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HEALTH
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ASSESSMENT OF THE CURRENT STATE OF THE COLD CHAIN OF COVID-19 VACCINES IN THE REPUBLIC OF KAZAKHSTAN

2022

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CONTENT

ABBREVIATIONS AND ACRONYMS

No.	Abbreviation	Definition
1	BCG	(short for Bacillus Calmette - Guérin, BCG) vaccine for tuberculosis (TB) disease
2	CDH	Central district hospital
3	CMPC	Committee for Medical and Pharmaceutical Control
4	CP	City polyclinic
5	CSEC	Committee of Sanitary and Epidemiological Control
6	DSEC	Department of Sanitary and Epidemiological Control
7	EVM	Effective Vaccine Management
8	HD	Health Department State Institution
9	II	Inventory items
10	Immunobiologicals	Immunobiological medicinal products
11	INDB	'Individuals` National Database (IS)
12	IRD	Internal regulatory documents
13	IS	Information system
14	LEB	Local executive body
15	MH RK	Ministry of Health of the Republic of Kazakhstan
16	MIS	Medical information system
17	MO	Medical organization
18	NCEMMD	National Center for Expertise of Medicines and Medical Devices of the MH RK RSE
19	NCPH	National Center of Public Health of the MH RK RSE
20	PHC	Primary health care
21	RK	Republic of Kazakhstan
22	RLA	Regulatory legal acts
23	RMS	Resource Management System (IS)
24	SHIF	Social Health Insurance Fund NJSC
25	SK-Pharmacy	Samruk-Kazyna Pharmaceuticals LLP
26	SOP	Standard operating procedure
27	SPCSEEM	Scientific and Practical Center for Sanitary and Epidemiological Expertise and Monitoring
28	WHO	World Health Organization

STUDY SUMMARY

This study aims to contribute to the methodological improvement of the immunization system in Kazakhstan in terms of (ultra)cold chain processes by implementing Effective Vaccine Management (EVM) approaches.

The main and final beneficiary of the study are the children of Kazakhstan (boys and girls equally), since the results of the cold chain assessment are aimed at improving the immunization system, including routine, that is, ensuring the right of children to health.

The study audience can be divided into two categories:

- state stakeholders that decide on the implementation of EVM approaches (primarily, the Committee for Sanitary and Epidemiological Control of the MH RK, as well as the Committee for Medical and Pharmaceutical Control of the MH RK, Samruk-Kazyna Pharmaceuticals LLP, regional health departments, National Public Health Center and its subordinate organizations RSE, Republican e-Health Center RSE);
- all other stakeholders engaged in the (ultra)cold chain and able to use the proposed results (territorial authorities, storage facilities, medical organizations).

Effective Vaccine Management is a global initiative to increase immunization coverage by continuously improving the vaccine supply chain, ensuring availability for lifelong vaccination of the population whenever and wherever it is needed.

EVM is a tool that assesses each component of the vaccine supply chain (receipt, storage, management), identifying strengths and weaknesses and suggesting improvements.

At the design stage of the study (in the program document), the approaches adopted in the theory of change were used to formulate and link the results with the results defined in the higher-level program documents, divide them into activities, determine indicators for measuring results, and controls for each indicator.

The study objectives were implemented on the basis of the following methodological approaches:

Table 1. Study objectives and methodological approaches used for their implementation

No.	Objective	Methodological approach
1.	Cold Chain Assessment in 2 regions of RK	1. Adapted questionnaires based on the EVM 2.0 Assessor questionnaires were created, addressing cold chain issues as a primary topic. 2. The equipment functioning was monitored and inspected (paragraphs 2-5 were implemented, among other things, to triangulate information and minimize distortions (bias) that could be induced by the survey itself due to its focus on identifying gaps in the state system). 3. A demonstration of medical workers' activities while working with the cold chain was requested. 4. The documentation was examined in order to verify the answers. 5. An overview of the functioning of information systems and work in them was carried out. 6. The assessment was carried out and its results are presented in the context of supply levels
2.	Interviewing employees involved in working with the cold chain	The interviews were conducted in an online format (with recording and further transcribing) based on the Zoom communication web platform in accordance with a previously developed questionnaire covering various types of respondents. The results are grouped by supply levels and triangulated with the results of the field assessment, which also helped to minimize distortions (bias) that could be induced by the interview itself due to its focus on identifying gaps in the state system.
3.	Overview of regulatory legal acts (hereinafter referred to as the RLA) and available data	Analysis of relevant RLA in the context of regulations, with the identification of gaps. Overview of reporting forms and analytical tables, assessment of the fullness of their format, data validity, data analysis with the identification of outliers. (for example, negative values, values less than 1.0 with a valid minimum of 1.0, data sets with a wide spectrum spread or polarized data sets, 1-2 values more than 1.5 times different from other values equal to each other were considered as outliers; for more information about identifying and processing outlier values, see the section "Overview of normative legal acts", Subsection "Review of the data of reporting forms", item "Expense for 1 vaccination" and "Monitoring of the availability of cold equipment")

4.	Study of a technical tool / cold chain volume planning model	The UNICEF Cold Chain Sizing Tool based on Microsoft Excel software has been analyzed and recommended for implementation
6.	Conducting training sessions for employees involved in working with the cold chain	A series of 6 academic hours of professional development training sessions for each group was conducted online, covering all 20 regions of Kazakhstan, employees of subnational storage facilities and central level (a total of 240 people), in Kazakh and Russian languages. Training content is based on the study results, and is synchronized with methodological recommendations, combines theoretical and practical modules, and the effectiveness of the training is assessed using preliminary and final testing. At the end of the training, participants gave feedback for further program improvements

As part of ensuring compliance with the theory of change, it is assumed that as a result of the study (outcomes):

- awareness of the state of the cold chain of vaccination at different levels and in various aspects will increase (corresponding outputs: quantitative and qualitative evaluation results reflected in this report);
- awareness of the methods of ensuring the cold chain of vaccination at different levels will improve (relevant outputs: training coverage, methodological recommendations);
- the central level will be equipped with practical recommendations for improving the cold chain of vaccination (relevant outputs: recommendations reflected in this report; methodological recommendations).

The impact of the study is expected to improve the safety and rationality of the vaccination process through targeted cold chain management through the introduction of EVM.

The international practice today uses the EVM framework version 2.0, with access to the questionnaires provided on the basis of an official request from the country. Access to this questionnaire was not requested for Kazakhstan, therefore this assessment was conducted according to an adapted scheme described below. This assessment is the second document promoting EVM in Kazakhstan: the first was conducted by WHO in 2014 (Kazakhstan: Effective Vaccine Management Assessment).

Further EVM compliance assessments should include:

Table 2. Types of EVM assessments

No.	Assessment type	Assessment content	Frequency
1	Regular continuous assessments	All aspects of EVM (not only cold chain), all regions	every 3-4 years
2	Targeted assessments	Selected regions and vaccine storage levels	when required

Research has shown that there are a number of cold chain regulatory problems at the central level of immunization control. For example, RLA do not regulate the equipment standard for refrigeration equipment, the calculation process of its needs (the required volume of cold chain in the context of temperature regimes), technical requirements for cold chain equipment according to WHO prequalification, and the amount of irreducible stock of vaccines according to WHO recommendations. In addition, there is a need for a comprehensive information system for both cold chain and immunization management generally and for reliable temperature monitoring at all stages of vaccine distribution and transportation.

In turn, at the level of warehouses and medical organizations, problems of a more technical nature prevail, so, there are no standards of operating procedures (SOP) at the level of storage and medical organizations, or they are simply word-for-word excerpts from the MH RK Orders and their appendices; 25% of medical organizations have not concluded maintenance contracts for refrigeration equipment (which has become quite a non-standard finding); 50% of regional storage facilities and 60% of medical organizations have no backup refrigeration equipment; 50% of regional storage facilities have no fuel reserve for a generator to provide uninterrupted electric power, there is no SOP for emergencies practically everywhere; medical waste management has not been solved: sometimes medical organizations do not have contracts for waste disposal, which was also a surprise.

One of the key conclusions drawn from the results of observations at the subnational level and the level of district warehouses is that similar problems that occur at these two levels are expectedly more pronounced at the district level, and, moreover, management of unforeseen situations is weakened at the district level. Thus, as the practice of organizing regional warehouses shows, within the existing regulatory framework, the normal functioning of the cold chain is possible, but at the district level this is probably hindered by a shortage of organizational resources, material and financial support.

At the level of medical organizations, in some aspects, compared with the level of district warehouses, there is a positive trend (for example, in terms of logistics), which may be associated with the availability of own funds and the needs of the medical organization as a whole (for example, the availability of generators for uninterrupted supply of electricity); at the same time, the level of formal attitude to the observance of the cold chain at the level of medical organizations is increasing, which may be due to greater remoteness from control centers and the presence of many other functions of the organization.

In general, it can be concluded that storage levels that are more distant from control centers and less focused on the tasks of providing a vaccination cold chain require more attention for their proper functioning.

The study recommendations are divided into 4 categories ("Business Processes", "Staff", "Equipment and Components", "Information Systems") and outlined in the roadmap format used by government agencies (with an indication of areas, activities, affected by regulations, responsible for the implementation of organizations).

Some of the most relevant recommendations are:

in terms of business processes: revision of RLA in terms of functional distribution between bodies and organizations involved in immunoprophylaxis; alignment of RLA with the principles of the WHO Guidelines for Storage and Transportation of Temperature and Time Sensitive Pharmaceuticals, and creation of the National Guidelines for the Storage and Transportation of Temperature and Time Sensitive Pharmaceuticals; approval of standard SOPs for EVM, their regional adaptation and use; regulation of the storage of vaccines that require ultra-cold temperature regimes; consolidation of the policy of maintaining a reserve level of vaccine stock at all levels; implementation of medical waste management monitoring;

in terms of staff capacity building: expanding the recommended topics of elective components within the professional development cycles of medical workers on cold chain issues and developing a relevant working curriculum; regular advanced training (including on-the-job) among specialists of HD storage facilities and medical workers on effective vaccine management;

in terms of infrastructure: regulation of requirements to refrigeration equipment, which ensure its compliance with international recommendations and WHO prequalification requirements; approval of the standard of refrigeration equipment and methods of calculating the volume of (ultra)cold chain at all levels of vaccine storage; improvement of the inventory of cold chain equipment; definition of requirements for the service maintenance of refrigeration equipment;

in terms of information systems: introduction of unified vaccine management software with the necessary integrations and continuous recording of refrigeration equipment temperature at all stages of vaccine transportation and storage.

Based on the study results, it is expected that state stakeholders will initiate an update of the RLA and consider the need for regular EVM 2.0 assessments.

STUDY RELEVANCE AND CONTEXT

UNICEF Kazakhstan Country Office started a series of immunization research studies as part of its child health agenda in conjunction with the COVID-19 pandemic. The (ultra)cold chain issues have become particularly relevant due to the distribution of Covid vaccines, in particular mRNA vaccines requiring special storage conditions. It was a major challenge for Kazakhstan, as well as for many other countries, to urgently process a significant volume of vaccines requiring special temperature conditions and to introduce the ultracold chain.

As a result of the emergence of new global infectious challenges (as well as local epidemiological peculiarities common in Kazakhstan), the requirements for cold chain immunization management have increased; at the same time, the introduction of cold chain assessment tools, which are currently lacking in Kazakhstan, is also required.

The study aims to bring new approaches to cold chain management: the most recent assessment (WHO, 2014, "Kazakhstan: Effective Vaccine Management Assessment") was conducted in the pre-pandemic era, based on the EVM 1.0 framework; other (local) methods of immunization infrastructure assessment, as well as reliable data from information systems, require further improvement. Thus, the study will assess the actual situation in the field and demonstrate the comprehensiveness of EVM tools.

Based on the study results, it is expected that key government stakeholders will initiate an update of the RLA and consider the need for regular EVM 2.0 assessments, and other stakeholders involved in the (ultra)cold chain will be able to use the proposed tools.

The significance of the study for these stakeholder groups is high because of the national political context, including the recently adopted Law No. 122-VII dated May 21, 2022 "On Biological Safety of the Republic of Kazakhstan" and the availability of a separate direction No. 2 "Formation of Modern Epidemiological Forecasting and Response System" in the "Healthy Nation" Quality and Accessible Health Care for Every Citizen National Project.

STUDY APPROACH

This section describes the approaches used in conducting the study, including various aspects of managing the process, engaging stakeholders, and providing them with information and opportunities to provide constructive feedback.

Roles and responsibilities of project team members

Funds for the implementation of this project were provided by the United States Agency for International Development (USAID) for UNICEF, as part of the COVID-19 Vaccine Roll-out project.

For the practical implementation of the study, the UNICEF Country Office in Kazakhstan entered into an agreement with the ALE in the FA "Health Analysts Association". At the same time, the following functions remained for UNICEF:

- development of the research concept;
- selection of an organization for the study;
- participation in the development of the study protocol;
- ensuring access to organizations involved in the provision of the cold chain;
- discussion of the preliminary results of the assessment with the researchers;
- discussion of the assessment results with national counterparts;
- participation in the preparation of the report.

