The Congenital Cardiology Cloud – optimizing long-term care by connecting ambulatory and hospital medical attendance via telemedicine

Eine Cloud für die Kinderkardiologie – Optimierung der Langzeitversorgung durch die Kopplung von ambulanter und klinischer Versorgung via Telemedizin

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ABSTRACT

Background Patients with complex congenital heart disease frequently undergo a life-long ambulatory therapy with the need for repeated hospital interventions. To optimize this manifold interplay, we designed and implemented a tele-medical service, the Congenital Cardiology Cloud (CCC). This study aims to analyse the requirements for its implementation through the comprehensive assessment of design, installation and impact on patient´s care.

Methods CCC's development comprised the analysis of historically raised admission and discharge management and the definition of technical and organizational requirements. Elaboration of procedural flow charts, description of data formats and technical processes as well as distribution of patient structure formed part of this process.

Results Analysis of existing workflows uncovered a need for the rebuilding of admission and discharge process and decision making for further treatment. The CCC reduces conference-meetings in general and repetitive meetings up to less than a third. Real-time dispatch of discharge documents guarantees an instantaneous access to patient-related data. Comparative analyses show a more complex patient group to be involved in tele-medical services.

Conclusions The CCC enables the sharing of complex clinical information by overcoming sectoral barriers and improves mu-

tual patient advice. Implementation of a tele-medical network requires willingness, perseverance and professional engagement. Future application analysis and possible introduction of refinancing concepts will show its long-term feasibility.

ZUSAMMENFASSUNG

Hintergrund Patienten mit komplexen angeborenen Herzfehlern benötigen vielmals eine lebenslange ambulante Betreuung, gepaart mit wiederholten Klinikaufenthalten. Für eine Optimierung dieses vielschichtigen Zusammenspiels haben wir einen telemedizinischen Service konzipiert und eingeführt, die Congenital Cardiology Cloud (CCC). Diese Studie zielt darauf ab, die Voraussetzungen für die Implementierung durch die Einflussgrößen Entwicklung, Einrichtung und Impact auf die Patientenversorgung zu analysieren.

Methoden Die Entwicklung der CCC beinhaltete die Analyse von bestehendem Aufnahme- und Entlassmanagement sowie die Definition von technischen und organisatorischen Anforderungen. Die Erarbeitung von prozeduralen Ablaufprogrammen, die Beschreibung von Datenformaten und technischen Prozessen formten ebenso Teil dieses Prozesses wie die Verteilung der Patientenstruktur.

Ergebnisse Die Analyse bestehender Workflows ergab Bedarf für die Umstrukturierung des Aufnahme- und Entlassmanagements und der Entscheidungsprozesse in Bezug auf zukünftige Behandlungen. Die CCC reduziert die generelle Anzahl an Konferenztreffen sowie die Zahl erneuter Treffen auf weniger als ein Drittel. Der Versand von Entlassdokumenten in Echtzeit garantiert einen sofortigen Zugang zu patientenbezogenen Daten. Vergleichende Analysen zeigen eine komplexere Patientengruppe unter Beteiligung telemedizinischer Services.

Zusammenfassung Die CCC ermöglicht das Teilen komplexer klinischer Informationen durch das Überwinden von Sektorgrenzen und verbessert die gemeinsame Patientenversorgung. Die Implementierung eines telemedizinischen Netzwerks erfordert Einsatzbereitschaft, Durchhaltevermögen und professionelles Engagement. Zukünftige Anwendungsanalysen und die mögliche Einführung von Refinanzierungskonzepten werden die langfristige Realisierbarkeit zeigen.

ABBREVIATIONS

AVI	Audio Video Interleave
CCC	Congenital Cardio Cloud
CD-ROM	Compact Disk Read Only Memory
CHD	Congenital Heart Disease
CIS	Clinical Information System
CT	Computer Tomography
DICOM	Digital Imaging and Communications in Medicine
DIN	Deutsches Institut für Normung (German Institute for Standardization)
DMZ	Demilitarized Zone
DVD	Digital Versatile Disc
ECG	Electrocardiogram
HL7	Health Level 7
JPEG	Joint Photographic Experts Group
ISO	International Organization for Standardization
IT	Information Technology
MP3	Motion Picture 3
MP4	Motion Picture 4
MRI	Magnetic Resonance Imaging
PACS	Picture Archiving and Communications System
PDF	Portable Document Format
QR	code Quick Response Code
TM	Telemedicine
UCN-CHD	University Competence Network for Congenital Heart Disease
USB	Universal Serial Bus

