Physicians' preferences for the use of a clinical decision support system in the context of acutely ill children presenting to ambulatory care

A focus group study

Daniëlle Snijders, K.U. Leuven

Lennart Verlinden, K.U. Leuven

Promotor: prof. dr. Jan Verbakel, K.U. Leuven, Academisch Centrum voor Huisartsgeneeskunde, EPI-Centre

Co-promotor: Hannelore Dillen

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LIST OF ABBREVIATIONS

AMR	Antimicrobial resistance
BAPCOC	Belgian Antibiotic Policy Coordination Committee
BCFI	Belgian Centre for Pharmacotherapeutic Intervention
CDS	Centres for Disease Control and Prevention
CDSS	Clinical decision support system
CIA	Critically Important Antimicrobials
COREQ	Consolidated Criteria for Reporting Qualitative Research
CPG	Clinical practice guideline
CPOE	Computerised provider order entry
CRP	C-reactive protein
DID	Daily doses per 1000 inhabitants per day
DNA	Deoxyribonucleic acid
EHR	Electronic health record
ENT	Ear-nose-throat
EU	European Union
GP	General practitioner
MRSA	Methicillin-resistant Staphylococcus aureus
NHG	Dutch College of General Practitioners
PHR	Personal health record
POCT	Point-of-care test
WHO	World Health Organization

ABSTRACT

Introduction

Antimicrobial resistance (AMR) is a worldwide problem, which is significantly driven by the prescription of unnecessary antibiotics for acutely ill children. Several factors contribute to the over-prescription of antibiotics, including uncertainty regarding the diagnosis, doubts about the severity of the illness, physician unawareness, and demanding requests from patients or their parents. A clinical decision support system (CDSS) has the potential to guide physicians in their prescribing practices. However, further research is needed to identify the preferred content, functions, and barriers and facilitators of CDSS use.

Methods

Four focus groups were conducted with physicians from Belgium (Flanders), including general practitioners (GPs), paediatricians and ear, nose, throat (ENT) specialists. The focus groups were semi-structured by an interview guide. Two of the groups were via an online platform, the other groups were by physical meeting. The sessions were audio-recorded, transcribed, and subjected to a reflexive thematic analysis. The participating physicians were then asked for feedback on the themes.

Results

A total of 25 physicians took part in the focus groups. From the thematic analysis, four key themes were extracted.

1. Physicians expect little additional work from a CDSS, a pragmatic approach is preferred.
2. The advice generated by the CDSS should be concise, precise and unambiguous.
3. The CDSS can reduce uncertainty in diagnosing and treatment of acutely ill children.
4. The scope of the CDSS should be clear and it should rely on existing and reliable sources.

Conclusion

The findings of this study can contribute to the development of a user-friendly CDSS for diagnosis and treatment of acutely ill children in ambulatory care. Physicians prefer a CDSS that is pragmatic and clear, gives clear guidance on diagnostics and disease management with additional attention for reducing uncertainty regarding the severity of an illness. The implementation of a CDSS can play a role in reducing unnecessary antibiotic prescriptions in acutely ill children.

NEDERLANDSTALIGE SAMENVATTING

Introductie

Antimicrobiële resistentie (AMR) is een wereldwijd probleem en het voorschrijven van onnodige antibiotica aan acuut zieke kinderen draagt aanzienlijk bij aan dit probleem. Verschillende factoren dragen bij aan het overmatig voorschrijven van antibiotica, waaronder onzekerheid over de diagnose, twijfels over de ernst van de ziekte, onwetendheid van artsen en veeleisende verzoeken van patiënten of hun ouders. Een klinisch beslissingsondersteuningssysteem (CDSS) heeft het potentieel om artsen te begeleiden bij hun voorschrijfpraktijken. Er is echter meer onderzoek nodig om de voorkeursinhoud, functies en barrières en facilitators van CDSS-gebruik te identificeren.

Methodes

Er werden vier focusgroepen uitgevoerd met artsen uit België (Vlaanderen), waaronder huisartsen, kinderartsen en keel-, neus- en oorartsen (KNO-artsen). De focusgroepen waren semigestructureerd, gebaseerd op een vooraf opgestelde interviewgids. Twee van de groepen waren via een online platform, de andere groepen waren via fysieke bijeenkomsten. De sessies werden opgenomen, getranscribeerd en onderworpen aan een reflexieve thematische analyse. De deelnemende artsen werd vervolgens om feedback gevraagd over de naar voren gekomen thema's.

