US Disability Data

Part 1 - Overview of the Data

Bureau of Labor Statistics (BLS)

Update Date: November - 2022

Go to Part 2 - Rise in disabilities from 2021 Go to Part 3 - Relationship with Vaccine uptake Go to Part 4 - Relationship with Excess Deaths Go to Part 5 - Relationship with SAEs in mRNA clinical trials Go to Part 6 - Relationship with Severe AEs in Pfizer vaccine clinical trial

Layout of the disability analysis

The analysis of disabilities is split into 4 parts that can be read independently but are related and complement each other. Each section is written in a different web page within which at the top the user can find the links to navigate to the other sections. The 4 parts are:

Part 1 - Overview of the Data

This part provides the overall description of the data and shows the historical time series of disability rates for different population cohorts and age groups. It allows us to put in perspective the changes in disability rates, that started in 2021.

Part 2 - Rise in disabilities from 2021

This part provides a detailed examination of the changes in disabilities that ocurred from early 2021, which coincided with the vaccine rollouts.

Part 3 - Relationship with Vaccine uptake

This part analyses the relationship between the rise in disabilities with the Covid-19 vaccine rollout.

Part 4 - Relationship with Excess Deaths

This part investigates the relationship between excess mortality and the rise in disabilities that ocurred since early 2021. It also provides us with an estimate of how many disabilities occurred for each excess death, during the period.

<u>Go to Part 5 - Relationship with SAEs in mRNA clinical trials</u> <u>Go to Part 6 - Relationship with Severe AEs in Pfizer vaccine clinical trial</u> <u>Go to Part 7 - Relationship with Hospitalisations following vaccination reported in V-Safe</u>

Data:

Country: USA

Period: Monthly data from 2008 onwards.

Data Source (BLS): U.S. Department of Labor Disability Statistics Resources.

Link to the latest data release: <u>Table A-6. Employment status of the civilian population</u> by sex, age, and disability status.



Organization of the data

Baseline Numbers - Population

The following charts show the baseline total population numbers, with disability or without a disability (in thousands) for: the whole population, the civilian labor force and employed individuals. The chart on the left refers to ages 16 and above, while the chart on the right, to ages 16 to 64. These plots allow us to have a sense of the absolute magnitude of the effects that we are going to analyse in this study.

Total Population - Raw Data



Baseline Numbers - Population with Disability

The following charts show the baseline population numbers with disability (in thousands) for: the whole population, the civilian labor force and employed individuals. The chart on the left refers to ages 16 and above, while the chart on the right, to ages 16 to 64. These plots allow us to have a sense of the absolute magnitude of the effects that we are going to analyse in this study.

A quick inspection of the charts bellow brings out an observation that disabilities shot up from around mid-2021. In this study, we delve into a detailed analysis of the effect and venture some possible explanations. To do so, we measure the changes in disabilities as a percentage of the respective population cohorts.

Total Population with disability - Raw Data



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Population

This section investigates trends in disabilities in the whole population, of which some are in the civilian labor force and others are out.

Population - % with disability - Raw Data



- Declining trend in disabilities in population over 65 years from 2008 to 2019 (general trend in improvement in health conditions).
- Trend was broken in 2020 with a sharp decline in disabilities at the onset of the pandemic lockdowns. This is unlikely to be due solely to a decrease in the rate of acquiring disability, especially in the older population for whom lockdown is less of a protective factor from risky activities such as sports and car accidents. It is therefore likely due to:
 - Under-diagnosis of disabilities acquired during these months, due to reduced access to healthcare services.
 - Disproportionate impact of COVID deaths on those with disabilities, especially the older disabled population most vulnerable to COVID, as well as other deaths hastened by lack of access to healthcare, or unwillingness to engage with healthcare services due to perceived risk of COVID.
- From 2/2021 large rise in disabilities.
 - This is likely due to a combination of factors, including delayed diagnosis of disabilities acquired during lockdown, Long COVID syndrome, return to more normal economic activity (with inherent risk of injury), and vaccination impacts.

Population - % with disability (16y to 64y) - Calculated



- When looking at disabilities in the overall population aged 16 to 64, we observe that the long-term average disability rate is about 7.5%. However, from 2017 to 2019 the disability rate fell to about 7.3%.
- We observe a sharp drop in disabilities in 2020, in similarity to in older individuals, which was likely due to:
 - Less economic activity with lockdown reducing the risk of injury-related disability.

- Under-diagnosis of disabilities acquired during these months, due to reduced access to healthcare services.
- Working-age population less motivated to seek diagnosis and declare disability for the sake of disability benefits, if their employment/pay was already protected by pandemic-related social security measures.
- Disabilities in 16-64 recovered to pre-pandemic values in early 2021. From 5/2021 we observe a large rise in disabilities from 7.3% to 8.1% in September 2022, corresponding to a 11.0% increase.
 - This is likely due to a combination of factors, including delayed diagnosis of disabilities acquired during lockdown, Long COVID syndrome, return to more normal economic activity (with inherent risk of injury), and vaccination impacts.
 - From 5/2021, disabilities are above average, indicating excess disabilities rather than just delayed diagnosis.
- Disabilities in the overall population aged 16 to 64 follow similar trends in Men and Women (right-hand chart).

Civilian Labor Force

The civilian labor force corresponds to the population that is actively engaged in the labor market. This population is healthier than the general population, with a lower disability rate.

Civilian labor force with disabilities, 65 years and over



- We observe a declining trend in disabilities in CivLabForce 65+ from 2008 to 2019 and also in the population 65+ that are not in the labor force (general trend in improvement in health conditions).
- Trend was broken in 2020 with a sharp decline in disabilities and older individuals exiting the workforce. Possible causes are:
 - Less economic activity with lockdown reducing the risk of injury-related disability.
 - Under-diagnosis of disabilities acquired during these months, due to reduced access to healthcare services.
 - Disproportionate impact of COVID deaths on those with disabilities, especially the older disabled population most vulnerable to COVID, as well as other deaths hastened by lack of access to healthcare, or unwillingness to engage with healthcare services due to perceived risk of COVID.
- Disabilities in 65+ recovered to pre-pandemic values in early 2021. From 5/2021 we observe a sharp rise in disabilities and individuals exiting the workforce.
 - This is likely due to a combination of factors, including delayed diagnosis of disabilities acquired during lockdown, Long COVID syndrome, return to more normal economic activity (with inherent risk of injury), and vaccination impacts.
- From 5/2020, the percentage of over 65 Population Not in Labor force initially decreases, perhaps due to the disproportionate impact of COVID deaths on older and sicker people in this age group (those more likely to already not be in or seeking employment prior to the pandemic) and then tracks the trend in disabilities in the civilian labor force.

Civilian labor force with disabilities, all age-groups



- We observe that the trend in disabilities in labor force 65+ from 2008 to 2019 in declining albeit at a slower rate than the improvement in general population.
- For the workforce aged 16 and over or 16 to 64 years, we do not observe a noticeable drop in disabilities in 2020 which we observed in the overall population. Why was there no noticeable effect of the reduction in exposure to risky activities in the workforce? No effect of lockdowns or less mobility?
- We also observe a very noticeable rise in disabilities starting around 5/2021. For the 16-64 workforce this corresponded to a rise from 3.4% in 4/2021 to 4.2% in 9/2022, corresponding to a 23.5% rise.
- This is likely due to a combination of factors, including delayed diagnosis of disabilities acquired during lockdown, Long COVID syndrome, return to more normal economic activity (with inherent risk of injury), and vaccination impacts.

Civilian labor force with disabilities, by gender, 16 to 64 years



- For the 16-64 workforce also observe a very noticeable rise in disabilities starting around 5/2021 for both Men and Women. However, as we can clearly the rise in disabilities is much larger in Women than Men.
- For Women, the rise in disabilities went from a long-term average of about 3.3% in 4/2021 to 4.5% in 9/2022, corresponding to a 36.4% rise.
- For Men, the rise in disabilities went from a long-term average of about 3.3% in 4/2021 to 3.8% in 9/2022, corresponding to a 15% rise.

Employed

The employed population correspond to the civilian labor force that is currently employed. This population tends to be slightly healthier than the civilian labor force, with a lower disability rate.

