**Original Paper**

# The Pediatric COVID-19 Registry in Kuwait: Methodology and Results of Pilot Phase

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**Highlights of the Study**

- This manuscript describes the establishment of the Pediatric COVID-19 Registry in Kuwait and results of the pilot phase.
- Registry data elements were from the World Health Organization Case Report Form, and Research Electronic Data Capture was used as a secure database.
- Most children presented with mild disease, and the most common symptom was fever when infected with SARS-CoV-2.

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**Abstract**

*Objective:* Establishing a pediatric COVID-19 registry in Kuwait (PCR-Q8) was deemed imperative during the pandemic to study children infected with severe acute respiratory syndrome-related coronavirus 2 (SARS-CoV-2) focusing on mode of presentation, therapeutic interventions, disease severity, and early outcomes. This manuscript describes the rapid establishment of the PCR-Q8 registry showcasing an infrastructure of the development process and presents the results of the pilot phase. *Subject and Methods:* The registry was developed and implemented using the general key steps from a resource titled "Registries for Evaluating Patient

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Outcomes: A User's Guide" as a guide for best practice, experience from a previously established pediatric diabetes registry in Kuwait and several other COVID-19 registries developed globally. During the pilot phase, a convenience sample of 120 children was included, of whom 66 (55%) were male. **Results:** Experience and expertise from other COVID-19 registries; guidance provided by the World Health Organization; and effective collaboration and cooperation between the stakeholders, study group, and data enterers during these challenging times were critical for the development and implementation of the registry. Our results were similar to international reports which showed that most children presented with mild disease (69.2%), majority (70.2%) had normal chest X-ray, and the most common symptom at presentation was fever (77%). **Conclusion:** We anticipate the development of PCR-Q8 to be a stepping-stone for more in-depth investigation of SARS-CoV-2 infection in children in Kuwait and for the establishment of other registries.

## Introduction

On March 11, 2020, the World Health Organization (WHO) declared the global spread of severe acute respiratory syndrome-related coronavirus 2 (SARS-CoV-2), the causative agent for coronavirus disease 2019 (COVID-19), a pandemic [1]. By the end of the year 2020, more than 90 million cases had been confirmed to be infected with SARS-CoV-2, resulting in 1.9 million deaths in adults and children [2]. The virus caused enormous disruptions in people's lives, healthcare systems, and economies worldwide motivating people to join forces at national and international levels to address the pandemic. The overall disease severity in children was reported to be significantly milder than in adults [3–8]. Data from the USA until April 2020 reported 2,572 pediatric cases confirmed with COVID-19, including 15 admitted to an ICU, and 3 fatalities [9]. In Kuwait, for example, Al-Sharrah et al. [10] reported that children with COVID-19, diagnosed between February and April 2020, were in most cases asymptomatic (67.9%), and most symptomatic children presented with mild disease.

Early in the pandemic, the WHO recommended member states to collect standardized data describing clinical presentations, laboratory results, and outcomes of COVID-19 cases using the WHO Case Report Forms (CRFs) [11]. The WHO CRF is designed to collect data, retrospectively or prospectively, obtained from patient medical records, interviews, or examinations [12]. It has 3 modules: module 1 to be completed at admission at the health care facility; module 2 to be completed during hospital stay; and module 3 to be completed at discharge, death, or any other outcome. The establishment of a registry during an ongoing pandemic is critical for the collection of vital information, identification of factors associated with outcomes, and description of disease patterns and characteristics of the population studied. The experience gained can be useful during future pandemics and provide resources for future epidemiological research [13, 14].

Numerous observational disease registries have been established since and include the Viral Infection and Respiratory Illness Universal Study (VIRUS), the Lean European Open Survey on SARS-CoV-2 Infected Patients, and the COVID-19 Global Rheumatology Alliance (GRA) [13, 15, 16]. They include patients confirmed with SARS-CoV-2 infection and measure outcomes such as disease characteristics, severity, cardiovascular and neurological complications [13, 15, 16]. They found what facilitated the development of their registries was the rapid response and approval of the Ethical Review Board, critical need for open communication, and an assembly of a leadership team enabling multiple stakeholders [15]. The GRA attributes the strengths of their registry to the inspiration from the Inflammatory Bowel Disease registry that followed the Gliklich et al. [17] approach for creating registries. Strategies were identified that would have improved their processes include funding the data entry team and having an existing infrastructure for immediate use. Limitations in registries include potential selection bias and wide geographical variation in reporting. Nevertheless, collectively all registries used the secure web application Research Electronic Data Capture (REDCap) for collecting the registry data [18].

