



## AMAYEZA INFO SERVICES

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### **BCG vaccine and COVID-19**

**According to the World Health Organization (WHO), “There is no evidence that the Bacille Calmette-Guérin vaccine (BCG) protects people against infection with COVID-19 virus.”**

**Therefore, at this stage, it is not possible to make any recommendations on using BCG vaccine for COVID-19. Until the safety and efficacy of the BCG vaccine can be proven in the prevention of COVID-19, the mainstay of prevention of COVID-19 remains social distancing, cough hygiene and hand washing.**

#### ***Can the BCG vaccine prevent COVID-19?***

At this stage, the benefit of BCG vaccination on COVID-19 is a hypothesis. <sup>1</sup>This means that there is no medical proof that the BCG vaccine can prevent COVID-19. <sup>2,3</sup> Furthermore, the BCG vaccine has no registered indication for preventing COVID-19 or other viral diseases. <sup>4</sup>

#### ***If there is no proof, why is there so much media attention on BCG vaccine and COVID-19?***

A study conducted by Professor Otazu at the New York Institute of Technology, reported that there may be a correlation between BCG-vaccinated populations and reduced mortality and morbidity rates for COVID-19. During an interview with Alec Hogg from BizNews, Dr Otazu stressed the following point: “It’s a correlational study. So, I wouldn’t base any policy based on that study.” He went on to say, “There are many differences and there might be something else that I’m missing. So that’s why a controlled clinical trial is crucial to finding out if this correlation – if this relationship is a causal relationship.” <sup>2</sup>

#### ***Given that there is no cure or vaccine specifically against COVID-19, why is the information from the correlation study not sufficient to use BCG vaccine to prevent further spread of this pandemic?***

While any promising mechanism that relates to BCG or any form of treatment that could stop this pandemic is of interest, such information needs to be well researched before we can say it is useful. Additionally, the above-mentioned report by Dr. Otazu is, at this stage, a hypothesis and needs to be proven. <sup>5</sup> There are clinical trials in progress to test safety and efficacy of BCG in the fight against COVID-19. However, none of these trials have been completed and no information is available yet. <sup>1</sup>

The analysis shows that the countries that do not have a universal BCG vaccine program seem to have worse infection rates. It is too soon to say, even though it seems compelling, that this is the only factor that explains the differences in spread and mortality of COVID-19. <sup>5</sup>

#### ***What clinical trials are currently being conducted?***

In Australia, a clinical trial is currently underway in healthcare workers. It is an open-label, two-group, phase III randomised controlled trial in up to 4170 healthcare workers to determine if BCG vaccination reduces the incidence and severity of COVID-19 during the 2020 pandemic.

This study is led by Nigel Curtis, head of infectious diseases research, at the Murdoch Children’s Research Institute in Melbourne, who has stated, “We cannot guarantee that this will work. And of course, the only way to find out is with our trial.” The primary completion is expected in October 2020. <sup>6,7</sup>

In the Netherlands, Dutch scientists are planning to test whether the BCG vaccine could protect healthcare workers against coronavirus, since it is known to stimulate the immune system and may lead to milder symptoms in

healthcare workers who do get infected. The experiment will mean randomly giving 1000 workers either the vaccine or a placebo. If the vaccine appears to have an effect, all healthcare workers will be given the option to have the vaccine. <sup>8</sup>

***South Africa includes BCG vaccine in its vaccination program; is this why our COVID-19 disease and mortality rates are low, compared to the US and other countries?***

BCG vaccine against tuberculosis (TB) has been used in South Africa since 1940 and routinely administered to infants since 1960. <sup>9</sup> According to Dr. Otazu, there is no definitive information to suggest that the BCG vaccine is the only factor driving the low rates seen in countries that have BCG policies. <sup>2</sup> There is experimental evidence from both animal and human studies that the BCG vaccine has non-specific effects on the immune system. These effects have not been well characterised and their clinical relevance is unknown. <sup>12</sup> These countries (that have BCG vaccine policies) have also implemented social distancing, quarantines and widespread testing. There may be other factors and therefore the clinical trials are needed to determine if the relationship between BCG vaccine and COVID-19 is a causal one. <sup>2</sup>

***The BCG vaccine is available in South Africa, why don't we just vaccinate our population even if we have had it before?***

According to the Expanded Program on Immunisation (EPI) in South Africa, BCG vaccine should be administered at or soon after birth. <sup>9</sup> Furthermore, BCG should not be administered to previously vaccinated individuals as there is an increased risk of adverse reactions and no evidence of additional protection against TB. Evidence of a previous BCG vaccination includes documentary evidence; a clear, reliable history of vaccination; or evidence of a characteristic scar. <sup>3</sup> Most South Africans have been vaccinated with BCG vaccine at birth or early childhood and the reported observational studies did not show any link between re-vaccination after childhood with the BCG vaccine and a decreased risk of COVID-19 disease and its complications. <sup>13</sup>

Furthermore, there is no evidence to confirm the safety of the BCG vaccine in older adults. The use of any vaccine in the elderly needs to be studied to ensure patient safety is not compromised.