Employed with a disability



- We observe that the trend in disabilities in employed population aged 65+ from 2008 to 2019 is declining, but at a slower rate than the improvement in general population.
- The sharper decrease in the percentage of employed 65 years and over with a disability from around 9/2020:
 - May represent disproportionate loss of jobs for disabled older people compared with non-disabled older people, or difficulty competing with non-disabled people in the labor market during the economic rebound.
 - Withdrawal of pandemic-related enhanced social security benefits which may have kept some disabled older people in work during the earlier lockdowns in spite of worsening disability.
- For the employed aged 16 and over or 16 to 64 years, we do not observe a noticeable drop in disabilities in 2020 which we observed in the overall population.
- For Employed 16 years and over or 16 to 64 years, very noticeable rise in disabilities starting around 5/2021. For the 16-64 workforce this corresponded to a rise from 3.1% in 4/2021 to about 3.9% in 9/2022, corresponding to a 25.8% rise.
- This is likely due to a combination of factors, including delayed diagnosis of disabilities acquired during lockdown, Long COVID syndrome, return to more normal economic activity (with inherent risk of injury), and vaccination impacts.

Employed with a disability, by gender, 16 to 64 years



- For the employed 16-64 age group, we also observe a very noticeable rise in disabilities starting around 5/2021 for both Men and Women. However, as we can clearly the rise in disabilities is much larger in Women than Men.
- For Women, the rise in disabilities went from a long-term average of about 3.1% in 4/2021 to 4.3% in 9/2022, corresponding to a 38.7% rise.
- For Men, the rise in disabilities went from a long-term average of about 3.1% in 4/2021 to 3.7% in 9/2022, corresponding to a 19.3% rise.

Civilian Labor Force (Year-on-Year Change)

This section analyses the statistical significance of the change in the rate of disability over time. For that purpose we compute the year-on-year (YoY) changes (in percentage) in the disability rate from 2008 to 2022 for the Civilian Labor Force aged 16 to 64 (both sexes). By using yearly changes, we can measure the typical yearly volatility of changes in disability rates, while removing any seasonal patterns that might occur. We then normalise yearly changes in the disability rate by the standard deviation of the changes from 2008, which allows us to estimate how many standard deviations does the yearly change correspond to (lower chart).

Civilian Labor Force, YoY change



- For the civilian labor force 16 to 64 years, we see a very noticeable jump in YoY change in disabilities starting around 5/2021.
- This is likely due to a combination of factors, including delayed diagnosis of disabilities acquired during lockdown, Long COVID syndrome, return to more normal economic activity (with inherent risk of injury), and vaccination impacts.

Civilian Labor Force, Normalised YoY change



- When looking at the normalised changes in YoY changes in disability rates, we observe that they peaked at 3.7 on 3/2022. This is a strong signal.
- This means that the yearly change at March 2022 corresponded to 3.7 standard deviations (assuming a gaussian distribution for the YoY changes in disability rates over the period).
- This is likely due to a combination of factors, including delayed diagnosis of disabilities acquired during lockdown, Long COVID syndrome, return to more normal economic activity (with inherent risk of injury), and vaccination impacts.

Civilian Labor Force (Deviation from 2008-2019 trend)

When using year-on-year (YoY) changes (in percentage) in the disability rate, we have a tool to estimate significant changes in behaviour of a given time series, but it does not

give the full picture as cumulative trends that are longer than a year can be overlooked. Therefore, in this section we analyse changes in disabilities relative its linear trend spanning from 2008 to 2019 (the pre Covid-19 pandemic period). To normalise the changes in disabilities in 2020 onwards relative to the baseline trend, we use as a volatility metric, the standard deviation of the deviation from trend for the period 2008 to 2019.



Civilian Labor Force, % Deviation from trend

- For the civilian labor force aged 16 to 64, we see a very noticeable rise in the deviation from trend in disabilities starting around 5/2021.
- The deviation from trend reached about 29% at 9/2022.

Civilian Labor Force, Normalised Deviation from trend



- When looking at the normalised deviation from trend in disability rates, we observe that they rose above 6.0 by 3/2022. This is a strong signal.
- This means that the deviation from trend in disability rates, in March 2022, corresponded to more than 6 standard deviations (assuming a gaussian distribution for the YoY changes in disability rates over the period).

Conclusions

- Older individuals (65+) as well as younger (16-64) individuals those who were not in the labor force experienced a decline in disability rates in 2020, probably due to the reduced exposure to risky activity (with a likely contribution from the lockdowns). This effect is not observed in younger (16-64) individuals who are in the labor force.
- We found that there is statistically significant increase in disability rates in both older and younger individuals, that started around 5/2021. For 16-64 year olds who are in the labor force we show, by two different methods, that the change in disability rates

after 5/2021 has a very high statistical significance. It is a strong signal. The rise in disabilities for 16-64 year-olds who are in the labor force is larger in Women (36.4%) than in Men (15%).

- The rise in disabilities for employed 16-64 year-olds is even more impressive, with a (38.7%) rise in Women and only (19.3%) in Men .
- Although a range of factors may be at play, the timing and sudden nature of the increase in disabilities suggest that rollout of vaccination programmes could have caused a significant impact. Other factors (those related to a return of more normal economic and healthcare activity) would be more likely to cause a gradual change in disability rates, beginning earlier in the post-lockdown recovery phases of mid-late 2020.

Go to Part 2 - Rise in disabilities from 2021 Go to Part 3 - Relationship with Vaccine uptake Go to Part 4 - Relationship with Excess Deaths Go to Part 5 - Relationship with SAEs in mRNA clinical trials Go to Part 6 - Relationship with Severe AEs in Pfizer vaccine clinical trial Go to Part 7 - Relationship with Hospitalisations following vaccination reported in V-Safe



US Disability Data

Part 2 - Rise in disabilities from 2021

Bureau of Labor Statistics (BLS)

Update Date: November - 2022

<u>Go to Part 1 - Overview of the Data</u> <u>Go to Part 3 - Relationship with Vaccine uptake</u> <u>Go to Part 4 - Relationship with Excess Deaths</u> <u>Go to Part 5 - Relationship with SAEs in mRNA clinical trials</u> <u>Go to Part 6 - Relationship with Severe AEs in Pfizer vaccine clinical trial</u> <u>Go to Part 7 - Relationship with Hospitalisations following vaccination reported in V-Safe</u>

Overview:

In the previous section (Part 1) we observed that the rise in disability rates post 2/2021 is stronger in individuals who are in the employed and in the labor force than the general population. Being employed was not favourable in terms of health outcomes from 5/2021. We think that the vaccination mandates may have played a role; as individuals in some sectors of the job market had no choice but to be vaccinated in order to find work or stay at work.

In this section we expand on this question and deepen the analysis of the changes in disabilities from 2/2021. For that purpose we consider different metrics that help us

understand what is going on. The figure below provides a schema that clarifies the problem at hand.



The schema shows the disabled and non-disabled populations for two different time periods (2/2021 and 11/2022 in our example). This is valid for each population cohort (population, civilian labor force, employed, etc) and different age groups. The difficulty in examining the problem is that from period 1 to period 2, while there might be an increase/decrease in disabilities (from A' to B') but there might also be an increase/decrease in the non-disabled population (for instance when considering the cohort "not in the labor force"), for instance due to changes in economic circumstances. Consequently, measuring the disability rate in both periods, might not provide us an accurate measure for the changes in disabilities. To tackle this problem we compute and analyse different metrics:

- Change in disabilities, (B'-A').

This represents the total rise in the number of disabilities for a given cohort and age group.

- Disability rate, r1=A'/(A+A') and r2=B'/(B+B').

This represents the disability rate at the different time periods.

- Change in the disability rate, (r2-r1).

The change in disability rate attempts to capture the absolute change in disabilities in a given cohort, adjusted for the population size. This is valid for the whole population cohort as an individual has to belong to this cohort by definition. However, when measuring the change in disability rate in the Civilian Labor Force cohort, we must consider the possibility of changes in the disability rate being due to changes in individuals originating from the "not in the labor force" cohort. This might mean, for example, that a rise in the disability rate might be attributed to more disabled individuals actively searching for work, instead of being out of the workforce.

- Rate of change in the disability rate, (r2/r1-1).

The rate of change in disability rate attempts to capture the relative change in disabilities in a given cohort, adjusted for the population size. This is valid for the whole population cohort as an individual has to belong to this cohort by definition.

When measuring the rate of change in disability rate in the Civilian Labor Force cohort, we must consider the possibility of changes in the disability rate being due to changes in individuals originating from the "not in the labor force" cohort. This might mean, for example, that a rise in the disability rate might be attributed to more disabled individuals actively searching for work, instead of being out of the workforce.

- Rate of new disabilities, (B'-A')/A.