Various frameworks and guidelines are available to aid in the development and planning of a registry with general key steps [17, 19, 20]. For example, the steps described by Gliklich et al. [17] during phase one include defining the purpose of the registry, determining if a registry is the appropriate method to use, identifying key stakeholders, and assessing feasibility. Phase two includes building a team, establishing an oversight plan, determining scope and rigor, identifying datasets, and developing the protocol and a project plan.

The main purpose of the COVID-19 registry is to record all cases of SARS-CoV-2 infection in pediatric population aged 0–12 years, as officially defined by the health authorities in the country, living in Kuwait, focusing on mode of presentation, complications, therapeutic inter-

ventions, severity of disease, and early outcomes. This manuscript describes the establishment of the Pediatric COVID-19 Registry in Kuwait (PCR-Q8) registry and presents results of the pilot phase based on 120 cases.

## Subjects and Methods

### Creating and Implementing the Registry

The Pediatric COVID-19 Task Force at the Ministry of Health (MOH) was created to coordinate the response to the coronavirus pandemic nationally and recommended the establishment of a pediatric COVID-19 registry in Kuwait during early 2020. The Task Force initiated the creation and implementation of the registry in close collaboration with experts from the MOH and the Kuwait University by formulating the PCR-Q8 Group representing different specialties in pediatrics. The PCR-Q8 Group was given the mandate to identify stakeholders and partners within the government healthcare system to create teams for the implementation phase. An executive team was also created to oversee activities and to report to the PCR-Q8 registry group on a regular basis. The different members of the teams were responsible for different tasks (Fig. 1). The registry teams also partnered with the Dasman Diabetes Institute in Kuwait to utilize their resources in research and IT software development to benefit from the experience with the well-established Childhood-Onset Diabetes electronic Registry (CODeR) [21, 22] during the development of the PCR-Q8. Further partnerships were established with the Kuwait Institute for Medical Specializations and the Kuwait Medical Student Association to recruit pediatric residents and medical students for building field teams responsible for data collection. The project plan, including a timeline, was developed using key performance indicators by the executive team (Fig. 2). All project tasks and activities were monitored and updated on a weekly basis by the executive team. Patient identification was done using the national COVID-19 reporting system. The database includes all SARS-CoV-2 polymerase chain reaction (PCR) results from all public and private laboratories, and it includes test results done on symptomatic patients, close contacts, routine hospitalization screening, pretraveling and arrival screening. Primary data sources identified for the registry were all facilities where SARS-CoV-2 testing was done, i.e., the nation's six government hospitals (Al-Farwaniyah, Al-Amiri, Al-Sabah, Mubarak Al-Kabeer, Al-Adan, Al-Jahra) and one COVID-19 referral center (Jaber Al-Ahmad COVID-19 Referral Center). Additional secondary sources of data were gathered from primary care centers, quarantine facilities, dispatch call center, and public health laboratories (includes results from drive thru swabs) (Fig. 3).

