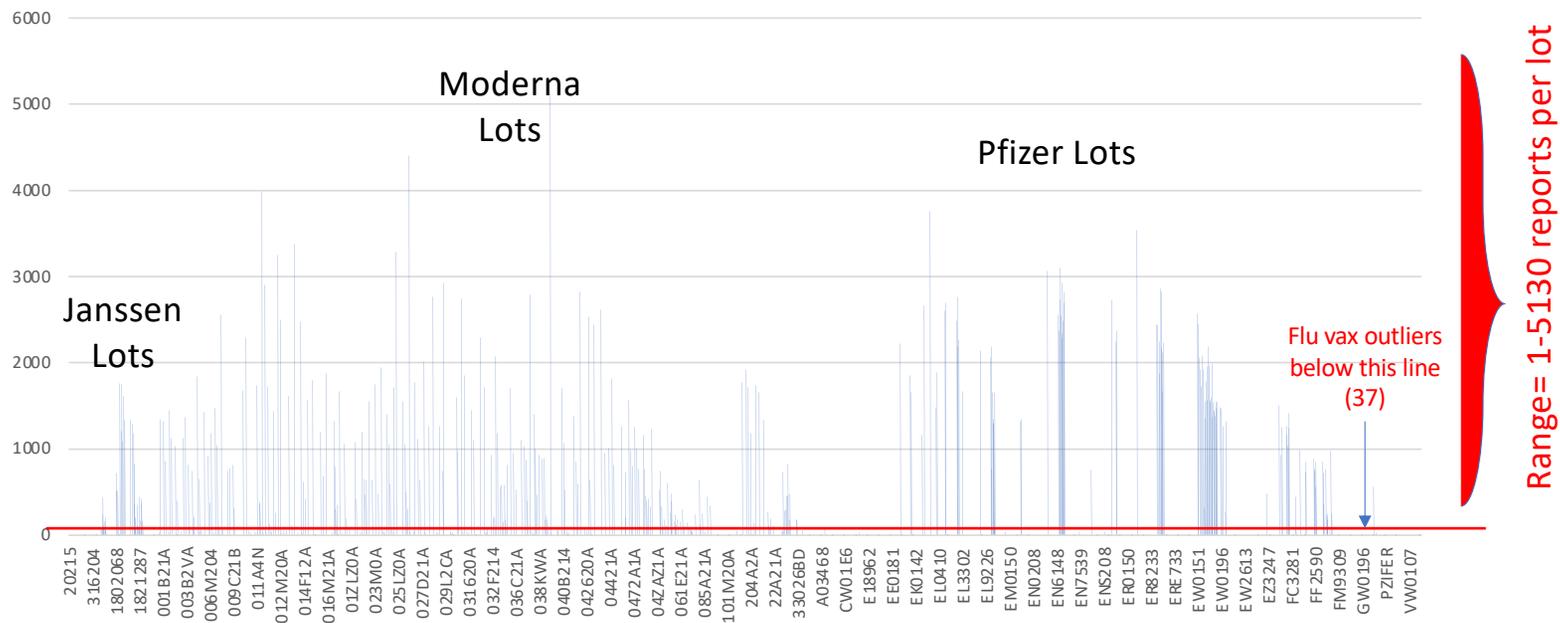
Covid Vaccines: Does this look like the same consistent product by manufacturer and by lot?