This tries to measure the change in disabilities in a given cohort relative to the previous non-disabled individuals. We believe this measure provides a better approximation to the rate of change in disabilities in a given cohort. However, it still does not solve the problem of individuals (disabled or not) that are "not in the labor force" at the start date, jumping to the Civilian Labor Force in the end date, or vice versa.

Age group 16-64 Change in disabilities from 2/2021 to 11/2022

This section investigates the changes in disabilities in the different population cohorts, namely, the whole population, of which some are in the civilian labor force and others are out, and the employed.

The following table provides a summary of different statistics that measure different aspects of the nature of the changes in disabilities that occurred from 2/2021 to 11/2022. The table condenses a lot of information which we will explain below.

	Equation	Population, 16-64	Civilian Labor Force, 16-64	Not in Labor Force, 16-64	Employed, 16-64
Non Disabled 2021/02	А	190,499,000	144,768,000	45,731,000	135,500,000
Disabled 2021/02	A'	14,888,000	4,978,000	9,910,000	4,285,000
Population 2021/02	N1=A'+A	205,386,000	149,746,000	55,641,000	139,785,000
Non Disabled 2022/11	В	190,878,000	146,843,000	44,035,000	142,047,000
Disabled 2022/11	В'	16,348,000	6,344,000	10,004,000	5,962,000
Population 2022/11	N2=B'+B	207,226,000	153,187,000	54,039,000	148,009,000
Disability rate 2021/02	R1 = A'/(A'+A)	7.25%	3.32%	17.81%	3.07%
Disability rate 2022/11	R2 = B'/(B'+B)	7.89%	4.14%	18.51%	4.03%
Change in disabilities	B' - A'	1,460,000	1,366,000	94,000	1,677,000
Change in disability rate	R2-R1	0.64%	0.82%	0.70%	0.96%
Rate of change in disability rate	R2/R1-1	8.83%	24.58%	3.94%	31.41%
Rate of new disabilities	(B'-A')/A	0.76%	0.93%	0.21%	1.18%
Relative to Not in LF		358.32%	435.78%	100.00%	553.06%

Rise in disabilities: Absolute numbers.

- For the general population aged 16-64, from 2/2021 to 11/2022, the absolute numbers of the increase in disabled individuals amounted to about 1.460 million, of which 1.366 million were in the Civilian Labor Force and only 94 thousand were not in the labor force.
- The disabilities in the employed population rose by 1.677 million, which is a conundrum as it above the rise in the whole population and Civilian Labor Force. The explanation is that the unemployment rate dropped significantly during that time period and therefore there was a drop in the absolute number of unemployed individuals with disability. The record low unemployment rate and tight labor market led to the employment of a higher number of disabled individuals (within the labor force) that added to the rise in disabilities in the employed population.

Relative rise in disabilities.

 In relative terms, we can observe that increase in the disability rate was 0.64% for whole population which corresponded to a 8.8% rise. For the Civilian Labor Force the rise in the disability rate was to 0.82%, corresponding to a 24.6% rise for the period.

We observe that the overall population suffered a lower relative rise in the disability rate (8.8%) when compared to the Civilian Labor Force (24.6%), which seems to suggest that perhaps the vaccine mandates for employment contributed to the higher relative rise in disability rates. However, as previously mentioned we must be cautious before making that statement as the whole population had a much higher base disability rate (7.25%) when compared to the Civilian Labor Force (3.3%).

• A preferable method measure to compare the rise in disabilities in the whole population vis-à-vis the Civilian Labor Force is to use the rate of new disabilities. For

the whole population we can observe that the rate of new disabilities for the 2/2021 to 11/2022 period was 0.76% while for the Civilian Labor Force it was 0.93% (which is a 22.3% higher rate).

Perhaps the best way to have an idea if being in the workforce, and therefore subject to the vaccine mandates for employment, was detrimental to one's health compared to opting to be "not in the workforce" (with the choice of taking the vaccine or not) is by comparing the rate of new disabilities in these two cohorts. For individuals in the Workforce, the rate of new disabilities was 0.93% for the period, while for those not in the workforce it was 0.21% (which is a 4.4x lower rate).

These results add support to the hypothesis that having "choice" in taking the inoculation was beneficial to one's health during the rollout period.

Age group 65+

Change in disabilities from 2/2021 to 11/2022

This section investigates the changes in disabilities, for the 65+ age group, in the different population cohorts, namely, the whole population, of whom some are in the Civilian Labor Force and others are out, and the employed.

The following table provides a summary of different statistics that measure different aspects of the nature of the changes in disabilities that occurred from 2/2021 to 11/2022. The table condenses a lot of information which we will explain below.

	Equation	Population, 65+	Civilian Labor Force, 65+	Not in Labor Force, 65+	Employed, 65+
Non Disabled 2021/02	А	40,470,000	9,279,000	31,191,000	8,812,000
Disabled 2021/02	A'	15,062,000	983,000	14,079,000	924,000
Population 2021/02	N1=A'+A	55,532,000	10,262,000	45,270,000	9,736,000
Non Disabled 2022/11	В	41,068,000	9,660,000	31,408,000	9,384,000
Disabled 2022/11	В'	16,414,000	1,425,000	14,989,000	1,356,000
Population 2022/11	N2=B'+B	57,482,000	11,085,000	46,397,000	10,740,000
Disability rate 2021/02	R1 = A'/(A'+A)	27.12%	9.58%	31.10%	9.49%
Disability rate 2022/11	R2 = B'/(B'+B)	28.56%	12.86%	32.31%	12.63%
Change in disabilities	B' - A'	1,352,000	442,000	910,000	432,000
Change in disability rate	R2-R1	1.43%	3.28%	1.21%	3.14%
Rate of change in disability rate	R2/R1-1	5.28%	34.20%	3.88%	33.03%
Rate of new disabilities	(B'-A')/A	3.29%	4.58%	2.90%	4.60%
Relative to Not in LF		113.62%	157.92%	100.00%	158.89%

Rise in disabilities: Absolute numbers.

- For the general population aged 65+, from 2/2021 to 11/2022, the absolute numbers of the increase in disabled individuals amounted to about 1.352 million, of which 0.442 million were in the Civilian Labor Force and only 0.910 million were not in the labor force.
- The disabilities in the employed population aged 65+ rose by 0.432 million.

Relative rise in disabilities.

 In relative terms, we can observe that increase in the disability rate was 1.43% for whole population which corresponded to a 5.28% rise. For the Civilian Labor Force the rise in the disability rate was to 3.28%, corresponding to a 34.2% rise for the period.

We observe that the overall population suffered a lower relative rise in the disability rate (5.28%) when compared to the Civilian Labor Force (34.2%), which seems to suggest that perhaps the vaccine mandates for employment contributed to the higher relative rise in disability rates. However, as previously mentioned we must be cautious before making that statement as, for the 65+ age group, the whole population had a much higher base disability rate (27.12%) when compared to the Civilian Labor Force (9.58%).

 As mentioned previously, a preferable method measure to compare the rise in disabilities in the whole population vis-à-vis the Civilian Labor Force is to use the rate of new disabilities. For the whole population we can observe that the rate of new disabilities for the 2/2021 to 11/2022 period was 3.29% while for the Civilian Labor Force it was 4.58% (which is a 39.2% higher rate). Perhaps the best way to have an idea if being in the workforce, and therefore subject to the vaccine mandates for employment, was detrimental to one's health compared to opting to be "not in the workforce" (with the choice of taking the vaccine or not) is by comparing the rate of new disabilities in these two cohorts. For individuals in the "Not in the Workforce", the rate of new disabilities was 2.90% for the period, while for those in the Workforce it was 4.58% (which is a 57.9% higher rate).

These results add support to the hypothesis that having "choice" in taking the inoculation was beneficial to one's health during the rollout period.

Observations

Comparing the rise in disabilities in younger (16-64) and older (65+) individuals.

For the period of 2/2021 to 11/2022 we observed a total rise in disabilities of 2.812 million for the whole population of which 1.460 million in the 16-64 age group and 1.352 million in the 65+ age group. We should note that the base level for the population aged 16-64 was 205.386 million while only 55.532 million for the 65+ age group.

In relative terms, the rise in the disability rate in the 16-64 population was 0.64% (corresponding to a 8.83% rise) while for the 65+ population it was 1.43% (corresponding to a 5.28% rise).

The rate of new disabilities in the 16-64 population was 0.76% while in the 65+ population it was 3.29% (which is 4.3x higher than the younger population). These numbers suggest that the impact of the inoculations is being felt more in the older population than in the younger age groups. This is not talked about at the moment, as most attention is focused on disabilities and deaths in younger individuals.

