

# South Asian Declaration—Consensus Guidelines for COVID-19 Vaccination in Cancer Patients

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## Abstract



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We provide the South Asian Declaration, containing the consensus guidelines for coronavirus disease 2019 (COVID-19) vaccination in cancer patients.

## Keywords

pandemic, immunity, recommendations, vaccine, Covishield, Covaxin, Sputnik V

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## Introduction

The global coronavirus disease 2019 (COVID-19) pandemic has thrown up unprecedented challenges in every walk of life.<sup>1-3</sup> Fortunately, technological advances, impressive infrastructure, and past experience laid the foundations for the development of the COVID-19 vaccine at lightening pace.<sup>4,5</sup> While the drug authorities in many countries have given emergency authorization for several candidate vaccines (based on data from collective experience in more than 100,000 individuals in phase III clinical trials), the social media is buzzing with controversies and questions that remain to be unanswered. Since there is lack of robust efficacy, toxicity, and immunogenicity data amongst cancer patients (because most studies excluded patients with significant co-morbidities including cancer), our expert group of oncologists and infectious disease specialists decided to put together consensus guidelines for the use of COVID-19 vaccine for cancer patients in South Asia.

## Overview

The second wave of COVID-19 is playing havoc across the globe, and especially in South Asia and India.<sup>1</sup> The concept of herd immunity was based on the premise that any population exposed to the virus (infection) will develop protective IgG antibodies.<sup>6</sup> While their titers may go down after 3 to 4 months, they continue to be detectable for a couple of years. Also, T-cell immunity was expected to confer protection for 10 years or more (some suggested lifelong). Therefore, recurrence of COVID-19 was predicted to be an exceptional occurrence.<sup>7</sup> This was supported by the fact that amongst the millions of people infected globally very few developed a second infection and hardly any of it was of a severe nature. Situational modelling also indicated that the pandemic would come under control when 70% of the population develops immunity (either via natural infection or through vaccination). This is also the rationale on the basis of which United Kingdom enforced strict lockdown and focused on getting 70% of their population vaccinated. Once this target was achieved, they released the lockdown on April 12, 2021 and normal life is expected to return very quickly.<sup>8</sup>

Indian studies indicate that protective antibodies are prevalent in approximately 30 to 40% of the population.<sup>9</sup> Hence vaccination is a top public health priority.

## COVID-19 Vaccines and Adverse Reactions

The COVID-19 vaccines currently available in the region (manufactured in India; Serum Institute of India's Covishield; and Bharat Biotech's Covaxin) are safe for use in all cancer patients. Neither of these are live virus vaccines. Both these vaccines are similar in terms of efficacy and adverse reactions. The third vaccine to receive emergency authorization (Sputnik V through Dr Reddys) is also expected to have similar benefit.

Absolute contraindications include previous history of anaphylaxis; drug reaction causing angio-edema or severe allergic reaction; and previous history of allergy to polysorbital.<sup>10,11</sup> In such patients, the vaccine should not be given. These recommendations are unchanged for patients who have cancer.

COVID-19 adverse reactions usually occur in the first 2 to 3 days following administration of the vaccine.<sup>12</sup> Their severity may be higher after the second dose. Side effects are also more frequent in those who are younger (<55 years).

## COVID-19 Vaccination for Cancer Patients

Our expert group has taken into consideration all available data, scientific rationale, and the landscape of cancer patients in our region.<sup>13-25</sup> As experienced oncologists and infectious disease specialists we believe that the following consensus guidelines will provide the best protection to cancer patients from the COVID-19 virus pandemic. This is especially important since many of us are facing the second wave/peak of the infections (in February 15, 2021, India had 9,131 new cases [76 deaths]; since then the number of daily new cases has steadily increased to 47,009 [213 deaths] by March 21, 2021).<sup>1</sup>

We followed the Delphi method to arrive at a robust consensus recommendation, using three rounds of voting interspersed with discussion about updated data that became published from time to time. This process was undertaken over a period of 60 days (February to April 2021).<sup>26</sup>