*Includes lots with non-zero SAE Reports only, N= 4,122 Lot Numbers

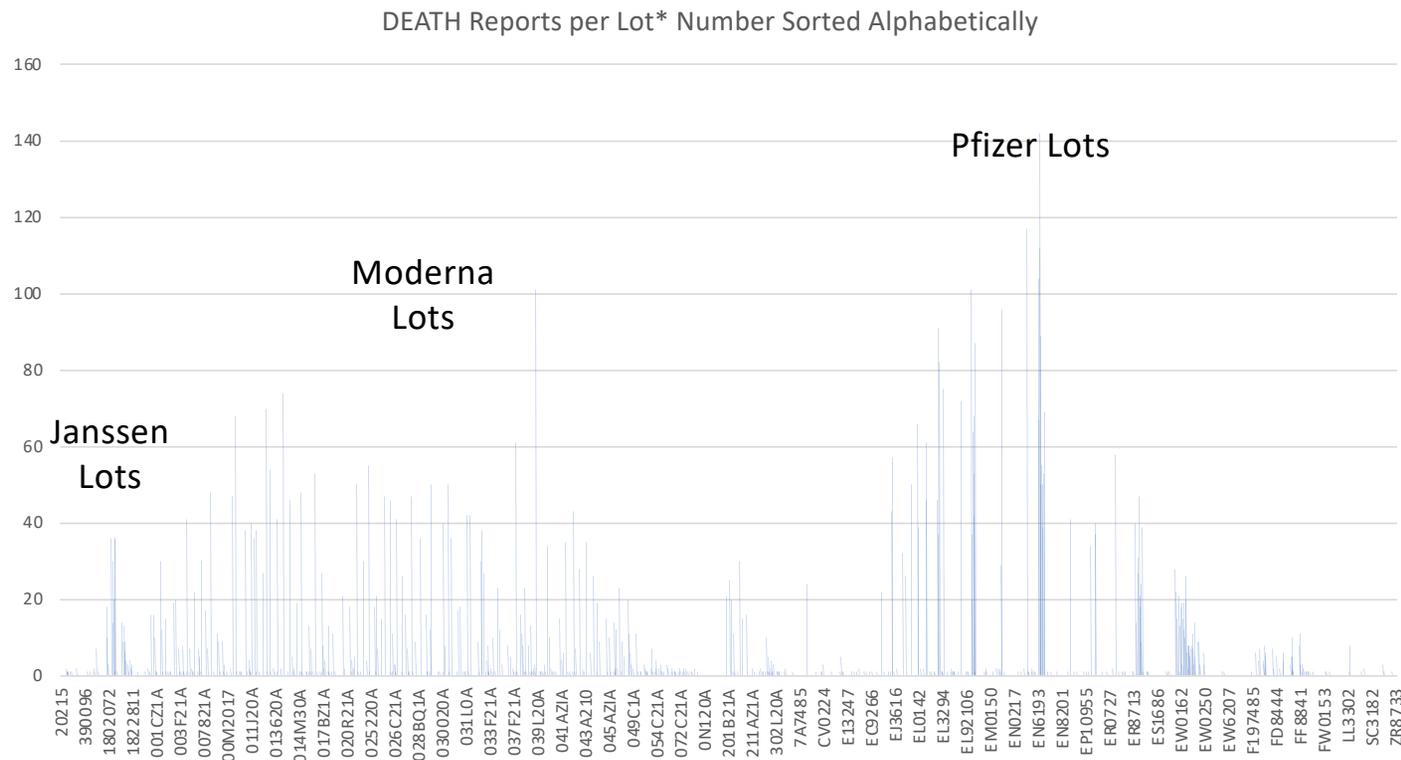
The unusual pattern persists even after removing typos in lot numbers...

