Key results of the "Laboratory services" priority area

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Section 5. Laboratory services

■ 5.1. Optimize the laboratory network with due regard to rational geographic location, effective functioning, principles of fair, equal access and financial protection of the population within the framework of development and implementation of a master plan for the formation of a rational and effective network of health facilities

What was done

- In 2018, the Swiss Embassy's "Health Facilities Autonomy" project was completed which resulted in the centralization of several laboratories on the basis of the clinical diagnostic laboratory of Issyk-Kul Oblast Merged Hospital (labs of FMCs and Territorial hospitals of Ton and Tyup rayons and Zhety-Oguz GPC).
- MoH Order № 466 of 29.06.2018 "On the centralized laboratory on the basis of Issyk-Kul Oblast Merged Hospital"
- In August 2021, WHO experts conducted a performance and cost-effectiveness assessment showing positive results

What was done

- Merging 19 FMCs in 4 districts of Bishkek and creating 4 UFMCs (MoH Orders No. 589-592 of 13.08.2018)
- Second stage was planned for 2020-2021 the consolidation of laboratories within one district
- Hematology and biochemistry analyzers were procured and installed in the head UFMCs, 2019-2020.

Master Plan for the Development of the National Health Care Delivery System. Final Report, June 2020

- Unification, consolidation of medical laboratories at the district level was recommended.
- In autumn 2020, inpatient clinics and FMCs were consolidated/merged at the administrative level
- Now it is necessary to merge laboratories.

What is being done

- The Coordinating Laboratory Council (CLC) is developing a plan to optimize clinical diagnostic laboratories and public health laboratories.
- Initially for Bishkek and Osh cities, Chui and Osh oblasts (ADB is launching a Regional Health Security Strengthening Project in September 2022)
- Other provinces and cities until 2025.

5.1.1.a Develop and approve a plan to optimize laboratories, taking into account the approved master plan, the concept of development of public health services, III quarter of 2020

- Plan for Chui oblast was not approved by the Ministry of Health of the Kyrgyz Republic and was postponed due to the pandemic.
- Now the Coordinating Laboratory Council is developing a new optimization plan, taking into account the comments received

5.1.1.6 Develop and implement a list of laboratory tests for different levels IV quarter of 2019.

It was developed for centralized laboratories

(MoH Order № 466 of 29.06.2018 "On the centralized laboratory")

- 5.1.2. Development and implementation of a sample transportation system based on international standards of safety, sample/biomaterials quality.

 Ill quarter of 2020
- 5.1.2.a Analyze the pilot introduction of different transportation systems, develop criteria for the use of different transportation mechanisms
- Analysis was conducted in three pilot projects (ICL, AIDS, BT) with technical support from WHO
- "Methodological guidance on transportation of biological materials and specimens for laboratory testing" was developed

5.2. Optimize mechanisms of regulation and quality control of the activities of laboratories of health care organizations, including public health service laboratories, testing laboratories for evaluation of diagnostic drugs, medicines and medical devices, as well as mechanisms to ensure the safety of laboratory research

5.2.1. Development and introduction of mechanisms to regulate and control the activities of laboratories, regardless of the form of ownership

- Within the framework of the WHO/Europe "Better Labs for Better Health" initiative, the quality management system (international ISO 15189 standards) is being introduced in 10 laboratories of MCH organizations (7 oblast merged hospitals, NCMCH, 2 perinatal centers in Bishkek and Osh). 5 bacteriological laboratories are being introduced ISO15189 standards through mentoring visits supported by WHO.
- Clinical laboratory of Issyk-kul oblast hospital and the sanitary-bacteriological laboratory of the Osh Center for Disease Prevention are ready for ISO 15189 accreditation, as assessed by a WHO expert.
- Laboratories of the Republican Center for Quarantine and Highly Infectious
 Diseases have been accredited for ISO 15189 by the Kyrgyz Accreditation Center under the Ministry of Economy
- PHC clinical diagnostic laboratories are monitored and audited to determine glycated hemoglobin and urinary bacteriuria.
- As part of SWAP in 2018, 10 MCH laboratories were equipped with laboratory equipment for \$841,000
- In 2019, 17 primary care laboratories (7 UFMCs, REC, 4 UFMCs in Bishkek and 5 district FMCs) were equipped with hematology and biochemical analyzers for \$ 500,000.

