



BMJ Open Service provision and utilisation in German paediatric primary care practices during public health crises: Protocol of the mixed-methods COVID-19 PedCare Study

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ABSTRACT

Introduction Public health crises such as pandemics can cause serious disruptions to the utilisation and provision of healthcare services with negative effects on morbidity and mortality. Despite the important role of paediatric primary care in maintaining high-quality healthcare services during crises, evidence about service utilisation and provision remains limited especially in Germany. This study, therefore, explores the utilisation and provision of paediatric primary care services during the ongoing COVID-19 pandemic and their barriers and facilitators.

Methods and analysis The study uses a convergent mixed-methods design and comprises online surveys to parents, adolescents and primary care paediatricians (PCPs) and semistructured interviews with parents and PCPs. We recruit parents and adolescents from paediatric primary care practices and PCPs via email using mailing lists of the German Professional Association of Paediatricians and the German Society of Ambulatory Primary Care Paediatrics. The parent and adolescent surveys assess, *inter alia*, the utilisation of paediatric primary care services and its correlates, aspects of parental and child health as well as socioeconomic characteristics. The PCP survey investigates the provision of paediatric primary care services and its correlates, aspects of PCP health as well as sociodemographic and practice characteristics. The semistructured interviews with parents and PCPs explore several aspects of the online surveys in more detail. We use descriptive statistics and generalised linear mixed models to assess service utilisation and provision and specific correlates covered in the online surveys and apply qualitative content analysis to explore barriers and facilitators of service utilisation and provision more broadly in the semistructured interviews. We will integrate findings from the quantitative and qualitative analyses at the interpretation stage.

Ethics and dissemination The study was approved by the Medical Ethics Review Board of the Medical Faculty Mannheim at Heidelberg University (2020–650N). Study results will be published in journals with external peer-review.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The current study is among the first to comprehensively explore utilisation and provision of paediatric primary care services as well as their barriers and facilitators during a major public health crisis in Germany.
- ⇒ Using a convergent mixed-methods design, we explore the perspectives of parents, adolescents and primary care paediatricians.
- ⇒ The rate of response to the parent and adolescent surveys may limit generalisability of the quantitative findings, although semistructured interviews will be useful in uncovering insights that will guide future research in this area.
- ⇒ We are not able to attribute findings to particular phases of the pandemic such as lockdown or inter-lockdown periods.

INTRODUCTION

Public health crises such as pandemics can cause severe disruptions to both the provision of paediatric healthcare services and their utilisation.^{1 2} Both provision and utilisation of services should be considered to fully understand the impact of crises on healthcare systems and to identify strategies to strengthen their resilience because high-quality care might be compromised by disruptions to service provision, decreased service utilisation or a combination of both.

The extent to which the utilisation and provision of paediatric healthcare services is affected by public health crises is not fully understood. Substantial changes in the utilisation of paediatric emergency care were observed during past epidemics.^{1–3} Early evidence on the ongoing COVID-19 pandemic and its concomitant lockdown and social distancing measures suggests declines in the utilisation of paediatric healthcare

services, including paediatric emergency care,⁴ services for children with special healthcare needs such as occupational therapy or physiotherapy⁵ and vaccinations.⁶⁻⁹ Service provision during the COVID-19 pandemic has been compromised by cancellations or deferrals of elective or non-emergency surgeries and by temporary closures of paediatric oncology departments.¹⁰⁻¹²

Reduced utilisation of paediatric healthcare services and disruptions to service provision during public health crises can contribute to higher morbidity and mortality. An increased proportion of severe ketoacidosis in children and adolescents newly diagnosed with type 1 diabetes and more complications in young people with acute appendicitis during the COVID-19 pandemic, compared with the prepandemic period, were most likely caused by delayed presentation.¹³⁻¹⁵ It is expected that the deferral of chronic care during the pandemic will be accompanied by increased morbidity and mortality in the future.¹⁶

Paralleling the role of General Medicine for adult patients, paediatric primary care plays an important role in responding to disruptions to service utilisation and provision during public health crises.¹⁷ Several countries in Europe and elsewhere (eg, Spain, Czech Republic, USA) have paediatrician-based systems or ones in which both general practitioners, family doctors and paediatricians provide paediatric primary care (eg, Austria, France, Germany).¹⁸ In countries with paediatrician-based and combined systems, primary care paediatricians (PCPs) are the first point of contact with the healthcare system for most children and adolescents, providing acute, chronic and preventive care, counselling as well as coordination of services with community-based service providers.

Paediatric primary care has the potential to contribute to high-quality healthcare services during public health crises due to its role in the provision of accessible and equitable services in light of protracted emergencies and its potential to reduce non-emergency-related morbidity and mortality.¹⁷ Minimising disruptions to service utilisation and provision in paediatric primary care should, therefore, be a priority. To our knowledge, however, only one study has examined the utilisation of paediatric primary care services during the COVID-19 pandemic, reporting declines in in-person consultations ranging from 40% to more than 80% between March and August 2020 compared with previous years.¹⁹

Reasons for reduced utilisation of paediatric healthcare services during pandemics are not well understood. Potential explanations may include parental fear of infection,^{20 21} pending mandatory SARS-CoV-2-test results²⁰ or disruptions to service provision due to closed healthcare facilities, staff shortages²² or changes in practice opening hours.²³ Given its central role within the healthcare system especially during public health crises, studies comprehensively assessing the scope of disruptions to paediatric primary care service utilisation and provision, their associated factors and leverage points to strengthen paediatric primary care in times of crises are urgently needed.