Other roles and responsibilities were distributed as follows:

Table 3. Distribution of roles and responsibilities of the project team

No.	Command type / Function group	Roles	Responsibilities
1	Project management	PM / Analyst (Marat Mamayev)	Project management, analysis of aspects where no special knowledge is required

2	Methodological team	Team Leader (Ali Nurgozhaev)	Management of the methodological team; setting tasks; summarizing the final results; quality control
3		Methodologist (Lena Kasabekova, Gulmira Utesheva)	Implementation of the project in the methodological aspect
4		Cold Chain Specialist	Implementation of the project in a special technical part
5	Providing access to stakeholders and data	(Aidar Abdizhapparov)	Ensuring and accelerating access to stakeholders and data
6	Organization and conduct of interviews	Sociologist, recruiter, interviewers (PaperLab team: Serik Beisembaev, Anna Klimchenko, Saule Aliyeva)	Organization and conduct of interviews
7	Technical team	Text editor, Layout designer, Designer, Translators into Kazakh and English	Technical functions
8	Administration	Administrator, accountant	Project administration, including in the financial aspect

A comprehensive briefing was conducted with the members of the project team on the need to register and submit reports on possible undesirable phenomena during the implementation of the project. Also, the team members have successfully completed the relevant training on the issues of PSEA. No incidents were recorded during the study.

To ensure a comfortable working environment, all team members were instructed on the issue of reporting undesirable events that potentially occur in the workflow. An appropriate procedure has been established for the transmission of such messages, and an indicative range of possible responses has been preliminarily defined.

Data, record keeping and quality control

All records throughout the project were stored in a standardized (according to pre-designed forms) and mainly in electronic format; data were subjected to validity controls, including by requesting supporting documents and triangulation with results from other objectives (for example, answers received during interviews were compared with data from the field study).

Results quality control was conducted by team members distinct from the team mem-

bers who received the above results. This included quality control by comparing results within various objectives, joint discussions on the practical implementation of a previously defined methodology, etc.

Stakeholder engagement

Key stakeholders were formally informed of the study immediately after it started; at the same time, an extensive data set was requested; in the process of obtaining the data, the project team was able to explain the goals and objectives of the project to the stakeholders. All further activities, such as conducting a field study, were also formally coordinated both at the central level (CSEC) and with the regional bodies (DSEC, HD). In addition, there was direct participation of individual stakeholder representatives in the study as researchers, interview respondents, and trainers.

As expected, in terms of confidentiality, the interview data proved to be the most sensitive, and therefore the personal data of respondents were not reflected in the research paper.

Before presenting the study results, relevant materials were sent to the key stakeholder so that we could get their feedback. Later, in the course of a long (80-minute) presentation and discussion of the study results with the wide range of stakeholders engaged, stakeholders were given the opportunity to provide detailed feedback on the conclusions and recommendations of the study.

The results of the assessment (as well as the details of the study at all its stages) were discussed with the UNICEF Country Office in Kazakhstan. Clarifications on the Cold Chain Sizing Tool were received from Svetlana Stefanet (UNICEF), and valuable comments regarding the report draft were received from Priti Chaudhary and Hye Rin Park (UNICEF). In addition, inputs were received from the representatives of the national partners during the presentation of the results at the level of the Vice Minister of Health.

Ethical and documentary aspects

During the implementation of the project, the research team followed the UNICEF Procedures for Ethical Standards in Research, Evaluation, Data Collection and Analysis regarding ethical standards in research, evaluation, data collection and analysis. Document number CF/PD/DRP/2015-001 dated April 1, 2015, available on the web, has been duly reviewed and brought to the attention of the team members.

In the process of work, the principle of “do no harm” was applied, in particular, in the aspect of minimizing risks for study participants. Measures were also taken to prevent participants from unethically benefiting from the interventions. The latter was ensured at all stages of field work and in cooperation with third parties, mainly by signing relevant obligations with team members, regulating the minimum required level of information retrieved and requested, and by ensuring selectivity of communications between specific team members and other participants in the study, depending on the profile the activities of both.

All data were requested, and activities were agreed upon in a formal manner (through correspondence on behalf of UNICEF) to engage key stakeholders, ensure their acceptance of the data and research findings, and reliably record the stages of the study.

Respondents were verbally informed about recording the interview before the interview was conducted. An option to depersonalize the interview was provided; respondents were also informed that their data would not be mentioned in the public report, which helped to minimize bias that could be induced by the fact of the interview due to its focus on identifying gaps in the state system. There were no refusals received for the interview to be recorded.

The study results were presented by team members who were the most neutral towards the key stakeholders to minimize potential negative effects for team members who are dependent on these stakeholders to some level.

In the interest of ethical compliance, and to enhance the privacy and security of research participants, the report does not reflect directly or indirectly identifying information about research participants when it is not necessary.

In general, in all cases where it was required, data confidentiality was ensured, following the principle of the necessary minimum of information both within the research team and in external communications.

The study did not extract the personal data of patients or recipients of medical services and did not carry out other interventions that potentially jeopardize the observance of human rights, children's rights and gender balance and equity.

The main and final beneficiaries of the study are the children of Kazakhstan, since the results of the project are aimed at improving the immunization system, including routine immunization, that is, ensuring the right of children to health, equally for girls and boys. In addition, the applied implementation of the recommendations of the study will contribute to the proper organization of the HPV vaccination campaign for adolescent girls.

OVERVIEW OF THE REGULATORY LEGAL ACTS

The following documents form the basis of the legal and regulatory framework for the regulation of vaccination-related relationships (such as vaccine storage and transportation) as well as accounting and reporting documents for vaccine accounting and movement:

1. Code of the Republic of Kazakhstan dated July 07, 2020 No. 360-VI ЗРК "On public health and health care system".

2. Resolution of the Government of the Republic of Kazakhstan No. 612 dated September 24, 2020.

3. Order of the Minister of Health of the Republic of Kazakhstan dated July 19, 2021 No. ҚР ДСМ-62 On approval of "Sanitary and epidemiological requirements for storage, transportation and use of immunobiological medicinal products (immunobiologicals)" sanitary rules that determine the order of storage, transportation and use of immunobiological medicinal products (hereinafter - immunobiologicals).

4. Order of the Acting Minister of Health of the Republic of Kazakhstan dated June 13, 2018 No. 361 "On approval of "Sanitary and epidemiological requirements for preventive vaccination of the population" sanitary rules".

5. Joint Order of the Minister of Health of the Republic of Kazakhstan No. 463 dated June 26, 2017 and the Minister of National Economy of the Republic of Kazakhstan No. 285 dated July 20, 2017.

1. Overview of the RLA

Table 4. Issues not regulated by the RLA

No.	RLA/ field	Regulated	Not regulated
1	Order No. ҚР ДСМ-62/ Storage conditions	A number of forms and temperature conditions of storage of immunobiological products	– issues of storage of vaccines requiring special conditions, i.e. ultra-cold temperature regime (-70 ... -80°C); – requirements for ultra-cold chain equipment; – storage conditions of vaccines for each level separately

2	Order No. ҚР ДСМ-62 / Refrigerated and dry storage volume	General requirements for the sufficiency of refrigeration equipment, refrigeration and freezer rooms / chambers to meet the maximum level of immunobiologicals stock and the availability of redundant equipment in the cold chain	− method of compliance checking (comparing) the volume (capacity) of refrigeration equipment to the volume of the maximum stock of immunobiologicals. Calculation / planning of the necessary capacity of refrigeration equipment on a uniform methodology is not carried out; control compliance is carried out visually / subjectively; − Model Standards of Operating Procedures (hereinafter - SOP) in case of failure of refrigeration equipment or in emergency situations
3	Order No. ҚР ДСМ-62/ Buildings, refrigeration equipment	Requirements for the set of rooms, equipment, location, layout of storage, in addition, other RLA have requirements for the location of the storage, heating, ventilation, artificial and natural lighting	− specific requirements for the refrigeration equipment used to ensure compliance with international recommendations and, in particular, with WHO prequalification requirements for vaccine storage equipment; − requirement for a diesel generator set in case of a power outage;
			− regulations for the availability and number of thermocontainers and refrigerated units for vaccine evacuation in case of a power outage, as well as the vaccine evacuation plan itself;
4	Order No. ҚР ДСМ-62 / Transport	Requirements for the transportation of immunobiologicals (carriers, equipment of refrigerated trucks, temperature conditions, deadlines)	The need for an on-board temperature log for vehicles

5	Order No. ҚР ДСМ-62 / Maintenance of buildings, equipment	− preventive technical inspection of the condition of storage and their communal facilities, refrigeration equipment, refrigerating and freezing rooms or chambers; − calibration of temperature and humidity monitoring and monitoring devices.	Requirement to have a written plan for the supervision and preventive maintenance of buildings
6	Order No. ҚР ДСМ-62/ Inventory Management	Storage periods of immunobiologicals depending on the storage level	− the volume of the irreducible stock (maximum, minimum) of vaccines recommended by WHO for the country; − specific requirements for medical organizations and vaccination centers of schools conducting immunization on the planning of the immunization contingent in order to minimize the risks of disruption of the cold chain when returning vaccines to a higher level. In particular, when organizing and conducting revaccination against tuberculosis of 1st grade children in schools, the BCG vaccine should be obtained only after the results of the Mantoux reaction and determining the number of BCG to be revaccinated
7	Order No. ҚР ДСМ-62/ Effective distribution of vaccines	Issues of safe distribution (transportation) of vaccines: the use of thermal containers and their marking, thermal indicators	− availability of a schedule for each level, assignment, etc.; − model SOP for vaccine packaging; − FIFO (first in – first out) requirements for the use of vaccines

8	Order No. ҚР ДСМ-62 / The practice of effective vaccine management	Sanitary and epidemiological requirements for the safe use of immunobiologicals: compliance with storage temperature, transportation, expiration date, compliance with instructions, "open vial" policy, destruction of vaccine residues, return of unused vaccines	Accounting for vaccine losses and calculation of the corresponding indicator
9	Order of the Acting MH RK dated June 13, 2018 No. 361 / Inventory Management	The volume of the stock of vaccines and other immunobiological products provided for in the preparation of the annual plan of preventive vaccinations	The level of the irreducible supply of vaccines
10	Order of the Acting MH Rk dated June 13, 2018 No. 361 / Effective distribution of vaccines	Responsibility for the coordination and control of the completeness of preventive vaccinations to the population, population accounting and planning	Timing of planning with a preliminary account of the stock of vaccines at each level

2. Overview of accounting and reporting documentation

The Order of the Minister of Health of the Republic of Kazakhstan dated December 22, 2020 No. ҚР ДСМ-3133/2020 “On approval of the forms of accounting documentation in the field of healthcare" approves:

- form No. 3 of the report on the movement of vaccines and other immunobiological products;
- form No. 4 of the report on the coverage of preventive vaccinations.

According to these forms, the following types of organizations provide information monthly:

- outpatient polyclinic organizations;
- non-governmental medical (subdivisions) organizations;

- organizations (divisions) of other state bodies providing medical care to children, adolescents and adults;
- paramedic and obstetric stations in rural areas;
- district, city hospitals and (or) polyclinics;
- regional health departments;
- “Scientific and Practical Center for Sanitary and Epidemiological Expertise and Monitoring” branch of the National Center of Public Health of the MH RK RSE on REM.

In general, the structure of the report on Form No. 4 “On coverage with preventive vaccinations” meets the needs of stakeholders (HD, DSEC, SPCSEEM, CSEC MH RK).

Form No. 3 “On the movement of vaccines and other immunobiological products" does not contain reasons for writing off vaccines, this information is collected manually on a monthly basis.

Also, no changes have been made to both forms for COVID vaccination.

Both forms are not digitized, accounting is carried out manually, without any synchronization of the process and results with medical information systems (hereinafter – MIS), accounting storage systems, etc. This can cause inconsistencies between these forms and the actual situation.

There is no single approved reporting form on the availability of refrigeration equipment. The Sanitary and Epidemiological Service conducts internal monitoring of the availability of refrigeration equipment, within the framework of which the collection and compilation of aggregated data on the availability of refrigerators, freezers, thermocontainers is carried out.

3. Overview of the data of the reporting forms

Form No. 3 “Report on the movement of vaccines and other immunobiological products”

The data indicate that there are problems in the regions with the storage and rational use of immunobiologicals.

Write-off for 2020

The source of data for the analysis of the reasons for the write-off of vaccines was the Acts of write-off of vaccines collected from the regions. The collection / provision of such acts by the regions in the SPCSEEM is not reflected in RLA, however, relevant activities are regularly carried out.

Write-off due to expiration date: see Table 5.

Table 5. Write-off of immunobiologicals due to expiration date in the context of vaccines and regions for 2020

Vaccine name	Regions	Doses / ml.
DTaP+Hib+IPV+HBV	East Kazakhstan Region	1,456
	North Kazakhstan Region	149
	Atyrau region	170
	Turkestan region	372
DTaP+Hib+IPV	Turkestan region	539
BCG	North Kazakhstan Region	5,080
	Karaganda region	1,900
	Atyrau region	1,620
	Zhambyl region	800
	Kostanay region	800
	Almaty region	480
	Turkestan region	440
	Aktobe region	40
DTaP	East Kazakhstan Region	13
	Turkestan region	325
Measles, rubella and mumps vaccine	East Kazakhstan Region	75
	Turkestan region	386
Hepatitis B virus vaccine	Turkestan region	254
Hepatitis A virus vaccine	Atyrau region	1,930
	East Kazakhstan Region	2
Pneumococcal infection vaccine	Turkestan region	410
Td	Turkestan region	311

Tick-born encephalitis immunoglobulins	North Kazakhstan Region	157 ml
	Almaty region	53 ml
	Karaganda region	10 ml
Anti-rabies vaccine	Akmola region	31
	East Kazakhstan Region	4,805
	Karaganda region	212
	North Kazakhstan Region	219
	Turkestan region	258
Anti-rabies immunoglobulin	North Kazakhstan Region	69 ml
	Turkestan region	280 ml
Tularemia vaccine	North Kazakhstan Region	135
Tuberculin	Atyrau region	45
	North Kazakhstan Region	21

The leaders in writing off various types of vaccines are Turkestan, Atyrau, East Kazakhstan, and North Kazakhstan regions. The obvious systematics indicates the presence of specific vaccine management in the listed regions, with a positive connotation (if the reasons related to scrupulous and conscientious attitude to procedure execution prevail) or negative connotation (if the reasons related to inaccurate planning and inefficient management prevail). It is necessary to develop a methodology for monitoring and assessment, as well as criteria for determining regions and outlier incidents.