Severe Adverse Event Reports per Lot Number* Sorted Alphabetically



*Includes lots with non-zero SAE Reports, after cleaning typos N= 2,244

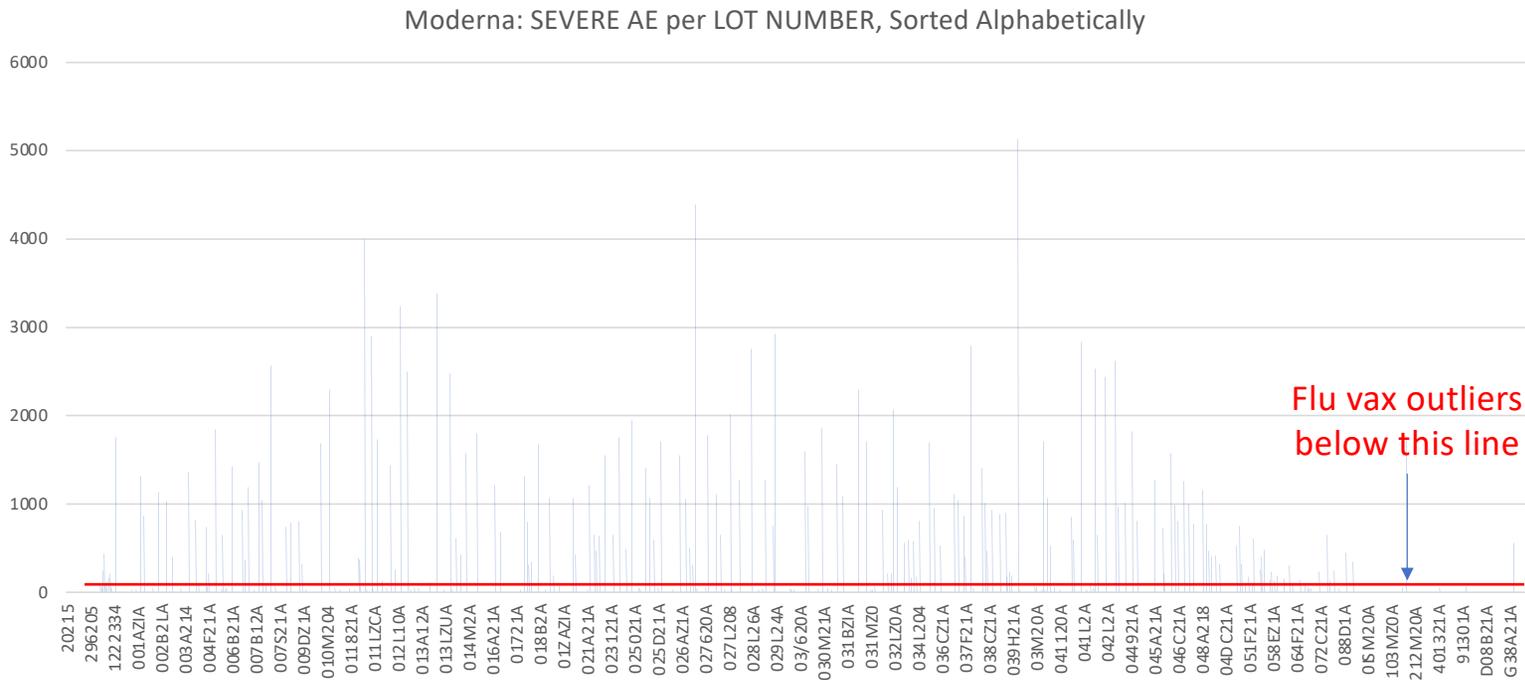
... and for Death Reports



*Includes lots with zero Death Reports, after cleaning typos N= 2,244

Range= 0 -142 reports per lot

Moderna: Does this look like the same consistent product lot-to-lot?



*Includes lots with non-zero SAE Reports, after cleaning typos N= 2,244

5-12 Times Higher Variability in C19 Vaccines Lot-to-Lot vs Control Dataset

Coefficient of Variation for Each Dataset		
Product Type	SAE Reports	Deaths
ALL COVID19 VACCINES	1019%	1195%
MODERNA ONLY	1005%	1159%
ALL FLU VACCINES	224%	99%

Variability in Adverse Events of C19 Vaccines Lot-to-Lot is Excessive and Unusual

- Excessive variability is a **highly unusual pattern** and must be investigated:
 - C19 Vaccines DO NOT show same consistency lot-to-lot as do flu vaccines when measured by the outcomes data
 - 5-12 times higher lot-to-lot variability
- Manufacturers make assurances of product consistency and GMP compliance when applying for EUA/FDA approval, in SEC filings, to public, Medicare/Medicaid and to private health insurers:
 - Are these assurances fraudulent?
 - If manufacturers are exempt from GMP for covid vaccines – do patients and providers know this? Do investors and insurers know this?
 - If manufacturers do not have liability – the vaccinators and mandate pushers certainly do!