Socioeconomic factors may introduce additional forces that affect service utilisation during public health crises differentially, aggravating existing health inequalities.^{24 25} During past epidemics, for example, health outcome indicators such as morbidity and mortality rates differed by socioeconomic characteristics at multiple levels: individuals from different occupational classes or socioeconomic strata showed different mortality rates, an indicator that also varied according to area-level socioeconomic deprivation.^{26 27} Such differences may be related to differential patterns of healthcare utilisation in families with different family-level vulnerability characteristics, the greater vulnerability of residents in socioeconomically deprived areas, in which healthcare services are often limited, or a dynamic interaction between these and other factors.²⁸ However, evidence on differential impacts of public health crises on service utilisation, as opposed to health outcomes, remains scarce.²⁹

In addition, organisational readiness for change may also play an important role in the ability of healthcare service providers to respond to changing circumstances that, in turn, can affect service provision. For example, at the beginning of the COVID-19 pandemic, PCPs had to reorganise multiple structures and processes in their practices under immense time pressure. This included the installation of physical barriers at reception desks and in consultation rooms, separate consultations for children with suspected infections or the extended use of telemedical services.^{19 30 31} In general, implementing change in healthcare organisations has proven challenging given different perspectives on the change process and its consequences within teams, insufficient information disseminated by the practice management during the change process or a lack of time for preparing for change.³² Organisational readiness for implementing change (ORIC), an indicator of the potential for change within healthcare institutions,^{33 34} has been described as an organisational construct comprising two components: (1) change commitment, organisational members' shared resolve to implement a change and (2) change efficacy, the shared belief in their collective capability to do so.³³ The extent to which ORIC plays an important role for paediatric primary care service provision during public health crises is unclear, yet such information could be valuable in improving the capacity of paediatric primary care to successfully respond to future challenges.

Here, we describe the protocol for a study, which will be among the first to comprehensively investigate disruptions to paediatric primary care service utilisation and provision during a major public health crisis and their underlying reasons. Insights from this study have the potential to improve the resilience of paediatric primary care and to contribute to continued high-quality and equitable primary care services for all children and adolescents. In addition, it will provide important insights that may help to minimise excess morbidity and mortality due to disruptions to paediatric primary care during the current and future public health crises.

Study objectives

In the COVID-19 PedCare Study, we aim to explore leverage points to strengthen paediatric primary care services during the current pandemic and future public health crises. Specifically, we pursue the following primary and secondary objectives:

Primary objectives

1. To investigate the utilisation of paediatric primary care services by families during the COVID-19 pandemic and to describe barriers and facilitators of service utilisation from the perspective of parents and adolescents.
2. To assess the provision of paediatric primary care services during the COVID-19 pandemic and to explore barriers and facilitators of optimal service provision from the perspective of PCPs.

Secondary objectives

1. To assess the independent association between both family-level factors of vulnerability and area-level socioeconomic deprivation and paediatric primary care utilisation during the COVID-19 pandemic.
2. To investigate the association between ORIC and the provision of paediatric primary care services and to describe barriers and facilitators of ORIC.

METHODS AND ANALYSIS

Study design

The COVID-19 PedCare Study, funded by the Ministry of Science, Research and Arts of Baden-Wuerttemberg, Germany, is based on a convergent mixed-methods

design³⁵ and consists of five parts (A-E; figure 1). To enable a comprehensive assessment of service utilisation and provision, we explore the perspectives of parents, adolescents and PCPs. Specifically, we conduct quantitative online surveys with parents (A), adolescents (B) and PCPs (C) and semistructured interviews with parents (D) and PCPs (E). We first collect and analyse quantitative and qualitative data separately and integrate the findings at the stage of interpretation.³⁵ Data collection for the online surveys and the semistructured interviews started in February and March 2021, respectively, and will be completed by August 2021. The reporting in this manuscript is based on the Checklist for Reporting Results of Internet E-Surveys³⁶ and the Consolidated Criteria for Reporting Qualitative Research.³⁷

Setting

The study is conducted in Germany, a nation with universal healthcare coverage, in paediatric primary care practices. Approximately 60%, 20% and 20% of all German children and adolescents below the age of 18 years, receive primary care services from board-certified paediatricians, general practitioners or a combination of both, respectively.³⁸ Paediatric primary care practices are heterogeneous in size and organisational structure and consist of mostly solo and group practices. Paediatric primary care practices are predominantly headed by one or more PCPs and usually comprise several medical assistants. Depending on the size of the practice, other board-certified paediatricians, paediatric residents and paediatric nurses may complement practice teams.