Write-off due to malfunction of refrigeration equipment: see Table 6.

Table 6. Write-off of immunobiologicals due to violations in the cold chain in the context of vaccines and regions for 2020

Vaccine name	Regions	Doses amount
MMR	Aktobe region	45
BCG		20
Typhoid fever vaccine		20
Anthrax vaccine		50
DTaP+Hib+IPV+HBV		128
Td		62
Oral poliomyelitis vaccine	Almaty region	410
Measles and rubella divaccina		700
Typhoid fever vaccine		25
Influenza vaccine		11

Write-off due to failure of current transformer in Shymkent: Measles and rubella divaccine (1,528 doses), DTaP (12 doses), DTaP+Hib+IPV+HBV (86 doses), DTaP+Hib+IPV (16 doses), BCG (240 doses), OPV (90 doses), tuberculin (90 ml), MMR vaccine (44 doses), Hepatitis B virus vaccine (30 doses), pneumococcal vaccine (76 doses), Hepatitis A virus vaccine (76 doses).

Write-off for 2021

A large volume of immunobiologicals were written off due to expiration in 2021, which indicates that the rational use approach was not followed (and also probably not enough "catch-up" vaccination) (see Table 7).

Table 7. Write-off of immunobiologicals due to expiration date in the context of vaccines and regions for 2021

Vaccine name	Regions	Doses amount
Tuberculin	Almaty region	9,964
	West Kazakhstan region	48
	Mangystau region	596
	North Kazakhstan Region	312
	Turkestan region	4,402
Plague vaccine	Shymkent	210
Anti-rabies vaccine	Akmola region	1,721
	Almaty region	2,896
	East Kazakhstan Region	55
	Zhambyl region	3,024
	West Kazakhstan region	40
	Karaganda region	169
	Kyzylorda region	779
	Mangystau region	2,231
	Turkestan region	20,208
	Shymkent	1,695
“Gam-COVID-Vac” Sputnik V 2 component	East Kazakhstan Region	11
QazCovid-in (QazVac)	Mangystau region	6
Anti-botulinum serum	Almaty region	106
	Zhambyl region	24
	Kyzylorda region	5
	Astana	183
Tick-born encephalitis immunoglobulins	Almaty region	135

Measles and rubella vaccine	West Kazakhstan region	100
	Kyzylorda region	360
Typhoid fever vaccine	West Kazakhstan region	45
DTaP+Hib+IPV	Akmola region	80
DTaP+Hib+IPV+HBV	Akmola region	366
DTaP	Akmola region	200
MRM vaccine	Akmola region	11

Write-offs of immunobiologicals due to violations of storage requirements (violations of the cold chain, power outages in vaccination centers) indicates insufficient control and monitoring of storage conditions of vaccines and other immunobiologicals by specialists in charge of this section of the work (see Table 8).

Table 8. Write-off of immunobiologicals due to violations in the cold chain in the context of vaccines and regions for 2021

Vaccine name	Regions	Doses amount
DTaP+Hib+IPV+HBV	Akmola region	23
	Mangystau region	124
DTaP+Hib+IPV	Akmola region	23
	Atyrau region	71
	West Kazakhstan region	4
	Mangystau region	135
DTaP	Akmola region	13
	Mangystau region	62
	North Kazakhstan Region	13
	Turkestan region	308

Oral poliomyelitis vaccine	Akmola region	20
	Mangystau region	40
Pneumococcal infection vaccine	Akmola region	36
	Mangystau region	128
Measles, rubella and mumps vaccine	Akmola region	25
	Mangystau region	164
Hepatitis A virus vaccine	Akmola region	24
	Mangystau region	244
	North Kazakhstan Region	2
Td	Mangystau region	100
“Gam-COVID-Vac” Sputnik V 1 component	Almaty region	420
	Kostanay region	1,245
	Mangystau region	415
“Gam-COVID-Vac” Sputnik V 2 component	Almaty region	290
	Mangystau region	75
	Astana	300
QazCovid-in (QazVac)	Mangystau region	71
Tuberculin	Mangystau region	3
CoronaVac	Mangystau region	135
Hepatitis B virus vaccine	Mangystau region	8
	Turkestan region	140
BCG	Turkestan region	480
Anti-rabies vaccine	Turkestan region	245
Grippol Plus	North Kazakhstan Region	1
SARS-CoV-2 (Vero Cell) Vaccine	Karaganda region	500
	Kostanay region	381

The write-off of immunobiologicals for other reasons indicates a weakening of control by specialists of sanitary and epidemiological control (see Table 9).

Table 9. Write-off of immunobiologicals for other reasons in the context of vaccines and regions for 2021

Vaccine name	Regions	Doses amount
Write-off due to breakage and cracks		
DTaP+Hib+IPV	Atyrau region	71
	West Kazakhstan region	4
"Gam-COVID-Vac" Sputnik V 1 component	West Kazakhstan region	10
QazCovid-in (QazVac)	West Kazakhstan region	3
	Kostanay region	9
CoronaVac	West Kazakhstan region	1
Write-off due to non-compliance with the attached instructions		
Anti-rabies immunoglobulin	North Kazakhstan Region	35
Write-off due to negligence of a medical worker		
CoronaVac	Mangystau region	1

Consumption per 1 vaccination

According to the results of the analysis of the data of Form No. 3 for December 2021, a number of obvious deviations from the norm were revealed in the column "Expenditure per vaccination" (the ratio of vaccines used during the period to the number of vaccinations made in a given month) (while in the vast majority of cases, the corresponding vaccinations were carried out in a statistically sufficient volume):

Table 10. Deviations in the consumption of doses per one vaccination for 2021

Vaccine name	Deviation type
Td	with a maximum value in other regions of 1.16 and an average of 1.09, in Kostanay region – 1.30, in Pavlodar – 1.54
BCG	the values are evenly distributed from 1.92 (Pavlodar region) to 3.96 (Akmola region), thus the spread between the minimum and maximum values of the spectrum exceeds 2 times
Oral poliomyelitis vaccine	with a maximum value in other regions of 1.63 and an average of 1.56, in Almaty region – 2.26, in Zhambyl region – 2.54
Hepatitis B vaccine	with a maximum value in other regions of 1.17 and an average of 1.12, in Akmola region – 1.47, in Zhambyl region – 1.46
Anti-rabies vaccine	with a value of 1.0 in all other regions, in the Turkestan region – 4.76, in Atyrau region – 0.69
Hepatitis A vaccine	with a value of 1.0 in all other regions, in the Karaganda region – 0.12
Tularemia vaccine	the spread between the minimum and maximum values of the spectrum is from 1.0 in Zhambyl region to 2.31 in Karaganda region
Anthrax vaccine	in Almaty region – 0.94
Covid vaccine	with a value of 1.0 in all other regions, in Kostanay region – 1.42
Covid vaccine (component 2 of Gam-COVID-Vac)	with a value of 1.0 in all other regions, in Kostanay region – 1.33
Covid vaccine (QazCOVID-in)	with a value of 1.0 in all other regions, in the Pavlodar region – 0.95

Cases with a noticeable excess of the average consumption per one vaccination are due to differences in the regional practice of using multi-dose packaging of vaccines (10-dose). This most likely indicates that practice varies widely in the field, there is not even minimal standardization of operating procedures, and, according to operational information, there is no disciplinary action by governing bodies for vaccine overuse (consequently, there are also no approved approaches to assessing the effectiveness of vaccine management). Under such conditions, it is difficult to make a reasonable assessment of the effectiveness of vaccine management. This situation has the most obvious consequence of problems with the accuracy of planning the volume of demand, procurement, and supplies.

The cases when the consumption per one vaccination (in the accepted forms for previous periods) is less than 1.0 vaccine (as well as their rather frequent occurrence) show the low quality of data, the lack of format-logical control, the procedures of data validation at the level of governing bodies.

Monitoring the availability of refrigeration equipment

The source of data on monitoring - "Comparative data on the availability of refrigeration equipment in medical organizations of the region, carrying out the immunoprophylaxis programme in the RK for 6 months of 2022" analytical table, which is collected under the lack, as mentioned above, of a single approved reporting form on the availability of refrigeration equipment.

In 2021 there were 6,317 vaccination rooms in Kazakhstan, the provision of refrigeration equipment, thermocontainers amounted to 100%. At the same time it is necessary to replace 73 refrigerators, including in Almaty (9), West Kazakhstan (14), Kostanay (14), Kyzylorda (2), North Kazakhstan (2), Turkestan (16) regions and Shymkent city (4). It is necessary to purchase additional 35 refrigerators, including in Almaty (2), Atyrau (4), West Kazakhstan (1), Kostanay (10), Kyzylorda (4), Mangistau (6), North Kazakhstan (5), Turkestan (2) regions.

According to the results of the analysis of the "Total thermocontainers needed" column (since the data of other columns are subjective interpretations), there is no need for thermocontainers in all regions except Akmola (25), Kyzylorda (15), Mangystau (16), Turkestan (66) regions and Shymkent city (14). Such polarization indicates a lack of norms for equipment, calculations that do not follow unified methodologies, and biased filling out of forms.

FIELD STUDY AND INTERPRETATION OF ITS RESULTS

1. Methodology

1.1. The questionnaires for the field study were compiled as follows:

- The EVM 2.0 questionnaire shown in the EVM Assessor application removed questions that record factual information (responses to these questions are probably used by the internal logic of the automated questionnaire to make adjustments to the shown questions and possibly in assigning points for responses; however, without access to the internal logic of the questionnaire, there was no need to address these questions);
- questions with a "yes" or "no" answer not allowing a clear decision on the assignment of a point are removed;
- questions that are not related to the primary meaning of the cold chain are removed;
- The remaining questions are distributed across the 9 EVM criteria (E1 Vaccine and Goods Arrival Procedures; E2 Vaccine Storage Temperatures; E3 Cold and Dry Storage Capacity; E4 Buildings, Refrigeration Equipment and Transportation; E5 Maintenance; E6 Inventory Management; E7 Efficient Distribution; E8 Effective Vaccine Management Practices; E9 Information Systems and Supporting Management Functions).

In conclusion, pre-testing of the questionnaires was carried out by the method of consultation and simulation within the research team to clarify the wording of the questions.

The field survey questionnaire is presented in Appendix 3.

1.2. The operation of the equipment was observed and inspected, which, along with items 1.3, 1.4 and 1.5, facilitated the triangulation of the information obtained during the completion of the questionnaires with more unbiased sources.

1.3. A demonstration of medical workers' activities while working with the cold chain was requested.

1.4. To verify the answers, the documentation (maintenance, financial, etc.) was reviewed.

1.5. An overview of the functioning of information systems and work in them was carried out.

The assessment was carried out in Aktobe and Turkestan regions in September 2022 in the following medical organizations regarding the level of supply:

Table 11. Regions and facilities covered by the study

Region	Subnational level (regional storage facilities)	District	Медицинские организации
Aktobe region	Regional vaccine storage in Aktobe	storage facilities	Medical organizations
			Rural outpatient clinic of Tamdy village
		District storage at the Shalkar District Hospital	Rural outpatient clinic of Zhyltyr village
			Rural outpatient clinic of Baykadam village
Turkestan region	Regional vaccine storage Shymkent	District vaccine storage Turkestan	Turkestan City Polyclinic
			"Akmaral" Hospital Institution
		District vaccine storage at the Saryagash district CDH	Polyclinic of the Saryagash district CDH
			Kyzylzhar Rural Outpatient Clinic

2. Potential limitations of the study

- the study is limited to 2 regions (usually a continuous assessment is carried out);
- the study is limited to cold chain issues (all aspects of vaccine management are studies as standard);
- data collection and validation were carried out by the same consultants;
- due to the lack of country access to EVM 2.0, the logical controls available in the current version were not used;
- a flat point system was used by adding positive and negative answers to each questionnaire question.

3. Summary results

Table 12. Summary results

Points according to criteria	E1 Vaccine and Goods Arrival Procedures	E2 Vaccine Storage Temperatures	E3 Storage and Transportation options	E4 Buildings, Refrigeration Equipment and Transportation	E5 Maintenance	E6 Inventory Management	E7 Efficient Distribution	E8 Effective Vaccine Management Practices	E9 Waste management
regional storage facilities	64.2	60	78.7	70	90	60.4	100	n/a*	75
district storage facilities	78	50	68.5	82.9	69	61.2	100	96.4	75
medical organizations	n/a*	21	80.4	72.8	67.5	30.4	n/a*	91.1	87.5

* n/a – not applicable
** 80+ high score; 60+ average score; 60- low score

It should be noted that UNICEF experts, as well as WHO staff involved in this topic, stated during discussions that, due to the limitations of the methodology and the fact that the study was only conducted on a small sample of regions and medical organizations, the quantitative results should be interpreted with caution and cannot be used as conclusive and definitive estimates.

