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COVID-19 Molecular Diagnosis Challenges Faced by Medical Laboratory Specialists in Hospitals of Jordan: A Qualitative Study

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Abstract

Objectives: The primary goal of this study was to identify the main obstacles to COVID-19 diagnosis in Jordan's public and private hospitals.

Methods: A semi-constructive questionnaire was utilized to identify the main obstacles experienced by COVID-19 diagnosis in Jordanian public and private hospitals as narrated by laboratory specialists. Between June and December of 2021, when COVID-19 was still actively spreading, sixteen phone interviews were carried out. Using open coding, line by line, the transcribed narratives were subjected to thematic analysis in order to identify themes and related subthemes.

Results: A qualitative analysis of the interviews indicated that there are significant obstacles preventing molecular testing from being fully utilized. These obstacles include a lack of reagents and skilled personnel, as well as communication issues between the MOH and laboratories. Staff training and redistribution of previously trained personnel, as well as the digitalization of sample labeling and result release, were implemented as quick fixes for these issues.

Conclusion: The successful expansion of RT-PCR units to cover all country is considered an exceptional success of MOH and must be sustained after COVID-19. Nonetheless, in order to be ready for pandemics in the future, a stringent CPD system and the usage of RT-PCR outside of COVID-19 should be established.

KeyWords: COVID-19, RT-PCR, Molecular Diagnosis, Medical Laboratory Specialist, Jordan.

1. Introduction

Corona Virus Disease 2019 (COVID-19) was initially identified in Wuhan, China, leading to a nationwide outbreak. Since then, through international travels, the number of patients increased rapidly to spread all over the world (*Https://Www.Who.Int/Emergencies/Diseases/Novel-Coronavirus-2019*, n.d.). On March 2020, the World Health Organization (WHO) declared COVID-19 as a pandemic, a public health event that requires worldwide attention and collaboration.

As with most countries, Jordan was also severely affected by the contagion (*Https://Www.Who.Int/Countries/Jor/.*, n.d.). Because we are a middle-income nation with limited resources in an insecure Middle Eastern region, more obstacles were faced to effectively combat the pandemic (Al-Tammemi, 2020). Despite the fact that the Jordanian public health response was exemplary and promising in the early stages, by the end of December 2023, COVID-19 cases have increased to 1746997 infections and 14,122 deaths (*Https://Www.Who.Int/Countries/Jor/.*, n.d.).

Effective isolation and treatment of patients was essential to breaking the COVID-19 transmission chain (*Https://Www.Who.Int/Emergencies/Diseases/Novel-Coronavirus-2019*, n.d.). For this, among many protective measures, timely diagnosis using sensitive and specific laboratory screening was crucial (Al-Tammemi, 2020).

According to the World Health Organization (WHO) and the Center for Disease Control and Prevention (CDC), the gold standard for COVID-19 laboratory diagnosis remains the real-time polymerase chain reaction (RT-PCR) test (Hasell et al., 2020; Porte et al., 2020). Still, in addition to RT-PCR being expensive (Mathuria et al.,

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Abbreviations:COVID-19: Corona Virus Disease 2019;MOH: Ministry of Health; WHO: World Health Organization; CDC: Center for Disease Control; RT-PCR: Real Time Polymerase Chain Reaction; CPD: Continuing Professional Development; SARS-CoV-2: Severe acute respiratory syndrome coronavirus 2; CPHL: Central Public Health Laboratory; USAID: United States Agency for International Development; LHSS: Local Health System Sustainability

2020), lack of reagents, test equipment, and kit assembly factories severely limited RT-PCR testing capabilities around the world (Natesan et al., 2020). With progressive viral spread, other challenges related to trained staff shortage and fear and anxiety among frontline healthcare workers were identified (Jafri et al., 2020). This has put the capacities of laboratories to detect COVID-19 infections in a timely manner to question (Mathuria et al., 2020).