Resultaten

In totaal namen 25 artsen deel aan de focusgroepen. Uit de thematische analyse kwamen vier hoofdthema's naar voren.

1. Artsen geven de voorkeur aan weinig extra werk van een CDSS, een pragmatische aanpak verdient de voorkeur.
2. Het advies dat door het CDSS wordt gegenereerd, moet beknopt, precies en ondubbelzinnig zijn.
3. Het CDSS kan onzekerheid in de diagnose en behandeling van acuut zieke kinderen verminderen.
4. De omvang van het CDSS moet duidelijk zijn en gebaseerd zijn op bestaande en betrouwbare bronnen.

Conclusie

De bevindingen van deze studie kunnen bijdragen aan de ontwikkeling van een gebruiksvriendelijk CDSS voor de diagnose en behandeling van acuut zieke kinderen in de eerstelijnszorg. Artsen geven de voorkeur aan een CDSS dat pragmatisch en duidelijk is, duidelijke richtlijnen biedt voor diagnostiek en behandeling en extra aandacht besteedt aan het verminderen van onzekerheid over de ernst van een ziekte. De implementatie van een dergelijk CDSS speelt een cruciale rol in het verminderen van onterecht antibioticagebruik bij zieke kinderen.

1. INTRODUCTION

Antibiotics play a vital role in modern medicine, allowing physicians to effectively treat infections and thereby save lives. They also enable various medical procedures, such as trauma surgery, cancer chemotherapy, and stem cell and organ transplantation, by preventing infections that could otherwise be fatal (1). However, the development and spread of antimicrobial resistance (AMR) has been occurring steadily since the introduction of the first antibiotics, posing a significant challenge to the ability to combat infections effectively (1). A huge contributing factor to AMR is antibiotic misuse, which makes AMR a serious threat to public health worldwide (2,3).

To combat this hazard, the World Health Organization (WHO) Expert Committee on Selection and Use of Essential Medicines introduced the AWaRe Classification system in 2017 to aid antibiotic stewardship efforts on a global level. This classification categorizes antibiotics into three distinct categories – Access, Watch, and Reserve – based on their impact on AMR to bring attention to the importance of proper antibiotic use (4).

First, the Access group comprises antibiotics effective against a broad spectrum of common pathogens, with a lower likelihood of developing resistance compared to other groups. These antibiotics are often recommended as primary or secondary treatment options for various infectious conditions by the ‘WHO Expert Committee’(5).

Next, the Watch group comprises antibiotic classes with a greater risk of resistance development, including many identified as Critically Important Antimicrobials (CIA) for Human Medicine (6). These antibiotics are considered high-priority targets for stewardship programs and surveillance. While some Watch group antibiotics are still recommended as primary or secondary treatments for specific infections, their use is more limited compared to Access group antibiotics. They are individually listed on the WHO Model Lists of Essential Medicines to ensure their availability while emphasizing cautious and selective use (5).

Finally, the Reserve group consists of antibiotics reserved for treating infections caused by multi-drug-resistant organisms and should only be used as a last resort. These antibiotics are listed individually on the WHO ‘Model Lists of Essential Medicines’ if they demonstrate a favourable risk-benefit balance and proven effectiveness against pathogens identified as "Critical Priority" or "High Priority" by the WHO Priority Pathogens List (7,8). While these antibiotics must be available, their use should be restricted to specific patients and situations where all other treatment options have been exhausted or are unsuitable.

To safeguard their effectiveness, national and international stewardship programs should prioritize monitoring and reporting on their utilization (5). The 2023 update of the AWaRe Classification serves as a valuable tool for monitoring antibiotic usage, setting targets, and evaluating the effectiveness of stewardship policies aimed at improving antibiotic use and combating AMR. As a

part of the WHO's 13th General Programme of Work, countries are encouraged to ensure that at least 60% of total antibiotic consumption consists of Access group antibiotics on national level (4).