Background

Congenital Heart Disease (CHD) is the most frequent congenital abnormality with a prevalence of about 1 % in newborn [1]. Repair and treatment strategies of CHD comprise serious surgical and transcatheter interventions disposed as single or repeated treatments. Patients' age span ranges from newborn to advanced adulthood. Modern techniques for pediatric heart surgery and catheter interventions have contributed to a good over-all survival of patients with congenital heart disease and surrounding supportive care contributes to a good quality of life [2, 3]. In addition to in-patient treatment, patients with CHD require life-long outpatient follow-up treatment by specialized cardiologists, including transition from pediatric to adult care [4]. The cooperation between ambulatory and hospital care is burdened though by a variety of responsible institutions, belonging to different regulatory bodies. Additionally, separated financial plans for the ambulatory and hospital sector complicate its interplay [5].

In order to encourage low-threshold specialized ambulatory care, our department (department of pediatric cardiology at a tertiary University hospital) had established the "University Competence Network for Congenital Heart Disease" (UCN-CHD) in 2008. The UCN-CHD is built by a University Pediatric Cardiology Heart Center, 25 ambulatory pediatric cardiologists, 14 pediatric hospitals and 2 University Pediatric Departments without facilities for pediatric cardiac invasive diagnostics and pediatric cardiac surgery. However, this setup requires a reliable and professional interchange of findings with respect to patient's needs, disease burden and treatment options.

This is, where the rapidly developing sector telemedicine comes into play, offering improved overall access and lower costs for health care systems and patients by reducing double consultations and transport costs [6, 7].

In order to allow for a thorough understanding of the patients' needs without repetition of necessary examinations, a tele-medical network could be crucial for the communication of significant diagnostic findings between ambulatory centers and the University hospital. In this study we describe the implementation of such a tele-medical network, the Congenital Cardiology Cloud (CCC), in order to:

- standardize and simplify the interchange between ambulatory and hospital care
- avoid repeated investigations
- keep all patient´s information and findings transparent and retrievable for all concerned participants
- harmonize patient´s advice and education
- encourage patient´s empowerment

Methods

Attendees and operators of the CCC

The development and installation of the CCC was conducted by a group of different professional competences from 01/2017-12/2019:

1. Pediatric cardiologists of the University hospital and ambulatory care
2. Software specialists, system engineers, and IT data security and protection officers of the University hospital's IT-department
3. Computer scientists and system engineers of the University Department of Computer Architecture
4. Software and application technology specialists of the industrial partner
5. Adult educationalist from the University Chair of Educational Science

Procedural implementation

The installation of the CCC was preceded by an implementation process, consisting of the analysis of the pre-existing infrastructure and procedural requirements.

Starting the project of the CCC, we evaluated actual process-flows concerning the exchange of patient related data within the UCN-CHD. We analyzed treatment planning, admission and discharge processes within the hospital and possible improvements through tele-medical services. This included:

- Analyzation of the planning, realization and documentation of patient related procedures by review of medical records.
- Assessment of the coordination of long-term medical care and hospital interventions based on a survey performed with the participating physicians of the UCN-CHD.
- Questioning about general interest in tele-medical interaction and its financial refund plus possible extra costs for required software installations/add-ons.

All interviews were either performed personally, via telephone or obtained in written form without a preexisting questionnaire.

- Personal interaction with referring physicians and hospital staff highlighted the aspect of applicability and suitability for daily use to be crucial for the CCC's success.
- Data protection matters and legal requirements were seen as a basic requirement for a long-term performance.

Technical implementation

The first step of the technical implementation included the analysis of pre-existing hard- and software installations by questioning the referring physicians or the hospitals IT-specialists (type of data storage/data formats, internet access/connection and method of data transmission/reception).

Further work stages implied the analysis of compatibility between patient related software programs and commercially available software as well as the development, adaption, installation and connection of the corresponding soft- and hardware.