• For the Civilian Labor Force we observed a total rise in disabilities of 1.808 million of which 1.366 million are in the 16-64 age group and 0.442 million in the 65+ age

group. We should note that the base level for the population aged 16-64 was 149.746 million while only 10.262 million for the 65+ age group.

In relative terms, the rise in the disability rate in the 16-64 Civilian Labor Force was 0.82% (corresponding to a 24.58% rise) while for the 65+ age group it was 3.28% (corresponding to a 34.20% rise).

The rate of new disabilities in the 16-64 Civilian Labor Force was 0.93% while in the 65+ population it was 4.58% (which is 4.9x higher than the younger age group). These numbers suggest that the impact of the inoculations are being felt more in the older age group than in the younger age group. This is not talked about at the moment, as most attention is focused on disabilities and deaths in younger individuals.

Conclusions

- Although a range of factors may be at play, as we'll show in <u>Part 3</u> the timing and sudden nature of the increase in disabilities suggest that rollout of vaccination programmes could have caused a significant impact. Other factors (those related to a return of more normal economic and healthcare activity) would be more likely to cause a gradual change in disability rates, beginning earlier in the post-lockdown recovery phases of mid-late 2020.
- The rise in disabilities seems to be impacting older individuals (65+) more than younger individuals (16-64), perhaps due to higher vaccination rates or higher susceptibility for being injured.
- Within each age group, the rise in disabilities seems to be impacting individuals who are in Labor Force more than individuals "not in the Labor Force", which we suspect is due to the vaccine mandates for employment.

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US Disability Data

Part 3 - Relationship with Vaccine uptake

Bureau of Labor Statistics (BLS)

Update Date: November - 2022

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Data:

Country: USA

Disabilities data

Period: Monthly data from 2008 onwards.

Data Source (BLS): U.S. Department of Labor Disability Statistics Resources.

Link to the latest data release: <u>Table A-6. Employment status of the civilian population by</u> <u>sex, age, and disability status.</u>

Vaccination data

Source for Vaccination data (CDC): COVID-19 Vaccinations in the United States.

Source for Population Estimates (UN - Population division): UN table: Population estimates.

Increase in disabilities vs Vaccine doses

Period: 2021/2 to 2022/11

This section analyses the relationship between the Covid-19 vaccine rollout and the increase in disabilities that started around 2/2021. We perform the analysis first for the Civilian Labor Force aged 16-64 and afterwards for the 65+ age group.

The Vaccination doses refer to the total vaccination doses as a percentage of the respective age group population. The vaccination age groups were 19-64 and 65+ as these were the closest age cohorts we could obtain from the CDC vaccination data, to match the BLS disability age cohorts.

Increase in disabilities in the Civilian Labor Force (16-64) vs Vaccine uptake

The following charts illustrate the relationship between the increase in the disability rate in the Civilian Labor Force (16-64) and the Covid-19 vaccinations.

The chart on the left shows the evolution of the disability rate from 2008 to 11/2022 (left axis) with the vaccination data superimposed (right scale). This chart shows the change in

disabilities, which started around 2/2021 and accelerated from 5/2021, in a wider context. When comparing with the vaccination data, the results are compelling.

The chart on the right shows the correlation between the rise in the disability rate since 2/2021 with the vaccination data. The regression R2 is close to 90% which is evidence for a strong relationship. We must always consider other external factors that might explain the rise in disabilities and which are also correlated to the vaccination data. This is usually stated as "correlation is not causation". However, in the absence of other explanatory factors, and strong medical evidence of the vaccines causing injuries and deaths, one must consider the relationship seriously.

Additionally, we realise that performing the correlation of cumulative time series is misleading and the R2 should not be taken as an indication of establishing a statistically significant relationship as both time series have autocorrelation.



Increase in disabilities in Civilian Labor Force (16-64) vs vaccine doses



Increase in disabilities in the Civilian Labor Force (65+) vs Vaccine uptake

The following charts illustrate the relationship between the increase in the disability rate in the Civilian Labor Force (65+) and the Covid-19 vaccinations.

The chart on the left shows the evolution of the disability rate from 2008 to 11/2022 (left axis) with the vaccination data superimposed (right scale). This chart shows the change in disabilities, which started around 2/2021 and accelerated from 5/2021, in a wider context.

The chart on the right shows the correlation between the rise in the disability rate since 2/2021 with the vaccination data. The regression R2 is close to 57% which is shows a clear relationship, albeit weaker than the one found for the 16-64 age cohort.

Increase in disabilities in Civilian Labor Force (65+) vs vaccine doses



Observations

- There seems to be clear evidence of a strong relationship between the Covid-19 vaccination rollout and increases in disability rates.
- The effect is stronger in the younger age group (16-64) as they have a low base rate of disabilities, and factors that might be detrimental to individuals' health are most noticeable in these individuals.

Go to Part 1 - Overview of the Data Go to Part 2 - Rise in disabilities from 2021 Go to Part 4 - Relationship with Excess Deaths Go to Part 5 - Relationship SAEs in mRNA clinical trials Go to Part 6 - Relationship with Severe AEs in Pfizer vaccine clinical trial Go to Part 7 - Relationship with Hospitalisations following vaccination reported in V-Safe



US Disability Data

Part 4 - Relation with Excess Deaths

Bureau of Labor Statistics (BLS)

Update Date: November - 2022

<u>Go to Part 1 - Overview of the Data</u> <u>Go to Part 2 - Rise in disabilities from 2021</u> <u>Go to Part 3 - Relationship with Vaccine uptake</u> <u>Go to Part 5 - Relationship SAEs in mRNA clinical trials</u> <u>Go to Part 6 - Relationship with Severe AEs in Pfizer vaccine clinical trial</u> <u>Go to Part 7 - Relationship with Hospitalisations following vaccination reported in V-Safe</u>

Data:

Country: USA

Disabilities data

Period: Monthly data from 2008 onwards.

Data Source (BLS): U.S. Department of Labor Disability Statistics Resources.

Link to the latest data release: <u>Table A-6. Employment status of the civilian population by</u> <u>sex, age, and disability status.</u>

Excess Mortality data.

The excess mortality data is obtained from our weekly time series, as shown in our <u>analysis sheet</u> for the US and then interpolated to obtain a monthly time series. The calculation of excess deaths is performed using our methodology decribed in our <u>reports</u> (method 2C) that adjusts for changes in the population of different age groups over time.

Period: The data is based upon weekly deaths data from the US CDC spanning from 2015 to 2022.

Source for Weekly Deaths (CDC): <u>Weekly Counts of Death by Jurisdiction and Select</u> <u>Causes of Death.</u>

Source for Vaccination data (CDC): COVID-19 Vaccinations in the United States.

Source for Population Estimates (UN - Population division): UN table: Population estimates.

Change in Disabilities versus Excess Deaths

Period: 2021/2 to 2022/11

This section analyses the relationship between excess mortality and the increase in disabilities that started around 2/2021. We perform the analysis first for the Civilian Labor Force as well as the whole Population aged 16-64 and afterwards for the 65+ age group.

The Vaccination doses refer to the total vaccination doses as a percentage of the respective age group population. The vaccination age groups were 19-64 and 65+ as these were the closest age cohorts we could obtain from the CDC vaccination data, to match the BLS disability age cohorts.

We should note that the Civilian Labor Force are the healthiest cohort in the population as these are individuals that are actively engaged in the labor market. From our analysis in part 2, we observed that in relative terms, this cohort was more impacted by the rise in

disabilities after 2/2021 (associated with the vaccination rollout) than the "not in the workforce" cohort. We also note that the Civilian Labor Force cohort represents about 76% of the population aged 16-64 and only about 23% of the population aged 65+.

As for excess mortality, the available age groups for the CDC weekly deaths date are 0-25, 25-44, 45-64, 65-74, 75-84 and 85+.

Therefore, we had to aggregate 25-44 + 45-64 = 25-64 for comparing with the 16-64 age group for disabilities. The 25-64 age group represents about 81.5% of the 16-64 age group for disabilities and consequently the comparison between both datasets should take that fact into account.

For the 65+ age group we estimated excess deaths by aggregating the 65-74, 75-84 and 85+ age groups. This aggregation matched the 65+ age group for disabilities.

Population 16-64

The following charts compare the rise in the total number of disabilities with the rise in excess mortality for the whole population aged 16-64. The chart on the left refers to the time series from 2/2021 (after the vaccine rollout) to 11/2022. The chart on the right, shows the correlation between both time series, with the respective regression line illustrated.