Huge efforts were made by the Jordanian Ministry of Health (MOH) to make the detection of COVID-19 infection more accurate and time-efficient. As one of Jordan's responses to COVID-19, MOH partnered with commercial biotechnology and pharmaceutical firms to set up COVID-19 PCR testing facilities across the country. A total of 16 new PCR units for molecular diagnosis were operational by early 2021, ensuring that each governorate had its own laboratory (A. Qaqish et al., 2022)

Many studies have determined challenges facing Jordan's health sector in managing the COVID-19 pandemic. Most of them reported problems related to vaccination challenges and physician/nurse burnout, but never related to diagnosis (Abu Farha et al., 2021; Algunmeeyn et al., 2020; Hatmal et al., 2021; Sallam et al., 2020, 2021).

Given the rapid and huge expansion of RT-PCR based diagnosis driven by MOH during COVID-19 spread in the country, this study aimed to use a qualitative semi-constructive questionnaire to identify the main obstacles that medical laboratory specialists at public and private hospitals encountered when diagnosing COVID-19 patients, and to identify the approaches used to overcome these obstacles.

2. Methods:

2.1. Design, participants and study context

A qualitative study under phenomenological descriptive approach study design was used to describe in depth the challenges of COVID-19 pandemic on clinical laboratories sector. Purposive sampling was employed in the participant recruitment process. By using purposeful sampling, the researcher can find individuals who are more likely to offer a detailed understanding of the phenomenon under investigation (Campbell et al., 2020). Prospective participants had to have been involved in the molecular diagnosis of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection for at least one month in order to be considered for inclusion in the study. Following a thorough explanation of the goals and methods of the study, participants were chosen and invited to participate. The sample size was estimated by achieving data saturation, which means no new data were identified in the analysis. The sample consisted of 16 medical laboratory specialists who worked in RT-PCR molecular diagnosis of COVID-19 from governmental and private hospitals located in various governorates of Jordan (table 1).

2.2. Ethical approval

The study was approved by the Institutional Review Board (IRB) at The Hashemite University of Jordan (No.4/14/2020/2021). Prior to participating in the trial, participants provided informed consent.

2.3. Patient and public Involvement

No patients or participants were involved.

2.4. Data collection and outcome measures

A semi-structured interview was employed to give a thorough understanding of the difficulties faced by clinical laboratory specialists involved in the molecular diagnosis of COVID-19 and their lived experiences in combating the pandemic in Jordan. Three authors reviewed and revised the interview questions, which focused on the work of the participants, obstacles and adaptations that participants went through during the early phases of the COVID-19 spread based on their lived experiences. A research assistant received training in qualitative interviewing. The semi-structured guide was then tested with two participants to assure its validity. To improve the interview's flow, a few minor changes were made to the questions and their arrangement. Table 2 details the questions of the semi-structured interview used in the study.

Phone interviews were done between June and December of 2021, while COVID-19 infections were still actively spreading. The researchers at the time believed that the most convenient and safest way to collect data was through phone interviews. The 30- to 45-minute interviews were recorded on audio with the participants' permission.

Privacy and confidentiality were assured by the investigators to all the participants. For privacy and confidentiality reasons, the names of the interviewees were not mentioned. Participants were referred to using a code, consisting of specifically designated hospital code.

2.5. Data analysis

This study employed a thematic analysis approach to identify key challenges, solutions, and insights related to the implementation of RT-PCR testing in Jordanian laboratories during the COVID-19 pandemic. Thematic analysis (Braun & Clarke, 2006) was chosen for its flexibility in identifying, analyzing, and reporting patterns within qualitative data. This approach allowed us to systematically capture the complex experiences of laboratory personnel across various sectors (governmental, private, and military hospitals). The analysis was conducted in the following phases: familiarization, coding, searching for themes, defining themes and naming, and produce report. For familiarization with the data, all interviews were transcribed verbatim, and the transcripts were read and re-read by the research team to gain a comprehensive understanding of the data. Then significant data were systematically coded across the entire dataset. Codes were grouped into broader themes. Through iterative discussions among the research team, themes were refined and organized based on their relevance to the research questions. The identified themes were reviewed in relation to the coded extracts and the entire dataset to ensure they accurately represented the data and reflected the key issues raised by the participants. The final themes and sub-themes were clearly defined and named to encapsulate the core findings of the study, including the challenges faced by the laboratories, the solutions implemented, and the potential future uses of RT-PCR technology. The themes were organized into a coherent narrative that reflected the experiences of the participants. Quotes pertinent to the themes that emerged were translated from Arabic into English using forward and backward translations; to guarantee the analytical process's credibility. NVIVO were used to produce the map.