Clinical practice guidelines (CPGs), issued by national health authorities, aim to assist physicians in making appropriate treatment decisions, including their choice of antibiotics (9). CPGs aim to streamline the process by synthesizing research and expert consensus to aid healthcare professionals in decision making. Despite efforts to promote evidence-based decision-making, adherence to CPGs remains inconsistent (10,11). National health authorities publish CPGs to guide antibiotic selection, such as the Belgian Guide to Anti-Infectious Treatment in Outpatient Practice by the Belgian Antibiotic Policy Coordination Committee' (BAPCOC), which offers expert recommendations based on available evidence (12).

Despite the availability of such guidelines, primary care physicians often prescribe antibiotics unnecessarily (9). Potentially due to misinterpretation or lack of confidence in these guidelines, given that they leave room for doubt (13,14).

This introduction will explore the problem of AMR, antibiotic over-prescribing by primary care physicians, with special attention for acutely ill children. It will also explain the maintaining factors such as the complexity of medical decision-making, disregard for CPGs, and the role of CDSSs in mitigating this challenge.

1.1. Antimicrobial resistance

1.1.1. What is antimicrobial resistance?

Microorganisms (bacteria, fungi, parasites, and viruses) evolve so that they become resistant to antimicrobial medications, this is called AMR (15). Antibiotics have been used effectively for decades but it has been well known that microorganisms are able to develop a resistance against antimicrobial agents (16). It is this AMR that is a growing threat for healthcare across the globe (17,18).

In 2019, AMR was associated with an estimated 4.95 million deaths worldwide (19,20). According to the Centres for Disease Control and Prevention (CDC) in the United States, 2 million people are infected with bacteria resistant to antibiotics leading to 23 000 deaths a year. Methicillin-resistant Staphylococcus aureus (MRSA) has a higher mortality rate than emphysema, HIV/AIDS, Parkinson's disease, and homicide combined (21).

In Europe 25,000 deaths annually are attributed to AMR (24,25), of which, of which 533 deaths a year in Belgium (24). These numbers are predicted to rise quickly: for Belgium it is estimated that between 2015 and 2050, accumulated 22,500 people will die from AMR if no additional action is taken to combat AMR (24–26).

1.1.2. What is the reason for antimicrobial resistance?

The reason for AMR knows multiple factors: anthropogenic, commensal, and environmental (22). However, the clinical setting is considered the primary factor contributing to AMR, particularly due to the use and misuse of antibiotics in human medicine and disease prevention, with antibiotic overprescription being a key driver. Next to this, the use of antibiotics in the control and treatment of quickly growing food-producing animals is another reason for AMR (22). Resistance in bacteria caused by prescription of antibiotics is called acquired resistance.

AMR can occur in two ways: bacteria can either have specific gene mutations or bacteria can take up foreign DNA that codes for antibiotic resistant genes (27). There are several resistance mechanisms bacteria can acquire: decreased drug accumulation, drug inactivation or modification, alteration of target or binding sites or alteration of metabolic pathways (27). The rapid reproduction of bacteria leads to random gene mutations and when stressed by exposure to antibiotics, this can lead to a selective survival of bacteria that are resistant to antibiotics (27).

In the past, the introduction of each antibiotic has eventually been followed by resistance to that antibiotic (16,27). During February of 2017, the WHO published its list of bacteria for which new antibiotics are urgently needed. In 2019 the WHO identified only 32 antibiotics that were under development that would address these ‘priority pathogens’ (17,28). There is not enough development of new antibiotics against multi-drug-resistant gram-negative bacteria (particularly those producing carbapenems) and none of the currently clinical available antibiotics are effective (29). This lack of research and development of new antibacterial drugs only further increases the risks AMR could pose to healthcare systems worldwide (30).

1.2. Antibiotic overprescription

1.2.1. Antibiotic overprescription in general

Antibiotic prescription varies largely between countries. Within Europe, there is a significant difference between countries in antibiotic prescription rates. In 2010 on average, the consumption of antibiotics was 18.3 (defined as daily doses/1000 inhabitants/day [DID]). The highest rate was in Turkey with 42.3 DID and Greece with 39.4 DID and lowest in two Baltic countries (Estonia and Latvia) with 11.1 DID and the Netherlands with 11.2 DID (31). Belgium had a DID of 28.4 in 2010 (21,31,32). In a more recent report from 2022, the mean consumption was 19.4 DID in Europe, with a DID of 9.1 in The Netherlands to a DID of 22.5 in Cyprus. For Belgium, this was 20.4 DID in 2022 (33). A statistically significant decrease, however intensified efforts will be needed to reach the antimicrobial consumption targets as set by the European Council Recommendation on stepping up European Union (EU) actions to combat AMR (33).

