

RISK ASSESSMENT AND RISK MANAGEMENT PLAN

Risk Description	Rating	Mitigation Measures	Responsibility
I. Technical			
1. Unit price exceeds project estimates, resulting in less coverage of the vaccines procured under ADB, World Bank, and IsDB loans; or the allocation by COVAX AMC is for less than 20% of the population.	H	The Government of Pakistan allocated \$280 million to procure vaccines. Pakistan still has a \$748 million OCR allocation in APVAX left that can be used for further procurement of vaccines.	NCOC, MONHSR&C, ADB
2. Implementation of the NDVP gets delayed by administrative bottlenecks, including on-site readiness of final delivery locations.	M	The milestones will be agreed with MONHSR&C as the EA and Federal EPI as the IA, and the evaluation of progress will be part of the project's monitoring mechanism. Experts on procurement and supply chain management will be provided at national and provincial levels to build capacity at EA and IA.	NCOC, MONHSR&C, DPCC
3. Implementation of the NDVP is challenged by skepticism, lukewarm attention, and vaccine hesitancy.	S	The project will draw on and support further development of the RCCE, which is a core part of the NDVP and has been vetted by line ministries and approved by NCOC. The RCCE is a framework aimed at individuals, families, and communities, and collaborates with religious leaders, to ensure the public's support of the NDVP, i.e., encourage targeted population segments to have more faith in the health system and increase vaccine uptake. PMU will be supported by a RCCE specialist through World Bank funding, while ADB will support a gender specialist for input to the RCCE, keeping in mind the challenges for the elderly, persons with disabilities, and remote residents.	MONHSR&C, World Bank, Federal EPI, DPCC
4. Vaccine not allocated according to the prioritization plan	S	Performance auditor to assess the economy, efficiency, and effectiveness of the vaccination program. The monitoring and evaluation specialist will provide real-time monitoring and evaluation of the vaccination program.	MONHSR&C, Federal EPI, DPCC
5. Inventories are used for or administered to incorrect recipients.	M	Training is given whenever a new vaccine is introduced, with repeated refresher courses for vaccinators. SOPs and guidelines are developed.	MONHSR&C, Federal EPI
6. Combining manual and automated mechanisms to control item tagging, storage, warehouse transfers, and consumption may generate gaps in the inventory system.	S	The audit of inventory management performance will include annual assessments of the design and operating effectiveness of the inventory management system.	MONHSR&C, Federal EPI
7. Inadequate cold chain equipment in terms of number, locations, required temperature levels, and infrastructure support	M	- VIRAT/VRAF assessment showed weakness with regard to ultracold storage equipment, which was remedied with ADB funds. ^a - Sufficient funds are available within the operational costs of the Planning Commission Proforma No. 1 (PC-1) (i.e., the combined loans of ADB, World Bank and IsDB) for more cold chain equipment	MONHSR&C, Federal EPI
8. Inaccurate reports and data	M	Computerized and online inventory system, COVIM, is in place and adequately provides accurate information.	MONHSR&C, Federal EPI