3. Results:

As depicted in Table 3 and Figure 1, upon interviewing the 16 laboratory diagnosis specialists enrolled in the study, 12 from governmental hospitals and 4 from private sector hospitals, 3 themes were identified: Challenges, Solutions, and Importance of RT-PCR beyond COVID-19. "Challenges" encompassed 3 sub-themes: shortage of resources, operational processes and staff well-being. On the other hand, "solutions" involved 5 sub-themes: RT-PCR laboratory capacity building, staff management, turnaround time, digitalization, and screening with RAPID antigen testing.

3.1. Theme 1: Challenges

3.1.1. Shortage of Resources

All laboratories identified high challenge in clinical laboratory capacity in terms of staff, equipment, and kits availability for COVID-19 PCR testing. All governmental hospitals, except the Central Public Health Laboratory (CPHL) in the capital Amman, did not have a RT-PCR service before COVID-19. Private hospitals already had RT-PCR services, but laboratories were not ready for the quick shift in service demand. Thus, finding well-trained medical technologists to conduct RT-PCR was very challenging. In addition, the quick spread of the pandemic made it difficult to train enough medical technologists in a short period of time. Many contamination events happened due to the lack of employee proper training and awareness in sample handling during RNA extraction step. During curfew, not all hospitals were able to perform COVID-19 tests due to lack of RT-PCR kits. Hence, testing was restricted to the CPHL.

3.1.2. Operational Processes

One big challenge was in the way of samples' data entry and result release that relied on a paper-based system. The error rate in sample collection, labelling, and storage was high due the huge number of tests. Moreover, lack of understanding of strict infection control policy in RT-PCR laboratories in some hospitals allowed patients to get into RT-PCR laboratories to ask for their test results.

Many labs pointed out the challenge of having clear policies and regulations from the government regarding coordinating COVID-19 testing between labs. The quick changing policies, especially at early stages of the pandemic, and the absence of effective communications sometimes hindered the work coordination between governmental hospital labs and the Ministry of Health Central lab. A medical technologist at Governorate Central Lab in the North of Jordan Stated,

"There was a problem in work coordination with the Ministry of Health Central Laboratory in Amman, when a large sample number that exceeded the lab storage capacity reached a central governmental laboratory in the Northern Jordan. This resulted in sample accumulation of several days before we were able to send them to Amman Central Lab. Moreover, there were quick changes in lab heads and managers. This led to having conflicts in workplace. New managers had different operational styles and work organization. Hence, it was challenging to find a common language and reach a systematic work routine." Interview number 3

3.1.3. Staff Well-Being

Due to extended working hours to cover the screening demand, lab workers experienced harsh work burnouts and psychological stress. Some employees did not take a vacation for 2 years in arrow, and other did not see their families for months to prevent transmitting the disease to them.

3.2. Theme 2: Solutions

Many actions had been taken by the Ministry of Health and private sectors in order to address the pandemic stress on clinical laboratories. This emerged in 2 themes: RT-PCR laboratory capacity building and process improvement.

