

TAI Audit Question Bank

National Rollout of COVID-19 vaccines

This list of illustrative questions is linked to TAI audit objectives outlined in IDI's practical guide: "Audit of Transparency, Accountability and Inclusiveness of the Use of Emergency Funding for COVID-19 (TAI Audits)".

The questions identified relate to two key objectives of TAI audits

1. To ascertain the extent to which compliance frameworks (national rollout of COVID-19 vaccines) provide for transparency, accountability and inclusiveness.
2. To ascertain the extent to which governments have complied with applicable laws, rules, regulations and policy decisions in terms of transparency, accountability and inclusiveness in the national rollout for COVID-19 vaccines

The list of questions is illustrative. We have attempted to write the questions at a global, principle-based level so that each SAI team can adapt them to the scope of their audit and local context. We encourage users to also further contribute to the questions.

The illustrative list of questions is limited to propriety and regularity compliance audit objectives. It does not contain audit questions linked to performance audit objectives such as the economy, efficiency and effectiveness.

What is transparency, accountability, and inclusiveness?

It is first important to reflect on the definition of accountability, transparency and inclusiveness, which are the key dimensions of a TAI audit.

Transparency can be defined as the basic and commonly agreed-upon principle of disclosure to make policies, legal and institutional frameworks and information related to decisions available to the public in a comprehensible, accessible and timely manner.¹

Accountability is about the relationship between the State and its citizens, and the extent to which the State is answerable for its actions. The concept of accountability refers to the legal and reporting framework, organisational structure, strategy, procedures, and actions to help ensure that every organisation that uses public money and make decisions that affect people's lives can be held responsible for its actions. The principles and concepts necessary to public sector accountability include transparency, fairness, integrity, and trust.²

Inclusiveness refers to the process of improving the terms for individuals and groups, in particular for those marginalised / in danger of being left behind, to take part in society and to be able to benefit adequately from public spending for COVID-19. The aim is to leave no one behind and include measures in public spending for COVID-19 that help improve the ability, opportunity, and dignity of marginalised or potentially marginalised. Marginalisation may differ depending on the country context.

In context of COVID-19 resources, WHO's guidance underlines the importance of the decisions to deploy vaccines based on "explicit values with evolving scientific and economic evidence will help keep decision-makers accountable" and "being clear and explicit about the full range of reasons behind

¹ Methodology for Assessing Procurement Systems (MAPS). <https://www.mapsinitiative.org/methodology/1-what-is-MAPS-presentation.pdf>

² <https://oag.parliament.nz/2016/accountability/part2.htm>

allocation and prioritizing decisions will permit groups who think they qualify under the reasoning to press their case for inclusion.”³

COVID-19 pandemic has impacted most public health programmes, creating a fragile environment and context. Ensuring the acquired vaccines reach the intended recipients requires considering the supply chain. It is the network of activities and organisations involved in delivering vaccines to the intended recipients. It includes storage and distribution, as well as related tasks and functions such as quality control⁴.

With respect to COVID-19 vaccines, four issues dominate their management, storage and handling⁵. While ensuring the integrity of the supply chain, and the processes and procedures associated.

1. Governance, planning and logistics in order to oversee and deploy COVID-19 vaccines.
2. The preparation, provision, and supervision of public health human resources, including clear roles and responsibilities being established.
3. The integrity of the supply chain; and
4. The administration and documentation, tracking how vaccines, resources and records are deployed.

The roll-out of COVID-19 vaccines via an approved national immunisation programme may need to be adjusted several times during the pandemic and should be expected to adapt as strategies targeting different target population groups are refined, based on the initial experiences from rolling out the vaccine.

TAI auditor needs to obtain a clear understanding of how a national programme of immunisation is governed, designed, implemented and monitored in consideration of the relevant audit implications. She/he needs to pay particular attention to what rules and guidelines were in place at specific times for specific national entities, that governing principles were respected, and to further examine whether the overall policy framework and its implementation was clear, consistent, and communicated effectively.

Considering the short- and long-term impact expected from TAI audits, the auditor may consider including these activities as part of their audit scope. Guidance from WHO and COVAX⁶ provides a good basis for TAI auditors to select audit questions to the asked related to the rollout of vaccines. A risk assessment matrix developed by GAVI⁷ is also available for TAI auditors as a source of potential audit questions.