Increase in disabilities in population (16-64) vs vaccine doses



We can observe from the charts above that the rise in disabilities from 2/2021 was accompanied with a rise in excess mortality. The relationship is quite strong as can be observed by the chart on the right. The slope of the regression line is 4.4 which suggests that for each excess death during this period, there were 4.4 more disabilities. As previously mentioned, as the excess mortality age group (25-64) represents roughly 81.5% of the population of the disability age group (16-64) we need to make this

adjustment to the slope of the regression, which results in: each excess death during this period corresponded to about 3.6 more disabilities.

When measuring the absolute numbers, we can observe that from 2/2021 to 11/2022 there was an increase of about 1,500,000 disabilities in the Population aged 16-64 while there were about 300,000 excess deaths (for the 25-64 age group), during that period. After adjusting the size of the 25-64 age group for excess deaths to the 16-64 age group of the disabilities (by dividing by 81.5%), we obtain an estimate of excess deaths of about 352,900 excess deaths.

The ratio of the increase in disabilities divided by the excess deaths is $R=1,500,000/352,900 \sim 4.25$.

Civilian Labor Force 16-64

The following charts compare the rise in the total number of disabilities with the rise in excess mortality for the Civilian Labor Force aged 16-64. The chart on the left refers to the time series from 2/2021 (after the vaccine rollout) to 11/2022. The chart on the right, shows the correlation between both time series, with the respective regression line illustrated.

Increase in disabilities in Civilian Labor Force (16-64) vs vaccine doses



We can observe from the charts above that the rise in disabilities from 2/2021 was accompanied with a rise in excess mortality. The relationship is quite strong as can be observed by the chart on the right. The slope of the regression line is 4.0 which suggests that for each excess death during this period, there were 4.0 more disabilities. As previously mentioned, as the excess mortality age group (25-64) represents roughly 81.5% of the population of the disability age group (16-64) we need to make this

adjustment to the slope of the regression, which results in: each excess death during this period corresponded to about 3.26 more disabilities.

When measuring the absolute numbers, we can observe that from 2/2021 to 11/2022 there was an increase of about 1,400,000 disabilities in the Civilian Labor Force aged 16-64 while there were about 300,000 excess deaths (for the 25-64 age group), during that period. After adjusting the size of the 25-64 age group for excess deaths to the 16-64 age group of the disabilities (by dividing by 81.5%), we obtain an estimate of excess deaths of about 352,900 excess deaths.

The ratio of the increase in disabilities divided by the excess deaths is $R=1,400,000/352,900 \sim 4.0$

Population 65+

The following charts compare the rise in the total number of disabilities with the rise in excess mortality for the whole population aged 65+. The chart on the left refers to the time series from 2/2021 (after the vaccine rollout) to 11/2022. The chart on the right, shows the correlation between both time series, with the respective regression line illustrated.

Increase in disabilities in Population (65+) vs vaccine doses



We can observe from the charts above that the rise in disabilities from 2/2021 was accompanied with a rise in excess mortality. The relationship is quite strong as can be observed by the chart on the right. The slope of the regression line is 2.71 which suggests that for each excess death during this period, there were 2.71 more disabilities.

When measuring the absolute numbers we can observe that from 2/2021 to 11/2022 the was an increase of about 1,400,000 disabilities in the Population aged 65+ while there were about 400,000 excess deaths during that period. The ratio of the increase in disabilities divided by the excess deaths is R=1,400,000/400,000 = 3.5.

Observations

- At the population level, we found that there is strong correlation between the increase in disability rates and the rise in excess mortality, in both older (65+) and younger individuals (16-64), starting 2/2021 and extending to 11/2022.
- For the 16-64 age group, each rise in excess death seems to be accompanied by a multiplier of about 4 increased disabilities. The multiplier is lower (at about 3.5) for the 65+ age group, which makes sense as these individuals have higher disability rates as a starting point.
- The relationship between the rise in disabilities and excess deaths in the Civilian Labor Force for the 16-64 age group, is even stronger (with higher correlation). We believe that the relationship is stronger as the Civilian Labor force have a lower baseline disability rate and consequently, if the Covid-19 vaccines are adversely affecting individuals, then we'd expect to see a similar rise in disabilities and deaths, albeit at different multiples.

It does not make sense in showing the plot for the 65+ individuals that are in the Labor Force, as they represent a small percentage of the overall population in that age group.

<u>Go to Part 1 - Overview of the Data</u> <u>Go to Part 2 - Rise in disabilities from 2021</u> <u>Go to Part 3 - Relationship with Vaccine uptake</u> <u>Go to Part 5 - Relationship SAEs in mRNA clinical trials</u> <u>Go to Part 6 - Relationship with Severe AEs in Pfizer vaccine clinical trial</u> <u>Go to Part 7 - Relationship with Hospitalisations following vaccination reported in V-Safe</u>



US Disability Data

Part 5 - Relationship with SAEs in mRNA vaccine clinical trials

Data Sources:

1 - Disabilities data from Bureau of Labor Statistics (BLS). 2 - Paper from <u>J. Fraiman et al., 9/2022</u>, which was reviewed by us <u>here</u>.

Update Date: February - 2023

<u>Go to Part 1 - Overview of the Data</u> <u>Go to Part 2 - Rise in disabilities from 2021</u> <u>Go to Part 3 - Relationship with Vaccine uptake</u> <u>Go to Part 4 - Relationship with Excess Deaths</u> <u>Go to Part 6 - Relationship with Severe AEs in Pfizer vaccine clinical trial</u> <u>Go to Part 7 - Relationship with Hospitalisations following vaccination reported in V-Safe</u>

Overview:

In <u>part 3 of our US disabilities analysis</u> we observed that the rise in disability rates post 2/2021 correlates closely with the rollout of the vaccination schedule. When looking at changes in disabilities on a wider time frame (since 2008) we observe that the disability rates rose or fell from month to month but tended to be relatively stable over time. However, as shown in <u>part 1</u>, the change in behaviour since early 2021 is clearly an

abnormal occurrence with high level of statistical significance. It happens to be highly correlated to the cumulative Covid-19 vaccine rollout, but we cannot state that the correlation is statistically meaningful as it is based on a cumulative plot with obvious autocorrelation.

In this section we provide further evidence that the most likely cause of the rise in disabilities is the Covid-19 vaccines. For that purpose, we model the expected rise in disabilities due to the vaccination rollout in the general population. We do so by using the rates of Serious Adverse Events (SAEs) obtained by the safety analysis of the mRNA vaccine (Pfizer and Moderna) clinical trials, performed in the Vaccine journal paper we reviewed here.

In summary, the paper found a rate of 13.2 SAEs per 10,000 participants in the combined (Pfizer + Moderna) vaccine groups in excess of the placebo groups. They also found an increased rate of 12.5 per 10,000 SAEs of special interest in the vaccine groups versus the placebo groups. (SAEs are considered 'of special interest' if they are events known to be associated with vaccines in general, have been previously observed with the vaccine being studied, or could be associated with the vaccine based on animal models or theoretical models relating to Covid-19 pathology. The definition of an SAE of special interest is therefore narrower, but can be considered more likely to be related to the vaccine than when all SAEs are counted.)

The SAEs were measured from August 2020 to December 2020, before the unblinding of the clinical trials. The SAEs were recorded following dose 1 with a median follow up period of at least 2 months. For the Pfizer trial, SAEs stopped being recorded after 1 month after dose 2.

Estimating a time series of SAEs from the mRNA trials

We want to investigate the relationship between the rise in disabilities observed in the BLS data with an estimate of SAEs that would be observed over time, taking as a baseline the rate of excess SAEs in vaccinated individuals when compared to the placebo groups, in the mRNA vaccine clinical trials. We use the rate of 13.2 per 10,000 for SAEs observed during an estimated 2-month period of observation.

An event that leads to a permanent disability would meet the criteria for an SAE, and consequently it is not unreasonable to use the rate of SAEs as a basis for projecting the rise in disabilities from 2021.

Furthermore, the clinical trials were performed mostly in individuals aged from 16 to 69 (relatively young and healthy individuals). Consequently, we believe that the best subset of the population for which we should investigate the relationship between disabilities and SAEs, is either the Civilian Labor Force or Employed population aged 16-64.

In order to compute a time series of estimated SAE during the vaccine rollout, we use the rate of excess SAEs computed in paper and extrapolate them using the assumptions listed below.