BCG vaccine is a live attenuated vaccine and is not recommended for use in individuals who are immunocompromised/immunosuppressed as it can lead to significant complications. The ageing process is also associated with a decline in immune functioning in general (called immunosenescence) and thus there may be issues with using a vaccine like BCG in this age group. <sup>10</sup>

Due to the high incidence of TB in South Africa, it is also likely that >80% of older South African adults may have been exposed and asymptotically infected with "latent" TB during their lifetime. Since TB is a mycobacterium very similar to BCG vaccine, and latently infected people show similarities in immune response to BCG-vaccinated people, it seems unlikely that BCG vaccination of older adults would offer additional non-specific protection against COVID-19. <sup>10</sup>

It must be emphasized that BCG vaccine for COVID-19 is not a proven intervention. <sup>1-4</sup> If this vaccine is used for the unproven prevention of COVID-19, it could result in the country running out of this vaccine, thereby leaving many newborns without protection against TB. The hypothesis made cannot be used as a basis for decision-making. The safety and efficacy of the BCG vaccine in preventing COVID-19 must first be evaluated in robust clinical trials. Furthermore, the safety implications of repeating the vaccine in previously vaccinated populations have yet to be addressed. <sup>1, 2, 5</sup>

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#### References

1. Miller A, Reandelar MJ, Fasciglione K, et al. Correlation between universal BCG vaccination policy and reduced morbidity and mortality for COVID-19: an epidemiological study.
2. Is BCG-jab Covid-19's silver bullet? – NYIT's Dr Gonzalo Otazu. Full Transcript. Available from: <https://www.biznews.com/inside-covid-19/2020/04/06/gonzalo-otazu-bcg-jab-covid-19>
3. Public Health England. Tuberculosis: the green book, chapter 32. 2018
4. BCG. Package Insert
5. Inside Covid-19: NYIT's Dr Otazu on his research BCG may provide shield; How SA medics protect themselves. Available from: <https://www.biznews.com/inside-covid-19/2020/04/05/inside-covid-19-bcg-vaccine-nyit>
6. BCG Vaccination to Protect Healthcare Workers Against COVID-19 (BRACE). ClinicalTrials.gov Identifier: NCT04327206. Available from: <https://clinicaltrials.gov/ct2/show/NCT04327206>
7. Gale J. Century-Old Vaccine Investigated as a Weapon Against Coronavirus. Bloomberg. 30 March 2020. Available from: <https://www.bloomberg.com/news/articles/2020-03-30/century-old-vaccine-investigated-as-a-weapon-against-coronavirus>
8. Will TB vaccine help healthcare workers fight corona? Dutch hospitals experiment. Dutch New. 18 March 2020. Available from: <https://www.dutchnews.nl/news/2020/03/will-tb-vaccine-help-healthcare-workers-fight-corona-dutch-hospitals-experiment/>
9. Kotze D. Primary Health Care: Administration of intradermal BCG vaccine. 2002. Available from: <http://www.edoc.co.za/modules.php?name=News&file=article&sid=386>
10. BCG and COVID-19: Implications for South Africa. Data on file. Amayeza Information Services
11. National Institute for Communicable Diseases (NICD). COVID-19 Prevention. Available from: <https://www.nicd.ac.za/diseases-a-z-index/covid-19/covid-19-prevention/>
12. World Health Organization. Bacille Calmette-Guérin (BCG) vaccination and COVID-19. Scientific Brief. 12 April 2020. Available from: [https://www.who.int/news-room/commentaries/detail/bacille-calmette-gu%C3%A9rin-\(bcg\)-vaccination-and-covid-19](https://www.who.int/news-room/commentaries/detail/bacille-calmette-gu%C3%A9rin-(bcg)-vaccination-and-covid-19)
13. South African Health Products Regulatory Authority. SAHPRA STATEMENT: BCG Vaccination and COVID-19 Disease. April 2020

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