### Inclusion Criteria for the Registry

Children aged 0–12 years: (a) living in Kuwait and seeking medical care due to complaints suggestive of COVID-19 infection, (b) returning travelers (the policy for testing of returning travelers changed according to the stage of the pandemic, e.g., 100% were tested during repatriation and when new virus mutations were identified. In addition, all people arriving from specific countries [hot zones] were tested upon arrival. At other times, either 10% or 20% of arrivals were randomly tested as Kuwait requires a recent negative PCR test from the country of origin), and (c) children identified by contact tracing. Close contacts
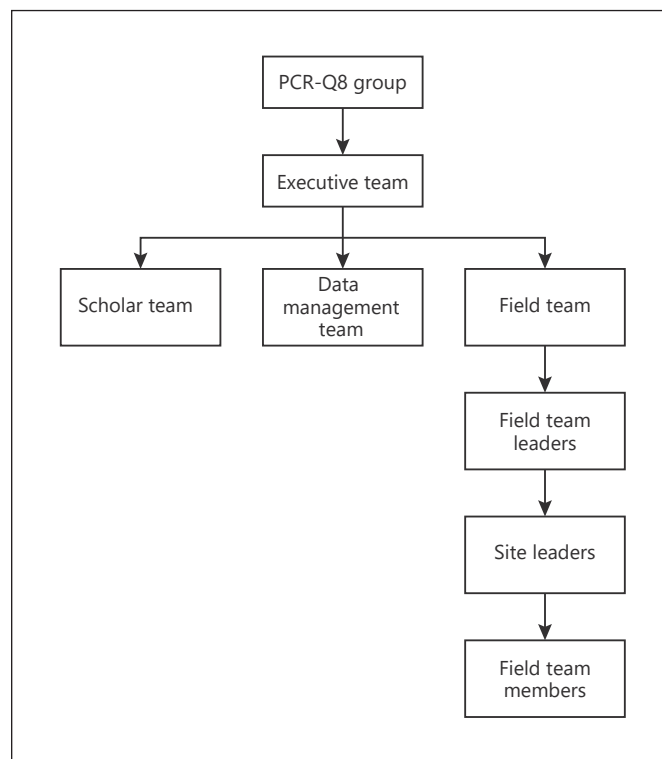


**Fig. 1.** PCR-Q8 registry group structure. The PCR-Q8 registry group was responsible for governance and oversight of the registry, drafting the grant proposal, obtaining ethical approval, establishing collaborations, and supervising data collection and reporting to MOH. The executive team (ET) was responsible for overseeing the activities of the scholar, data management (DMT), and field teams (FT). ET facilitated the study implementation, identifying obstacles and finding solutions, delegated tasks, and communicated with the other teams. The scholar team's (ST) role was to compile and review emerging evidence on COVID-19 worldwide and to update research directions, map and plan potential research outputs accordingly. The DMT was responsible for monitoring data entry, generating weekly reports (data collection rate, cleaning, verifying), and reporting data collection and management recommendations to the ET. FT leaders were responsible for training site leader and field team members data collection and entry, monitoring data collection, coordinating with site leaders, and implementing any recommendations made by the ET. Site leaders were the leaders of their data source site and thus also the leaders of the FT members (i.e., residents/data collectors) of that site. They were responsible for ensuring data was collected, arranging weekly meetings to ensure accuracy and reliability of data, and communicating with other site leaders.

identified during contact tracing are usually tested for SARS-CoV-2 virus. Close contacts are defined as people within 2 meters of an infected person for a duration of ≥15 min. Participants excluded from the registry include children above the age of 12 years, those who do not have a positive PCR test, and those with inconclusive PCR tests.
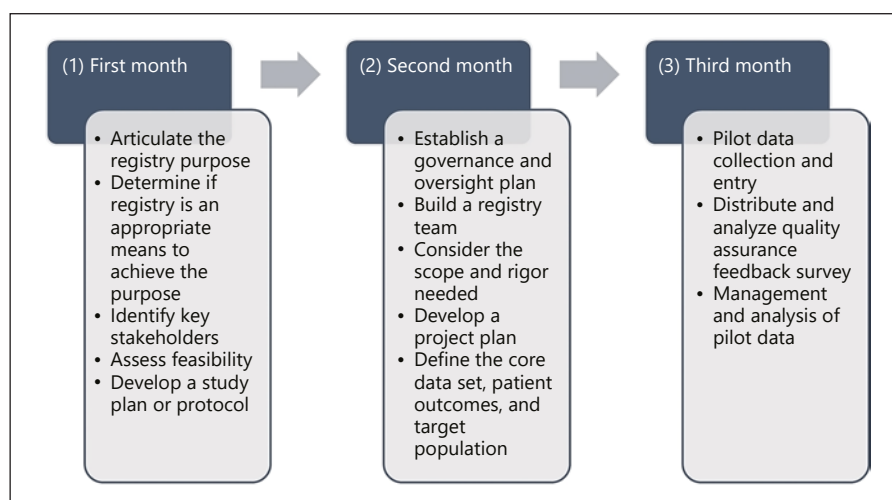
**Fig. 2.** Timeline of key steps in registry planning PCR-Q8 using the framework of Gliklich et al. (17).