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II. Governance			
9. Empowerment of NDMA role as chairmanship in procurement might be beyond procurement committee and result in change in the project governance structure and roles and responsibilities of EA and IAs	M	Any change to the project governance structure as presented in PAM need to be agreed with ADB and PAM would need to be amended. The current NDMA role as part of procurement committee is agreed by World Bank and ADB and any change to the role that would impact project governance structure would need to be discussed with development partners and additional due diligence would need to be performed on the enhanced role of NDMA .	NCOC, NDMA, MONHSR&C, ADB, WB
10. Capacity of Federal EPI to deliver vaccines in parallel to ongoing immunization programs is reduced.	M	Federal EPI as the IA has been effectively running federal immunization programs. Consultants will support the IA and build its capacity for implementing the COVID-19 vaccination plan as part of the NDVP in addition to their regular immunization programs.	MONHSR&C, Federal EPI, DPCC
11. Oversight of vaccination program is lacking, which could lead to corruption and/or fraud.	M	The DGA will conduct and submit to ADB audits of the project in each financial year of its implementation, and report significant findings to stakeholders. NAB is mandated to look at all public sector procurement exceeding a threshold of RPs50 million (about \$318,250). An independent entity will be appointed to monitor compliance with the end-to-end integrity plan of the project.	MONHSR&C, Federal EPI, DGA, NAB, ADB
12. The scope for political interference and delays in the appointment of key officials in integrity institutions may reduce their effectiveness, raising the risk of corruption and fraud.	H	Several partners are providing support for legal and judicial reforms. ADB will work with the government to effectively insulate ADB-funded projects from corruption risks in accordance with ADB's Anticorruption Policy.	NCOC, MONHSR&C, ADB/DPCC
13. Exclusion of ADB-funded projects in the internal audit plan of MONHSR&C; or insufficient authority given to internal financial control and audit units; or inadequate capacity could reduce the effectiveness of financial management, control of expenditures, and accountability, raising the risk of misuse of funds or gaps between projected revenues/expenditures and actual realization.	S	<ul style="list-style-type: none"> - The internal audit unit will be obligated to audit the ADB funds, and the detailed scope of this audit will be agreed with MONHSR&C and Federal EPI. This includes considering various aspects of ADB funds and auditing all project accounts in accordance with International Standards for the Professional Practice of Internal Auditing. - The Ministry of Finance's Internal Audit Department supports building the capacity of internal audit units in line ministries, including drafting an audit charter, manuals, and guidelines. - ADB will make provisions for financial management, including assistance for capacity development, in ADB-funded projects. 	MONHSR&C, Federal EPI, Ministry of Finance, ADB
14. Ensuring good governance under the pressure of having to procure the COVID-19 vaccines in timely fashion and rolling out the vaccination program promptly is challenging.	S	<ul style="list-style-type: none"> - Cabinet Procurement Committee, NCOC, National Coordination Committee, and National Vaccine Task Force will supervise and oversee the COVID-19 vaccine deployment. - A joint PMU will be set up to ensure adequate project oversight and efficient development partner coordination, to prevent and mitigate corruption risk. - MONHSR&C will staff the PMU with qualified and experienced staff to manage, implement, and monitor ADB-financed projects, including inventory procurement, asset management, and financial management 	Various entities and stakeholders

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		<ul style="list-style-type: none"> - ADB's complete sanctions list needs to be accessible and used to ascertain the eligibility of potential contractors, consultants, and suppliers. - ADB, under its technical assistance, will conduct integrity knowledge management session/s for MONHSR&C, Federal EPI, and other project stakeholders to increase their awareness of and compliance with ADB's Anticorruption Policy. 	
III. Procurement			
15. The project finances ineligible vaccines.	M	No withdrawal request is made from the loan account in relation to a COVID-19 vaccine until ADB has received a letter from the borrower confirming which of the eligibility criteria have been satisfied.	NCOC, MOHNSR&C, Federal EPI, ADB
16. Severely constrained vaccine supply market and/or manufacturer's inability to meet delivery times	H	<ul style="list-style-type: none"> - Use COVAX, which has confirmed supply deals commensurate with needs. - Identify multiple avenues for procurement to spread risk, and prioritize unapproved vaccines with smaller order books (balance portfolio). 	MONHSR&C
17. Unavailability of sufficient quantities of syringes and safety boxes	S	Plan in advance the procurement of syringes and safety boxes, and establish a framework agreement with suppliers.	MONHSR&C, Federal EPI
IV. Financial Management			
18. MONHSR&C and Federal EPI have no previous experience with the financial management and audit requirements of ADB projects. Moreover, current staff may be overburdened by the additional project activities related to vaccines.	S	<ul style="list-style-type: none"> - ADB will work closely with MONHSR&C and Federal EPI to implement the project as per guidelines and requirements of ADB. The ministry has worked on several projects financed by external development partners. - New financial management staff and consultants with prior ADB or World Bank project experience will be recruited for the project. ADB will provide training to MONHSR&C staff on ADB's financial management and disbursement guidelines and policies. - ADB will also train Federal EPI accounting staff on ADB financial management and disbursement guidelines and policies. 	MONHSR&C, ADB
19. Funds might be misspent, fraudulently misappropriated, or not accounted for adequately.	M	Allocation of budget to already approved PC-1 document is maintained, and not a single rupee can be spent out of the purview of the approved PC-1. Given the threat of audits, every custodian avoids misappropriation of funds.	MONHSR&C, ADB
20. Double payment of expenditure may occur, or funds from other financiers may be merged and not accounted for properly.	S	<ul style="list-style-type: none"> - A separate bank account will be opened for each financier, i.e., ADB, World Bank, and IsDB. - The FMS to provide to ADB a quarterly reconciliation document for expenditure categories funded by multiple financiers. - Federal EPI to provide additional reconciliation documents from other development partners with which ADB shares costs. - Regular coordination meeting on project progress and joint project review missions. - The coordination meeting must include corruption and integrity risk and control considerations in relation to procurement, asset management, and financial management. 	MONHSR&C, ADB
21. Delays in the external audit of ADB project accounts and failure to resolve outstanding audit observations in time continue to expose Federal	M	External financial audits of Federal EPI are conducted annually by the Auditor General of Pakistan.	MONHSR&C, Federal EPI,