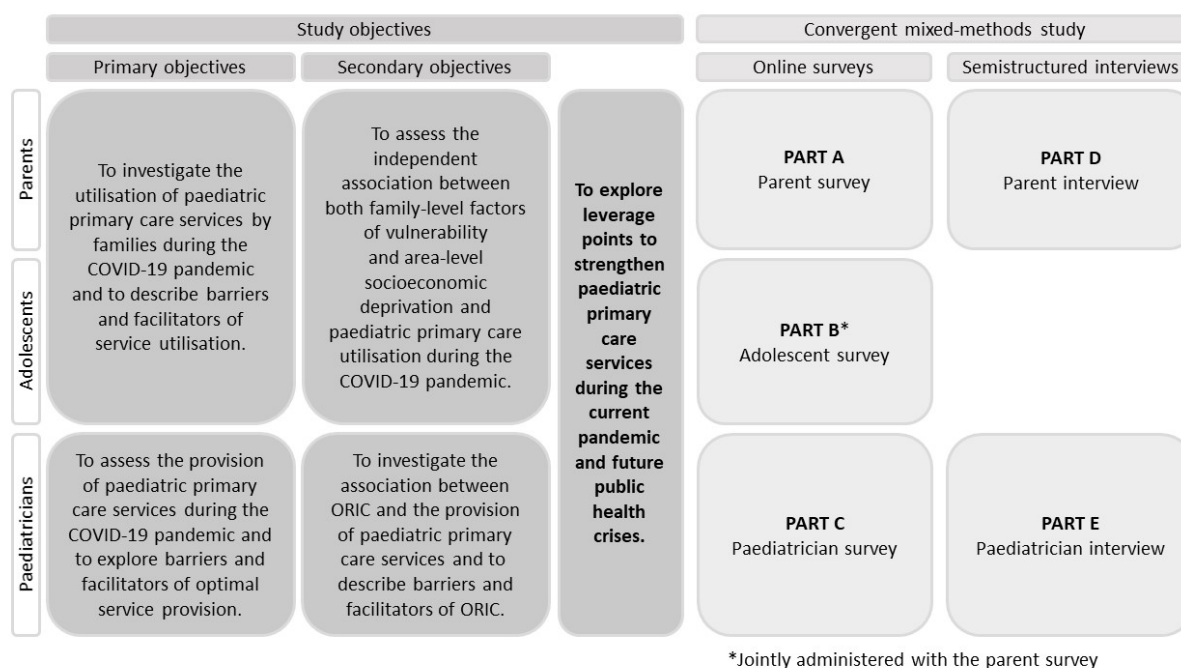


Figure 1 Overview of the COVID-19 PedCare Study: Objectives and study parts. To enable a comprehensive assessment of the utilisation and provision of paediatric primary care services, the COVID-19 PedCare Study uses a convergent mixed-methods design comprising quantitative online surveys and semi-structured interviews and integrates the perspectives of parents, adolescents and primary care paediatricians. ORIC, organisational readiness for implementing change.

Participants and recruitment

Parent and adolescent surveys (parts A and B)

We follow a two-step process to recruit parents (A) and adolescents (B) for the online surveys. In the first step, the German Professional Association of Paediatricians (*Berufsverband der Kinder- und Jugendärzte, BVKJ*) has agreed to invite all PCPs in Baden-Wuerttemberg, a federal state of 11.1 million inhabitants in the southwest of Germany, to take part in the study.³⁹ Information on the study is distributed via the mailing list of the BVKJ. PCPs interested in participating in the study are invited to contact the research team via email and receive detailed information on study procedures. No exclusion criteria are defined at the level of PCPs. In the second step, participating PCPs and their staff are asked to invite families consulting their practices to take part in the parent and adolescent online surveys by providing leaflets containing detailed information on the study. The parent and adolescent surveys are open surveys targeting all parents and adolescents visiting the paediatric primary care practices and result in a convenience sample of the target population. To reduce selection bias, we ask PCPs to consecutively invite parents and adolescents for participation. After having completed the parent survey, all parents with adolescents aged 12 years or older are asked to consent to their child's participation in the adolescent survey. No exclusion criteria are defined for parents and adolescents. However, those unable to take part in an online survey (eg, no internet access, no access to an electronic device) or to complete a survey in German or in a version translated into one of the three languages most often spoken by families with migration background in the target region (English, Turkish, Italian)⁴⁰ are excluded from the study *de facto*.

Paediatrician survey (part C)

Out of respect for increased demands faced by PCPs during the pandemic and to reduce the burden of participation, we conduct the paediatrician survey in different paediatric primary care practices than those involved in identifying parents and adolescents in Parts A and B. All members of the BVKJ with paediatric primary care practices in the German federal states of Bavaria (13.1 million inhabitants; number of PCPs: 1080; south-eastern part of Germany) and Berlin (3.8 million inhabitants; number of PCPs: 311) and all members of the German Society of Ambulatory Primary Care Paediatrics (*Deutsche Gesellschaft für Ambulante Allgemeine Pädiatrie, DGAAP*) are invited to participate in the paediatrician survey. The DGAAP is the academic association of PCPs in Germany with 210 current members and membership open to all paediatricians. Information on the study is distributed via email using the mailing lists of the BVKJ chapters in Bavaria and Berlin and the DGAAP. The paediatrician survey is an open survey aimed at all PCPs within the target population and without the application of exclusion criteria. PCPs without internet access or access to an electronic device are excluded from the study *de facto*.