Quantitative analysis

We performed a quantitative analysis of admission numbers, including prior consultations at our outpatient clinic, the type of treatment and the number of cardiac conferences and compared a period before the implementation of the CCC (05-07/2017) with a similar time interval after the implementation (05-07/2020). Further analysis included patient demographics respectively their severity of disease prior (01-12/2017) and post implementation (03-10/2020).

Method of investigation was a retrospective review of medical records and process cards of the hospital quality management system. Further numbers were obtained by the internal data storage of the CCC`s technical application. No ethics vote was required as data analysis was completely anonymous and solely on a statistical level.

Results

1. Procedural implementation: Pre-existing process flows and their transformation due to the CCC

Referring and admission management

- Historical communication showed to be unilateral from referring physician to hospital via fax/post/telephone or screenshot and was changed to CCC use with doctor letters, ECG, echocardiographic-loops etc. accessible for all authorized physicians via cloud.
- Decisions of preoperative congenital heart conferences were based on doctor letters, preoperative ambulatory presentations or consultation of the referring physician via phone calls on admission. This procedure was adapted to a singular preadmission conference with the recent patient related findings immediately transmitted via cloud. This way, admission is now with present diagnostical data and precise treatment plan, accessible for all authorized staff at any time.
- Transmission of decisions to referring physicians and patients' education via phone call were renewed by automated dispatch of conference results and optional multi-user videoconference for complex case discussions (real-time

communication with screen sharing). Optional patient participation was enabled.

Discharge management

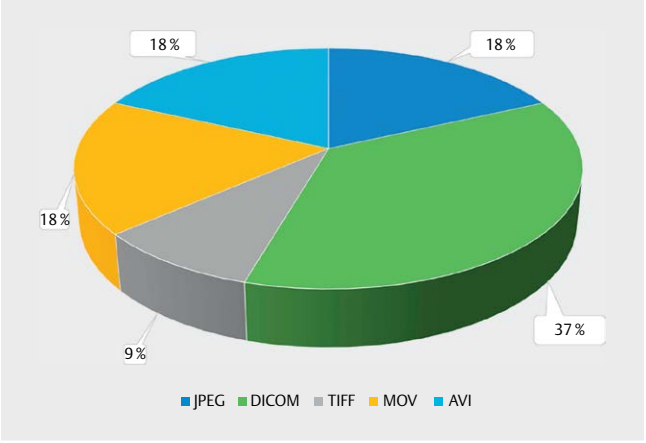
Hand-out of discharge letters and angiographies on CD-ROM was changed to automated upload of discharge documents and semi-automated upload of patient findings to the CCC prior to the first follow-up appointment at the ambulatory setting. Patient related data is automatically accessible for the corresponding professional members of the CCC. Parents and patients can access their data within the CCC on demand at any time.

1. Technical infrastructure

- Analysis showed a variety of programs for processing and storage of patient related data designed by different IT-companies (Soarian, Custo Med, SyngoDynamics, SyngoVia, and others) with a multitude of data storage types (▶ **Fig. 1**). Besides data-security for the multidirectional exchange, this required compatibility of the CCC with the different hard- and software systems of the participating parties, their processability and transfer of large amounts of electronical information.
- In only 22 %, the internet connection of the referring physicians allowed for access to the medical file system and only 34 % of the partners of the UNC-CHD were interested in tele-medical interaction. Additional costs for lacking DICOM interfaces amounted up to 5000€, which could not be provided. Connection issues were addressed via technical support and on-sight teaching.

On the basis of these requirements, a commercial data secure cloud system was selected, adapted and integrated into the complex clinical IT-structure, offering data security, exchange of large amounts of diagnostical data and all-time accessibility as depicted in ▶ **Fig. 2**. The optional participation of parents and patients in the CCC is not especially listed in ▶ **Fig. 2**. More detailed technical information is displayed in the **supplementary material**.

1. Quantitative analysis



▶ **Fig. 1** Distribution of data storage types Data storage options used by the members of the UNC-CHD revealed various types of file archiving. DICOM-files are displayed disproportionally high, reflecting a higher percentage of interview responses of the hospital partners of the UNC-CHD.