³ World Health Organisation (2020), "WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination» <https://www.who.int/publications/i/item/who-sage-values-framework-for-the-allocation-and-prioritization-of-covid-19-vaccination>

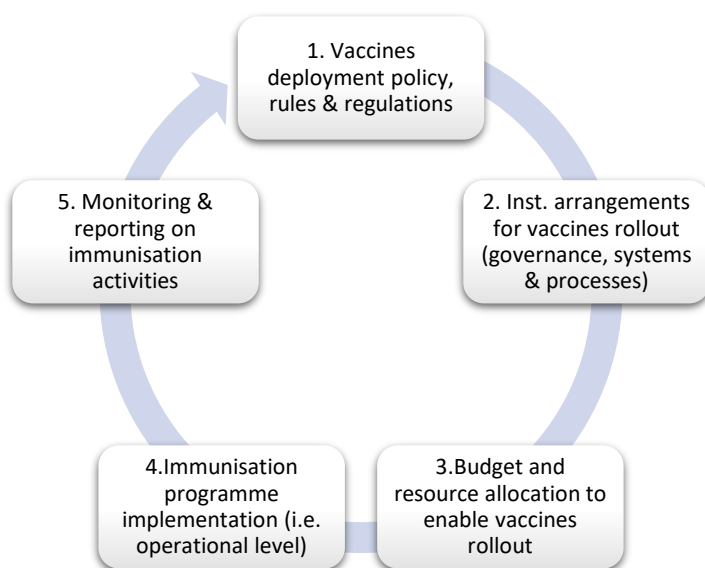
⁴ See *Integration of Vaccine Supply Chains with other Health Commodity Supply Chains*, PATH and World Health Organization, 2013
https://www.who.int/immunization/programmes_systems/supply_chain/optimize/vaccine_supply_chains_integration_report.pdf?ua=1

⁵ Audit questions related to procurement, management of donations of vaccines are available in the audit question bank on emergency public procurement, management of donations and supply.

⁶ For auditing the vaccine supply chain, please see WHO-GAVI, The Vaccine Alliance Guidance.
<https://www.gavi.org/>

⁷ GAVI *Risk Assessment Matrix*. (provide link)

Value framework of national rollout of COVID-19 vaccines:



TAI Auditors can examine the two key audit objectives from the perspective of a holistic 'value framework'. Following the framework will help the auditor in determining if the vaccine rollout met its purpose and reached the intended beneficiaries. The framework has five dimensions. The TAI auditor can ask audit questions related these dimensions on vaccine rollouts.

The questions under each dimension cover transparency, accountability and inclusiveness.

The nature of the questions will depend on the scope of the audit, the audit topic and the local context. We have attempted to include audit questions on each dimension in the question bank.

Based on the value framework, the audit questions on national rollout of COVID-19 vaccines are divided into five sections:

1. Vaccine deployment policy, rules and regulations
2. Institutional arrangements for vaccine rollout (governance, systems and processes)
3. Budget and resource allocation to enable vaccine rollout
4. Immunisation programme implementation activities
5. Monitoring and reporting on immunisation activities

The audit questions in the following list are linked to two key audit objectives and the five dimensions of value framework ensuring the transparency, accountability, and inclusiveness of vaccine rollout.

Vaccine rollout policy, rules, and regulations

1. Do the policies, rules and regulations provide for an appropriate managerial and governance framework to oversee the planning, coordination and execution of a COVID-19 vaccine rollout?
2. Does the compliance framework for vaccine rollout provide for prioritisation of vulnerable sections and disadvantaged populations within the vulnerable groups e.g people with disabilities, persons with low socioeconomic status, ethnic minorities, rural poor, migrants refugees, internally displaced persons, or others?
3. Were the laws, regulations, and policies governing vaccine allocation and prioritisation, published and easily accessible to the public?