*COVID-19 Testing Procedures in Kuwait*

Tests are usually performed by collecting samples from the respiratory system. Samples may include nasopharyngeal, oropharyngeal, nasal swabs, saliva samples, or respiratory tract aspirate. Samples are tested using reverse transcriptase-polymerase chain reaction technique [23, 24]. The registry used the standard WHO COVID-19 case definitions to identify SARS-CoV-2 infected patients [12] which are (1) positive nucleic acid amplification test and (2) asymptomatic person with a positive SARS-CoV-2 antigen-RDT who has been identified as a contact of a probable or confirmed case [25].

*Defining Data Elements*

The data collection form was inspired by the WHO COVID-19 data elements (5), St. Jude's hospital [26], and expert review by the Task Force (Table 1). The Dasman Diabetes Institute provided a secure server hosting the REDCap survey [18]. An electronic data collection form was created in REDCap and was available through access granted to the registry team members from multiple devices.

*Pilot Data Collection*

A pilot phase was implemented over a 1-week period to test the procedures and logistics of data collection. In preparation for the pilot study, training of field staff was organized. The study protocol was approved by the Standing Committee for Coordination of Health and Medical Research (Ethics Review Committee) at the MOH of Kuwait (Reference No. 1559/2020). The research was conducted ethically in accordance with the World Medical Association Declaration of Helsinki. A convenience sample of 120 children with COVID-19 infection was randomly selected and included in the pilot phase. The random sample was chosen from the official list of reported cases in the country which was provided by the Department of Technical Affairs from the MOH. In detail, a convenient sample of 20 children was chosen from each of the six data sources (Fig. 3) during February 2020–October 2020. At the end of the pilot phase, a feedback survey was distributed to all the data collectors, and final adjustments were made to the data collection form.
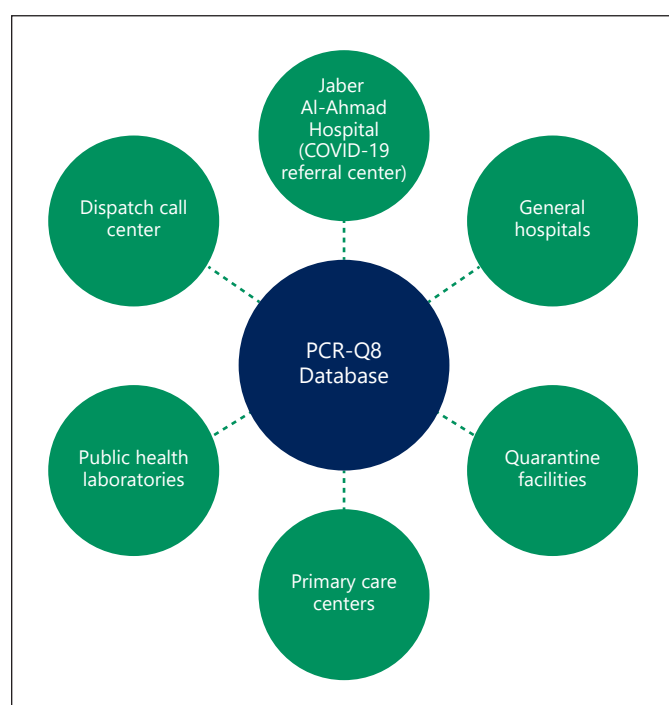


**Fig. 3.** Data source mapping.

Statistical analyses were performed using STATA software13.1 (STATA Corp, College Station, TX, USA). Differences with *p* value of less than 0.05 were deemed to be statistically significant. Non-normally distributed continuous variables were expressed as median (interquartile range). Wilcoxon Rank-Sum test was used to test for the differences in continuous variables, while Pearson's $\chi^2$ test or Fisher's exact test was used to test for differences in categorical variables as appropriate. We also tested the differences in distribution of gender using exact binomial probability test.