Hospitalization numbers

We compared a period prior to tele-medical work (05-07/2017) to a period post-implementation of the CCC (05-07/2020). The number of surgeries/interventions, emergency admissions, pre-admission appointments and post hospital presentations did not reveal major differences. A substantial reduction was seen in the number of interdisciplinary heart conferences (130 vs. 74). Prior to the CCC, the number of repetitive, sometimes multiple congenital heart conferences in patients with either catheter-intervention or surgery was more than three times higher as afterwards. In case of repeated conferences, between two and three conferences were held for the same patient. Relevant numbers are shown in detail in ▶ **Fig. 3** and ▶ **4**.

Patients' demographics

Prior to the CCC, 74 % of the hospital admissions consisted of patients with congenital heart disease (mild CHD 18 %, moderate CHD 21 %, severe CHD 24 %, CHD not classified 11 %). Classification is accordingly to Lindinger et al. [8]. After implementation of the CCC this changed, with a clear emphasis on patients with CHD in general (87 %) and severe CHD (42 %) in particular, both displayed in ▶ **Fig. 5**.

Acceptance of tele medical network

After successful implementation of the CCC (12/2019), 51 % of the partners of the UNC-CHD participated in tele-medical interactions (21 centers in total consisting of 13 pediatric cardiologists, 7 pediatric clinics and 1 university hospital without options for pediatric cardiac surgeries or interventions, ▶ **Fig. 6**).