Parent interview (part D)

PCPs contributing to the recruitment of parents and adolescents for the online surveys advertise the opportunity for parents to participate in interviews by distributing flyers in their practices. Following contact with the research team, interested parents receive detailed information on the objectives of and procedures for the interview. To elicit different parental perspectives, we use a purposive sampling strategy maximising the diversity of interviewees with respect to the following aspects: age of child/adolescent, age and gender of parent, having a child with/without chronic health condition, educational attainment and migration background. We anticipate achieving theme saturation after interviewing approximately 15 parents.

Paediatrician interview (part E)

We also invite PCPs involved in identifying parents and adolescents in parts A and B to participate in the paediatrician interview. PCPs receive an email detailing the objectives of and procedures for the interview and inviting them to contact the research team if interested in participating. To maximise the diversity of perspectives, recruitment is guided by the following aspects: gender, duration practising as a PCP, practice size (solo or group practices), location of practice (rural or urban) and area-level deprivation (operationalised by the estimated proportion of patients with low educational attainment). We anticipate achieving theme saturation after interviewing approximately 15 PCPs.

Incentives for study participation

Parents participating in the interviews receive a book voucher worth 20 Euros. PCPs contributing to the recruitment of parents or taking part in the paediatrician interview obtain an incentive for participation of 40 Euros due to the increased burden associated with recruitment and longer interviews. Monetary or in-kind incentives for completion of the study surveys are not offered.

Data collection

Parent and adolescent surveys (parts A and B)

Strict infection control measures preclude paper-based data collection at paediatric primary care practices. Given that 93% to 96% of Germans aged 14 to 59 years own a smartphone,⁴¹ we used LimeSurvey (V.3.22.1, LimeSurvey GmbH, Hamburg, Germany), a customisable online survey platform, to produce and deliver the parent and adolescent surveys. Parents access the parent survey via a link or QR code on the leaflet distributed at their paediatric primary care practices and complete the anonymous survey on their own devices. Once parents with adolescents aged 12 years and older have completed the parent survey, they are asked to consent to the participation of their child in the adolescent survey. Adolescents complete the adolescent survey on their parents' device. Given an adaptive design used to limit respondent burden and increase the response rate, the parent and adolescent surveys (online supplemental

appendix 1) contain a maximum of 52 and 12 items, respectively, translating into an estimated completion time of 20 minutes in total.

Paediatrician survey (part C)

PCPs access the paediatrician survey via a link in the invitation email and complete the anonymous online survey, produced using LimeSurvey, on their devices. Similar to the adaptive design used for the parent and adolescent surveys, the paediatrician survey (online supplemental appendix 2) contains a maximum of 54 items with an estimated completion time of 15 minutes. PCPs contributing to the recruitment of parents and adolescents are also asked to complete the paediatrician survey. However, their data are recorded pseudonymously enabling the linkage of data between the parent, adolescent and paediatrician surveys based on the identifiers of paediatric primary care practices that are recorded once parents submit the parent survey.

Technical details of data collection in the online surveys (parts A, B and C)

Items are introduced non-randomly in the online surveys. We provide non-response options for all items and enforce selection of one response option throughout, as advised in previous work.³⁶ Participants are able to review and change previously chosen response options using back and forward buttons in the online surveys. No completeness checks are conducted prior to survey submission. To comply with data protection regulations in effect in Germany, we do not use cookies or store IP-addresses of study participants. For the pseudonymous paediatrician survey, PCPs receive a personalised token only valid once, thereby avoiding duplicate entries. For the anonymous parent, adolescent and paediatrician surveys, we do not use tokens. After study completion, data will be stored for 10 years. Only members of the research team have access to the data.

Parent and paediatrician interview (parts D and E)

Three members of the research team with prior training in qualitative research methods conduct the interviews either by video conferencing or telephone, depending on interviewees' preferences (ME: MD; man; paediatrician, paediatric health service researcher and principal investigator of the study; NE: PhD; woman; epidemiologist; LF: MSc; woman; health scientist). We did not establish relationships with the interviewees prior to commencing the study. All interviews are conducted in German and are audio-recorded and transcribed verbatim.

Measures

Parent and adolescent surveys (parts A and B)

Table 1 provides an overview of the parent and adolescent surveys, including the concepts addressed and the sources of items and scales. Briefly, we cover seven sections in the parent survey: (1) utilisation of paediatric primary care services, (2) utilisation of telemedical services, (3) correlates of paediatric primary care utilisation, (4) leverage points for strengthening paediatric primary care, (5) aspects of child, (6) parental health and (7) sociodemographic characteristics.