Rational use of medication would entail that patients receive medications tailored to their specific clinical needs, in appropriate dosage, for the necessary duration, and at the most cost-effective price for both them and their community (34). However, from all the antibiotic prescriptions done,

the irrational use of medicines is a significant global issue. According to the WHO, more than half of all medications are prescribed, dispensed, or sold inappropriately, with around half of patients failing to take them correctly (34).

This misuse -whether through overuse, underuse, or incorrect use- leads to the wastage of valuable resources and poses widespread health risks (such as inappropriate treatment of a disease and allergic reactions). Examples of such improper use include prescribing multiple medications to a single patient (i.e., polypharmacy), using antibiotics unnecessarily or in incorrect doses for non-bacterial infections, preferring injections over oral medications when unnecessary, deviating from clinical guidelines in prescribing, self-medicating by patients with prescription-only drugs or failing to adhere to prescribed dosing schedules (34). All these reasons lead to unnecessary antibiotic prescriptions, which eventually leads to a higher AMR.

1.2.2. Antibiotic prescription in primary care

The highest rate of antibiotic prescriptions is in primary care (35,36). For Europe, 80-90% of all prescriptions of antibiotics are in primary care (35). Most of the antibiotics are prescribed for respiratory tract infections (21).

In most of these (respiratory tract) infections, antibiotics are not necessary since the patient's immune system is capable to combat simple, mostly viral, infections (20,22). The reason for overprescription of antibiotics in primary care by general practitioners (GPs) has been a topic of research and several reasons have been discovered: maintaining a good relationship with patients, lack of concern for AMR, lack of adherence to clinical guidelines, diagnostic uncertainty, lack of continuity of care, lack of time to explain why antibiotics are not necessary, pressure from patients/patient demand, or patients being unaware or uneducated about AMR (37). Also mentioned as reasons by GPs are cultural aspects, (cultural) beliefs of prescriber and patient, and sociocultural and socio-economic factors (e.g., poor health literacy, sub-optimal diagnostic capability, and inadequate healthcare provider training) (21,38).

Other factors that mentioned in research are related to the professional care-delivery system of antibiotics: coordination, collaboration with other professionals, teamwork and communication, and the knowledge of the physician (21).

1.2.3. Antibiotic overprescription in children

Especially children are at risk for antibiotic (over)consumption. The consumption of antibiotics in children is high. In 2021 in Belgium: 43.8% of all the children aged 0-4 years used antibiotics once a year, for children from 5-14 this percentage was 21.5% (39).

Children have not yet fully developed an immune system and are therefore more susceptible to infectious diseases (either bacterial or viral) (40). Whereas the majority of the infections are self-limiting and of viral aetiology (12,41,42). Acute infection and/or fever are the most common reasons

for children to be seen in ambulatory care (43). Only 1% of the visiting children in primary care will be diagnosed with a serious infection (44). In four out of five cases, this serious infection is caused by pneumonia or urinary tract infections. Rare infections in children are sepsis, meningitis or osteomyelitis (43). Recognition of these infections is difficult; children can present atypically and in early stages of the disease, a misdiagnosis can easily be made (43,44). This difficulty combined with the expectations and concerns of parents are known to result in inappropriate antibiotic prescriptions in children (43,44). Furthermore, an incorrect posology and dose and a lack of options (since some antibiotics are contraindicated in children) can contribute to AMR (45). Timely recognition and appropriate referral for serious illnesses could not only prevent unnecessary treatment, testing, referral, and hospitalisation, but also alleviate stress for both children and parents while reducing health care costs (46).

Despite understanding the link between antibiotic overuse and AMR, inappropriate prescribing rates in children remain high, with approximately 50% of the antibiotic prescriptions for children written by primary care physicians being unnecessary (47–49). Between February 2013 and February 2014, 37.4% of prescriptions for an antibiotic written by Belgian GPs were deemed inappropriate due to overprescription (50).

1.2.4. Outcomes of inappropriate antibiotic prescribing behaviour

Antibiotic misuse poses a significant global health concern (3), leading to unnecessary healthcare expenditures, patient harm from adverse drug events, and the rise of antibiotic-resistant bacteria (51). Physicians working in ambulatory healthcare settings acknowledge AMR as a growing concern but have a significant underestimation of the extent of AMR within their own facilities (52,53).