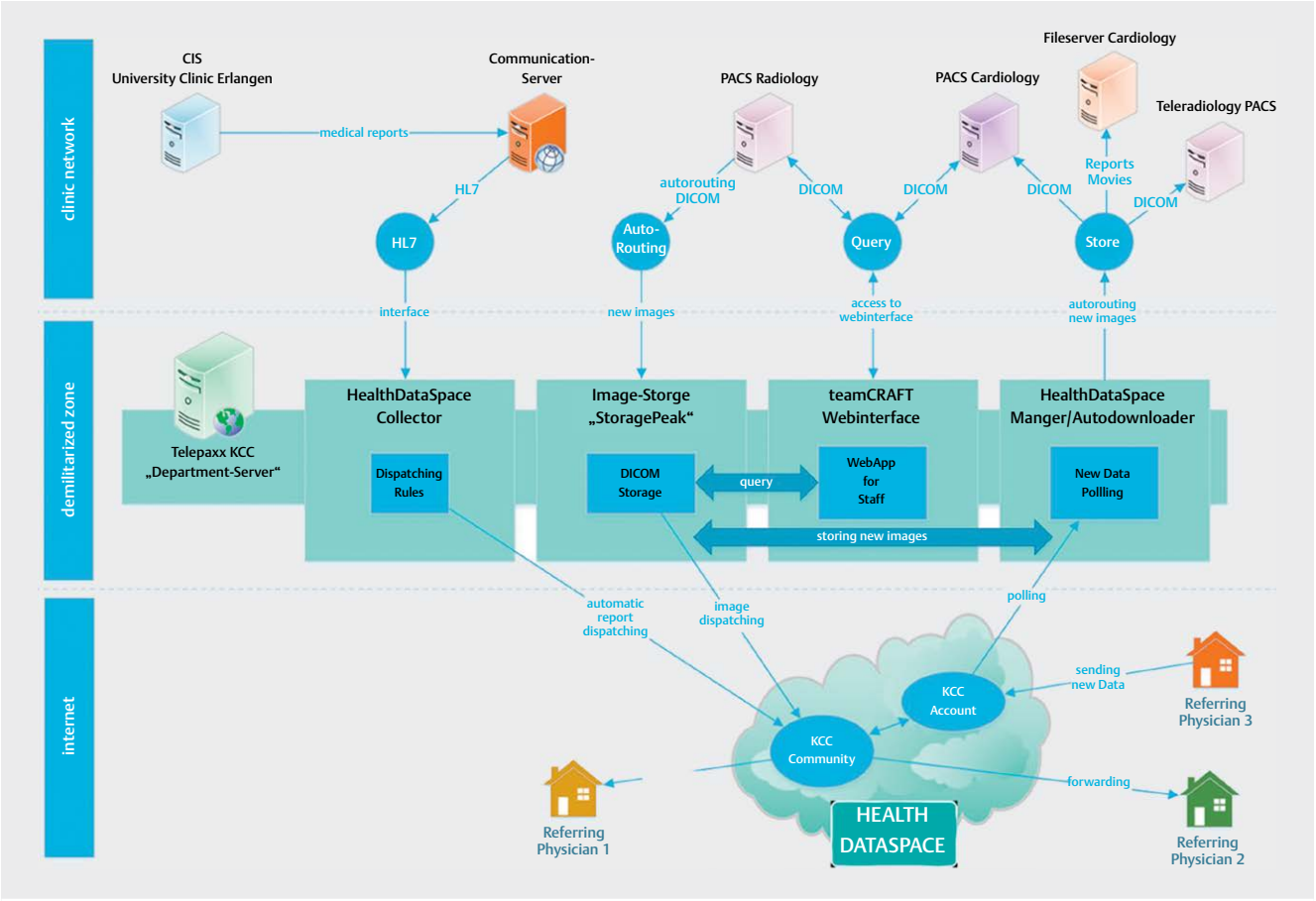
Discussion

Interest in tele-medical applications concerning the medical sector showed a fast increase in the recent years, leaving no doubt about the importance of telemedicine (TM) and its new opportunities [9, 10]. Coordination of therapeutic and diagnostic interventions in pediatric patients with CHD, combined with ready access to diagnostic information can facilitate necessary hospital stays.

The Congenital Cardiology Cloud (CCC) is the first TM network in pediatric cardiology in Germany and focuses on the processes and the interplay of ambulatory and hospital care in the triangle of patient, ambulatory doctor and heart centre [9, 11].

The installation of a specific network for pediatric cardiologists (UNC-CHD) represents a first step towards a better linkage of medical professionals. Particular weakness of pre-existing process-flows was found in the exchange of patient-related data with insufficient transmission of diagnostical data and uncoordinated admission/discharge management, leading to repetitive examinations and little time for important therapeutic decisions.

From the aspect of the CCC process management, we had to overcome a number of obstacles concerning technical, procedural, financial and data security issues [7, 10, 12, 13]. Due to data safety issues, the university hospital disposes of separated and highly complex IT networks which can only share medical data in a surrounding that is organized in an extremely elaborated and appropriately security-cleared way [12, 14, 15]. In contrast, obstacles at the ambulatory practices were isolation of software and absence



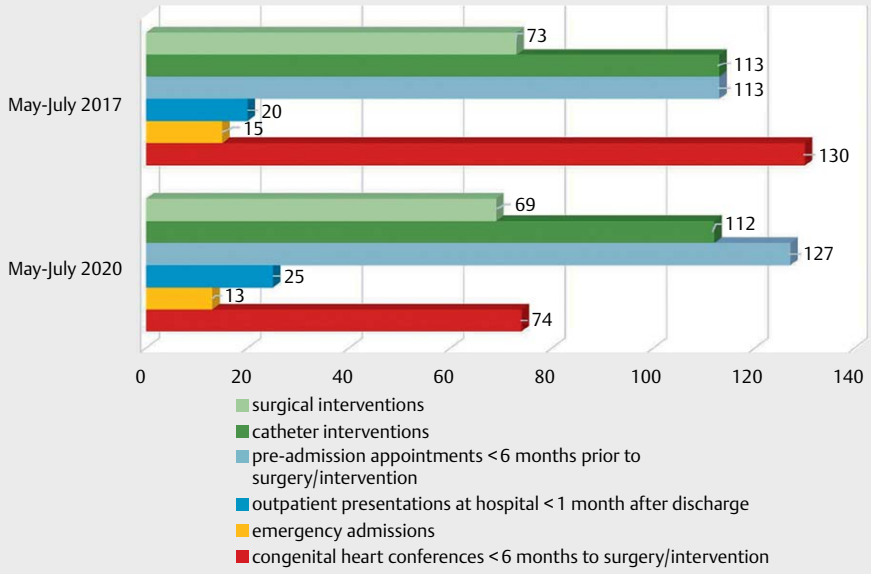
▶ **Fig. 2** Technical Structure of the CCC (Patient related data protection, necessary protection of the CIS to the external and complex network structure of a university hospital´s CIS (upper axis) make it necessary to establish a separate department server (middle axis). Standardized data exchange is performed automatically. Referring physicians upload their data from storage files to a PC, which is connected via internet to the CCC. Access control is in university hospital`s hands (lower axis).) CIS: Clinical Information System, PACS: Picture Archiving and Communication System, HL7: set of international standards for transfer of clinical and administrative data, DICOM: Digital Imaging and Communications in Medicine, CCC: Congenital Cardio Cloud, RP: Referring Physician, RH: Referring Hospital, P: Patient.

of interfaces, implicating the necessity of hard- and software installations without reciprocal financing. These conditions required a technical project management both of the CCC and of every single IT system involved. Additional work during the implementation process was not financially refunded for the ambulatory practices. This is especially important, as their work is based on the principal of "time is money".