4. Subnational level results

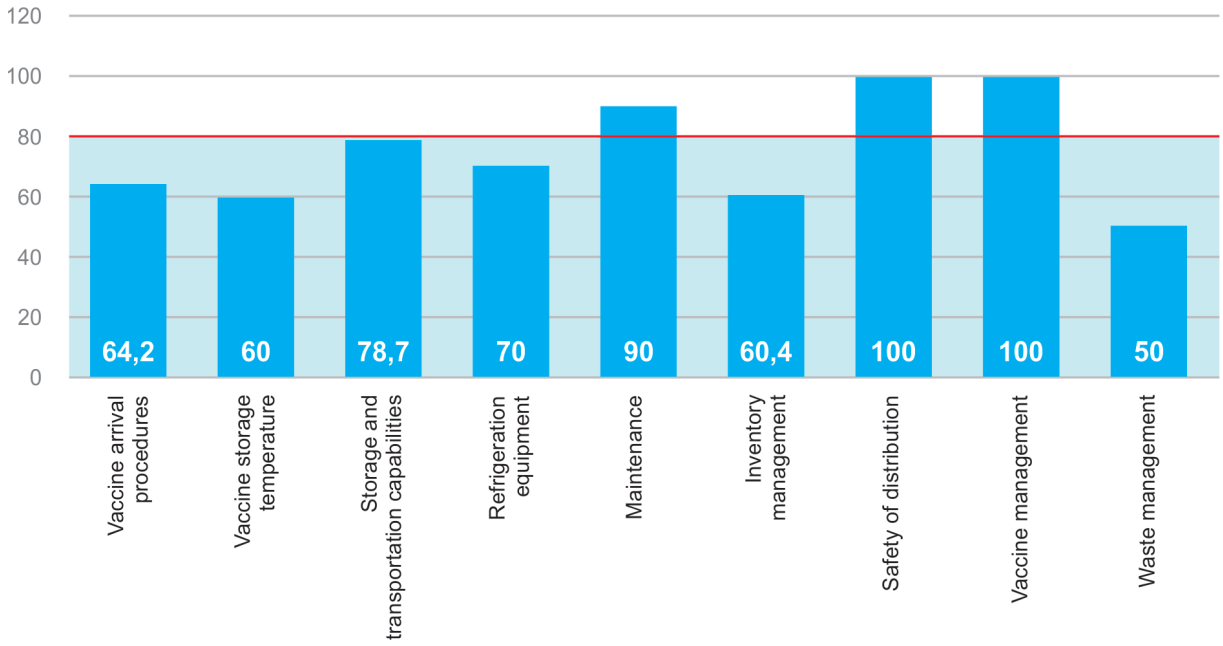
4.1. The results of the assessment of storage facilities at the subnational level

Table 13. Results of the subnational level assessment

№	Criteria	Point	Explanations (key issues)
E1	Vaccine arrival procedures in subnational storage facilities	64.2%	− lack of an organized system and record of notification of the vaccine arrival; − lack of an incoming vaccine tracking system; − lack of a computerized system for drawing up vaccine acceptance certificates; − vaccine acceptance certificates and accompanying documents are not stored for 3 years.
E2	Compliance of vaccine storage temperature monitoring	60.0%	− lack of a complete automated system for continuous monitoring of temperature conditions, records are kept manually on paper, leading to incorrect records of the temperature of Refrigeration equipment; − cold chain temperature logs are not stored for 3 years; − records of thermal recorders of refrigerated trucks are not stored; − alarm records are not viewed at least once a month.
E3	Compliance with storage and transportation capabilities	78.7%	− in one of the storage facilities, the ventilation and air conditioning system is out of order, the sanitary condition of the building does not meet the requirements (vaccine storage facilities are located in the buildings of medical organizations; there are leaks on the ceiling since 2021, inspection certificates of 2021, the cause is not identified and not eliminated), the building electrical supply does not meet the requirements; − the storage facilities do not provide rooms for packaging and unpacking vaccines; − emergency plans are not available in every location in case of failure of refrigeration equipment and emergencies.

E4	Infrastructure and equipment of the institution	70%	− maintenance of the buildings is not carried out properly in all storage facilities: deficiencies in terms of backup refrigeration equipment since 2021 have not been eliminated; − the volume of refrigeration equipment does not meet the maximum supply of vaccines, especially during the influenza vaccination period, when the maximum amount of vaccines is delivered to the regions; − the amount of refrigeration equipment is insufficient, given the plan to include new vaccines (HPV) in the National Vaccine Calendar starting from 2024.
E5	Maintenance and repair of refrigeration equipment and vehicles	90.0%	Maintenance of the refrigeration equipment is carried out regularly. One of the storage facilities has 1 reserve chamber and 1 non-functioning refrigerator
E6	Inventory management policy and practice	60.4%	− keeping records and movement of vaccines is carried out untimely; − not all columns are filled in the logs; − the reserve is provided only for the 1st quarter of the following year; − there is no record of vaccine loss; − standard operating procedures have not been developed.
E7	Safety of distribution of vaccines and dry goods	100%	The distribution of vaccines is carried out according to the annual immunization plan. There are accompanying documents available for each batch of vaccines delivered, and each batch of vaccines is accompanied by thermal indicators along the way.
E8	Vaccine management	-	-
E9	Waste management	50.0%	− the issue of medical waste management has not been solved in general; − there are quarantine areas for vaccines subject to a decision, but the issue of disposal is not provided for; − no waste disposal contracts have been concluded.

Diagram 1. Results of the subnational level assessment



4.2. Knowledge of medical workers at the subnational storage level

Based on discussions with storage staff, it would be beneficial to continue to improve knowledge of vaccine inventory management, use of thermal indicators, vaccine rejection and disposal, accounting for unopened vial losses, and the timing and procedure of the "shake test".

4.3. Conclusions on the subnational level

Strengths: the distribution of vaccines is carried out according to the immunization plan in the context of districts, accompanying documents for the dispensed batch of vaccines are available and for each batch of vaccines is accompanied by thermal indicators on the way. Storage staff are trained and certified to work with vaccines. Medical vehicles are used to transport vaccines, and medical workers who have been certified in the workplace have been designated to transport them. All planned deliveries have been completed.

Weaknesses: no organized system and no record of notification of vaccine arrivals, no system for tracking incoming vaccines, no computerized system for compiling a vaccine acceptance report. Problems with storing documents. Lack of a complete automated system for continuous monitoring of the temperature regime, recording of thermoregisters of refrigerated trucks, viewing of alarms. Keeping records and the movement of vaccines is carried out untimely, there is no record of the loss of vaccines. Standard operating procedures have not been developed.

5. Results of the level of regional vaccine storage facilities

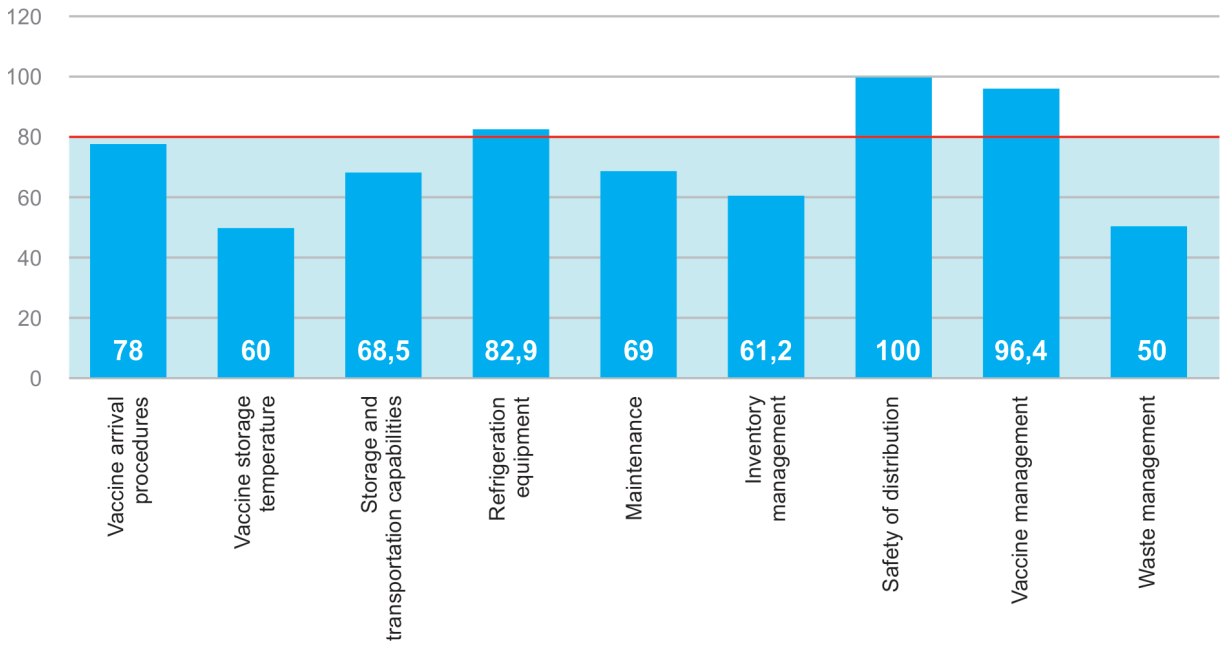
5.1. The results of the storage assessment of the district storage level

Table 14. Results of the assessment of the level of regional storage facilities

No.	Criteria	Point	Explanations (key issues)
E1	Vaccine arrival procedures in subnational storage facilities	78,0%	− lack of an organized system and record of notification of the vaccine arrival; − lack of an incoming vaccine tracking system; − lack of a computerized system for drawing up vaccine acceptance certificates.
E2	Compliance of vaccine storage temperature monitoring	50,0%	− lack of an automated system for continuous monitoring of temperature conditions, records are kept manually on paper, leading to incorrect records of the temperature of refrigeration equipment; − alarm records are not viewed at least once a month; − there are no records of emergency situations in the cold chain; − at one of the facilities, cold chain temperature logs are not stored for 3 years.
E3	Compliance with storage and transportation capabilities	68,5%	− there are no premises for packing and unpacking vaccines, areas are allocated for this work; − emergency plan is not drawn up in every location in case of failure of refrigeration equipment and emergencies. − 50% of the facilities do not have a fuel reserve for the generator to provide uninterrupted electricity.
E4	Infrastructure and equipment of the institution	82,9%	− in 75% of the facilities, major repairs have not been carried out in the last 3 years, there is no schedule for maintenance of buildings or premises; − the amount of refrigeration equipment available is insufficient for the maximum supply of vaccines in September; − 50% of facilities do not have air conditioning systems, backup refrigerators.

E5	Maintenance and repair of refrigeration equipment and vehicles	69,0%	− there are no maintenance schedules for vehicles in all facilities; − in 25% of the facilities, there are no contracts for the maintenance of vehicles.
E6	Inventory management policy and practice	61,2%	− there is no vaccine supply in all facilities; − no action plan and SOP for contingencies at the vaccine storage facility have been developed; − there are gaps in records, documentation is filled in poorly; − in one of the facilities, the actual amount of vaccines left in the refrigerator does not match the amount of vaccines in the vaccine logs;
E7	Safety of distribution of vaccines and dry goods	100%	
E8	Vaccine management	96,4%	− in one of the facilities there are no labels indicating the expiration date of vaccines on the equipment.
E9	Waste management	75,0%	− most facilities do not have waste disposal schedules.

Diagram 2. Results of the assessment of the level of regional storage facilities



5.2. Knowledge of medical workers at the district storage level

Based on discussions with storage staff, it would be beneficial to continue to improve knowledge of vaccine inventory management, the use of thermal indicators, and the timing and procedure of the "shake test."

5.3. Conclusions on the district storage level

Strengths: the distribution of vaccines is carried out according to the immunization plan, accompanying documents for the dispensed batch of vaccines are available and for each batch of vaccines is accompanied by thermal indicators on the way. Storage staff are trained and certified to work with vaccines. Medical vehicles are used to transport vaccines, and medical workers who have been certified in the workplace have been designated to transport them. All planned deliveries have been completed.

Weaknesses: very low points for monitoring the temperature of vaccine storage, there is no automated system for continuous temperature monitoring, paper media often contain erroneous records, there is no information about temperature fluctuations, the same temperature of refrigeration equipment is constantly indicated, there is often a shortage/lack of fuel for generators. There is no irreducible supply of vaccines, an action plan and SOP for contingencies at the vaccine storage facility have been developed; There are no maintenance schedules for vehicles in all facilities; In 25% of the facilities, there are no contracts for the maintenance of vehicles.