Whenever available, we used validated scales. When no validated scales were available, we translated and adapted items from international studies (referenced in table 1) or created new items. Furthermore, we assess several family-level factors of vulnerability pertaining to different sections of the parent survey such as parental educational attainment or symptoms of parental depression or anxiety (marked with * in table 1). Based on a literature review, we cover several potential confounders of the association between family-level and area-level deprivation and service utilisation (marked with † in table 1). In the adolescent survey, we cover four sections: (1) utilisation of telemedical services, (2) correlates of paediatric primary care utilisation, (3) leverage points for strengthening paediatric primary care and (4) aspects of adolescent health. The items in the adolescent survey are based on the respective items in the parent survey. However, we simplified complex expressions such as telemedical services or COVID-19. To increase participation of families speaking languages other than German, and, thus, to improve external validity, we provide translations of the parent and adolescent surveys in English, Turkish and Italian. Whenever available, we used validated foreign-language versions of standardised scales (eg, Patient Health Questionnaire-4, Children with Special Healthcare Needs Screener).^{42 43} Professional translators translated the remainder of the parent and adolescent surveys. Each foreign-language version was independently checked by a second translator for content accuracy. The parent and adolescent surveys underwent pretests with nine parents and three adolescents aged 12–18 years to ensure full comprehensibility and technical functionality of the online survey. No adaptations were necessary for the parent and adolescent surveys after the pretests.

Area-level socioeconomic deprivation

We use the German Index of Socioeconomic Deprivation (GISD) to investigate area-level socioeconomic deprivation, described in detail elsewhere.⁴⁴ In brief, the index comprises three dimensions, namely, education, occupation and income, each consisting of a different number of factors. While the three dimensions have equal weight, the weights of the contributing factors were determined by factor analyses. To assess area-level deprivation, we use GISD data at the level of municipalities classified into three categories based on quintiles of socioeconomic deprivation as recommended by the developers of the GISD (low (lowest quintile), medium (middle three quintiles) and high (highest quintile)). The GISD values are provided in the public domain by Kroll *et al.*⁴⁵

Paediatrician survey (part C)

Table 2 provides an overview of the content of the paediatrician survey, including the concepts addressed and the sources of items and scales. The survey covers nine topics: (1) provision of paediatric primary care services, (2) provision of telemedical services, (3) infection control measures implemented in paediatric primary care practices, (4) correlates of paediatric primary care service provision, (5) ORIC, (6) leverage points for strengthening paediatric primary care

Table 1 Content of the parent and adolescent surveys (parts A and B)

Domain	Concept	Source of items and scales	Parent survey (part A)	Adolescent survey (part B)
(1) Utilisation of paediatric primary care services	(1.A) Deferral and cancellation of different types of paediatric primary care services	Modified from McDonnell <i>et al</i> ⁵¹	X	
(2) Utilisation of telemedical services	(2.A) Utilisation of different types of telemedical services before and during the COVID-19 pandemic	*	X	X
(3) Correlates of paediatric primary care utilisation	(3.A) Concerns about visiting the paediatric primary care practice (eg, fear of infection in the paediatric primary care practice)	Modified from McDonnell <i>et al</i> ⁵¹ as well as free-text question	X	X
	(3.B) Sense of security in paediatric primary care practice	*	X	X
	(3.C) Perceived implementation of infection control measures in paediatric primary care practice	*	X	
	(3.D) Personal experiences related to the pandemic (eg, member of risk group in household, personal experience with quarantine)	*	X	
	(3.E) Fear of child's infection with COVID-19	Modified from McDonnell <i>et al</i> ⁵¹	X	X
	(3.F) Reasons for not using telemedical services (eg, limited internet access, lack of technical equipment)	*	X	
(4) Leverage points for strengthening paediatric primary care	(4.A) Possibilities to facilitate lower risk consultations at paediatric primary care practices during the COVID-19 pandemic	Free-text question	X	X
(5) Aspects of child health	(5.A) Chronic conditions of childrent†	CSHCN screener (adequate internal consistency (Cronbach's alpha 0.76); precise measurement among children experiencing elevated health-condition-complexity trait levels) ⁴³	X	
	(5.B) Parent-reported/child-reported general child health status	KIGGS baseline study ⁵²	X	X
(6) Aspects of parental health	(6.A) General health status	A single item from the Short Form 36 Health Survey Questionnaire ⁵³	X	
	(6.B) Parental stress†	Perceived Stress Scale-4 (PSS-4; adequate internal consistency (Cronbach's alpha 0.60); ⁵⁴ construct validity was shown for the PSS-10, which the PSS-4 is based on, in a German population ⁵⁵)	X	
	(6.C) Perceived parental depression and anxiety†‡	Patient Health Questionnaire-4 (scale to screen for symptoms of depression and anxiety; good internal consistency (Cronbach's alpha 0.82); convergent validity was shown in a German population) ⁴²	X	
(7) Sociodemographic characteristics	Child	(7.A) Age‡ ⁵⁷	X	
		(7.B) Gender	X	
		(7.C) Migration background†‡ ⁵⁸	X	
	Parent	(7.D) Age	X	
		(7.E) Gender	X	
		(7.F) Educational attainment†‡ ⁵⁹	X	
		(7.G) Single parent†‡ ⁶¹	X	
<p>The English version of all items developed for this study and all adapted items are provided in the online supplemental appendix 1. A subset of items of the parent survey are also included in the adolescent survey.</p> <p>*Items developed by the research team.</p> <p>†Family-level factors of vulnerability potentially driving adverse changes in service utilisation.</p> <p>‡Potential confounders of the association between family-level and area-level deprivation and service utilisation.</p> <p>CSHCN, children with special healthcare needs; ISCED, International Standard Classification of Education; KIGGS, German Health Interview and Examination Survey for Children and Adolescents (<i>Studie zur Gesundheit von Kindern und Jugendlichen in Deutschland</i>).</p>				