Institutional arrangements for vaccine rollout (governance, systems and processes)

1. Has an overall appropriate authority for COVID-19 vaccine roll-out been put in place, including relevant assignation and delegation of key roles and responsibilities?
2. Did the government make provisions for adequate planning, preparation, logistics and documentation of the necessary processes to manage and deploy a COVID-19 vaccine campaign?
3. Has a country led National Deployment and Vaccination Plan (NDVP) plan been developed in line with WHO-SAGE guidance and international best practices guidance, including appropriate vaccination strategies to equitably reach the identified target populations prior to the beginning of vaccination?
4. Was the decision-making process for identifying target populations country led or closely consulted with the National Immunization Technical Advisory Groups (NITAG) or an equivalent technical advisory group, in consultation with stakeholders?
5. Was a clear consultation process put in place to determine what scientific, public health, and values criteria should be used, in order to make decisions about vaccine allocation?
6. Were civil society organisations, recipients of care, and minority groups represented in decision-making structures regarding target population prioritisation?
7. Is there an evidence-based COVID-19 decision-making and planning process in place which is coordinated with other components of the health system?
8. Did the government ensure adequate participation of all demographic groups in defining the vaccine prioritisation process?
9. Does the national vaccine prioritization process include equity considerations, such as the vulnerabilities, risks and needs of groups who, because of underlying societal, geographic or biomedical factors, are at risk of experiencing greater burdens from the COVID-19 pandemic?
10. Has the country's national immunisation technical advisory group (NITAG or equivalent) provided evidence-based recommendations and policy guidance specifically related to COVID-19 vaccines, to allow for informed decision-making by the government?
11. Did the government put in place adequate national or subnational communication strategies and platforms to inform the public of the availability of COVID-19 vaccine? was the information adapted and clearly communicated to target priority groups?

Budget and resource allocation to enable vaccine rollout

1. Have sufficient national budgetary appropriations been determined to ensure the smooth delivery of COVID-19 vaccines, bearing in mind the different phases of vaccine allocation to the country and the identification of the relevant tiers of target population?
2. Have all national, donor emergency funds and in-kind contributions towards the COVID-19 outbreak been appropriately identified, tracked and managed, with respect to pandemic response and national immunisation efforts?
3. Does the budget and resource allocation include equity considerations, such as the vulnerabilities, risks and needs of groups who, because of underlying societal, geographic or biomedical factors, are at risk of experiencing greater burdens from the COVID-19 pandemic?
4. Are there sufficient public health personnel in place trained to address and supervise the pandemic response (or individuals have been identified and are ready to be deployed), along with segregation of duties and clear roles defined and documented?

5. Is timely information related to vaccine rollout budgets and resource allocation available to all sections of the population?

Vaccine rollout activities

1. Did the government adequately plan, prepare, and document the necessary processes to manage and deploy a COVID-19 vaccine campaign?
2. Were suitable COVID-19 immunisation micro-plans developed in line with clearly documented programme objectives?
3. Have accurate estimates of target subpopulations been determined and did the resultant response plans include all inhabitants in the country?
4. Have details of the prioritisation plan and priorities been appropriately disseminated to the teams implementing the COVID-19 vaccine rollout?
5. Were the vaccines deployed as per planned prioritisation policy? Did the vaccines reach the marginalised/ vulnerable groups/at risk groups as provided for in the plans and policy framework?
6. Did the government communicate and engage widely with vulnerable and marginalized population using different platforms (e.g., hotline, social media, celebrities, press conferences etc.) or trusted authority/spokesperson for vulnerable and marginalized population during the vaccine rollout?
7. Was an appropriate system of checks and balances put in place to ensure that rollout activities complied with applicable policy framework?
8. Have independent quality checks on vaccine rollout activities been carried out as per provisions?

Monitoring and reporting of vaccine rollout

1. Has a reporting and management structure, to ensure the deployment, implementation and monitoring of a COVID-19 vaccination activities been put in place, which is aligned with the country's COVID-19 strategic preparedness and response plan (i.e. the National Deployment Vaccination Plan)?
2. Is accurate, sufficient and disaggregated data available to ascertain the extent to which the vaccine rollout is carried out as per plans?
3. Were vaccine and immunisation records, data and supporting documents accurate, complete and timely reported?
4. Are government reports on vaccine rollouts and government decisions related to vaccine rollout easily accessible to all stakeholders in a timely manner?