Given that antibiotics are predominantly prescribed in primary care settings and many prescriptions are deemed unnecessary, these settings have a crucial role in combating AMR (47–49).

Not only AMR is a risk of overuse of antibiotics, but there are also other side-effects to consider. All medications carry potential side effect, which is also the case for antibiotics. In the United States, 20% of all the drug-related emergency department visits are related to antibiotics. This is mostly due to an allergic reaction, but also included are gastrointestinal side effects or neurological or psychiatric disorders (21).

1.3. Clinical decision support system

1.3.1. What is a clinical decision support system?

A clinical decision support system (CDSS) is a tool constructed to help healthcare workers, (i.e., physicians, nurses, or other healthcare providers), with making decisions concerning patient care. A CDSS can be integrated into an existing electronic health record (EHR) system or used as a standalone tool. To make these decisions, CDSSs use a variety of data (i.e., patient data, medical expertise, and guidelines) to grant healthcare professionals with best care suggestions (54–56).

These suggestions can include diagnostic suggestions, treatment options, and medication management. CDSSs intend to improve the quality of care, boost patient safety, and aid healthcare professionals in making adequate decisions for their patients. It is important to note that CDSSs are not a replacement for clinical judgment or decision-making. Rather they are intended to support and augment the decision-making process by providing additional information and recommendations based on available data (57,58).

Currently, CDSS are frequently implemented through web applications or integrated with EHR and computerised provider order entry (CPOE) systems. These systems can be accessed via different devices, such as computers, tablets, smartphones, biometric monitors, and wearables (59).

1.3.2. Functions and components of a clinical decision support system

CDSSs can assist clinicians in many ways. Patient safety, clinical management, cost containment, administrative function and automation, diagnostics support, patient decision support, better documentation and clinical workflow integration (59).

1.3.3. Challenges for a clinical decision support system

CDSSs can be incredibly valuable tools in healthcare, but they also come with their own set of challenges. Examples are alert fatigue, overreliance on technology, costs and resource constraints, system and content maintenance challenges and user distrust of CDSS (59). Other factors are transportability and interoperability, dependence on computer literacy, inaccurate and poor-quality data or information and a disrupted or fragmented workflow (59).

Addressing these challenges requires planning, ongoing evaluation, and continuous improvement efforts to optimise the effectiveness and usability of CDSSs in clinical practice.

1.3.4. Clinical decision support system and antibiotic prescribing

CDSS can specifically aid physicians in adequately prescribing antibiotics and therefore aid in the prevention of overprescribing (60). There are different CDSSs (in relation to antibiotic prescription) available for GPs, in 2020 there were 58 CDSS available, from which 18 where especially for GPs (61). However, these CDSS were not optimal. They did not for example cover all the infectious diseases that GPs frequently encounter (62). Rawson et. al described that the CDSS were unable to achieve the primary outcome because of low uptake and poor adherence to the advice generated by the CDSS (63). According to the WHO, a successful implementation of policies will help in tackling AMR (62).

1.4. Research question

AMR is a worldwide problem, with an important role for GPs (in Belgium) when prescribing antibiotics. A CDSS can aid GPs in this process and assist in prevention of overprescription of antibiotics, but they must be tailored exactly to their needs to be successful. *With this focus group study, we aim to explore facilitators, barriers, and the preferred delivery mode (i.e., content and function) of a CDSS in the context of acutely ill children presenting to ambulatory care.*

2. METHODS

2.1. Study design

A focus group study was conducted, following the methodology for focus group studies as described by Krueger et al. (63). The Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist was used to report methods and findings (Addendum I). The study protocol is added as an addendum (Addendum II). The research was set in Flanders, Belgium and the language in the focus groups was Dutch.

2.2. Recruitment and selection of participants

Eligible participants were Dutch speaking ambulatory care physicians treating acutely ill children and using an EHR (i.e., GPs, paediatricians and ear-nose-throat (ENT) physicians). Physicians were recruited by either contacting participants from previous research conducted by the research unit working on this study, if they gave approval to do so. Physicians were also recruited via advertisements in relevant newsletters and websites. Professional medical organisations were contacted to promote the study to their members (as mentioned in Addendum II). A poster and a small video were used as recruiting materials (Addendum III). Interested physicians were contacted face-to-face, via e-mail and/or via telephone to schedule the focus groups and to gather demographic information. Reminders were sent every two weeks. Each focus group was designed to accommodate five to ten participants, based on previous studies on CDSS use in primary care (64–67). Participants completing the focus group received a gift voucher.