3.2.1. Capacity Building (RT-PCR Infrastructure)

The scarcity of RT-PCR kits during curfew was addressed by excluding these materials from import curfew restrictions and speeded up by collaboration with private vendors. In collaboration with private pharmaceutical and biotechnology companies, MOH established 16 new RT-PCR settings spread around the country to encompass every governorate and border crossing. Every laboratory was intended to contain two physically distinct rooms (the PCR and extraction rooms) and a separate workstation for preparing the master mix. The private firms constructed partition walls at multiple locations in order to comply with the construction standards for a PCR laboratory. This departmentation reduced sample contamination and employee infections rate. By the end of 2020/beginning of 2021, the MOH driven decentralization of COVID-19 molecular diagnosis allowed PCR testing at governmental labs outside the capital Amman to include every governorate in the country. Also, it allowed private labs to perform COVID-19 testing at borders and airports. Soon after, testing became available at the majority of well-equipped private labs in the country. As noted by a government hospital medical laboratory head in Central Jordan,

"We started doing RT-PCR in Oct. 2020 where medical technologists from the Ministry of Health Central Lab in Amman came and helped us to establish the molecular diagnosis department. Later, our lab technologists were trained by "Genetics", a private pharmaceutical/biotechnology company, which still supervises the work till now. Further extended training was accomplished by United States Agency for International Development (USAID)." Interview number 8

Most Private hospital laboratories had RT-PCR molecular diagnosis services before COVID-19 pandemic. However, these services had a low capacity in terms of equipment and staff. The pandemic pushed these hospitals to expand the service by doubling the RT-PCR machines and transforming the RNA extraction process into a fully automated one. New machines increased the lab testing capacity and the number of samples analyzed per day was doubled or tripled.

3.2.2. Staff Management

Shortage of well trained in RT-PCR medical technologists was overcame by staff reallocation, hiring new employee, and having a temporarily supporter from other labs or supplying companies. The MOH along with the Local Health System Sustainability Project (LHSS)/USAID and RT-PCR supplying companies trained medical technologist how to conduct the test. LHSS, gave extensive explanation of the basic science behind the test, in addition to troubleshooting advice.

3.2.3. Process Improvement-Turnaround Time

COVID-19 testing at the early stage of the pandemic used to take from 3 to 7 days to reveal. Now it takes 24 hours, and the expedited test takes 3-5 hours. This was achieved by molecular diagnostics capacity building discussed previously. In addition, working hours changed to accommodate the needs from day shift into 24/7 around the clock service.

3.2.4. Process Improvement -Digitalization

Most of governmental clinical laboratories relied on the traditional paper-based method in ordering the test and reporting the results. This pushed MOH to purchase a digital platform that connects all labs and speeds up the result release to patients and healthcare providers. In addition, private labs COVID-19 test results were synched to the MOH COVID-19 patients tracing and tracking digital system.

“One of the biggest challenges we faced at the beginning of the pandemic is the manual and paper-based lab. order system. This was resolved by adopting SUNDUS information system for patients orders and results entry in the ministry of health governmental labs, which reduced a lot of effort and time.” Interview number 2

3.2.5. Screening with Rapid Antigen Testing

COVID-19 rapid test was used as a quick screening method at emergency rooms, inpatient wards, and for the screening of healthcare workers. Only those with positive test or had COVID-19 symptoms and tested negative were then tested with RT-PCR for confirmation. This alleviated some of the pressure on RT-PCR service.

3.3. Theme 3: Future Perspectives

Every participant acknowledged the need for RT-PCR diagnostic testing to be expanded to detect other infections and cancer. Only one participant from a low volume private hospital expressed his doubts about the need of RT-PCR without COVID-19 pressure.

“We did not need such service at borderline before COVID-19; thus, I think we should expand such service in the Central Laboratory that could serve as a reference lab when such tests are needed.” Interview number 6

4. Discussion:

After having only 1 central molecular diagnosis laboratory in the capital Amman, the establishment of 16 new RT-PCR units to cover every governorate in the country is considered an exceptional success of the MOH. Still, this was faced with many obstacles. Similar stories of rapid expansion in the number of sites conducting molecular testing for COVID-19 were reported in low-income countries such as Ethiopia and Indonesia (Abera et al., 2020; Aisyah et al., 2021; Hendarwan et al., 2020; Kebede et al., 2021). In fact, Ethiopia demonstrated the conversion from no molecular diagnosis laboratories at all to 65 RT PCR testing settings (Abera et al., 2020; Kebede et al., 2021). Despite these many reported expansion stories around the world, full utility of these settings was not reached. Even in high-income countries, such as the US, COVID-19 RT-PCR testing capacity did not meet the needs of the pandemic situation (Du et al., 2021).