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EPI to significant risks in terms of its financial records.			
22. Financial statements are being generated from the SAP system maintained by the Auditor General of Pakistan Revenue along with regular financial reports. However, MONHSR&C and Federal EPI use their accounting system manually. Inaccurate and incomplete financial information based on spreadsheet monitoring of the project will also delay the overall monitoring and reporting.	M	<p>A computerized accounting software for the project will be considered for Federal EPI to ensure timely reporting of financial information and to reduce errors.</p> <p>The financial management specialist will prepare quarterly reports on the ADB project with financial and disbursement information, as well as variance analysis of physical and financial progress. The report should include the status of the financial management action plan.</p>	MONHSR&C, Federal EPI,
23. Potential theft, misappropriation, late replenishment, and/or incorrect administration of items might occur.	M	<p>- NDVP implementation is closely monitored through COVIM and NIMS at EA and IA levels. Performance audit firm will be hired throughout the project to detect red flags, recommend risk prevention measures, and check if vaccines are administered to the targeted population.</p> <p>- SOPs exist for storekeepers, security guards, and vaccinators, with an established accountability and transparency framework.</p>	MONHSR&C, Federal EPI
V. Safeguards			
24. Medical waste management	M	<p>- Federal EPI, in collaboration with the World Bank, prepared an ESMP for the safe collection of EPI waste; similarly, a PREP-ESMP was prepared in accordance with Hospital Waste Management Rules, 2005 for the safe collection, storage, transportation, and environment-friendly disposal of COVID-19 waste.</p> <p>- A detailed due diligence study during the implementation phase will be carried out to identify further gaps in the ESMP and to provide suitable recommendations to fill these gaps. An environmental consultant will be recruited during the implementation phase to carry out this due diligence study.</p> <p>- A firm commitment to manage the medical waste in an adequate manner was also provided in the Governor's letter:</p> <ul style="list-style-type: none"> ▪ Gaps identified in the ESMP and mentioned in the previous section will be overcome to ensure compliance with ADB's Safeguard Policy Statement (2009). ▪ Monitoring reports on management of medical waste will be submitted to ADB on a regular basis. ▪ An environmental consultant along with two waste management consultants will provide overall supervision and oversight to junior staff at the district levels to ensure compliance with applicable national and ADB-specific regulations and guidelines. <p>- The environmental consultant and the waste management consultants will provide training to</p>	MONHSR&C, Federal EPI, ADB

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		health care workers and nongovernment organizations to strengthen their capacity for managing medical waste.	
25. Occupational health and safety	L	The NDVP describes the SOPs to follow. - Suitable safety standards for all workers and facility visitors are implemented. - First aid equipment, mandatory personal protective equipment, and safety gear are provided where required. - Safe drinking water and sanitation facilities for health care staff are arranged.	MONHSR&C, Federal EPI

ADB = Asian Development Bank; APVAX = Asia Pacific Vaccine Access Facility; COL = concessional ordinary capital resources lending; COVID-19 = coronavirus disease; COVIM = COVID-19 Vaccine Inventory Management System; DGA = Directorate General Audit; DPCC = Development Partners Coordination Committee; EA = executing agency; ESMP = environmental and social management plan; EPI = Expanded Programme on Immunization Pakistan; FMS = Financial Management Specialist; H = high; IA = implementing agency; IsDB = Islamic Development Bank; L = low; M = moderate; MONHSR&C = Ministry of National Health Services, Regulations and Coordination; NAB = National Accountability Bureau; NCOC = National Command and Operation Center; NDVP = National Deployment and Vaccination Plan; NMDA = National Disaster Management Authority; NIMS = national immunization management systems; OCR = ordinary capital resources; PAM = project administration manual; PREP = Pandemic Response Effectiveness in Pakistan; RCCE = risk communication and community engagement strategy; S = substantial; SOP = standard operating procedure; VIRAT = Vaccine Introduction Readiness Assessment Tool; VRAF = Vaccine Readiness Assessment Framework.

^a ADB. 2020. [Regional Support to Address the Outbreak of Coronavirus Disease 2019 and Potential Outbreaks of Other Communicable Diseases](#). Manila.

Source: Asian Development Bank.