

# Revakcinacija: už ir prieš

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Skirtingų šalių pozicijos ir taikoma praktika

Gamintojų duomenys

Ekspertų ir oficialių institucijų nuomonė

## Izraelio pozicija dėl revakcinacijos (busterio)

- Pateikė mokslinių tyrimų duomenis apie mažėjančią apsaugą nuo užsikrėtimo Delta atmaina ir sunkios ligos;
- Pirmiausia pradėjo revakcinuoti rizikos grupes (07.30),
- Šiuo metu siūlo revacinaciją visiems >12 m. gyventojams paskiepytiems anksčiau nei **prieš 5 mėnesius**;
- Pateikė duomenis apie nepageidaujamas reakcijas po 3 dozės – jos panašios kaip po 2 dozės;

<https://www.bbc.com/future/article/20210916-covid-19-how-effective-is-a-third-vaccine-dose>

- Pateikė duomenis, kad 3 dozė po 12 d. sukuria žymiai didesnę apsaugą nuo infekcijos (**11x**) ir nuo sunkios ligos (**19x**)

<https://www.nejm.org/doi/full/10.1056/NEJMoa2114255>

# JAV pozicija dėl revakcinacijos (busterio)

This is subject to authorization by the U.S. FDA and recommendation by CDC's Advisory Committee on Immunization Practices (ACIP).

- Nuo 08 mėn. JAV revakcinuoja imunosupresuotus asmenis
- 09.17 d. FDA rekomendavo **Pfizer** vakciną **>65 m.** asmenims, praėjus **8 mėn.** po 2 dozės
- Atmetė siūlymą revakcinuoti visus >16 m. (*16 prieš, 3 už*)
- ✓ *some scientists said they believed that boosters were unlikely to have a significant impact on the course of the pandemic.*

# Kitų šalių pozicija dėl revakcinacijos (busterio)

## ➤ Italija:

- ✓ Revakcinuoja imunosupresuotus, **>80 m.** gyventojus, slaugos namų gyventojus, didžiausios rizikos zonoje dirbančius medikus;
- ✓ Revakcinuoja po **6 mėn.**, išskyrus imunosupresuotus (po 28 d.)

<https://www.reuters.com/world/europe/italy-approves-booster-covid-19-shots-vulnerable-groups-2021-09-09/>

## ➤ Jungtinė Karalystė:

- ✓ JK vaistų agentūra patvirtino AZ ir Pfizer vakcinas busteriui;
- ✓ JCVI rekomendavo revakcinuoti imunosupresuotus, slaugos namų gyventojus, **>50 m.** gyventojus, rizikoje dirbančius medikus;
- ✓ Revakcinuos po **6 mėn.** Pfizer vakcina

<https://www.bbc.com/news/health-58499863>

<https://www.bbc.com/news/health-58550833>

## ➤ Kitos šalys: Kanada, Rusija, Kinija, Singapūras

# **Pfizer** says Israel data shows third Covid shot restores protection from infection to 95% as it makes case to FDA for boosters

➤ While the effectiveness of the mRNA vaccine wanes over time, a **booster shot was shown to elicit an immune response** similar to the protection generated after a second dose, said Pfizer.

<https://www.bbc.com/news/health-58486526>

➤ The company and its partner on the Covid vaccine, BioNTech, are seeking the agency's OK to distribute booster doses to people 16 and older across the U.S.

➤ The FDA released the data as the agency faces pressure from the Biden administration to authorize booster shots for the general population as early as next week.

<https://www.cnbc.com/2021/09/15/covid-boosters-pfizer-says-israel-data-shows-third-shot-restores-efficacy-to-95percent.html>

# **Moderna** releases new data on Covid breakthrough cases it says supports need for booster shots

- Moderna shared a new analysis from its phase three study that showed **the incidence of breakthrough Covid cases**, which occur in fully vaccinated people, was less frequent in a group of trial participants who were **more recently** inoculated, suggesting immunity for earlier groups had started to wane.
- There were **88** identified breakthrough cases out of 11,431 people vaccinated between December and March, the company said in a release, compared with **162** breakthrough cases out of 14,746 trial participants vaccinated in July through October of last year.
- “If you take that number, which in the paper is roughly 28 cases per 1,000 person, and you extrapolate that across the 60 million Americans who’ve received that vaccine. The incremental number of cases of Covid-19 that would happen between here and the hospitals is about 600,000, more than half a million cases of Covid-19,”