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**Table 1.** Key data elements captured in the Pediatric COVID-19 Registry (PCR-Q8)

| Variable groups | Key data elements |
|---|---|
| *Retrospective phase*<br>A. Demographics | 1. Gender<br>2. Date of birth<br>3. Nationality<br>4. Source of data<br>5. Hospital admission |
| B. Past medical history, comorbidities, vaccinations | |
| C. (1) COVID-19/SARS-CoV-2 testing | 1. Suspected or confirmed infection<br>2. Where was the first SARS-CoV-2/COVID-19 test done?<br>3. Result of COVID-19 test (PCR) |
| C. (2) RT-PCR (real-time PCR) | |
| C. (3) SARS-CoV2-(immunoassays) | |
| D. History of presenting illness signs and symptoms at hospital admission/first medical assessment | |
| E. Signs and symptoms on admission/or 30 days prior to positive COVID-19 test | |
| F. Vital signs/growth/other examination remarks | |
| G. Oxygen therapy/intensive care | |
| H. (1) Therapy and medications | |
| H. (2) Antibiotic and other medications | |
| I. Complications | |
| J. Diagnostics, imaging | |
| K. (1) Microbiology/pathogen testing (bacterial pathogen testing) | |
| K. (2) Microbiology/pathogen testing | |
| L. (1) CBC and coagulation profile | |
| L. (2) Renal function test | |
| L. (3) Liver function test | |
| L. (4) Other tests | |
| L. (5) Other tests not listed | |
| M. Outcome | 1. What was the final diagnosis? |
| *Prospective phase (baseline, 4, 12 weeks)*<br>A. Demographics | |
| B. Parents/legal guardian interview | |
| C. History at x weeks follow up | |
| D. New signs and symptoms (new health events) x weeks after COVID-19 diagnosis | |
| E. Medical chart review COVID-19/SARS-CoV-2 testing (if done after the initial positive testing) | |
| F. Growth/vital signs/other examination remarks | |
| G. Laboratory results (record units if different from those listed) date within x weeks after diagnosis with COVID-19 | |

**Table 2.** Clinical characteristics of 120 patients with COVID-19 infection

| Variables | Total N = 120 (100.0%) | Male N = 66 (55.0%) | Female N = 54 (45.0%) | p value |
|---|---|---|---|---|
| Age, years, median (IQR) | 3.1 (0.8, 8.6) | 2.9 (0.8, 8.6) | 3.7 (0.8, 8.7) | 0.9244 |
| Nationality, n (%) | | | | |
|     Kuwaiti | 53 (44.2) | 31 (46.7) | 22 (40.7) | 0.494 |
|     Non-Kuwaiti | 67 (55.8) | 35 (53.3) | 32 (59.3) | |
| Symptomatic (yes), n (%) | 96 (80) | 50 (75.8) | 46 (85.2) | 0.199 |
| Presence of comorbidities[a] (yes), n (%) | 20 (16.7) | 9 (13.6) | 11 (20.4) | 0.338 |
| Chest X-ray findings[b,c] n (%) | 57 (47.5) | 26 (45.6) | 31 (54.4) | |
|     Normal | 40 (70.2) | 21 (80.8) | 19 (61.3) | 0.149 |
|     Abnormal | 17 (29.8) | 5 (19.2) | 12 (63.2) | |
| Disease severity[d,e], n (%) | 96 (80.0) | 49 (74.2) | 47 (87.0) | |
|     Asymptomatic | 17 (17.7) | 10 (20.4) | 7 (14.9) | 0.369 |
|     Mild | 66 (68.8) | 33 (67.3) | 33 (70.2) | |
|     Moderate | 8 (8.3) | 3 (6.1) | 5 (10.6) | |
|     Severe | 1 (0.9) | 1 (1.7) | 0 (0) | |
|     Critical | 4 (4.2) | 2 (4.1) | 2 (4.3) | |
| Outcome: care needs at discharge[f], n (%) | | | | |
|     Same as before illness/better | 91 (87.5) | 45 (49.5) | 46 (50.5) | 1.00 |
|     Worse | 2 (1.9) | 1 (50) | 1 (50) | |