6. Results of medical organizations level

6.1. The results of the storage assessment of the medical organizations level

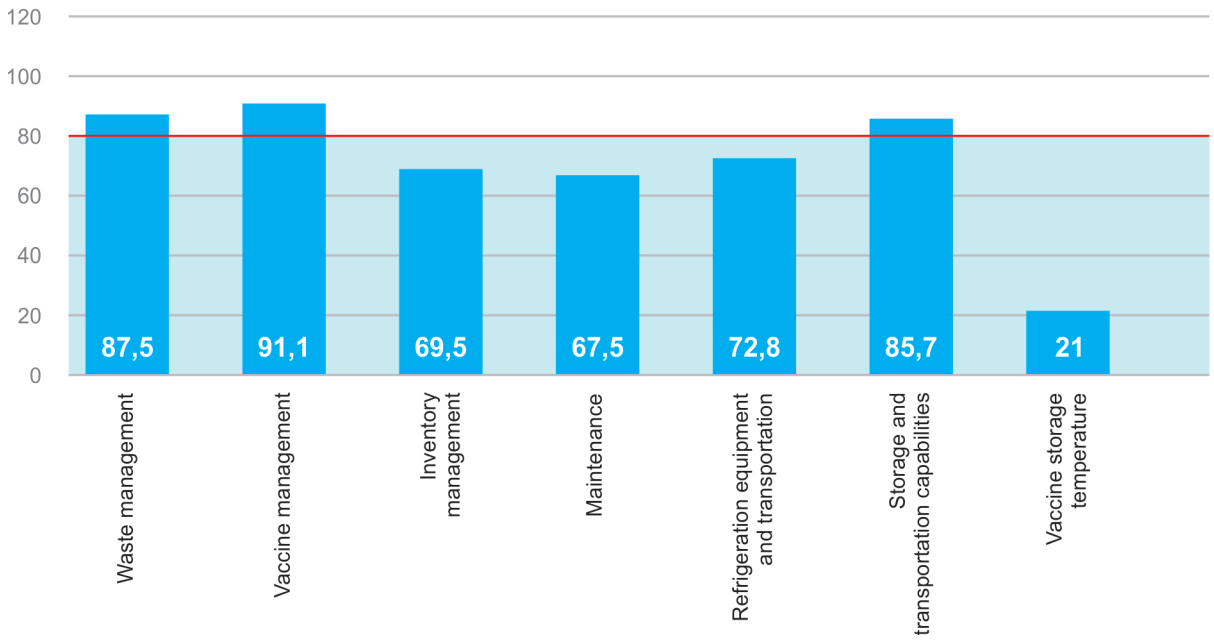
Table 15. The results of assessment of the medical organizations level

No.	Criteria	Point	Explanations (key issues)
E1	Vaccine arrival procedures in subnational storage facilities	-	-
E2	Compliance of vaccine storage temperature monitoring	21,0%	− refrigerators are equipped with thermometers for cold chain compliance, records are kept manually; in one medical organization one refrigerator was equipped with one thermometer, the other refrigerator was without a thermometer;

			− cold chain temperature logs are mostly filled in fictitiously, they do not comply with the forms, the records are not kept for 3 years; − records of emergency power outages are not reviewed, at the time of assessment there was a power outage in one medical organization, the record was not recorded in the log, no corrective measures have been taken.
E3	Compliance with storage and transportation capabilities	85,7%	− vaccines are stored in the refrigerators of the vaccination room in a safe environment; − medical organizations are equipped with generators for an uninterrupted supply of electricity for emergencies; − more than 60% of medical organizations do not have an emergency plan in case of an emergency to ensure the cold chain.
E4	Infrastructure and equipment of the institution	72,8%	− in most medical organizations (60%) there is no backup refrigerator equipment; − the volume of refrigeration equipment in one medical organization does not match the volume of vaccines supplied, given that this medical organization distributes the vaccine received to its two branches; − medical organizations are not equipped with air conditioning; − the room temperature logs are filled in fictitiously, the log data indicators do not correspond to the hygrometer indicators.
E5	Maintenance and repair of refrigeration equipment and vehicles	67,5%	− two medical organizations have not concluded a contract for the maintenance of refrigeration equipment; − in most cases, maintenance of refrigeration equipment was not carried out; − an ambulance is used to transport vaccines from a storage to a medical organization; − in one organization there is no contract for the verification of thermometers for refrigerators.

E6	Inventory management policy and practice	69,6%	− record keeping and movement of vaccines is not done in a timely manner, not all columns are filled in the logs, the logs do not match the forms, the remains of vaccines do not match the balances according to the logs; − the reserve is provided only for the 1st quarter of the following year; − there is no record of vaccine loss; − standard operating procedures have not been developed with an action plan in case of refrigerator breakage, power outages and emergencies.
E7	Safety of distribution of vaccines and dry goods	-	-
E8	Vaccine management	91,1%	− in 25% of medical organizations, labels indicating the type of vaccine, batch number and expiration date are not pasted on refrigerator shelves.
E9	Waste management	87,5%	− one medical organization has not signed a contract for the disposal of medical waste.

Diagram 3. The results of assessment of the medical organizations level



6.2. Knowledge of medical workers at the medical organizations level

Based on discussions with health care providers, it would be beneficial to continue to improve knowledge of vaccine inventory management, the use of vial thermal indicators, vaccine rejection and disposal, and the main types of losses of unopened vials.

6.3. Conclusions on the medical organizations level

Strengths: All medical organizations are provided with generators for an uninterrupted supply of electricity, the supply of vaccines is carried out according to the vaccination plans for the current year.

Weaknesses: there is a fictitious control of cold chain observance in medical organizations, as evidenced by thermometer readings during the year without change (+4 ... +8 °C), accounting and reporting forms are not timely kept, they do not correspond to forms, there are no SOP with action plans in case of refrigerator breakdown, power outage and emergencies in medical organizations.

INTERVIEWS WITH EMPLOYEES WORKING WITH THE COLD CHAIN AND INTERPRETATION OF ITS RESULTS

1. Methodology

Interviews were conducted in online format (with recording and further transcribing) via Zoom web communication platform in accordance with the previously developed questionnaire (separate questionnaires for different types of respondents) during September and October 2022 on the following list of respondent types:

The main criterion for the formation of the sample of respondents was its completeness: coverage of all levels of organization of the cold chain (starting from the level of regulation and management - the Committee, SK-Pharmacy, regional level management structures and ending with the level of a medical organization, as well as all links of the cold chain included in the study - from regional warehouses to the final point of vaccination - PHC).

From a territorial perspective, the sample covered 2 cities of republican significance out of 3, two regions (Aktobe and Kyzylorda) in which the field assessment was carried out, as well as other southern and western regions, for higher comparability of answers and information obtained by different methods.

The sample size of 20 respondents allowed all the above criteria to be met. As a result, the interviews were conducted according to the following list of types of respondents:

Table 16. Regions and types of respondents

No.	Region	№	Specialty / place of work
1	Turkestan region	1	DSEC Specialist
2	Aktobe region	2	Specialist of the Health Department (hereinafter – HD)
3	Kyzylorda region	3	Employee of the regional vaccine storage facility
		4	Head of the Department of the Department of Sanitary and Epidemiological Service (hereinafter – DSEC)
4	West Kazakhstan region	5	Deputy Head of the Regional Center for the Prevention and Control of AIDS
5	Zhetysu region	6	Head of the DSEC Department
		7	Epidemiologist of the City Polyclinic (hereinafter – CP)
6	Almaty region	8	Immunologist of the Central District Hospital (hereinafter – CDH)
		9	CDH Specialist
7	Almaty	10	CP Immunologist
		11	Epidemiologist at the branch of the Scientific and Practical Center for Sanitary and Epidemiological Expertise and Monitoring of the National Center for Public Health (hereinafter - SPCSEEM NCPH of MH RK)
		12	DSEC Specialist
		13	Allergist-immunologist of a Private Medical Organization, trainer of the Asfendiyarov KazNMU Simulation Center, consultant Sanitary and Epidemiological Service for Immunoprophylaxis
8	Zhambyl region	14	HD Epidemiologist
		15	DSEC

9	Astana	16	Management of Samruk-Kazyna Pharmaceuticals LLP (hereinafter – SK-Pharmacy)
		17	SK-Pharmacy Specialist
		18	SK-Pharmacy Specialist
		19	Epidemiologist of the SPCSEEM NCPH OF MH RK
		20	Specialist of the Committee for Medical and Pharmaceutical Control (hereinafter – CMPC of MH RK)

Pre-testing of the questionnaires was carried out with the involvement of relevant specialists (1 for each questionnaire), to clarify the wording of the questions.

Interview questionnaires are presented in Appendixes 4 and 5.

At the end of the interview, the results were triangulated with the results of the field study to verify the answers of the respondents.

2. Results of interviews with employees of PHC organizations: third level (city and district)

The main blocks of questions for physicians of medical organizations are questions related to cold chain compliance (22 questions), as well as documents regulating cold chain compliance (2 questions).

Availability of equipment

According to respondents, the cold chain equipment is available in full. However, not all regions/medical organizations have/are using special equipment to provide ultra-low temperature cold chain.

Maintenance of cold chain equipment

Active equipment upgrades and additions, including retrofitting of electric thermal containers to transport the Sputnik V vaccine and refrigerators, were carried out during the active phase of the COVID-19 pandemic. However, maintenance of refrigeration equipment, including recently purchased, needs to be additionally addressed.

Temperature monitoring

Transportation of vaccines from the storage facilities is provided by medical organizations that are equipped with thermal containers. In general, thermal control at the stage of transportation and storage of vaccines in medical institutions is carried out manually, without the use of any unified system of operational monitoring of the temperature regime at all stages of transportation and storage of vaccines in medical institutions.

Thermal control in medical organizations is carried out manually:

- the collection of temperature measurements of refrigeration equipment according to the schedule is not automated,

- records are made on paper (the corresponding temperature log),
- electronic records are limited to entering data into tables based on MS Excel software.

In some cases, refrigeration equipment with a built-in electronic thermometer may not account for temperature differences in different parts of that refrigeration equipment. In this case, it is compensated by the use of ordinary thermometers.

Uninterrupted operation

Temperature stability of the refrigeration equipment during power outages is ensured by the autonomous generators. According to respondents, medical organizations, among others, have an action strategy in place in the event of a requirement to transport vaccinations in the event of a lengthy power outage or in an emergency circumstance (which, however, contradicts the results of the field study in at least two pilot regions, which revealed the absence of appropriate standards of operating procedures in this part or their formality).

Vaccine management and volume planning

The whole management process and planning of vaccine volumes is done manually, without a unified system of digital data collection, transfer and exchange.

Coverage of compliance with cold chain issues in the professional development process

Topics of advanced education, training, and professional development focus on outreach, communication with the public, and vaccination coverage. Topics of professional development (additional, informal education) on the provision and compliance with the cold chain were not mentioned by respondents.

3. Results of interviews with specialists at the national, subnational level: HD, DSEC

Focus is given to planning, management of inventory items (here - vaccines) in storage, monitoring temperature regimes, transportation of vaccines to medical organizations.

Regional Health Departments (hereinafter - HD) annually plan vaccine volumes for three years with annual adjustments, the plan is agreed with the Committee for Sanitary and Epidemiological Control (hereinafter - CSEC) and approved by the management of the local executive body (hereinafter - LEB). The agreed and approved plan is transferred to Samruk-Kazyna Pharmaceuticals LLP (hereinafter – SK-Pharmacy) with further updating of data related to volume adjustment. HD purchases only tuberculosis vaccines and anthrax vaccines.

Regional storage facilities for vaccines are located at medical organizations (regional hospitals, AIDS centers, polyclinics and other healthcare entities). Operating expenses for the maintenance of storage facilities are managed by medical organizations, HD

finances the maintenance within budget funds. However, the financing of storage operations (their maintenance) is often considered to be an additional financial burden by representatives of medical organizations.

HD representatives state that the regulatory legal acts (hereinafter - RLA), regulating the cold chain, fully cover all the aspects on the basis of which the SOPs are defined. At the same time, the same respondents acknowledge the fact that the standard of equipping with refrigeration equipment is not approved by the RLA and the process of calculating the need is not regulated.

The management of inventory items vaccines in storage facilities is rarely carried out with the help of special information programs.

Vaccines are transported to medical organizations, including for the ultra-low temperature cold chain by refrigerated trucks.

There is no unified information system for transportation management, accounting, and inventory management of vaccines in storage facilities.

Service providers for medical organizations within the framework of public procurement are responsible for the maintenance of refrigeration equipment at medical organizations.

There is quarantine of vaccines. It is conducted in case of violations of the requirements to ensure the cold chain. Control of compliance with the requirements of the RLA (state control) is carried out by the DSEC. HD conducts monitoring visits to warn and prevent violation of requirements.

Respondents point out the lack of tools at the national level to influence the upgrade of refrigeration equipment purchased by local executive bodies at the subnational level.

4. Results of interviews with specialists at the subnational level: SK-Pharmacy, national centers

The exchange of operational data related to the provision of the cold chain during transportation between SK-Pharmacy and distributors is carried out only if there are relevant requirements in the contract. Operational temperature monitoring of cold chain equipment during vaccine transportation is performed by temperature sensors.

There is no information system for collecting, processing and exchanging data for vaccine planning, automated temperature monitoring.

Respondents pointed out the following main problems:

- insufficient number of staff-employees of the cold system system in polyclinics and storage facilities;
- the need to expand and deepen coverage of medical workers with training courses related to immunoprophylaxis and cold chain maintenance.

KEY PROBLEMS OF THE COLD CHAIN

1. Problems of the central level

RLA do not regulate:

- equipment standard for refrigeration equipment, the calculation process of its needs (the required volume of cold chain in the context of temperature regimes),
- technical requirements for cold chain equipment according to WHO prequalification;
- the volume of the undiminished supply of vaccines recommended by WHO for the country.

There is no comprehensive information system for both cold chain and immunization management generally and for reliable temperature monitoring at all stages of vaccine distribution and transportation.

2. Storage/Medical organization level problems

- There are no SOP at the level of storage facilities and medical organizations, or they are simply word-for-word excerpts from the MH RK Orders and their appendices;
- 25% of medical organizations have not signed a contract for the maintenance of refrigeration equipment (an unexpected finding due to a direct violation of the procedure);
- in 50% of district storage facilities and 60% of medical organizations there is no backup refrigeration equipment;
- in 50% of district storage facilities, there is no fuel supply for the generator to provide uninterrupted electricity. There is no SOP for emergencies almost everywhere;
- the issue of medical waste management has not been solved: contracts for its disposal have not been concluded (also an unexpected finding).

LESSONS LEARNED

An analysis of the cold chain problems and findings in the research process indicates that the presence of regulations fixed by legal acts (including those related to financial discipline and public procurement practices) and even the likely liability for failure to comply with such regulations does not mean their automatic implementation.

In connection with this observation, the need for routine and reliable monitoring of all processes associated with the cold chain increases as these processes and the organizations providing them move away from the starting point and from the central level.