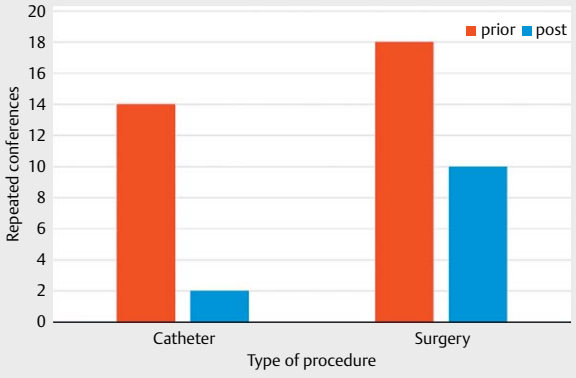
Apart from operational issues, interdisciplinary wording showed to be a substantial stumbling block with medical requirements and workflows having to be translated into technical language and vice versa. Implementation process was accompanied by certain resistant behaviours of the future user. Natural human resistance to unknown technologies as well as necessary change in habits are considered to be causative [7, 10, 13]. During the development of the CCC, a notable need for specialised training for all involved professions became obvious, which we could address to by handing out task- and peer group-oriented training documents and offering expert pedagogical care [7]. We see our efforts reflected with a total of 51 % successfully recruited network partners while only 34 % of them had shown a general interest in the CCC at the beginning.

Less repetitive conferences due to short note discussions show the advantages of a structured tele-medical admission. Clearly, tele-medically processed patients consisted of more complex cases. Due to the character of the data we did not apply a statistical model. Still, our results march along with a previous study by Marcin et. al., pointing out a higher severity of disease in tele-consulted patients [16].This reveals the need for mutual discussion of patients with severe CHD and underlines the importance of present diagnostical data in the case of difficult treatment decisions.

The CCC offers the opportunity to substantially improve the interplay between ambulatory and hospital sector. Thus, present diagnostical findings can be discussed among an interdisciplinary team and further treatment plans are directly sent back to the outpatient care. This way, doctors are fully informed at any time and patients are well educated and self-empowered, possibly resulting in a higher quality and a bigger acceptance of a certain treatment. Discharge management within the CCC supplies the referring physician instantly and automated with important patient related data for the first post-hospital appointment. This way, assessment can be placed on the broader basis of latest information on the case,



▶ **Fig. 3** Admission numbers pre and post implementation of the CCC (Admission numbers by type of admission and number of congenital heart conferences between 05-07/2017 and 05-07/2020. Main difference: lower number of congenital heart conferences after implementation of the CCC.).



▶ **Fig. 4** Repeated conferences prior and post CCC (Comparison of repeated conferences in order to type of procedure (Catheter intervention/Surgery) prior (red) and post (blue) implementation of the CCC.).

potentially improving its quality. CCC's optional participation of parents and patients supports patients' empowerment. All-time and location-independent accessibility to personal diagnostical data facilitates the obtaining of second opinions, journeys and relocations for families with chronically ill children and this way hands over a part of the disease management.