In this qualitative investigation, we aimed at determining major challenges that faced COVID-19 diagnosis in governmental and private hospitals of Jordan as reported by medical laboratory specialists. Challenges reported here are very similar to those reported in similar settings in the literature. Major challenges limiting the full utility of molecular testing capacity were listed to include workforce shortage, problems in logistics distribution, complex administration, shortage of reagents, non-reliability of some tests and, particularly, shortage of skilled staff (Abera et al., 2020; Kebede et al., 2021; Kroft, 2020; B. Qaqish et al., 2022; Walker et al., 2020).

Challenges were tackled with prompt acting solutions. Like many parts of the world, increasing sample load was managed by increasing the number of RT-PCR settings, re-allocation of trained staff, adopting a 24-hour working model and the use of rapid antigen testing (Okeke et al., 2020). Biosafety issues and truthfulness of testing results were ensured by extensive training of working staff, applying strict quality control measures, and digitalization of sample labeling and result release (Braunstein et al., 2021; Hu, 2016; Mögling et al., 2020). Proper control of viral spread was achieved by collaboration between diagnostic, surveillance and infection control networks facilitated by a connecting digital network (Hu, 2016).

It could be very challenging to establish and run a quantitative molecular testing facility within high biosafety requirements, such as that of COVID-19 diagnosis, concurrently with an epidemic crisis, and even more, during peaks of transmission. In such a case, priorities are given to transmission control measures, accomplished by sample screening and testing rather than training. Still, proper training is essential for fulfilling such anticipated control. This brings an important question: Since the least educated of our participants holds a bachelor’s degree in Biological Sciences, is RT-PCR and biosafety settings included in university curricular courses? If not in Biological Sciences, these must be listed in university curricula of Medical Laboratory Sciences. At least, graduates of such specialties must have the tools to self-educate themselves on every new technology in the world of diagnosis. This is an invitation for universities to update courses for the sake of coping with the accelerating developing technologies in such fields and to strengthen the basics that would help understanding emerging technologies after graduation. In addition, this is an invitation for MOH to give training courses on a yearly basis, to enable employees to catch up with all what is new in the world of diagnosis and to run annual examinations in order to encourage employees to keep up with the continuously evolving diagnostic technologies. Interestingly, in July 2021, LHSS/USAID signed a contract with MOH to strengthen the capacity of healthcare personnel to provide high-quality healthcare by instituting a system of ongoing professional development (CPD) that is required for the renewal of professional licenses (*Https://Jordankmportal.Com/Resources/as-Is-*

Process-for-Continuing-Professional-Development-and-Relicensing-Health-Care-Professionals-in-Jordan, n.d.).

Future pandemics are a possibility, thus being ready and able to act quickly is essential, including early identification and tracking of infected people (*Https://Www.Who.Int/Publications/i/Item/WHO-2019-NCoV-Lab-Testing-2021.1-Eng*, n.d.; Madhav et al., 2017). The use of molecular testing appears vital for rapid response to emerging infections (Okeke & Ihekweazu, 2021), which also reflects the ability to conduct molecular testing for other pathogens as well as other conditions, such as malignancies and genetic disorders.

One major limitation of this study lies in lack of information obtained from the Royal Medical Services and Private Diagnostic Laboratory Chains in the country. Both parties participated heavily in the molecular diagnosis of COVID-19 in Jordan but refused to take part in this study considering the unlikeliness of obtaining permissions from their managing heads.