# J&J/Janssen vakcinos veiksmingumas

- ✓ Gamintojas išbando antrą dozę **po 2 mėn ir po 6 mėn.**, teikia duomenis EVA ir FDA, netrukus bus sprendimai
- ✓ Duomenys bus paskelbti NEJM
- ✓ Po 1 dozės - apsauga nuo sunkios ligos **~75 proc.**, išlieka bent 6 mėn.
- ✓ Nepakanka duomenų apie apsaugą nuo Delta atmainos
- ✓ Nebeįmanoma rinkti duomenų iš placebo grupės
- ✓ Išbandomi heterologinės vakcinacijos variantai
- ✓ Vokietijos Roberto Kocho instituto duomenys: po Janssen vakcinos infekcijos atvejų dažnis 3 kartus didesnis nei po Pfizer (2 dozių).
- ✓ Gamintojas patvirtina, kad vakcina labiau apsaugo nuo ligos nei nuo infekcijos



# AstraZeneca bosses warn against rush for boosters

- ✓ Moving too quickly to give people Covid booster jabs would **deprive scientists** of data on how well the vaccines work
- ✓ We do not yet know whether that third dose is clinically needed
- ✓ any decision to give a third jab "to large swathes of the population", to extend their protection from the first two, must be **based on clinical data**
- ✓ We don't know what mix of antibodies and T-cells are needed to prevent serious illness - the correlates of protection.
- ✓ This is why we need **the weight of the clinical evidence** gathered from real-world use before we can make an informed decision on a third dose.

# Paskelbta ekspertų grupės pozicija dėl busterio

- Any decision should be **evidence-based** and consider the **benefits and risks** for individuals and society.
- COVID-19 vaccines **continue to be effective** against severe disease, including that caused by the delta variant
- Current evidence **does not show a need for boosting** in the general population, in which efficacy against severe disease **remains high**. Even if humoral immunity appears to wane, reductions in neutralising antibody titre **do not necessarily predict** reductions in vaccine efficacy
- if boosters are widely introduced too soon, or too frequently there are risks of immune-mediated **side-effects** such as myocarditis or Guillain-Barre syndrome
- If unnecessary boosting causes adverse reactions, there could be implications **for vaccine acceptance** in general

[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)02046-](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02046-8/fulltext?fbclid=IwAR2-)

[8/fulltext?fbclid=IwAR2-0ta1JINOk3ULk2EJltp5DgYsHhPQI2QASkvnyJZb0WK3498szgmgEbQ](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02046-8/fulltext?fbclid=IwAR2-0ta1JINOk3ULk2EJltp5DgYsHhPQI2QASkvnyJZb0WK3498szgmgEbQ)

# WHO Interim statement on COVID-19 vaccine booster doses

## 2021 08 10

- Introducing booster doses should be **firmly evidence-driven** and targeted to the population groups in greatest need. The rationale for implementing booster doses should be guided by evidence on waning vaccine effectiveness, **in particular a decline in protection against severe disease** in the general population or in high risk populations, or due to a circulating VOC.
- To date, the **evidence remains limited and inconclusive** on any widespread need for booster doses following a primary vaccination series.
- WHO is carefully monitoring the situation and will continue to work closely with countries to obtain the data required for policy recommendations.

<https://www.who.int/news/item/10-08-2021-interim-statement-on-covid-19-vaccine-booster-doses>

# ECDC Interim public health considerations for the provision of additional COVID-19 vaccine doses

2021-09-01

- Based on current evidence, **there is no urgent need** for the administration of booster doses of vaccines to fully vaccinated individuals
- All vaccines authorised in the EU/EEA are currently highly protective against COVID-19-related hospitalisation, severe disease and death
- It is important **to distinguish** between booster doses for people with normal immune systems and additional doses for those with weakened immune systems.
- Consideration could also be given to providing an additional dose to older frail individuals, in particular those living in closed settings such as **residents of long-term care facilities**
- Advice on how vaccinations should be given remains the prerogative of the **national immunisation technical advisory groups** (NITAGs). These bodies are best placed to take into account the local conditions, including the spread of the virus, the availability of vaccines and the capacities of national health systems.

*<https://www.ecdc.europa.eu/en/publications-data/covid-19-public-health-considerations-additional-vaccine-doses>*

# Apibendrinimas

- Gana vieninga teigiama pozicija dėl imunosupresuotų asmenų revakcinacijos
- Išsiskiria pozicijos dėl masinės revakcinacijos
- Paskelbti Izraelio duomenys apie geresnę apsaugą po 3 dozės
- Ekspertų, PSO ir ECDC pozicija:
  - ✓ nepakanka mokslinių įrodymų apie revakcinacijos būtinybę
  - ✓ antikūnų lygio sumažėjimas nebūtinai reiškia apsaugos sumažėjimą
  - ✓ turi būti įvertintos galimos rizikos asmeniui ir visuomenei

**Ačiū už dėmesį**