Limitations

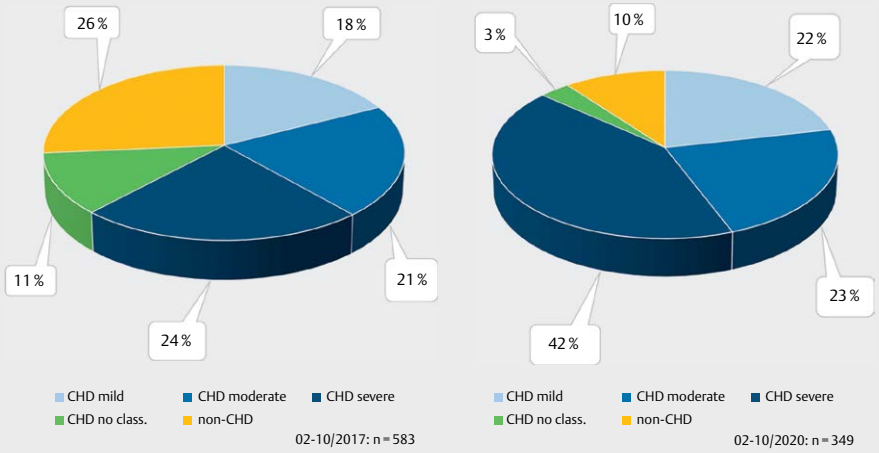
The utility of the tele-medical platform is difficult to scale. A lesser number of ambulatory double investigations may only be a specious advantage for patients and saving of costs and efforts for the medical staff. On the other hand, it is overt that the allocation of the complete medical history to all medical staff members at any time and any place is appropriate to improve patients' and physicians' satisfaction. However, instruments to measure these effects and specially to measure patient engagement are still missing and should be designed for future evaluation of tele-medical platforms.

Conclusions

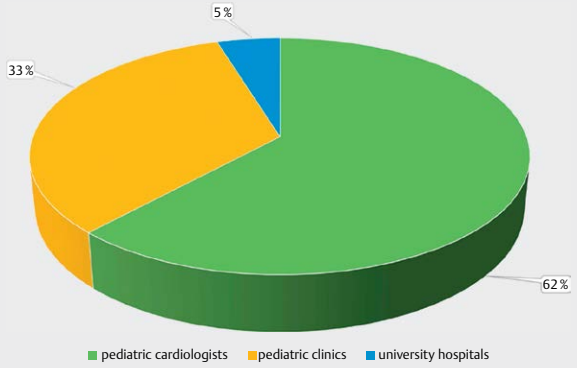
Originally, with the implementation of the CCC we intended to standardize and simplify the interchange between ambulatory and hospital treatment. Standardization needed technical programming, configuration and ongoing management. The CCC improved the kind and number of exchanged formats and as a consequence, in particular the quality and basis of decision-making for upcoming treatments. The CCC keeps all patients' information and findings transparently and retrievable for all authorized staff, avoiding repeated investigations, thereby helping to harmonize patients' advice and education. The patient partially takes over responsibility, possibly supporting patients' empowerment and ability for future decision making. Upcoming application analysis and possible introduction of governmental-guided refinancing concepts will show the long-term feasibility.

Contributor's Statement

K. R. and U. D., structured the tele medical team and mainly coordinated this project. S. D., contributed all necessary background information to this project and supported the team in developing new tele medical standards and by creating extra time slots for project work during clinical routine. S. P., M. R. and . D. F. from the Department of Computer Science were commissioned with the selection and integration of a data secure videoconferencing tool. .J. G.,



▶ **Fig. 5** Patient demographics prior to CCC vs. telemedical patient demographics (Patient demographics with regard to severity level of CHD and non-CHD. Severity level was classified into mild, moderate and severe according to Lindinger et al. (8). Comparison is drawn between patients attended prior to the implementation.)



▶ **Fig. 6** Classification of members of the UNC-CHD. After implementation of the CCC, 51 % of the members of the UNC-CHD perform tele medical interaction (21 in total, 13 pediatric cardiologists, 7 pediatric clinincs, 1 university hospital without pediatric cardiac intervention/surgery).

staff of the Chair of Education with a Focus on Organizational Education, supported the project by analysing the interindividual and intersectoral communication barriers. A. D., CEO of the software providing company, provided and developed the CCC´s software according to the specific requirements of this project. F. R. . established doctor, supported this project by facilitating on site visits in his medical practice and therefore helped to analyze the specific requirements of the referring physicians. C. S., member of the UCN-CHD, helped with the integration of the Department of Pediatrics of the participating University Hospital and its data security related issues. R. C., head of the Department of Pediatric Cardiac Surgery, provided the required surgical related data for our analysis. K. R. and S. D. drafted the manuscript as a joint cooperation with the contribution of written composition of the fellow authors according to their subject area. All authors critically read and approved the final version of the manuscript.

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Conflict of Interest

The authors declare that they have no conflict of interest.

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