Table 2 Content of the paediatrician survey (part C)

Domain	Concept	Source of items and scales
(1) Provision of paediatric primary care services	(1.A) Deferral and cancellation of different types of paediatric primary care services	*
	(1.B) Change in opening hours	*
	(1.C) Provision of COVID-19-specific services (eg, SARS-CoV-2 smears, medical certificates)	*
(2) Provision of telemedical services	(2.A) Provision of different types of telemedical services before and during the COVID-19 pandemic	*
(3) Infection control measures implemented in paediatric primary care practices	(3.A) Implementation of infection control measures in paediatric primary care practices (eg, masks, social distancing, separate infectious disease consultations)	*
(4) Correlates of paediatric primary care service provision	(4.A) Factors related to the pandemic affecting service provision (eg, staff shortage, implementation of time-consuming infection control measures)	*
	(4.B) Reasons for not providing telemedical services (eg, limited internet access, lack of technical equipment)	*
	(4.C) Opinion towards telemedical services	*
	(4.D) Personal experiences related to the pandemic (eg, member of risk group, personal experience with quarantine)	*
(5) Organisational readiness for implementing change (ORIC)	(5.A) Change commitment, defined as the organisational members' shared resolve to implement a change	Change commitment scale of ORIC (good content and structural validity as well as internal consistency and inter-rater reliability ⁶²)
	(5.B) Change efficacy, defined as the organisational members' shared belief in the collective capability to implement a change	Change efficacy scale of ORIC (good content and structural validity as well as internal consistency and inter-rater reliability ⁶²)
(6) Leverage points for strengthening paediatric primary care services	(6.A) Concerns and support needs related to the upcoming months	Free-text questions
	(6.B) Ideas how to improve paediatric primary care services during the COVID-19 pandemic for children and adolescents in general and those with special healthcare needs	Free-text questions
(7) Aspects of primary care paediatrician health	(7.A) General health status	One question of the Short Form 36 Health Survey Questionnaire ⁵³
	(7.B) Burden related of the COVID-19 pandemic	Modified from Foley <i>et al</i> ⁶³ and Kramer <i>et al</i> ⁶⁴
	(7.C) Stress of paediatrician	Perceived Stress Scale-4 (PSS-4; adequate internal consistency (Cronbach's alpha 0.60); ⁵⁴ construct validity was shown for the PSS-10, which the PSS-4 is based on, in a German population ⁵⁵)
	(7.D) Perceived paediatrician depression and anxiety	Patient Health Questionnaire-4 (scale to screen for symptoms of depression and anxiety; good internal consistency (Cronbach's alpha 0.82); convergent validity was shown in a German population) ⁴²
(8) Sociodemographic and professional characteristics	(8.A) Age	< 30, 30–39, 40–49, 50–59, ≥ 60 years
	(8.B) Gender	Female/male
	(8.C) Number and age of own children	Number of children aged 0–1, 2–5, 6–11 and 12–18 years
	(8.D) Subspecialty training	Yes No No, I am still in a residency training programme
	(8.E) Experience in paediatric primary care	< 5, 5–9, 10–19, 20–29, 30–39, ≥ 40 years
	(8.F) Employment status	Self-employed/employed
	(8.G) Weekly working hours	< 10, 10–19, 20–29, 30–39, 40–49, ≥ 50 hours
	(8.H) Practice characteristics	Solo practice Group practice Multispecialty medical care centre
(9) Practice characteristics	(9.A) Type of practice	Solo practice Group practice Multispecialty medical care centre
	(9.B) Practice size	Based on the number of statutory health insurance claims and the number of children with private health insurance
	(9.C) Population of the municipality the paediatric primary care practice is located in	< 5000, 5000 to < 20 000, 20 000 to < 50 000, 50 000 to < 100 000, 100 000 to < 500 000, ≥ 500 000 inhabitants

The English version of all items developed for this study and all adapted items are provided in the online supplemental appendix 2.

*Items developed by the research team.

services, (7) aspects of PCP health, (8) sociodemographic and professional and (9) practice characteristics. Whenever available, we used validated scales. When no validated

scales were available, we translated and adapted items from international studies (referenced in table 2) or created new items. The paediatrician survey underwent pretests with six

Box 1 Content of the interview guides for parents and primary care paediatricians

Interview guide for parents

- ⇒ Care at the paediatric primary care practice during the COVID-19 pandemic.
- ⇒ Experiences with telemedical services in paediatric primary care.
- ⇒ Leverage points for strengthening paediatric primary care to ensure high-quality care for children and adolescents during the COVID-19 pandemic.