IQR, interquartile range. [a] Comorbidities: asthma (n = 6), choanal atresia (n = 1), chronic duodenitis and GERD (n = 1), congenital adrenal hyperplasia and eczema (n = 1), iron deficiency anemia (n = 1), osteopenia (n = 1), global development delay (n = 3), Fanconi anemia (n = 1), liver cirrhosis (n = 1), corrected hypospadias, left kidney hydronephrosis, recurrent UTI, corrected lenticonus, eye squint (n = 1), asthma, left pulmonary artery dysplasia, epilepsy on VP shunt, GDD, GERD (n = 1), mod biventricular hypertrophy with mod septal hypertrophy, VLCAD (n = 1), VUR, febrile convulsion (n = 1), recurrent pyelonephritis (n = 1), nephrotic syndrome (n = 1). [b] Chest X-ray done on 57 out of 120 patients (n = 26 male and n = 31 female). [c] Abnormal findings such as interstitial infiltrates (n = 11), increased bronchovascular marking (n = 2), cardiomegaly (n = 1), bilateral infiltration (n = 1), lobar consolidation (n = 1), multifocal or patchy opacity (n = 1). [d] Disease severity as per the definition of the WHO [27]. [e] Missing on 24 subjects (n = 17 male and n = 7 female). [f] Missing on 27 subjects (n = 20 male and n = 7 female).

## Results

Key steps of the registry development were met, fulfilling the Gliklich et al. [17] framework, with slight modifications to fit the regulations and procedures mandated by the MOH of Kuwait (Fig. 2). After the first month of appointing leadership team and relevant key stakeholders, the study protocol and data fields (Table 1) were finalized using the WHO COVID-19 data elements released and extrapolated from the International Severe Acute Respiratory and Emerging Infection Consortium CRF to ensure data comparability with other international registries data. In addition, all six governorate hospitals enrolled in the registry. During the pilot phase, a convenience sample of 120 children was included, of whom 66 (55%) were male. Pre-existing comorbidities were reported in 16.8% of the study population. A majority (69.2%) of subjects had mild illness, and 70.2% has a normal chest X-ray. Clinical characteristics of these children are shown in Table 2. Out of the total of 120 children included in the pilot, 96 (80%) were symptomatic with the most common symptoms of fever (77.1%) and cough (39.6%) (Table 3).

## Discussion

This manuscript describes the establishment of the PCR-Q8 registry and results of its pilot phase, based on data from a convenience sample of 120 children with CO-VID-19 infection in Kuwait. The PCR-Q8 was developed and implemented using the general key steps from Gliklich et al. [17] as a guide for best practice. All data were collected to fulfill the aims of the registry despite the challenges of working within a healthcare system without well-established electronic health records and lack of compatibility between different systems used in different facilities by an extensive network of healthcare professionals and manual data collection. The development of

**Table 3.** Signs and symptoms in 96 children with COVID-19 infection

| Sign/symptom | Frequency, N (%) |
|---|---|
| Fever | 74 (77.1) |
| Cough | 38 (39.6) |
| Runny nose | 29 (30.2) |
| Fatigue/malaise | 24 (25.0) |
| Anorexia | 21 (21.8) |
| Vomiting/nausea | 18 (18.8) |
| Diarrhea | 16 (16.7) |
| Inability to breastfeed or poor feeding | 14 (14.6) |
| Abdominal pain | 10 (10.4) |
| Shortness of breath | 9 (9.4) |
| Irritability | 7 (7.3) |
| Sore throat | 6 (6.3) |
| Headache | 6 (6.3) |
| Conjunctivitis | 5 (5.2) |
| Skin rash | 5 (5.2) |
| Others* | 23 (24.0) |

* Muscles aches, wheezing, seizures, mucocutaneous changes, altered consciousness/confusion, inability to walk, lower chest wall indrawing, joint pain, and hemorrhage. Frequency of less than 5 times and therefore grouped together.

this registry was inspired by the WHO response to CO-VID-19 and used information based on the limited data describing clinical manifestations of the infection in children available in the literature [27]. We also built on experiences from other registries such as the GRA, VIRUS, Lean European Open Survey on SARS-CoV-2 Infected Patients, and CODeR which were developed using the data elements from the WHO CRF and used REDCap as their secure web-based electronic data capture tool [11, 13, 15, 16, 22]. The key data elements collected in the PCR-Q8 registry are described in Table 1.

As COVID-19 is caused by a novel virus with only limited data on its clinical manifestations and other aspects of the infection, it can be expected that data from this registry will contribute to international epidemiological studies. For example, the registry helps to systematically collect data, and compare diagnostic and treatment patterns, disease severity, and outcomes with other hospitals. It also creates an infrastructure and culture of enhanced quality of care [19, 20].