The use of continuous (where possible), selective (in more advanced procedures) and automated monitoring methods would expand its coverage and depth in all aspects, and therefore increase the likelihood of proper fulfillment of cold chain requirements.

RECOMMENDATIONS

Table 17. Recommendations

No.	Category	Activity	RLA	Ex
1	**Business processes**			
1.1	Revision of the RLA, SOP	* To revise the RLA governing the storage, transportation and use of vaccines and other immunobiological products, ensuring a clear distribution of functionality between the bodies and organizations involved in immunoprophylaxis (MH, CSEC, CMPC, NCEMMD)	Orders of MH RK No.62, No.361	MH, CSEC, CMPC
1.2		To revise and supplement the Orders of MH RK No. 62 and No. 361 in accordance with the principles of the WHO Guidelines for the Storage and Transportation of Temperature- and Time-sensitive Pharmaceuticals. To consider creating a National Guideline for the Storage and Transportation of Temperature- and time-sensitive pharmaceuticals. To provide for the use of freezing indicators on the route of vaccines sensitive to freezing, to introduce a "shake test" at all levels of vaccine storage	Orders of MH RK No.62, No.361	CSEC
1.3		To develop and approve model standard operating procedures for effective vaccine management at the national level by the appendices of the Order of MH RK No. 62. To adapt these model SOPs/methodological guidelines for sub-national, district and medical organization levels (cold chain contingency and emergency response plan, procedures for vaccine packaging, storage and distribution, cleaning and maintenance of refrigeration equipment, thermocontainer packaging, use of multi-dose vials in accordance with WHO Policy, etc.) with consideration of regional specificities	Order of MH RK No.62	CSEC

1.4	Planning	To include requirements for medical organizations and immunization offices of schools conducting immunization to plan the contingent for immunization in order to minimize the risks of cold chain violation when vaccines are returned to the higher level, in Order of the MH RK No. 361. In particular, when organizing and conducting revaccination against tuberculosis of 1st grade children in schools, the BCG vaccine should be obtained only after the results of the Mantoux reaction and determining the number of BCG to be revaccinated	Order of MH RK No. 361	CSEC
1.5	Distribution	To include in the Order of MH RK No. 361 issues of effective distribution of vaccines in general, including the availability of a schedule for each level, discharge, etc.	Order of MH RK No. 361	CSEC
1.6	Transportation	To include in the Order of MH RK No. 62 the need for an on-board temperature log for vehicles	Order of MH RK No. 62	CSEC
1.7	Storage	↑ To include in the Order of MH RK No. 62 issues of storage of vaccines requiring special conditions, i.e. ultra-cold temperature regime (-70… 80°C), storage conditions of vaccines for each level separately	Order of MH RK No. 62	CSEC
1.8		To ensure the use of officially approved forms (paper) of accompanying documents for vaccines (invoices, requirements) at the level of medical organizations	-	DSEC, LEB, MO
1.9	Use	To regulate by Order of MH RK No. 62 the FIFO (first in – first out) requirements for the use of vaccines, approaches to the use of multi-dose packaging of vaccines. To ensure monitoring and assessment of vaccine use practices	Order of MH RK No. 62	CSEC
1.10		To supplement the Order of MH RK No. 62 regarding the accounting and calculation of the vaccine loss index	Order of MH RK No. 62	CSEC
1.11		To supplement the Order of MH RK No. 361 regarding the safe handling of vaccines	Order of MH RK No. 361	CSEC

1.12	Stocks	To develop and reflect in the Orders of MH RK No. 62 and No. 361 the policy of maintaining the reserve level of the vaccine stock at all levels, including regulating the volume of the non-reduced stock (maximum, minimum) of vaccines (taking into consideration WHO recommendations), to set planning deadlines with preliminary consideration of the vaccine stock at each level	Orders of MH RK No.62, No.361	CSEC
1.13	Waste management	To ensure monitoring of medical waste management at all levels (availability of waste disposal contracts, waste disposal schedules, etc.)	-	DSEC, LEB, MO
1.14	Emergency	To provide monitoring of fuel reserves (especially at the level of district storage facilities) for the generator to ensure uninterrupted power supply	-	DSEC, LEB, MO
1.15		To ensure monitoring of power outage records at all levels	-	DSEC, LEB, MO
1.16		To introduce into the Order of MH RK No. 62 the requirement of a vaccine evacuation plan at all levels	Order of MH RK No.62	CSEC
2	**Staff**			
2.1	Topics and training programmes	To supplement the recommended topics of components of choice within the professional development cycles of medical workers with the "Safe handling of vaccines, cold chain and immunization" topic	Order of MH RK No.62	CSEC, DSHR
2.2		To provide methodological assistance and administrative incentives to medical schools to develop an advanced training programme on "Safe Handling of Vaccines, Cold Chain and Immunization". To include vaccine inventory management, thermal indicators, vaccine rejection and disposal, accounting for unopened vials, time and procedure for the "shake test" in training programs		CSEC, DSHR, HEI

2.3		To revise the list of training topics for certification of medical workers on preventive vaccinations with including questions on compliance with the cold chain		CSEC, DSHR, HEI
2.4		To develop an internal training programme for medical organizations on storage, transportation, and use of vaccines for systematic training of staff		MO
2.5	Professional development	To add the requirement to conduct appropriate professional development (additional, non-formal education) to the terms of the contract with the Social Health Insurance Fund	SHIF IRD	SHIF
2.6		↑ To conduct annual professional development (including on-the-job training) among HD storage specialists regarding the transportation and storage of vaccines, as well as preventive maintenance of cold chain equipment		HD, DSEC
2.7		To conduct annual (including on-the-job training) training on effective vaccine management for medical workers		HD, DSEC
2.8		To approve and follow an internal training schedule for medical workers (including on-the-job training) in charge of storage, transportation, and use of vaccine products		MO
2.9	Assessment of knowledge	To discuss with NCIE the possibilities of expanding and deepening cold chain issues, including those based on EVM, in the process of assessing the knowledge of medical workers of the relevant specialties		CSEC, DSHR, NCIE
3	**Equipment and components**			
3.1	Requirements for cold chain equipment	To approve by Order of MH RK No. 62 the requirements for refrigeration equipment, ensuring its compliance with international recommendations and WHO prequalification requirements for vaccine storage equipment	Order of MH RK No.62	CSEC

3.2	Cold chain planning	To develop a methodology for calculating the volume of the (ultra)cold chain at all levels of vaccine storage (implying a standard of equipment) based on an assessment of the need for the region and taking into consideration the maximum volume of supplies, including due to the new vaccines in the National Vaccination Calendar and other campaigns. To provide backup refrigeration capacity (include an appropriate requirement for the availability of a diesel generator set). To provide evacuation means for the vaccine in case of power outages (to include the norm for the availability and number of thermocontainers and refrigerated cells). To approve by Order of MH RK No. 62. To form a plan to bring the equipment to 100%	Order of MH RK No.62	CSEC, SK-Pharmacy, MO
3.3		To approve by Order of MH RK No. 62 the reporting form on the provision of refrigeration equipment. To conduct regular data monitoring and analysis	Order of MH RK No.62	CSEC, DSEC
3.4		↑ To ensure compliance of data on refrigeration equipment in the RMS IS with the 1C data of the relevant organizations and the actual availability. To conduct an inventory of cold chain equipment at all levels of vaccine storage on an annual basis		DEHC, REHC, LEB, MO
3.5	Commissioning	Ensure monitoring of the proper commissioning of the (ultra)cold chain equipment purchased by the LEB		CSEC, DSEC, LEB
3.6	Equipment maintenance	↑ To approve by Order of MH RK No.62 the requirements for the maintenance of refrigeration equipment. To collect and analyze information on maintenance costs	Order of MH RK No.62	CSEC, DSEC, LEB

3.7	Buildings	To ensure regular monitoring of the condition (with further budgeting) of storage infrastructure (ventilation, air conditioning, power supply, including emergency; separate rooms for packaging and unpacking of vaccines, etc.)	-	CSEC, DSEC, LEB
3.8		To amend Order of MH RK No. 62 to require a written plan for the surveillance and preventive maintenance of vaccine storage buildings	Order of MH RK No.62	CSEC
3.9	Vehicles	To ensure regular monitoring of maintenance of vehicles for the transportation of vaccines (availability of contracts, maintenance schedules)	-	CSEC, DSEC, LEB
4	**Information systems**			
4.1	IS	To implement a unified software (information system) for vaccine management during transportation and in storage facilities at subnational/regional/district levels, to digitize the registration and movement of vaccines. Provide the necessary external integrations (with the information systems of the SK-Pharmacy, INBD, etc.). To provide functionality for keeping forms of vaccine logs, and temperature records of refrigeration equipment. To provide analytical functionality (planning, requirement estimation, etc.)	-	DEHC, REHC, MDDIAI
4.2	Reporting	To digitize reporting forms No. 3 and No. 4. To provide reconciliation with medical information systems (MIS), 1C data	-	DEHC, REHC, MDDIAI, LEB
4.3		To develop and approve procedures for format-logic control and validation of data from reporting forms No. 3 and No. 4 at the IRD level of SPCSEEM	SPCSEEM IRD	CSEC, SPCSEEM

4.4		To amend reporting form No. 3 concerning the disposal of vaccines, to add a "Reasons for Disposal" column. To develop and approve a methodology for monitoring and assessing vaccine write-offs, as well as criteria for identifying regions and outlier incidents at the IRD level of SPCSEEM	Order of MH RK No.313, SPCSEEM IRD	CSEC, SPCSEEM
4.5	Thermal control	To improve temperature monitoring at all levels with the use of a single electronic system for continuous temperature recording of refrigeration equipment at all stages of transportation and storage of vaccines. To ensure long-term data storage. To provide functionality for regular checking of temperature records by managers	-	CSEC, SK-Pharmacy, DEHC, REHC, MDDIAI
4.6		To ensure the use of computerized temperature monitoring systems with an alarm system and the capability to send notifications to the concerned staff at the subnational level; to implement 30-day temperature recorders in district storage facilities and medical organizations	-	CSEC, SK-Pharmacy, DEHC, REHC, MDDIAI
4.7	Documentation	To ensure the storage of vaccine acceptance certificates and accompanying documents for 3 years	-	DSEC, LEB

* "↑" marks the highest priority recommendations

COLD CHAIN PLANNING TOOL

Currently, a cold chain planning tool based on Microsoft Excel software already exists and is in use by countries. UNICEF Cold Chain Sizing Tool is a comprehensive model recommended for implementation in RK as a ready-to-use solution with a number of built-in and updatable classifiers.

Table 18. UNICEF Cold Chain Sizing Tool Inputs and Outputs

No.	Sheets	Content
1	**Data input**	
1.1	Vaccine Storage Facilities	List of vaccine storage and distribution points and their characteristics
1.2	Vaccine Volumes	Vaccine Storage Volumes
2	**Output data: results of planning for routine vaccination**	
2.1	routine_illustration	Diagrams
2.2	Cold_Storage	Cold Chain Volume Assessment for Storage Facilities
2.4	Service_delivery	Cold Chain Volume Assessment for Medical Organizations
2.5	ColdChainCost	Cold Chain Equipment Cost
2.6	Transport	Transportation and Safe Injection Equipment Volume Assessment
2.7	Dry_Storage	Net Diluent Storage Assessment and Safe Injection Equipment for Routine Needs
2.8	Waste_Generated	Vaccination Waste Assessment
2.9	Vaccination_ Sessions	Vaccination Sessions Assessment
2.10	Routes	Summary of quantities to be transported along the distribution route
3	**Output data: Results of planning for supplementary vaccinations**	
3.1	SIAs_Planning	Assessment of Requirements for the Deployment and Utilisation of Vaccines and Safe Injection Equipment

3.2	siaCCECost	Cold Chain Equipment Costs and Volume
3.3	SIAs_illustration	Diagrams
4	**Output data: results per one recipient**	
4.1	Volume_Inject	Diluent Volume Assessment and Safe Injection Equipment
4.2	Weight_Inject	Weight Assessment of Safe Injection Equipment
4.3	Qty_Waste	Injection Waste Quantity Assessment
4.4	Cost_Supplies	Cost Assessment of Vaccines and Safe Injection Equipment
5	**References**	
5.1	Vaccines	Vaccine type
5.2	supplies	Safe Injection Supplies and Cold Chain Equipment (classifier)
5.3	PQEqpt	Refrigerator and Freezer Database (manufacturers, models, characteristics)
5.4	Passive_containers	Passive Container Database (manufacturers, models, characteristics)

TRAINING FOR EMPLOYEES WORKING WITH THE COLD CHAIN

Professional development for medical professionals responsible for vaccine management and cold chain compliance is now limited to annual one-day seminars at the medical organization level, followed by certification and authorization to work with vaccines. There are also no requirements for immunoprophylaxis training in the qualification requirements for such medical workers.

Therefore, in developing human resources capacity, a training course was held, taking into account the results of this study.