### For Patients with Solid Tumor Cancers

All patients with solid tumor cancers are recommended to get the COVID-19 vaccine at the first available opportunity. In case they get infected in the future, vaccination shall help reduce COVID-19 related mortality and severity. Vaccination shall also enable patients to continue their planned anticancer therapy as per schedule without delay or reduction in dose intensity, factors that are vital to ensure optimal benefit. Vaccination should be planned in such a way that the patient's anticancer therapy is not required to be interrupted or postponed. These recommendations are applicable to all solid tumor patients receiving or planned to undergo surgery, radiation therapy, or cancer-directed systemic therapy (chemotherapy, corticosteroids, hormonal therapy, targeted therapy, and immunotherapy).

Under special circumstances, the treating oncologist should take into consideration the following supplementary recommendations on a case-to-case basis (→Table 1).<sup>13,15,17</sup>

**Table 1** Guidelines for special circumstances among patients with solid tumor cancers

| Sr. no | Special circumstance   | Recommendation   |
|--------|--|--|
| 1      | If cancer Rx is to start after 2 wk or more.                     | Give COVID-19 vaccine now.   |
| 2      | If cancer Rx is ending now or in the near future.                | Give COVID-19 vaccine 2 wk after the recovery from myelosuppression/ end of the Rx.            |
| 3      | If cytotoxic chemotherapy cycles are ongoing.                    | Time COVID-19 vaccine in between cycles when the patient is unlikely to have myelosuppression. |
| 4      | If there is flexibility in scheduling COVID-19 vaccination date. | Plan so that side effects do not occur on days of administration of anticancer Rx.             |
| 5      | If immunotherapy or steroids are to be given for cancer Rx.      | No need to schedule a specific interval or timing.   |

**For Patients with Hematological Malignancies<sup>13,14,19,25</sup>**

For patients with hematological malignancies, several factors have the potential to influence the effect of COVID-19 vaccination. The main ones include cancer originating in and compromising the immune system; drugs (chemotherapy, targeted therapy, monoclonal antibodies, B/T cell inhibitors, steroids, supportive care) affecting the immune system/immune response.

With so many variables, it is vital to take into consideration the local status of the global COVID-19 pandemic. If the center/region is having few daily new cases, health care infrastructure is not stressed, risk of developing serious COVID-19 illness is low, and the urgency to get vaccinated is not high. Patients with hematological malignancies in such circumstances can wait for the ideal time to get vaccinated (when their immune system is in a position to mount the best response). On the other hand, when the second wave is growing exponentially (current scenario in several urban areas in India), vaccination should be offered to patients at the first available opportunity—even if their immune system is only capable of mounting a muted response.

For patients requiring drugs like rituximab (classic example of lymphocyte-depleting therapy; other examples are blinatumomab, antithymocyte globulin, and alemtuzumab),

COVID-19 vaccination should be delayed till 6 months after completion of therapy if possible. Reconstitution of depleted lymphocytes will be sufficient when ALC (absolute lymphocyte count)  $\geq 1.0$  and/or B cell counts  $\geq 50$ , in which case the vaccine can be given earlier.

For newly diagnosed patients requiring any such medication, anticancer therapy should be given priority over COVID-19 vaccination.

For patients undergoing hematopoietic stem cell transplantation, COVID-19 vaccination is recommended to be administered 6 months later. COVID-19 vaccination may be initiated earlier (after interval of 2–3 months) provided their immune system showed sufficient recovery (peripheral blood B cells  $>50$ ; CD4+ T cells  $>100$ ; and being IVIG independent).