*Lessons Learned and Challenges Faced*

Many lessons were learned while establishing and implementing this national registry during an ongoing pandemic. Effective coordination between stakeholders and team members involved was critical. New approaches to communication, such as virtual meetings, were useful in obtaining rapid responses and approvals by the Ethical Committee and other administrative clearances. The multidisciplinary effort and commitment of all parties involved in the response to COVID-19 demonstrated the importance of teamwork in establishing a registry. Experience with CODeR facilitated the use of REDCap secure data collection and storage. Challenges faced while implementing the registry included data collection and entry procedures. Creating the REDCap forms required numerous edits and revisions to reach the final version, thus having a software expert on hand was deemed imperative. Also, to ensure data entry validity and any lack of experience with REDCap, all data enterers received training. The data entry forms were tested during the pilot phase and were approved based on feedback forms. Another challenge faced was the coordination and communication between different hospital sites. This required management skills; each site was assigned a site leader who relayed information from the Task Force to the data enters. As expected, it was also a challenge for medical residents to balance their clinical duties and data entry during the pandemic in a timely manner.

We present results from 120 children in a pilot phase which is clearly not representative of the total pediatric population in Kuwait. Asymptomatic children can be assumed to be under-represented in this preliminary data set, and efforts targeting wider SARS-CoV-2 testing in this population are needed. However, based on our preliminary data, children included in the registry infected with COVID-19 mostly presented with mild symptoms which agrees with local and international reports [3–7, 10, 28, 29]. The most common symptom at presentation with COVID-19 in our pilot was fever as reported previously [4, 6, 28].

A few limitations should be noted. First, this is an observational design that does not allow for establishing causal inferences from the results. There is a potential for selection bias (e.g., entering more severe cases) in a registry; however, our registry has data from various sources and not only hospitals [13, 19]. Second, limitations of data in a registry include data incompleteness and duplicated records. To combat these issues, weekly data monitoring reports were generated by the data management team. There could also be wide variations in reporting by different sites, sources, and data collectors which could lead to heterogeneity in data validation and verification [13, 19, 20]. Lastly, registered patients may not be representative of the entire pediatric population infected with COVID-19 as many children were asymptomatic or had mild symptoms or did not seek medical attention, although residents all over Kuwait have access to healthcare services.

## Conclusion

As part of the national response to the SARS-CoV-2 pandemic, a pediatric COVID-19 registry was developed and implemented in Kuwait. Expertise from other international COVID-19 registries as well as guidance from the WHO were critical in the development of the registry. The results demonstrated the importance of effective collaboration and cooperation during these challenging times. We anticipate that the PCR-Q8 registry will provide invaluable information on COVID-19, its effects on children in Kuwait to guide clinical practice and contribute to international epidemiological studies of COVID-19 in children.

## Statement of Ethics

The study protocol was approved by the Standing Committee for Coordination of Health and Medical Research (Ethics Review Committee) at the Ministry of Health of Kuwait (Reference No. 1559/2020). The research was conducted ethically in accordance with the World Medical Association Declaration of Helsinki.

## Conflict of Interest Statement

The authors have no conflicts of interest to declare.

## Author Contributions

Conception and design study: H.A.-H., KS, H.A.-K., D.A.-A., M.G., Z.H., S.B.-H., and A.F. Acquisition of data: H.-H., H.S., D.-A., K.K., M.A., and Z.H. Analysis/interpretation of data: D.-A., S.Q., M.-K., S.B.-H., M.G., and K.S. Drafting the manuscript: S.Q., D.A., H.K., and M.K. Edit and approval of final version: H.-H., K.S., H.-K., D.-A., M.G., Z.H., S.B.-H., A.F., M.A., K.K., M.-K., and S.Q. All authors certify that they have participated sufficiently in the work to take public responsibility for the content, including participation in the concept, design, analysis, writing, or revision of the manuscript.

## Data Availability Statement

The data that support the findings of this study are available from the Ministry of Health (MOH) and Dasman Diabetes Institute (DDI), but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are, however, available from the authors upon reasonable request and with permission from the MOH and DDI.

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