Interview guide for primary care paediatricians

- ⇒ Service provision in paediatric primary care practices during the COVID-19 pandemic.
- ⇒ Experiences with providing telemedical services during the COVID-19 pandemic.
- ⇒ Motivation, that is, change commitment, and capabilities, that is, change efficacy, of paediatric primary care practice teams to implement changes during the COVID-19 pandemic.
- ⇒ Possibilities to support paediatric primary care practices in providing high-quality care during the COVID-19 pandemic.
- ⇒ Leverage points for strengthening paediatric primary care to ensure high-quality care for children and adolescents during the pandemic.

PCPs, resulting in modification of the wording of a single item to enhance its comprehensibility. No modifications were required with respect to the technical functionality of the online survey.

Interview guides for the parent and paediatrician interviews (parts D and E)

The interviews are based on interview guides comprising open-ended and non-directive questions. We iteratively refined initial drafts of the interview guides following discussions within the research team. The content of the final interview guides for the parent and paediatrician interviews is summarised in [box 1](#). The first three interviews were used to pretest the interview guides with parents and PCPs to ensure comprehensibility of the guiding questions. As no major changes were applied after the pretests, we will include the pretest interviews in the qualitative content analysis.

Sample size considerations

Due to the exploratory nature of the study, we did not conduct formal sample size calculations. Based on previous studies in paediatric primary care and out of respect for the increased challenges facing paediatricians during the pandemic, we anticipate a response rate for the paediatrician survey between 10% and 15% amounting to 160 and 240 completed surveys. Moreover, we aim to sample 750 parents for the parent survey.

Analysis

Parent, adolescent and paediatrician surveys (parts A, B and C)

We will use univariate analyses to describe the provision and utilisation of paediatric primary care services during the COVID-19 pandemic. For paediatric primary care practices whose parents and adolescents participate in the parent and adolescent surveys, we will link data from the parent,

adolescent and paediatrician surveys. This will enable us to consider correlates of paediatric primary care utilisation both at the family-level such as migration background or parental educational attainment and at the practice-level like practice size or implementation of infection control measures. Taking into account the clustering of parent surveys in paediatric primary care practices, associations between the utilisation of paediatric primary care services and correlates will be assessed with generalised linear mixed models incorporating a random effect for paediatric primary care practices. Associations between the provision of paediatric primary care services and correlates will be investigated with generalised linear models.

To investigate the independent association between paediatric primary care utilisation and (a) family-level factors of vulnerability such as migration background or single parent status and (b) area-level socioeconomic deprivation operationalised by the GISD,⁴⁴ we will fit multivariable generalised linear mixed models with a random effect for paediatric primary care practice, adjusting for potential confounders. The association between ORIC and changes in the provision of services in paediatric primary care practices will be investigated with multivariable generalised linear models.

We will consider p values <0.05 for two-sided tests significant and will conduct complete case analyses. Completeness of data will be assessed by investigating missing data at item-level. All analyses will be performed in RStudio (V. 1.3.1093, RStudio, Boston, Massachusetts).

Parent and paediatrician interviews (parts D and E)

We will apply qualitative content analysis to analyse the parent and paediatrician interviews.⁴⁶ We will use a mixed coding strategy comprising both deductive and inductive elements. At the outset, we will deduce codes from the interview guides. During the analysis process, we will refine the initial coding scheme by adding additional codes as they emerge from the interview material. Within codes, we will finally identify major and minor themes by paraphrasing coded text segments and by subsequently summarising paraphrases with related meaning.⁴⁶ Each interview will be analysed independently by two out of three researchers (ME, LF and SK). Interim results will be regularly presented and discussed in meetings of the research team. Discrepancies will be resolved by discussions. We will use MAXQDA 12.3 to conduct the qualitative content analysis (VERBI Software GmbH, Berlin, Germany).

Integrated interpretation of quantitative and qualitative results

Utilisation and provision of paediatric primary care services are multifaceted phenomena. Given this complexity, combining the findings from the quantitative and qualitative analyses at the interpretation stage will facilitate the recognition of important insights related to each of the study objectives. Specifically, we will use findings from the semistructured interviews to illustrate results from the online surveys, combine qualitative and quantitative results to triangulate findings and potentially explore inconsistencies in

results from the two methods to gain additional insights.⁴⁷ Data will not be integrated at the analysis stage by converting qualitative and quantitative data into the other data type, respectively.

Patient and public involvement

Parents, adolescents and PCPs were not directly involved in the development of the study objectives and the study design. However, we considered the feedback of several parents, adolescents and PCPs when preparing the online surveys and interview guides.

Ethics and dissemination

Ethical considerations

The COVID-19 PedCare Study fully complies with the Declaration of Helsinki⁴⁸ and was approved by the Medical Ethics Review Board of the Medical Faculty Mannheim at Heidelberg University (2020–650N). Participation in all study parts is voluntary. We obtain written informed consent from all parents and PCPs participating in the interviews and from PCPs taking part in the recruitment of parents and adolescents for the online surveys to allow for data linkage between the three surveys. The parent and adolescent surveys are exempt from written informed consent as only anonymous data are collected.

Output and dissemination

Study results will be presented at national and international health services research conferences and will be published in journals with external peer-review. The data will be made available on reasonable request.