### Health Care Community's Opinion and Perception about the Role of COVID-19 Vaccine in Cancer Patients

We ascertained the current perception amongst community oncologists by conducting an online survey. A total of 101 unique responses (after removing duplicates) were received and analyzed (→Table 2). These answers were taken into consideration to ensure that we develop a consensus

**Table 2** Survey results from responding oncologists from South Asia (N = 101)

| Sr no. | Question/Statement   | Yes            | No            | Not sure      |              |             |
|--------|--|----------------|---------------|---------------|--------------|-------------|
| 1      | Are cancer patients more vulnerable to COVID-19 infection?   | 88             | 6             | 7             |              |             |
| 2      | If infected with COVID-19, do cancer patients have higher chances of severe infection or death—as compared with the general population?          | 85             | 6             | 10            |              |             |
| 3      | Should all cancer patients take the COVID-19 vaccine?  | 65             | 17            | 19            |              |             |
| 4      | If a Cancer patient is to receive COVID-19 vaccine, which of the currently available vaccine (in India) is your preference?                      | Covishield 61  | Covaxin 15    | 25            |              |             |
| 5      | Is the COVID-19 vaccine less effective in cancer patients—as compared with general population?   | 30             | 20            | 51            |              |             |
| 6      | Is special monitoring required after COVID-19 vaccination in cancer patients?  | 35             | 46            | 20            |              |             |
| 7      | What is the best time to get COVID-19 vaccine for cancer patients currently on active anticancer chemotherapy?                                   | Immediately 41 | After 1 mo 22 | After 3 mo 13 | After 6 mo 5 | Not sure 19 |
| 8      | Should cancer patients who have recovered from COVID-19 get vaccination?   | 84             | 7             | 10            |              |             |
| 9      | If a cancer patient who has recovered from COVID-19 is to be vaccinated, should decision be taken as for a normal person without co-morbidities? | 73             | 17            | 11            |              |             |
| 10     | Can patients receiving rituximab be given COVID-19 vaccine?  | 39             | 20            | 42            |              |             |
| 11     | Is COVID-19 vaccine safe in stem cell transplant recipients?   | 26             | 20            | 55            |              |             |
| 12     | Can patients with active malignancies be simultaneously administered other vaccines along with COVID-19 vaccine?                                 | 29             | 28            | 44            |              |             |
| 13     | Should there be any travel restrictions for cancer patients given all the doses of COVID-19 vaccine?   | 25             | 64            | 12            |              |             |
| 14     | If cancer patient already vaccinated for COVID-19 develops COVID-19 infection, should he/she be treated similar to a noncancer patient?          | 78             | 06            | 17            |              |             |

**Table 3** South Asian Declaration—consensus guidelines for COVID-19 vaccination in cancer patients

| Sr no. | Consensus statement   | Consensus agreement | Alternate recommendation  |
|--------|---|---------------------|---|
| 1      | Cancer patients are more vulnerable to COVID-19 infection.  | 36/36 (100%)        | None  |
| 2      | If infected with COVID-19, cancer patients have higher chances of severe infection or death—as compared with the general population.  | 35/36 (97%)         | Cancer patients without additional comorbidities have the same chance of severe infection or death as the general population.   |
| 3      | Covid-19 vaccination is contraindicated only in the few patients who have earlier had severe allergic reactions or anaphylaxis to substances that constitute part of the Covid-19 vaccine being considered for administration.                                    | 36/36 (100%)        | None  |
| 4      | All cancer patients should take the COVID-19 vaccine at the first available opportunity (with few exceptions as mentioned—see point 10 below).  | 36/36 (100%)        | None  |
| 5      | Cancer patients should receive whatever COVID-19 vaccine is available (none of the approved vaccines are live). All vaccines have similar efficacy in preventing serious infection, need for intensive care, and death.   | 36/36 (100%)        | None  |
| 6      | COVID-19 vaccine is likely to be less effective in cancer patients—as compared with general population. Still all cancer patients should be vaccinated—because some immunity is better than no immunity.  | 34/36 (94%)         | COVID-19 vaccine is equally effective in cancer patients as in persons without cancer.  |
| 7      | Special monitoring is usually not required after COVID-19 vaccination in cancer patients. Some exceptions exist that will be decided by your oncologist.  | 35/36 (97%)         | Cancer patients getting COVID-19 vaccination must be closely monitored as those on active treatment are prone to neutropenia or infections and may lead to adverse effects.   |
| 8      | For cancer patients currently on active anticancer chemotherapy, the best time to get COVID-19 vaccine is to be decided by the treating oncologist.   | 36/36 (100%)        | None  |
| 9      | Cancer patients, who have recovered from COVID-19, should also take the vaccine as soon as possible. Their vaccination timing should be decided by the treating oncologist based on overall health status and all relevant co-morbidities.                        | 36/36 (100%)        | None  |
| 10     | Cancer patients receiving drugs like rituximab (monoclonal antibodies directed against lymphocytes) or undergoing hematopoietic stem cell transplants should discuss with their treating oncologist regarding the safest time for receiving the COVID-19 vaccine. | 36/36 (100%)        | None  |
| 11     | If necessary, patients with active malignancies can simultaneously be administered other vaccines along with COVID-19 vaccine—as long as it is not a live vaccine.  | 34/36 (94%)         | The gap between different vaccine administration should be 2 wk for killed vaccines and 4 wk for live vaccines.   |
| 12     | When administering more than one vaccine, it is advisable to have a gap of 1 wk between doses of different vaccines.  | 34/36 (94%)         | Gap between doses of different vaccines should be 4 wk.   |
| 13     | Once they have completed 2 wk following their last dose of COVID-19 vaccines, cancer patients should be subject to the same travel restriction like any other normal person.  | 36/36 (100%)        | None  |
| 14     | If a cancer patient, who has already been vaccinated for COVID-19, now develops COVID-19 infection, he/she should be treated as having higher risk of complications, severity or death from the infection.  | 33/36 (92%)         | 1. Vaccinated cancer patients who develop COVID-19 infection have the same risk of complications and death as other noncancer patients.<br>2. Vaccinated cancer patients developing COVID 19 infection must be treated as per standard existing hospital protocols but closely monitored for higher complication rates. |