We multiply the monthly rate of SAEs by the percentage of the population, aged 19-64, that received a Covid-19 vaccine (any dose or brand), based on CDC vaccination numbers. We assume that the rate of SAEs declines monotonically over time following vaccination, according to a certain unknown function. As an approximation, we assume that the SAE rate declines linearly over a given period of time (6 months) and thereafter stabilises at a residual value.

Assumptions for computing the SAE time series:

-> The initial monthly rate of excess SAEs of special interest corresponds to 12.5 per 10,000 (the rate computed in the paper) divided by the median observation period of 2 months. The standard error (SE) was 5.2.

-> The initial monthly rate of excess SAEs corresponds to 13.2 per 10,000 (the rate computed in the paper) divided by the median observation period of 2 months. The standard error (SE) was 8.2.

-> After 2 months the rate of SAEs falls to 2/3 of the original value and after 4 months it falls to 1/3 of the original rate. After 6 months we assume that the rate of SAEs falls to 1/10 of its original value.

-> The assumptions are based on the thought that different types of severe or serious events could occur over an extended period, but also that most events will be frontloaded. Additionally, we speculate that the milder the event the more it is likely to be due to a reaction at the injection site and serious events could manifest over a extended time. The terminal rate of 1/10th of the original value attempts to capture the possibility of longer-term effects. These assumptions constitute our best guesses, and both the starting rate of AEs or SAEs and the assumption of how they decay (drop off) over time, could be adjusted as more information becomes available.

-> Furthermore, it should be noted that the limitations of the <u>paper</u> in estimating the SAEs rates must also be considered, namely, that the SAEs may be under-reported, as explained by the authors. Additionally, we must consider that the computed rates have a large standard error, partly due to the authors' not having access to participant data.

Finally, the rate of SAEs differed between the Pfizer and Moderna trials, and the combined rate computed in the paper might not reflect the number of each type of vaccine administered in the population groups of interest during 2021.

Increase in disabilities vs estimated rate of SAEs from mRNA vaccine trials

The following charts illustrate the relationship between the increase in the disability rate in the Civilian Labor Force (16-64) and the projected rate of SAEs, based on the Covid-19 vaccination administration rate for the 19-64 age group, while using the assumptions listed above. We compare both the SAEs of special interest, and the broader category of all SAEs, in separate analyses.

Serious adverse events of special interest.

The chart on the left shows the time series of the change in disability rate from 2/2021 to 12/2021 for the Civilian Labor Force (left scale), and also the time series of the projected rate of SAEs of special interest (right scale). The chart also shows the time series of SAEs of special interest considering the mean rate of SAEs minus 2 SE to the mean rate plus 2 SE.

The chart on the right shows the correlation between the rise in the disability rate since 2/2021 with the projected cumulative rate of SAEs of special interest. The regression R2 is 87.7% which is evidence for a strong relationship. We should also note that performing the correlation of cumulative time series is misleading, and the R2 should not be taken as an indication of establishing a statistically significant relationship as both time series have autocorrelation.

Nevertheless, the charts below strengthen the case for a causal relationship between the Covid-19 vaccines and disabilities, as the projected SAEs of special interest are based on the rates estimated from analysis of the mRNA vaccine clinical trials. Additionally, under the reasonable assumptions stated above, the time series are shown to be of the

same order of magnitude with each excess SAE of special interest (of vaccinated individuals versus placebo) translating into 2.71=1/0.369 disabilities (as measured using BLS data). In other words, the rate of projected SAEs of special interest appears to underestimate recorded disabilities by about 2.7.

We can observe that the rate of rise in disabilities is higher than the computed rate of rise in SAEs of special interest, which could be explained in several different ways, or by a combination of factors.

• By the definition of an SAEs of special interest being more extreme than the rate of disabilities reported by the individuals surveyed by the BLS i.e. some disabilities reported by the individuals surveyed by the BLS may be caused by adverse events that are not deemed SAEs of special interest, due to the criteria used to define an SAE being overly restrictive.

• The population of the Civilian Labor Force as a whole may be less healthy (and somehow more vulnerable to vaccine-related disabilities) than the vaccine trial populations, either due to the selection criteria for participation in the trial, or 'self-selection' bias.

- Under-reporting of SAEs of special interest in the trial populations.
- Other factors causing excess disabilities in the Civilian Labor Force in a concurrent timeframe to the vaccine rollout.





Serious adverse events (SAEs).

The chart on the left shows the time series of the change in disability rate from 2/2021 to 12/2021 for the Civilian Labor Force (left scale), and also the time series of projected rate of SAEs. The chart also shows the time series of SAEs considering the mean rate of SAEs minus 2 SE to the mean rate plus 2 SE.

The chart on the right shows the correlation between the rise in the disability rate since 2/2021 with the projected cumulative rate of SAEs. We should also note that performing the correlation of cumulative time series is misleading and the R2 should not be taken as an indication of establishing a statistically significant relationship as both time series have autocorrelation.

Under the assumptions stated above, the time series are shown to be of the same order of magnitude, with each excess SAEs (of vaccinated individuals versus placebo) translating into 2.56=1/0.39 disabilities (as measured using BLS data). In other words, the rate of projected SAEs appears to under-estimate recorded disabilities by about 2.6.

We can observe that the rate of rise in disabilities is higher than the computed rate of rise in SAEs, which could be explained by in several different ways, or by a combination of factors.

• Some disabilities reported by the individuals surveyed by the BLS may be caused by adverse events that are not deemed SAEs, due to the criteria used to define an SAE

being overly restrictive.

• The population of the Civilian Labor Force as a whole may be less healthy (and somehow more vulnerable to vaccine-related disabilities) than the vaccine trial populations, either due to the selection criteria for participation in the trial, or 'self-selection' bias.

• Under-reporting of SAEs in the trial populations.

• Other factors causing excess disabilities in the Civilian Labor Force in a concurrent timeframe to the vaccine rollout.

We also can observe that the rate of disabilities lies close to the computed SAEs using the mean rate of SAEs plus 2 SE. Therefore, the actual measured disabilities fall close to the upper 95% confidence interval of SAEs from the clinical trials.





Conclusions

- Our results provide a stronger case for establishing a causal relationship between disabilities and the Covid-19 vaccines. The time series of SAEs that were computed based on the rates estimated during the mRNA clinical trials are shown to be of the same magnitude as the rate of increase in disability rates in the 16-64 Civilian Labor Force. The rate of estimated SAEs appears to be under-reported relative the recorded rise in disabilities (according to the BLS survey) by about 2.6 times.
- These results were expected as we had already shown in part 3 of our study the high correlation between the rise in the disability rate since 2/2021 with the vaccine rollout. We realise that performing the correlation of cumulative time series is misleading and the R2 should not be taken as an indication of establishing a statistically significant relationship as both time series have autocorrelation.
- However, the coincidence of the rise in disabilities with the start of the Covid-19 vaccination rollout **in conjunction** with the similar magnitude of the rate of SAEs

(from the clinical trials) and changes in disabilities (from the BLS data) leads to a stronger case for asserting causation.

 We believe that a comprehensive investigation needs to be performed, either in the form of new phase III clinical trials for at least a 3-year period, or a programme of forensic autopsies in a large sample of deceased individuals where the Covid-19 vaccines were not suspected as a co-factor for cause of death.

<u>Go to Part 1 - Overview of the Data</u> <u>Go to Part 2 - Rise in disabilities from 2021</u> <u>Go to Part 3 - Relationship with Vaccine uptake</u> <u>Go to Part 4 - Relationship with Excess Deaths</u> <u>Go to Part 6 - Relationship with Severe AEs in Pfizer vaccine clinical trial</u> <u>Go to Part 7 - Relationship with Hospitalisations following vaccination reported in V-Safe</u>



US Disability Data

Part 6 - Relationship with Severe AEs in Pfizer vaccine clinical trial

Data Sources:

Disabilities data from Bureau of Labor Statistics (BLS).
2 - <u>Stephen J. Thomas et al., 9/2021</u>

Update Date: February - 2023

<u>Go to Part 1 - Overview of the Data</u> <u>Go to Part 2 - Rise in disabilities from 2021</u> <u>Go to Part 3 - Relationship with Vaccine uptake</u> <u>Go to Part 4 - Relationship with Excess Deaths</u> <u>Go to Part 5 - Relationship with SAEs in mRNA clinical trials</u> <u>Go to Part 7 - Relationship with Hospitalisations following vaccination reported in V-Safe</u>

Overview:

In <u>part 5 of our US disabilities analysis</u>, we compared the rise in disability rates post 2/2021 with the analysis of **Serious** Adverse Events (SAEs) performed in the paper by J. Fraiman et al. in Vaccine journal, where they average the rates of SAEs of both the Pfizer

and Moderna clinical trials. We showed that the projected rate of SAEs tends to underestimate the rise in disabilities observed at a population level.