1. Training characteristics

Table 19. Training characteristics

Parameter	Characteristic
Format	Professional development training
Place / form of training	Full-time, online / remote
Dates	From February 7 to February 14, 2023
Duration	4 academic hours (within 1 working day)
Coverage of regions	All 20 regions of RK, subnational storage facilities and employees of the central level
Number and profile of trainees	A total of 240 people, including: - central level – 5 people (group No. 1); - subnational storage facilities – 17 people (group No.1); - district storage facilities – 218 people (by number of districts; 5 groups, groups No. 2-6).
Language	Kazakh and Russian
Training materials	- session plans; - presentations on Effective Vaccine Management; - practical exercises (case studies); - exercise sheets and handouts

Methods	A diverse set of methods to ensure active interaction with participants. Combination of a theoretical module with a practical module (cases, thematic tasks) in the field of vaccine management and cold chain
Control	The effectiveness of training is assessed by preliminary and final testing. At the end of the training, participants gave feedback for further program improvements
Completion Form	Certificates by the number of trainees. Handouts are sent to the participants by email after the training is completed

2. Training objectives

The training's common objective is to improve immunization at all levels of effective vaccine planning and management and the cold chain, namely:

- providing participants with the knowledge and skills to identify and solve problems in vaccine and cold chain management;
- ensuring that participants understand comprehensive vaccine management through a vaccine life-cycle approach;
- providing participants with methodological support for effective cold chain management, including programme planning and vaccine supply forecasting.

3. Program

management through a combination of theory, exercises and group work. The following issues were considered during the training:

Table 20. Training program

Time	Topic	Lecturer's full name
Lectures		
14.30-14.40	Welcome speech	N.Yu. Azimbayeva Head of the Department of Control over Vaccine-controlled Infections of the CSEC of MH RK
14.40-15.20	Vaccination planning. Supply, storage, and distribution of vaccines. Inventory management	N.Yu. Azimbayeva Head of the Department of Control over Vaccine-controlled Infections of the CSEC of MH RK
15.20-16.00	Requirements for storage facilities for vaccines. Temperature control. Cold chain planning, cold chain maintenance	L.K. Kassabekova Head of the Department of Prevention of Infectious and Parasitic Diseases of the SPCSEEM
16.00-16.40	Requirements for the transportation and storage of vaccines in medical organizations. Supportive supervision of immunization	G.S. Utesheva Head of the Department of Medical Support of the Department of Clinical Work of the Asfendiyarov KazNMU NJSC
Practical exercises		
16.40-17.00	Lesson based on real cases of unforeseen problems in the cold chain system (power outage, failure of refrigeration equipment)	G.S. Utesheva Head of the Department of Medical Support of the Department of Clinical Work of the Asfendiyarov KazNMU NJSC
17.00-17.20	Case study of a systematic error during BCG revaccination in the Aktobe region	L.K. Kassabekova Director of the Department of Prevention of Infectious and Parasitic Diseases of the SPCSEEM
13.30-14.00	Discussion. Q&A	

CONCLUSION

The assessment of the study identified a number of areas for improvement at all levels of the (ultra)cold chain of vaccine management.

For example, there are a number of gaps at the central level of immunization management in the area of cold chain regulations concerning the standard of refrigeration equipment, the process for estimating requirements, technical requirements for equipment, and the volume of irreducible vaccine stock. There is a strong need for a comprehensive information system to manage the cold chain and immunization process altogether, as well as to reliably monitor the temperature regime.

An effort can be made at the storage and medical organization level to implement standards for operating procedures, cold chain continuity (maintenance, backup refrigeration equipment; fuel reserves for generators, SOPs for emergencies), medical waste management, and other areas.

The set of recommendations, categorized into "Business Processes", " Staff", "Equipment and Components" and "Information Systems", includes the revision of a number of RLA, including alignment with international practices and guidelines; development of national guidelines and standard operating procedures; implementation of monitoring various aspects of the cold chain; implementation of a set of measures in the field of professional development; improvement of infrastructure and technical aspects; development of relevant information systems.

However, it is important to be aware of the limitations of the methodology of this study, such as the small sample of regions and medical organizations, the limited use of only cold chain questions, the selective use of EVM 2.0 questionnaires, a flat point system, and others.

The study generally demonstrates the content of EVM solutions and related tools. On the basis of the results of the study, there is an opportunity to improve the RLA in terms of cold chain and to move towards the introduction of regular assessments of EVM 2.0 standards at the state level.

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4. Code of the Republic of Kazakhstan dated July 07, 2020 No. 360-VI ЗРК "On public health and health care system".

5. Resolution of the Government of the Republic of Kazakhstan No. 612 dated September 24, 2020.

6. Order of the Minister of Health of the Republic of Kazakhstan dated July 19, 2021 No. ҚР ДСМ-62 On approval of "Sanitary and epidemiological requirements for storage, transportation and use of immunobiological medicinal products (immunobiologicals)" sanitary rules that determine the order of storage, transportation and use of immunobiological medicinal products (hereinafter - immunobiologicals).

7. Order of the Acting Minister of Health of the Republic of Kazakhstan dated June 13, 2018 No. 361 "On approval of "Sanitary and epidemiological requirements for preventive vaccination of the population" sanitary rules".

8. Joint Order of the Minister of Health of the Republic of Kazakhstan No. 463 dated June 26, 2017 and the Minister of National Economy of the Republic of Kazakhstan No. 285 dated July 20, 2017.

APPENDIX 1

TECHNICAL TASK STUDY «ASSESSMENT OF THE CURRENT STATE OF THE COLD CHAIN OF VACCINES AGAINST COVID-19 IN THE REPUBLIC OF KAZAKHSTAN»

No.	Result / activity
Result 1:	**A methodology for conducting field work has been developed and agreed with the Customer. A desk study of the current situation was conducted**
Activity 1.1	Development and approval of the methodology for conducting field work
Activity 1.2	Collection of documentation and statistical data from national partners (Ministry of Healthcare of the Republic of Kazakhstan, National Public Health Center, CSEC)
Activity 1.3	Review of current regulations, accounting and reporting documentation, available data
Result 2:	**The state of the cold chain was assessed by segments of the relevant facilities, including:** **- infrastructure (estimation of the costs of maintenance and operation of existing cold chain equipment based on available data),** **- staffing and processes (including a series of interviews);** **- a brief overview of information systems**
Activity 2.1	Field study: business trip to 2 regions, 3 days in each region, including a trip within the region to a remote area
Activity 2.2	Online interview: preparing, conducting and processing the results of questionnaires
Activity 2.3	Analysis and interpretation of the results of the field study and online interviews
Result 3:	**A plan for the development of cold chain infrastructure at the level of the Republic of Kazakhstan has been formed**
Activity 3.1	Scenario planning of the cold chain infrastructure taking into account the National Vaccination Calendar, coverage targets, the use of vaccines from different manufacturers, additional vaccination campaigns: building an .xlsx model with assumptions

Activity 3.2	Filling .xlsx models with data and performing calculations, c. including sending formal and informal inquiries on the cost of components
Result 4:	**Recommendations developed to improve the cold chain infrastructure**
Activity 4.1	Development of recommendations for improving the cold chain infrastructure, including the necessary equipment and components, the state of human resources, information systems and business processes
Activity 4.2	Development of recommendations for additional training for specialists in various fields, aimed at addressing training gaps identified during the assessment
Result 5:	**The results of the assessment are presented in the form of a report and methodological recommendations, presented to stakeholders**
Activity 5.1	Formation of a final report with recommendations for addressing identified gaps in compliance with the cold chain
Activity 5.2	Writing cold chain guidelines for relevant healthcare professionals
Activity 5.3	Discussion of the research results at a workshop with national partners
Result 6:	**Conducted trainings for 40-60 people (2-3 relevant employees per region, coverage of all regions, training in groups of 9-12 people for 1 day)**
Activity 6.1	Conducting an online training based on methodological recommendations for relevant healthcare professionals
Result 7:	**Project administration and technical support of work**

APPENDIX 2

FIELD RESEARCH METHODOLOGY AND INTERVIEWS

I. FIELD STUDY

Study coverage:

2 regions of the Republic of Kazakhstan, 4 districts, 8 medical organizations.

Criteria and its value for selecting regions.

№	Criterion	Criteria value requirements	The value of the criterion for region 1 (Turkestan region)	Criterion value for region 2 (Aktobe region)
1	geographic location and specificity	representation of two different macro-regions (center, north, east, south, west) of the country, the length of the territory (increased load on the logistics function)	south; extended	west; extended
2	climatic/ temperature conditions	the least favorable for the functioning of the cold chain and the average level of favorableness relative to the regions of the Republic of Kazakhstan on average	the least favorable	average favorability
3	population	total population, population density (various)	high population, densely populated	average population, sparsely populated
4	immunization rate	average or below average immunization rates	average	below the average
5	staffing to assist in the conduct of the study	adequacy	Enough	enough

6	Frequency of vaccine write-offs due to malfunction of CC equipment, violation of storage rules, power outages	medium or high frequency	3 facts in 3 years (high level)	1 fact in 3 years (intermediate level)
7	Availability of CC equipment	medium or low security	low (needs to replace existing HC equipment to a high extent)	average

Sampling Rationale:

The definition of the criteria and the sampling itself were based on prior discussions with immunization program staff.

The selection was made in 4 stages.

1. The first stage is selection by geographic location, temperature conditions, and population.

a. The Turkestan region belongs to the southern macro-region of the country, the area of the region is 116,280 km² (4.3% of the territory of the Republic of Kazakhstan). The distance between the northernmost and southernmost sections in a straight line is 506 km. During the summer period, extreme temperature conditions for the Republic of Kazakhstan are observed in the region. The average temperature of the hottest month - July - ranges from 20-30°C. The absolute maximum is 51°C (Kyzylkum). Winter in the region is short, with frequent thaws, and mild. The coldest month is January, the average temperature of which is -9.6°C in the north of the region and -0.9°C in the south. The region was chosen as problematic in terms of climatic conditions, densely populated (by the standards of the Republic of Kazakhstan): the population is 2,025,125 people (17.5 people / km²), it has 14 districts, 3 cities.

b. Aktobe region represents the western macro-region of the country. The length of the territory from west to east is about 800 km, from north to south - about 700 km. The total area is 300,629 km². The climate is sharply continental; winters are cold, summers are hot and dry. The average temperature in July in the northwest is +22.5 °C, in the southeast +25 °C, in January, respectively, −16 °C and −25.5 °C, temperature fluctuations do not have a significant effect on the storage and transportation of vaccines, immunobiological drugs. The region was chosen as average in terms of climatic conditions, average in terms of population - 911,326 people, extremely sparsely populated (3.0 people / km²), number of districts - 12, 1 city.

2. The second stage of selection for assessing effective vaccine management (EVM)

is the warehouses where vaccines and other immunization supplies are stored and distributed, and the health facilities where immunization is carried out. The assessment is carried out at all levels of storage and use of vaccines: subnational (regional warehouse for storing vaccines), district (regional warehouses), medical organizations (vaccination rooms).

3. The third stage of selection is the determination within the regions selected at stage No. 1, for 1 district in the region, depending on the distance from the regional center. Selection criterion: the distance from the district to the regional center is inversely proportional to the speed of transportation and the level of compliance with the storage conditions of vaccines and is directly proportional to the influence of external temperature fluctuations and other factors that affect compliance with good delivery practices. It is proposed to define in each region 1 district at an average distance from the regional center and 1 remote district from the regional center (total 2 districts).

4. The fourth stage of selection - within the districts determined at stage No. 3, the selection of 2 settlements, each of which has 1 medical organization representing two different immunization scenarios, for example, one rural (remote) medical organization, and one urban or district (total 8 medical organizations).

Consolidation and statistical processing of data

To collect data in vaccine warehouses and medical organizations will use a questionnaire adapted to the specifics of the Republic of Kazakhstan based on WHO questionnaires (Appendix 3).

If necessary, the information from the questionnaires will be entered into a database created using the EpiInfo 7 (or other) software for Windows and processed using the specified software.

In addition to filling out the questionnaires, in the process of field work, in order to triangulate the information obtained in the course of filling out the questionnaires with more objective sources, the following actions will be carried out:

- monitoring and inspection of equipment;
- request for health workers to demonstrate their actions in the process of working with the cold chain;
- review of documentation (maintenance, financial, etc.);
- review of the functioning of information systems (IS) and work in them (if appropriate IS is available).

The questionnaire provides for the assessment of the following 3 levels:

1. Sub-national level (regional vaccine depots) that receives the vaccine from the primary depot, stores it for a specified period and distributes it to downstream depots or medical organizations.

2. District level of distribution (district vaccine depots), which receives vaccines from the primary or subnational warehouse and distributes them to medical organizations.

3. Points of delivery of immunization services (health organizations) where the vaccine is stored for a short time before it is administered to the target population.

Evaluation will be carried out according to 9 criteria by adding positive and negative answers to each question.

Site visits are planned according to the table:

Subnational level (regional warehouses)	District warehouses	Medical organizations
Aktobe	Alginsky district	By agreement
	Shalkar district	By agreement
Shymkent	Turkestan	By agreement
	Saryagash region	By agreement

II. ONLINE INTERVIEW

In addition to the field survey component based on the EVM questionnaires, a series of online interviews with key healthcare professionals/cold chain staff will be conducted to gather views on the challenges and potential of the cold chain. The interview will be conducted as a qualitative research study, using an open-ended questionnaire to explore issues in detail. A separate questionnaire will be developed for each group of respondents.

Questionnaire for specialists at the national, subnational level - according to Appendix 4.

Questionnaire for PHC employees at city and district levels - according to Appendix 5.

The results of the online interview will be recorded, analyzed and interpreted, and triangulated with the results of the field assessment.