statement that will specifically help in improving, understanding, and optimizing COVID-19 vaccination for cancer patients in the community.

This survey analysis documents the varied opinions held by oncologists—especially questions 5, 6, 7, 10, 11, and 12. Clearly better understanding of upto date information and systematic application of current recommendations was missing. Our consensus guidelines will go a long way in giving confidence to the health care professionals in providing optimal care to their cancer patients with respect to getting the best immunity against COVID-19.

## Consensus Guideline Statement for COVID-19 Vaccination of Cancer Patients

The South Asian Declaration of the Consensus Guidelines for COVID-19 vaccination in cancer patients are shown in ►Table 3. These were arrived at using the Delphi methodology and included three rounds of voting. The entire process took 60 days including online group discussions to evaluate evolving data that became available from time to time.

Updated document shall be available online from concerned medical associations and societies' websites from time to time. In the meantime, we urge all health care professionals and patients to use these consensus guidelines for all patients with active or treated cancer—based on emergency use authorization provided by drug authorities.

## Supplementary Considerations

1. Patients with cancer should not be forced to decide between taking the COVID-19 vaccine and participating in cancer clinical trials.
2. Additional doses (beyond standard authorization) are not recommended.
3. If cancer patients were administered COVID-19 vaccine during a period of immunosuppression, they should not undergo revaccination after recovery from their immunosuppressed status.
4. Whether a booster dose will be required or not shall only be ascertained in the future. Currently no evidence exists regarding this question.
5. Patients who have recovered from COVID-19 infection should also be offered vaccination. There is no recommendation for a minimum interval between infection and vaccination in recovered individuals.
6. Recovery from acute COVID illness is based on resolution of fever for at least 24 hours (without antipyretic medication) and with improvement of all other COVID-19 related symptoms.
7. If time to recovery from COVID-19 is beyond the scheduled subsequent dose, it should be postponed till recovery. When this happens, it is not necessary to restart the vaccination schedule.
8. There is no data that antibody titer correlates with immunity and protection against COVID-19 infection. Hence vaccination should be done for cancer patients even if they have high levels of COVID-19 IgG antibodies.

9. Patients with breast cancer should receive COVID-19 vaccine on the opposite arm. Vaccination can rarely cause enlargement of lymph nodes in the axilla which might be mistaken for recurrence of the cancer on mammography or clinical examination.

## Conflict of Interest

None declared.

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