- Republican Center for Quality Control of Laboratory Diagnostics of Communicable Diseases, "Preventive Medicine" Scientific and Production Association, was accredited in A2LA (USA) under ISO 17043 "Conformity Assessment. Basic requirements for proficiency testing" and conducts external quality control for infectious diseases in 14 programs including COVID-19 serodiagnosis in 170 laboratories of the republic regardless of ownership.
- Republican Center for Quality Control of Laboratory Diagnostics of Communicable Diseases, "Preventive Medicine" Scientific and Production Association accredited by Kyrgyz Center for Accreditation according to ISO 17025 "General requirements for the evaluation of testing and calibration laboratories". There are being tested the drugs for serodiagnosis of infectious diseases, including SARS-COV-2.
- The Association of Clinical Laboratory Diagnostics Specialists conducts interlaboratory comparison tests in the laboratories of Bishkek and Chui region on hematological tests (CBC), biochemical tests (12 types) and hormonal studies and oncomarkers (10 types)

- Since 2017 to date, Department for Disease Prevention participates on behalf of the Ministry of Health of the Kyrgyz Republic in the joint regional project of FAO/Rospotrebnadzor (Kazakhstan, Belarus, Armenia, Tajikistan), Reference Center of the Research Institute of Epidemiology.
- DDP&SSES participates in Professional Testing/External Quality Control Programs at the international level. DDP&SSES annually organizes inter-laboratory comparative tests with laboratories of subordinate organizations of state epidemiological surveillance to verify the quality of tests/studies.

5.2.1.a Analysis of situation including laws and regulations governing the activities of laboratories, regardless of ownership, followed by introducetion of amendments to the laws and regulations to strengthen quality control and management

The following regulatory documents were developed:

- ► "Program and strategy for the development of laboratory services in the health system of the Kyrgyz Republic for 2016-2025". (MoH Order No.347 of May 20, 2016).
- Order "On staffing of clinical and diagnostic laboratories" №780 of 30.08.2017"
- ► Methodological recommendations "Organization of work on implementation of the management system in medical laboratories and preparation for accreditation" 2018
- "Methodological guidance for transportation of biological materials and samples for laboratory research" 2018
- National standards for accreditation of medical laboratories in health facilities
- Regulation on Reference Laboratory (MoH Order № 458 of 28.06.2018)
- "Compendium of standard operating procedures for clinical diagnostic laboratories of the Kyrgyz Republic" was developed and printed. Four trainings were held in Bishkek and Osh for lab specialists on how to use the Compendium (approved by MoHSD Order No. 1074 of 06.08.2021)
- Handbook on laboratory types of research

COVID-19 laboratories in the Kyrgyz Republic have performed 1 824 701 tests as of 17.09.2021

Nº	Name of PCR laboratory	Start of operation	Number of PCR tests performed
1.	National virological laboratory of DDP&SSES	27.01.2020	186 325
2	Osh City CDP&SSES	20.02.2020	174 093
3	Bishkek City CDP&SSES	25.03.2020	161 948
4	RCQ&HID	25.03.2020	93 518
5	Jalal-Abad CDP&SSES	12.03.2020	58 681
6	Batken CDP&SSES	17.04.2020	52 088
7	Talas CDP&SSES	07.05.2020	39 622
8	Naryn CDP&SSES	14.05.2020	23 675
9	Issyk-Kul CDP&SSES	19.06.2020	18 122

	Nº	Name of PCR laboratory	Start of operation	Number of PCR tests performed
	10.	Jayil CDP&SSES	10.06.2020	45 643
	11.	Yssyk-Ata CDP&SSES	28.03.2020	57 225
	12	National Phtisiology Center	04.04.2020	90 434
	13	Karakol Antiplague Unit	15.08.2021	253
	14	Bonetsky Lab	April 2020	410 524
	15	Aqualab	12.03.2020	315 803
	16	Gemotest Lab		75 851
	17	Intelmedical Lab		2 420
	18	AMSBIO		9 314
	19	Express Laboratory		3 917

Problems

- Small share of payment for laboratory services in funding of HFs
- Large number of beneficiaries for laboratory services
- Obsolete material and technical base in the majority of laboratories
- The premises of medical laboratories are in need of repair, not meeting sanitary standards
- Unified medical information system, including laboratory, is developed, but needs to be introduced broadly
- Low capacity of laboratory staff
- In most laboratories quality management system for laboratory tests is not implemented
- Difficulty for medical laboratories to participate in professional testing programs due to financial costs

Possible solutions

Revise the share of funding for laboratory services in the total funding of health facilities

- Revise the list of beneficiary populations for laboratory services
- Centralize the laboratory services at the regional level, some at the national level, except for those located in hard-to-reach and remote areas.
- Develop reference laboratories by areas of laboratory services
- Renovate laboratory facilities in accordance with SanPiN and safety requirements
- Equip laboratories with high-capacity, high-tech laboratory analyzers
- Establish a transportation system for transportation of biomaterial for laboratory analysis
- /Implement a unified LIS located at the e-Health Center
- The need to support national providers to conduct external quality control
- Continuous update and development of regulatory framework governing medical laboratories
- Training of laboratory personnel through on-the-job mentoring, implementing a quality management system in medical laboratories
- Establish a training base for laboratory specialists at KSMIRCE