5. Conclusions:

Challenges faced by medical technologists upon the establishment and expansion of molecular diagnosis facilities in Jordan to combat COVID-19 were successfully tackled with prompt acting solutions. However, this urgent experience highlighted the need for updating university curricula with newest diagnosis technologies and for offering relevant training to students in the medial field. In addition, a stringent CPD system and the usage of RT-PCR beyond COVID-19 should be implemented in order to be ready for pandemics in the future, for the expansion of RT-PCR diagnosis beyond infections and for maintaining high health care standards in the country.

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Supplementary Tables

Table 1: Demographic characteristics of the participants

Occupation	Gender	Hospital type	Age	Hospital's region	Educational level and specialty
LT	F	P	27	CR	BSc/Biotech
LS	M	P	29	CR	BSc/MLS
LM	M	P	36	CR	BSc/MLS
LM	M	P	44	CR	BSc/Biology
LM	M	G	49	SR	BSc/MLS
LS	F	G	45	SR	BSc/MLS
LM	M	G	39	CR	Pathologist
LS	F	G	39	NR	BSc/MLS
LT	M	G	33	NR	BSc/MLS
LS	M	G	33	NR	BSc/MLS
LM	F	G	53	CR	MSc/MLS
LM	F	G	47	CR	BSc/MLS
LM	F	G	37	NR	Not Available
LT	F	G	33	CR	MSc/biology
LS	F	G	41	CR	BSc/MLS
LT	F	G	44	SR	BSc/MLS
	F%: 56.2%		SD: 7.36		
	M%: 43.8%		Average :39.3		

LM, laboratory manager; LS, laboratory supervisor; LT, laboratory technologist.
MLS, medical laboratory science.
F, female; M, male.
P, private; G, governmental.
CR, central region; SR, southern region; NR, northern region.

Table 2. Interview Questions.

1. Did you have RT PCR based molecular diagnosis at your hospital before the emergence of COVID-19?

If the answer is yes:

- For the detection of what pathogen(s)/disease(s)?
- After the emergence of COVID-19, did you use the exact same RT PCR machines already present at your hospital/laboratory, or you had to order special machines and create special laboratory set ups for that purpose? Please, elaborate on the set ups.

If the answer for question 1 is no:

- did your hospital/laboratory collect nasopharyngeal swabs from suspected patients? Where did you use to send collected samples for diagnosis?
- do you perform RT-PCR diagnosis of COVID-19 at your hospital/laboratory now? Since when did you start? Were you trained by a specialist for molecular diagnosis? Whom provided your training? Were you supervised by a specialist at the start-up of your RT-PCR practice?

2. How do you compare the turnaround time of RT-PCR diagnosis of COVID-19 over time? Please, be specific. Elaborate on how many samples you were able to run per day and how many machines you had.
3. What are the major challenges you faced upon starting RT-PCR diagnosis of COVID-19 at your hospital/laboratory? Were you able to face and manage these challenges? How?
4. Did you use other COVID-19 diagnosis techniques, such as Rapid Antigen and/or Antibody detection? If yes, when did you start and under which conditions? Did that completely replace molecular diagnosis? What was the strategy you used for confirming test results?
5. After COVID-19 is over, do you see any benefits for establishing RT-PCR molecular diagnosis at your hospital/laboratory? Please, elaborate.