DISCUSSION

The COVID-19 PedCare Study has great potential for adding to our understanding of the response of paediatric primary care to major public health crises by comprehensively assessing the utilisation and provision of paediatric primary care services and their barriers and facilitators from the perspectives of parents, adolescents and PCPs. We anticipate that this study will help to increase the resilience of paediatric primary care and thus limit excess morbidity and mortality as it contributes to the development of strategies to minimise disruptions to service utilisation and provision during public health crises. The study will complement the limited evidence on disruptions to service utilisation and provision in other sectors of paediatric healthcare such as elective surgeries^{10 11} or paediatric emergency care.^{1–4} The study results will be based on self-report data and will, therefore, provide an authentic view of paediatric primary care during a major public health crisis as perceived by important stakeholders. Additional insights could be gained by exploring the results of this study alongside objective measures of utilisation. A future study from this research group will, therefore, examine objective changes in utilisation of paediatric primary care services compared with the prepandemic period based on billing data.

By assessing the independent association between family-level vulnerability factors and area-level deprivation and paediatric primary care service utilisation, the study will help to identify families and communities particularly vulnerable to adverse changes in service utilisation during pandemics. Health authorities could use the study results to plan and implement targeted communication and outreach activities to prevent or at least attenuate unfavourable changes in service utilisation. At the family level, our results could help PCPs to identify families that would particularly benefit from close follow-up during public health crises and, thus, help to focus scarce resources of PCPs to the most vulnerable patients and families, containing and possibly reducing health disparities. Furthermore, to the best of our knowledge, the study will be the first to assess ORIC in paediatric primary care and to identify factors strengthening ORIC in this setting. We anticipate that these results could support practice teams to successfully implement necessary changes under time pressure during future public health crises.

Limitations

We acknowledge several limitations of this exploratory study. The following limits to the generalisability of our findings should be considered: (1) We use non-probability sampling for the online surveys. (2) Families exclusively relying on services of general practitioners are not covered in the study (20% of children and adolescents in Germany).³⁸ (3) Recruitment into this study is limited to families who *realised access* to healthcare services by consulting a PCP during the ongoing COVID-19 pandemic.⁴⁹ Families who despite universal healthcare coverage chose not to seek consultation in paediatric primary care (ie, those with *potential access*) for whatever reason are excluded *de facto*. This group might overlap with families with other dimensions of social or economic vulnerability for whom continued support by PCPs might be particularly important during public health crises. (4) The parent and adolescent surveys are only available in German, English, Turkish and Italian. While state statistics document that these languages are most often spoken by families in the target region of the surveys,⁴⁰ we exclude families speaking other languages *de facto*, potentially including particularly vulnerable groups such as recent immigrants or refugees. Despite these limitations to generalisability, our findings have the potential to provide important first insights into a complex topic with multidimensional influences. Future studies may overcome these limitations by including general practitioners and by increasing efforts to sample families not consulting PCPs during public health crises. In this context, computer-assisted telephone interviews based on a sample of families drawn from registers of residents could generate complementary insights. Studies specifically targeting socially or economically vulnerable families (eg, recent immigrants, refugees, those with parents with mental health problems) may also be useful in broadening our understanding of patterns and gaps that exist in paediatric primary care service utilisation during public health crises. Similarly, exploring strategies for these families that may better facilitate access to care when needed (eg,

resources for increasing family support or involvement of bilingual community workers in service provision) could be valuable in addressing disparities in health and well-being.⁵⁰ Use of recruitment strategies that involve representatives of faith communities or recognised community leaders may also be beneficial in increasing reach, while use of research approaches tailored to the specific needs or preferences of potential participants (eg, development of surveys in less commonly spoken languages, use of more structured interviewing techniques) also represent future potential directions.

We are not able to attribute study results to particular phases of the pandemic such as lockdown or interlockdown periods as differentiating between different phases of the pandemic retrospectively would probably be associated with substantial recall bias. The results will, however, provide valuable insights into service utilisation and provision during pandemics in general and might, therefore, be useful in devising generic strategies to limit disruptions to service utilisation and provision in light of major public health crises. Furthermore, due to limited resources, we are unable to conduct interviews with adolescents. While we are able to cover important aspects of service utilisation in the adolescent survey, future qualitative studies might complement our findings by uncovering previously unrecognised correlates of service utilisation not covered in the current quantitative adolescent survey.

Due to increased demands placed on paediatric practices in the delivery of care during the ongoing COVID-19 pandemic, including the implementation of strict infection control measures, it is not logistically feasible to collect data from non-responders. This limitation highlights the medium-term need for and potential value of improving the research capacity of paediatric primary care practices that may arise from enhancing IT infrastructure and strengthening collaborative ties with institutions and organisations that offer training and support for organised research activities in practice settings.

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Contributors ME is the principal investigator of the study. NE, LF, SK and ME conceptualised the study and developed the online surveys. NE, LF, SK, DL and ME developed the interview guides. NE, LF and SK are responsible for the study logistics. JK provided input to the analysis strategy. NE, LF, SK and ME contributed to the first draft of the manuscript. All authors made substantial contributions to subsequent drafts and approved the final manuscript.

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