APPENDIX 3

LIST OF EVALUATION QUESTIONS (field research)

	Information about the object
1.	Evaluation start date
2.	Evaluation end date
3.	Name of the object
4.	Object code
5.	Supply chain level (subnational, district, medical organization)
6.	Belonging (private, public)
7.	Address of the object
8.	Email address
9.	Telephone
10.	Contact person
11.	Total population
12.	Surname of the evaluator
	E1 – Arrival of the vaccine
13.	How does the vaccine arrive in the warehouse (Vaccine Acceptance Certificates)cates)
14.	How many planned shipments of vaccines were supposed to arrive at the warehouse in the last 12 months?
15.	Is there a system for tracking incoming batches of vaccines?
16.	Is the system of drawing up vaccine acceptance certificates computerized?
17.	Are the vaccine acceptance certificates stored in a secure location?
18.	Are the vaccine acceptance certificates and accompanying documents kept for at least 3 years?
19.	Who transports vaccines from national vaccine warehouses to subnational vaccine warehouses?
	E2 – Temperature control
20.	The presence of a device for continuous temperature recording in the refrigeration equipment
21.	Is the temperature control system for storing vaccines computerized or paper-based?

22. Availability and quality of records
23. Are temperature records stored in a safe place for at least 3 years?
24. Are temperature records and alarms officially reviewed at least once a month to identify temperature spikes and their causes?
25. If temperature records and alarms are officially viewed at least once a month, is there documentary evidence that corrective measures have been taken in response to deviations or breakdowns?

E3 – Storage and transportation capabilities

26. Storage rooms for vaccines, syringes
27. Are the conditions for safe storage of vaccines provided?
28. Facilities for storing, unpacking and packaging vaccines
29. Generator for uninterrupted power supply
30. Fuel reserve for the generator
31. Availability of an emergency plan in case of an emergency in the cold chain
32. The presence of permanently assigned personnel for the subsequent monitoring of the cold chain

E4 – Infrastructure and equipment

33. The contents of the cabinet (the organization itself, the state, other)
34. Has the building been renovated in the last 12 months?
35. Availability of equipment for storing vaccines:
36. Refrigerators (quantity, volume)
37. Cold rooms (quantity, volume)
38. Freezers (quantity, volume)
39. Ultra-cold equipment (quantity, volume)
40. Actual use of ultra-cold equipment (quantity, volume)
41. Availability of a functional backup generator at the facility
42. Backup:
43. Cold storage rooms
44. Refrigerators
45. Freezers
46. Freezers
47. Availability of thermal containers (quantity, volume)
48. Including active (quantity, volume)
49. The presence of dry ice or gel refrigerants (quantity)
50. How are the vaccine transportation operations organized in this warehouse?

51. Does the air conditioning system work?
52. Have employees received training on working with vaccines and safe operation in cold storage? (availability of a supporting document)

E5 – Maintenance and repair

53. Refrigerator repair service (contract)
54. Carrying out a preventive technical inspection by a qualified specialist (availability of a contract, acts of work performed)
55. Maintenance of vehicles for the transportation of vaccines (contract)
56. Schedule of preventive maintenance, records
57. Verification of thermometers (contract)

E6 – Inventory Management

58. Is the volume sufficient to meet the maximum level of vaccine stocks?
59. Are vaccine stocks replenished regularly according to schedule? (stock levels are documented for all vaccines)
60. Record in paper forms, journals accounting, movement of vaccines
61. Evaluation of reports on the receipt of vaccines received during (how many individual vaccines were brought?)
62. the reporting period:
63. Does the organization apply for vaccines?
64. application form
65. applications for vaccines are complete and documented
66. all vaccine applications are completed in full and on time
67. Does the organization keep records of vaccine stocks?
68. Does the organization keep records of the received vaccines?
69. Are there gaps in the accounts? If so, for what reason?
70. absence of employees
71. absence of forms
72. other
73. The status of vaccine stocks in this organization
74. Specify the number of doses of solvent for the vaccine based on the bacillus Calmette-Guerin (BCG) currently available in stock
75. Specify the number of doses of solvent for measles-containing vaccines currently available in stock
76. Have there been any emergencies related to the storage of vaccines in the last 12 months? (measures to protect vaccines in the event of a breakdown of refrigeration equipment, power outage or other emergencies)

77. Is there a contingency plan in the vaccine storage?
78. Are all measures outlined in case of equipment breakdown, power outage or other unforeseen circumstances?
79. Is there a SOP in case of unforeseen circumstances in the vaccine repository?
80. Are all actions outlined in case of equipment breakdown, power outage or other unforeseen circumstances?

E7 – Distribution of vaccines and dry goods

81. How are the operations for transporting vaccines organized in the facility (is there public, private or public transport?)
82. Do employees know how to prevent freezing during transportation at temperatures below zero?

E8 – Vaccine Management

83. Is there an annual plan for the need for vaccines and other IIBP?
84. Write-off of vaccines
85. Reasons
86. Supporting documents
87. Storage of vaccines (description):
88. Are labels affixed to all cold chain equipment indicating the type of vaccine, batch number, expiration date
89. The presence of labels on the lid of refrigerators and freezers or on the edges of shelves in freezers and refrigerators. Rating "n/a" if marking is not required
90. Are the vaccines laid out in the EEFO order, by type and by batch number?
91. Is the vaccine storage clean, dry and pest–free?

E9 - Waste Management

92. Is there a separate room for storing medical waste?
93. Is there a contract for the disposal of medical waste?
94. Is there a schedule for removal?
95. What do/would they do with expired vaccine vials?

Socio-demographic characteristics of respondents

96. Gender
97. Education level
98. Position
99. Work experience
100. Have you ever been trained to work with vaccines?

APPENDIX 4

QUESTIONNAIRE FOR SPECIALISTS OF THE NATIONAL, SUBNATIONAL LEVEL

Good day! My name is _____. I represent the PaperLab Research Center. We investigate the practice of vaccine management in the Republic of Kazakhstan in terms of cold chain processes. During the study, we plan to evaluate the cold chain management processes in the field and in the format of online interviews, identify problems and make recommendations for improving vaccine management.

Our study is supported by the United Nations Children's Fund (UNICEF) in Kazakhstan and approved by the Sanitary and Epidemiological Control Committee of the Ministry of Healthcare of the Republic of Kazakhstan. Based on the data obtained, a report will be prepared for the Ministry of Healthcare and methodological recommendations for healthcare workers working with elements of the cold chain.

Please tell us how you would like us to refer to you when preparing materials? If you do not want us to link to you, then we will ensure anonymity and will not provide your personal data.

№	Main Question	Clarifying question
Block A. Acquaintance		
1	Please tell us a little about yourself.	- Who and what organization do you work for? - How long have you been working in this field? - How does your work relate to cold chain management and immunization?
Block B. Effective vaccine management		
Let's talk about effective vaccine management		
2	What is effective vaccine management?	- What are the main criteria for vaccine management used in the Republic of Kazakhstan?

3	How are vaccines planned and procured?	- What legal acts regulate the procedure for planning and purchasing vaccines? - What services are involved in vaccine planning and procurement? - What is the functionality of each service? - What do you think, is the functionality of the structural organs in the system correctly distributed? (Show structure) - If not, what would you change? - Which RLA would be changed? - What do you think are the RLA's strengths and weaknesses?
4	How is the procedure for the arrival of vaccines and goods?	- What documents, manuals, official criteria do you rely on in the procedure for the arrival of vaccines? - How do you assess the quality of these documents, how clear and unambiguous they are? - Who is responsible at the country level for this function? - Do you think this is correct? - What would you change about this system? - Is there an information system for the arrival, registration and distribution of vaccines?
5	Vaccine Storage Temperatures	- Are there regulations governing the procedures for monitoring storage temperature conditions for certain types of vaccines? - If so, what documents record the storage temperature of vaccines? - In what kind of information systems? - Is there a responsible person at each level of vaccine storage who controls the temperature? (levels - republican hubs, regional, up to the polyclinic) - Where is this information stored? - What exactly is indicated? - What would you change in this section of the work?

6	Buildings, refrigeration equipment and transport	- Which regulatory legal acts regulate the requirements for buildings, cold equipment for storing vaccines, transport for transporting vaccines? - Do you think they meet the requirements? - If not, what needs to be improved or strengthened? - How is equipment maintenance organized? - Is there a need to make changes to the regulatory legal acts on technical issues? equipment maintenance? - Is there a single method for calculating the volume of refrigeration (freezing) equipment?
7	Inventory Management Policies and Practices	- Does your country have a vaccine buffer policy? - If so, in what legal acts it is regulated and how much %? - At what level is the reserve stock of vaccines maintained: national, regional, district? - Is there a unified information system for inventory management?
8	Vaccine Distribution System	- How is the distribution of vaccines implemented at the national, subnational level? - Is there a schedule for the distribution of vaccines at the national, subnational, district levels? - Can any administrative reasons affect the distribution of vaccines by territory? - How often are staff trained on the safe and efficient distribution of vaccines?
9	Vaccine policy and practice	- Are there specific training courses for staff on vaccine handling practices? - Are there requirements to allow only trained personnel to work with vaccines? RLA? - Is there a system in place to manage lost vaccines? - How is the waste management system implemented? - What would you change in this section?

10	Supportive Management Effectiveness	- Is there a structure in the country that acts as a national quality coordinator? - If so, do you agree with such a distribution of functional responsibilities in this system? - How often are internal and external evaluations of the CC system carried out? - How often are education and training for employees involved in the storage and transportation of vaccines? - Are there uniform guidelines, SOPs, guidelines, algorithms for applying for vaccines? - What are your suggestions for this section of work?
11	Is there anything else you would like to add?	- Please advise who else can I contact with these questions?

APPENDIX 5

QUESTIONNAIRE FOR EMPLOYEES OF PHC ORGANIZATIONS

Third level (city and district)

Good afternoon My name is _____. I represent the PaperLab Research Center. We investigate the practice of vaccine management in the Republic of Kazakhstan in terms of cold chain processes. During the study, we plan to evaluate the cold chain management processes in the field and in the format of online interviews, identify problems and make recommendations for improving vaccine management.

Our study is supported by the United Nations Children's Fund (UNICEF) in Kazakhstan. Based on the data obtained, a report will be prepared for the Ministry of Health and methodological recommendations for healthcare workers working with elements of the cold chain.

(!) Please tell us how you want us to refer to you when preparing materials? If you do not want us to link to you, then we will ensure anonymity and will not provide your personal data.

№	Main question	Clarifying question
Block A.		
1	Please tell us a little about yourself.	- Who and what organization do you work for? - How long have you been working in this field? - How is your work related to immunization?
Block B. Compliance with the cold chain system		
First, let's talk about the cold chain system in immunization.		
2	What cold chain equipment does your organization use?	- Is the vaccine stored in refrigerators? - What is the number of household refrigerators in your PHC organization? - How many refrigerators with additional ice protection? - How often do you change refrigerators?
3	How you spend refrigerator temperature control?	- Do all vaccine refrigerators have working thermometers stored with the vaccine? - How often are thermometers subject to metrological testing? - What is the temperature of the refrigeration equipment at the moment?

4	How do you keep records of refrigeration temperature?	- Do you record the refrigeration temperature manually? - How often do you keep temperature records? Are records kept for each equipment? - Would you like to change the temperature log? *listen to the respondent's proposals (make it electronic, add / remove some columns, change the rules of conduct)*
5	What to do if there is a power outage in the vaccination room	- Have you experienced a power outage during your employment? - If so, who did you notify of the alarm logs (power outage, refrigeration failure)? - Do the columns of the temperature log/sheet provide for the recording of alarms? - Is there a log of alarms (light out, refrigeration failure)?
6	What actions are taken in the event of a power outage?	- Does the head nurse call the electrician on the phone? - Did the electrician take corrective action?
7	What actions are taken if the causes of power outage **during the day are not eliminated** ?	- Does the person responsible for storing vaccines move vaccines into cold boxes and back-up refrigerators?
8	What actions are taken if the causes of a power outage **for more than a day are not eliminated** ?	- List events
9	How often do you defrost refrigeration equipment?	- More than once a month? - In the case when the thickness of the snow reaches 5 mm? - 1 time in two months?
10	Do you use Standard Operating Procedures (SOPs) to thaw vaccine refrigerators, with step-by-step thawing procedures?	- Have you received training on vaccine storage and cold chain requirements? - If yes, when was the last time? - Do you have an SOP for defrosting vaccine refrigerators? - If there is an SOP, is there your full name. on the list?

11	How often do you clean refrigeration equipment?	- Do you only clean when there is defrosting? - Do you clean once a month? - Is there an SOP for cleaning refrigerators?
12	Do you monitor according to the CCI (control card indicator)?	- Do you know how to use the CCI indicator? - Can you interpret the CCI readings?
13	Do you know about other vaccine indicators?	- Can you explain how the indicators on the vaccine vial work? - Can you interpret the indicator readings?
14	Anything other than the vaccine is stored in the refrigerator?	
15	Are the vaccines placed correctly in the refrigerator?	
16	Does vaccine management follow the FIFO principle?	- Do you know the FIFO vaccine management principle? - Do you follow it? *(First of all, the vaccines that were purchased first should be used - first in first out)*
17	Are expired vaccines in the refrigerator?	- What should you do if you find an expired vaccine?
18	Are there frozen vaccines in the refrigerator?	
19	Is the vaccine packaging area protected from direct sunlight?	
20	Is VVM (Vaccine vial monitor) status recorded for each vaccine?	
21	Have you composed the LMIS (Logistics Management Information System) reporting form and vaccine applications for the last month?	

22	When did you take a refresher course / training / seminar on the organization of immunization and immunization safety?	- Name of cycles/trainings/seminars, dates?
23	Have you received on-the-job training on cold chain compliance?	- Date of event, who hosted it? - Frequency?
Block C. Documents regulating compliance with the cold chain		
24	Are there any documents regulating the observance of the cold chain?	- What is the legal documentation?
25	What do you think can be done to improve the cold chain system?	3
Block D. Completion		
26	Is there anything else you would like to add?	- Please, advise to whom else it is possible to address with these questions.