In this part, we expand on the previous analysis by investigating the rates of adverse events (AEs) and Severe Adverse Events (Sev AEs) for the Pfizer trial. These were published in table S3 of the supplementary appendix of the paper by S. J. Thomas et al. that established the vaccine efficacy ("Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months", in New England Journal of Medicine, 9/2021).

A subgroup of participants was monitored for adverse events using an electronic diary for 7 days after each dose, and all participants' adverse events were recorded from dose 1 to 1 month after dose 2. These latter AEs are described as being 'unsolicited' as they were not prompted by the electronic diary. The AEs were measured from August 2020 to December 2020, before the unblinding of the clinical trial. The severity of these adverse events was considered to be mostly mild or moderate.

Comparison with the rate of Severe Adverse Events (Sev AEs) from Pfizer vaccine trial

Summary of the main adverse events

The numbers in the table below were obtained from table S3 of the paper's <u>supplementary appendix</u>. It summarises the Adverse Events during the blinded follow-up period (from dose 1 to 1 month after dose 2) in the Pfizer trial. The yellow shaded cells refer to computed values.

Total Events				
Adverse Event	Vaccine (N=21,926) (%)	Placebo (N=21,921) (%)	Risk Difference	Risk Ratio
Any Event	6617 (30.2)	3048 (13.9)	3569	
-Related	5241 (23.9)	1311 (6.0)	3930	
-Severe	262 (1.2)	150 (0.7)	112	

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-Life- threatening	21 (0.1)	26 (0.1)	-3			
Total Events (per 10,000) - Computed Values						
Any Event	3017.9	1390.4	1627.5	2.17		
-Related	2390.3	598.1	1792.2	4.0		
-Severe	119.5	68.4	51.1	1.75		
-Life- threatening	9.6	11.9	-2.3	0.81		

Severe adverse events (Sev AEs).

Assumptions for computing the Severe AEs time series:

-> The initial monthly rate of excess Sev AEs corresponds to 51.1 per 10,000 (the rate computed in the table above) divided by the median observation period of 2 months.

-> After 2 months the rate of SAEs falls to 1/2 of the original value and after 4 months it falls to 1/4 of the original rate. After 6 months we assume that the rate of SAEs falls to 1/10 of its original value.

-> The assumptions are based on the thought that different types of severe or serious events could occur over an extended period, but also that most events will be frontloaded. As Sev AEs are not as extreme as SAEs, we assumed a faster drop-off in the rate of events that would lead to a disability over time. The terminal rate of 1/10th of the original value attempts to capture the possibility of longer-term effects. These assumptions constitute our best guesses, and both the starting rate of Sev AEs and the assumption of how they decay (drop off) over time, could be adjusted as more information becomes available.

Severe Adverse events (Sev AEs) have a broader range of definition than Serious Adverse Events, resulting in higher numbers of Severe AEs being reported, as we can observe from the table above.

The chart on the left shows the time series of the change in disability rate from 2/2021 to 11/2022 for the Civilian Labor Force (left scale), and also the time series of the projected rate of Severe AEs from the Pfizer trial. For comparison it also shows the inferred rate of Serious Adverse Events (SAEs) from the combined Pfizer and Moderna trials, which was discussed previously in <u>part 5</u>.

The chart on the right shows the correlation between the rise in the disability rate since

2/2021 and the projected cumulative rate of Severe AEs for the Pfizer trial. The regression R2 is around 88% which is evidence for a strong relationship.

We can observe that the rate of rise in disabilities is very close to the computed rate of excess Severe AEs. We observe that there are 1.34 more projected Severe AEs than the rate of rise in disabilities implying that most Severe AEs could eventually lead to a disability. The rise in the rate of disabilities reported by the individuals surveyed by the BLS lies in between the projected rate of SAEs based on analysis of the combined Pfizer and Moderna trials, and the rate of projected Severe AEs based on those reported in the Pfizer clinical trial.





Observations

- Our results provide a stronger case for establishing a causal relationship between disabilities and the Covid-19 vaccines. The time series of Sev AEs that were computed based on the rate estimated during the Pfizer vaccine clinical trial is shown to be of the same magnitude as the rate of increase in disability rates in the 16-64 Civilian Labor Force during the vaccine rollout. The rate of estimated Severe AEs is about 34% higher than the recorded rise in disabilities (according to the BLS survey).
- It should be noted that our analysis does not attempt to establish that every estimated Sev AE or SAE leads to a disability. We are only trying to establish that the projected rates of SAEs and Sev AEs can explain the rise in measured disabilities at a population level (in the Civilian Labor Force aged 16-64, as measured by the BLS survey).

- We also show that the rise in the rate of disabilities since early 2021 lies in between the rate of SAEs for the combined Pfizer and Moderna trials (<u>analysed in part 5</u>), and the rate of Severe AEs reported in the Pfizer clinical trial.
- Our results provide a possible connection between safety data already observed in the vaccine clinical trials and observations at a population level, providing stronger evidence for a causal relationship between the rise in disabilities and the Covid-19 vaccines.
- We believe that a comprehensive investigation needs to be performed, either in the form of new phase III clinical trials for at least a 3-year period, or a programme of forensic autopsies in a large sample of deceased individuals where the Covid-19 vaccines were not suspected as a co-factor for cause of death.

<u>Go to Part 1 - Overview of the Data</u> <u>Go to Part 2 - Rise in disabilities from 2021</u> <u>Go to Part 3 - Relationship with Vaccine uptake</u> <u>Go to Part 4 - Relationship with Excess Deaths</u> <u>Go to Part 5 - Relationship with SAEs in mRNA clinical trials</u> <u>Go to Part 7 - Relationship with Hospitalisations following vaccination reported in V-Safe</u>



US Disability Data

Part 7 - Relationship with hospitalisations following vaccination reported in V-Safe

Data Sources:

Disabilities data from the Bureau of Labor Statistics (BLS).
2 - <u>V-Safe database</u> (available data described <u>here</u>).

3 - Analysis of SAEs from mRNA Vaccine Clinical Trials.

4 - Analysis of Severe AEs from Pfizer Vaccine Clinical Trial.

Update Date: March - 2023

<u>Go to Part 1 - Overview of the Data</u> <u>Go to Part 2 - Rise in disabilities from 2021</u> <u>Go to Part 3 - Relationship with Vaccine uptake</u> <u>Go to Part 4 - Relationship with Excess Deaths</u> <u>Go to Part 5 - Relationship with SAEs in mRNA clinical trials</u> <u>Go to Part 6 - Relationship with Severe AEs in Pfizer vaccine clinical trial</u>

Overview:

Using a completely independent database, namely the V-Safe database (described <u>here</u>), we estimate time series of hospitalisation events, conditional upon different thresholds for days lost at work, to obtain time series that represent different levels of severity of

hospitalisation events. We remind the reader that in <u>Part 3 of the V-Safe data analysis</u>, a hospitalisation event was defined as one that led to emergency care or hospitalisation. Consequently, some hospitalisation events might not have been associated with an overnight stay, but simply as an emergency consultation and observation period.

Our analysis shows that during the vaccine rollout process, the CDC had live real world data that corroborated the safety signals observed in the clinical trials This data could and should have been used to anticipate the harm of the vaccine rollout on a population level.

Prior work:

In <u>part 5 of our US disabilities analysis</u> we observed that the rise in disability rates after Jan-2021 not only correlates closely with the rollout of the vaccination schedule, but also with the rate of Serious Adverse Events (SAEs) in the Moderna and Pfizer clinical trials. These rates are also of similar order of magnitude and therefore can explain the rise in disabilities.

Additionally we showed in <u>Part 6 of our US disabilities analysis</u> that by modelling the rate of Severe Adverse Events (Sev AEs), using data obtained from the Pfizer clinical trial, we could explain the pool of individuals that we believe were the source of the rise in disabilities from early 2021.

Estimating a Time Series of Hospitalisations from the V-Safe Data

Our purpose is to investigate the relationship between the rise in disabilities observed in the BLS data with an estimate of hospitalisation events that would occur through the mass Covid-19 vaccination rollout. Even though there is not necessarily a direct link between a hospitalisation event and a future disability, it is reasonable to consider that most disabled individuals might have passed through the process of 1) experiencing an adverse reaction and 2) seeking emergency care with consequent hospitalisation and missed work.