Table 3. Summary of the main themes and subthemes

Codes	Sub-themes	Themes
• Sample number burst during the pandemic peak. • Manual data entry and result release. • Obstacles in communication and co-ordination between governmental labs. • Highly changing policies and regulations over short period of time. • Sample error: improper sample collection, labeling, and sample storage.	Operational Demands	Challenges
• Lack of testing kits during curfew. • Shortage of data entry staff. • Shortage of trained staff and slow training schedule.	Resource Shortages	
• Work burnouts • Psychological stress	Staff Well-being	
• Medical equipment and kits excluded from curfew. • Establish a new RT-PCR units in hospitals that doesn't have one. • Increase number of extraction and PCR machines. • Automation of the extraction procedure. • Departmentation: establish an extraction room and a PCR room. • Decentralization of COVID-19 testing labs to include all government hospitals and private sector. • Establish COVID-19 screening testing centers at borders.	RT-PCR infrastructure	Capacity Building
• Staff trained by the ministry of health, RT-PCR suppliers, and USAID. • Hire new trained staff. • Staff internal reallocation.	Staff management	
• Increase testing capacity (double number or tested samples). • Working hour became 24/7.	Turnaround time	Process Improvement
• Adopting an information system that digitalize test orders, and results release. • Synch all digital platform in all labs with the ministry of health COVID-19 test hub.	Digitalization	
• Used for screening in ER, inpatients and among healthcare workers.	Screening with Rapid test (Ag/Ab)	
• Expand the RT-PCR service to include other pathogens and cancer diagnostics.	Importance of RT-PCR service beyond COVID-19	Future perspectives

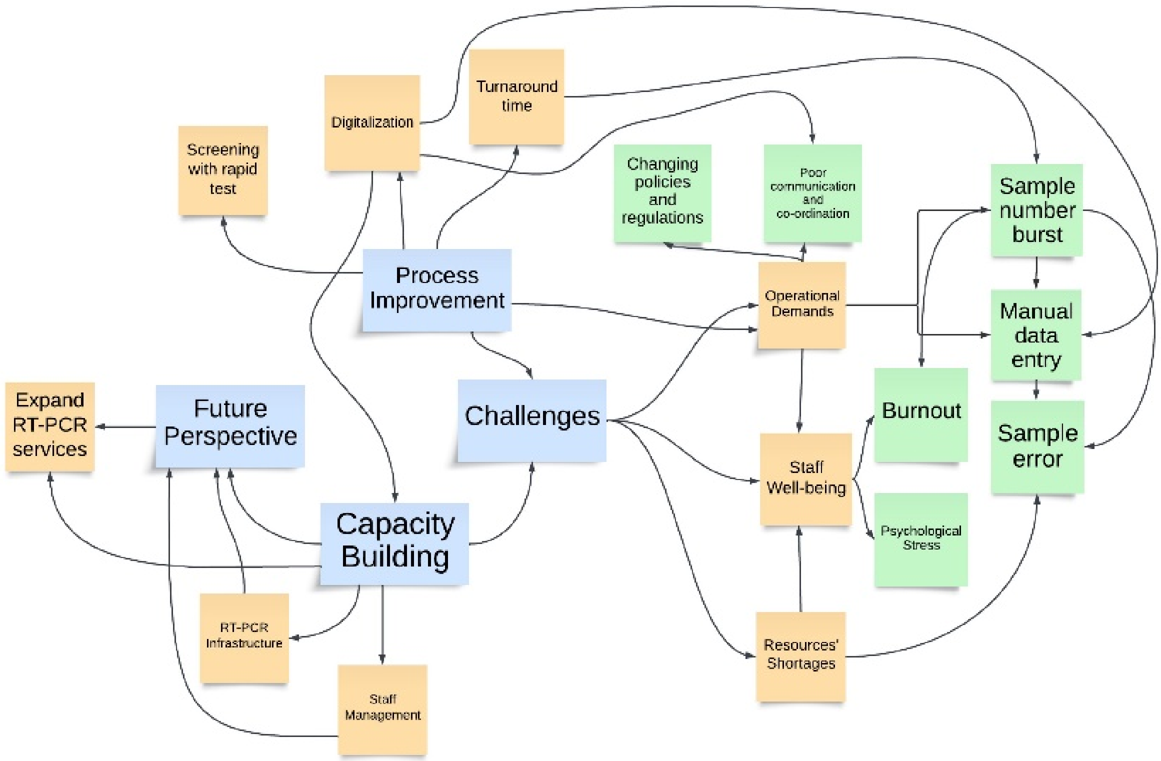

Figure 1. Thematic Analysis Map.