Likewise, it is reasonable to consider the link between the projected time series of hospitalisation events and with the modelled time-series of Serious Adverse Events

(SAEs) or Severe Adverse Events (Sev AEs) that were discussed in Part 5 and Part 6 of our US disabilities analysis.

The V-Safe database comprises a large sample of individuals that could be used to infer hospitalisation events on the population level. However, it should be used with caution as the V-Safe app was likely used by tech-savvy individuals, who, consequently, might be a younger, more pro-vaccine cohort which may not accurately represent the overall population.

Assumptions for computing the time series of hospitalisation events

To obtain a time series of hospitalisation events during the vaccine rollout, we compute the rate of hospitalisations following dose 2 of inoculation. Because we do not count hospitalisation events occurring before dose 2, the rate of hospitalisation is lower than the actual rate of hospitalisation events.

In order to obtain time series of different severities of events, we add a condition for individuals who missed work for 2 or more days (milder outcomes), or 5 or more days (which is the more severe outcomes).

We then multiply the rate of hospitalisation events following dose 2 by the population, aged 19-64, who received a Covid-19 vaccine (any dose or brand) each month, based on CDC vaccination numbers. This number is then halved to account for the majority of people receiving 2 doses. To simplify the analysis, we assume that the hospitalisation events occur on the date of vaccination, which we know is likely to be incorrect as the rate of SAEs declines monotonically over time following vaccination, (shown in <u>part 3</u>) of the V-Safe data analysis. Furthermore, assuming that half of the monthly doses are dose 2 is slightly inaccurate, especially in the early months of rollout.

To summarise:

-> Each time series of the rate of hospitalisations is calculated as the number of hospitalisation events following dose 2 (and that led to a 2+ or 5+ number of days of lost work), divided by the number of dose 2 inoculations.

-> The measured hospitalisation rate with 2+ days of lost work was 1.67% and the hospitalisation rate with 5+ number of days of lost work was 4.18%

-> Hospitalisation events are expected to occur at a certain baseline level, independently of individuals taking the vaccine or not, so an adjustment factor was applied to estimate the rate of hospitalisations associated with dose 2 inoculation versus the background hospitalisation placebo rate.

-> The adjustment factor was taken from the rate, over the placebo rate, of Severe Adverse Events (Sev AEs) for the Pfizer trial. These were published in table S3 of the supplementary appendix of the paper by S. J. Thomas et al. that established the vaccine

efficacy <u>("Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6</u> <u>Months", in New England Journal of Medicine, 9/2021</u>). S.J. Thomas et al. estimated a risk ratio of 1.74 of Severe Adverse reactions of those individuals who were inoculated with the Pfizer vaccine relative to the placebo group.

-> We assume that the total rate of hospitalisation occurs on the inoculation date and is not distributed over time.

Increase in Disabilities versus Estimated Time Series of V-Safe Hospitalisation Events

Disabilities versus V-Safe Hospitalisations

The following charts illustrate the relationship between the increase in the disability rate in the Civilian Labor Force (aged 16-64) and the projected rate of hospitalisation events with 2+ days of lost work and 5+ days of lost work, based on the Covid-19 vaccination administration rate for the 19-64 age group, and using the assumptions listed above.

The chart on the left shows the time series of the change in disability rate from Feb-2021 to Nov-2022 for the Civilian Labor Force (red), and also the time series of the projected rates of hospitalisations (green) associated with 2+ or 5+ days of lost work.

The chart on the right shows the correlation between the rise in the disability rate since Feb-2021 with the projected cumulative rate of hospitalisation associated with 5+ days of lost work. The regression R2 is 92% which is evidence for a strong relationship. The slope coefficient is 0.82 which means that there are fewer hospitalisations with 5 or more days of lost work than the observed increase in disabilities since Feb-2021.

We should also note that performing the correlation of cumulative time series is misleading, and the R2 should not be taken as an indication of establishing a statistically significant relationship as both time series have autocorrelation.

Nevertheless, the charts below strengthen the case for a causal relationship between the Covid-19 vaccines and disabilities, since the projected hospitalisation events are events that could lead to disability. Additionally, under the reasonable assumptions stated above,

the time series are shown to be of the same order of magnitude with each excess hospitalisation (of vaccinated individuals versus our assumed background rate) translating into 1.22=(1/0.82) disabilities as measured using BLS data. In other words, the rate of projected hospitalisation events with 5 or more days of lost work, appears to underestimate recorded disabilities by about 22%.



The higher rate of increase in disabilities than the computed rate of hospitalisation events with 5+ days of lost work could be explained in several different ways, or by a combination of factors including:

• By the definition of an a hospitalisation event with 5+ days of lost work being in general more extreme than the rate of disabilities reported by the individuals surveyed by the BLS. i.e. some disabilities reported by the individuals surveyed by the BLS may be caused by adverse events that do not require hospitalisation for at least 5 days.

• The under-reporting of hospitalisation events in the V-Safe due to participants not updating the mobile app.

• The adjustment factor applied to estimate the rate of hospitalisations associated with dose 2 inoculation relative to the background hospitalisation rate was projected using the ratio of Severe Adverse Events (Sev AEs) in vaccinated versus placebo participants in the Pfizer trial. This may not be an accurate model for estimating 'excess' hospitalisations.

• Other factors that may cause excess disabilities in the Civilian Labor Force in a concurrent timeframe to the vaccine rollout.

By selecting hospitalisation events with an added criteria of 2+ days lost of work, the rate of rise in disabilities is about half the computed rate of hospitalisation events. The broader definition for a hospitalisation event allows us to hypothesise that approximately half of those hospitalisations might have resulted in a disability.

Estimated SAEs and Sev AEs Versus Computed V-Safe Hospitalisation Events

Serious and Severe Adverse Events Versus V-Safe Hospitalisations

The chart shows the time series of the change in disability rate from Feb-2021 to Nov-2022 for the Civilian Labor Force (left scale), and also the time series of projected rate of SAEs (see Part 5) and Sev AEs (see Part 6). The chart also shows the time series of V-Safe hospitalisation events with 2+ and 5+ days of lost work.

The rate of hospitalisation events with 5+ days of lost work is higher than the projected rate of SAEs but lower than the rate of projected Sev AEs. Additionally, the rate of hospitalisation events with 2+ days of lost work is substantially greater than the rate of Sev. AEs.

The rate of increase in disabilities; the hospitalisation events with 5+ days of lost work; and the computed time series of Sev AEs, are of similar order of magnitude, with the increase in disabilities lying between the other two.



Observations

 Our results provide a stronger case for establishing a causal relationship between disabilities and the Covid-19 vaccines. We produced time series of hospitalisation events following dose 2 of the Covid-19 vaccine using the V-Safe database which provides further validation of our previous work, using an independent measure of safety events. The computed time series of hospitalisation events track closely the time series of SAEs and Sev. AEs that were computed based on the rates estimated during the mRNA clinical trials.

- We also observe that the rate increase in disabilities lies in between the hospitalisation events with 5+ days of lost work and the computed time series of Sev AEs, with these three time series being of similar order of magnitude.
- If we consider that there is a logical relationship between possible Severe Adverse Events following vaccination and subsequent hospitalisations events (as defined above) then we would have expected to observe similar rates of hospitalisations and Severe or Serious Adverse events. Our results confirmed our prior suspicions.
- The coincidence of the rise in disabilities with the start of the Covid-19 vaccination rollout **in conjunction** with the similar magnitude of the rate of SAEs and Sev. AEs (from the clinical trials) and now with the rate of hospitalisation events inferred from the V-Safe database, provides even stronger evidence towards asserting causation.
- We believe that a comprehensive investigation needs to be performed, either in the form of new Phase III clinical trials for at least a 3-year period, or a program of forensic autopsies in a large sample of deceased individuals where the Covid-19 vaccines were not suspected as a co-factor for cause of death.

<u>Go to Part 1 - Overview of the Data</u> <u>Go to Part 2 - Rise in disabilities from 2021</u> <u>Go to Part 3 - Relationship with Vaccine uptake</u> <u>Go to Part 4 - Relationship with Excess Deaths</u> <u>Go to Part 5 - Relationship with SAEs in mRNA clinical trials</u> <u>Go to Part 6 - Relationship with Severe AEs in Pfizer vaccine clinical trial</u>