2.3. Focus groups

Between March and November 2023, four focus groups were organized. Two meetings were organized online (via Microsoft Teams), one took place in Leuven (university building), and one focus group was held in a regional hospital in Heusden-Zolder. Each focus group lasted between 1.5 and 2 hours and was moderated by HD, whereas AD, DS and LV acted as observers.

Organized focus groups were semi-structured based on the interview guide (Addendum IV) There were six subjects that were discussed during the focus groups: overview of the purpose and rationale for the focus group and signing the informed consent form, introduction of the participants, possible experience (with CDSS by the participants with attention for facilitators and barriers; open for discussion), discussion between participants on what advice a CDSS should provide and how a CDSS should fit in the daily practice and lastly discussion of a clinical, made-up case of an acutely ill child that presents to primary care and how a CDSS could assist in this case (included in the interview guide, Addendum IV)

After each focus group, participants were given the possibility to submit any further commentary via email up to one week after the focus group they participated in (Addendum V). There was a reflection between the engaged researchers about possible improvements for the following focus

groups. For instance, after the first focus group the researchers noticed that the participants required more explanation than first expected to understand the context of a CDSS, so for the next focus groups more attention was given to the introduction about CDSSs.

2.4. Data analysis

The audio of all focus groups was recorded and during the focus groups, researchers made additional notes to identify important parts and relevant non-verbal communication between participants. After each focus group, participants received a pseudonym, and the audio was transcribed verbatim. The aim of the analysis was to create a framework that was explanatory for preferences of the physicians when using a CDSS. This was done by analysing the transcripts based on reflexive thematic analysis within a realist and constructionist framework, a method as described by Braun and Clarke (68,69).

The transcriptions were analysed in NVivo (release 1.7.1). HD, DS and LV all coded the entire dataset. The initial codes and themes were reviewed (together with AD and JV) to ensure the integrity of the analysis. A final list of codes and themes was composed, reviewed, and refined. The final themes were checked by the participating physicians. They received an email with the themes and were asked to score them on a 6-point Likert scale (from strongly disagree to strongly agree) and to provide additional comments. 21 of 25 participants answered and all agreed with the final themes (Addendum V). Quotes from participants (all Dutch speaking) were translated to English with DeepL software. These quotes were translated back to Dutch so researchers could check the translation of these quotes, and when deemed necessary correct them.

2.5. Reflexivity statement

HD (MSc) and AD (MSc), both white female biomedical scientists and PhD researchers born in Belgium, do not have clinical roles and are not directly involved with EHRs or CDSSs. Their insights are shaped primarily by their research background, which may differ from the perspectives of practicing clinicians. DS (MD), a white female GP in training, born in the Netherlands, worked in the same practice as three of the study participants. LV (MD), a white male GP in training, is born in Belgium. LW (prof.) is a white female epidemiologist, born in Belgium. JV (prof., MD), a white male experienced GP with 16 years of clinical practice, is born in Belgium. At the start of the study, all team members, except LW and JV, were not familiar with qualitative research. During the project, HD, AD, DS, and LV attended other focus groups, academic sessions, and reviewed relevant literature on qualitative research methods.

2.6. Ethical approval

This study was approved by the Ethical Review Board UZ/KU Leuven (Onderwijs-Begeleidingscommissie) on January 16th, 2023 (MP022375).

3. RESULTS

3.1. Participants

After recruiting, 42 physicians were interested in participating in the study. Of these 42, 25 physicians participated. The reasons for not participating were: reason not provided or inability to contact (eight), incompatible timing (four), unscheduled shift (two), travelling (two) and failure to meet fulfilment of eligibility criteria (one).

Four focus group in total were conducted. Of the 25 physicians, 11 participants (44%) were male. From these 25 physicians, there were 12 GPs (48%), ten paediatricians (40%), and three ENT physicians (12%). The number of years of clinical practice experience ranged from 0-5 years up to 41-45 years. Twelve participants worked in a group practice, ten solely in a hospital and three physicians worked in a hospital and private practice combined.

Table 1. Participant characteristics (N = 25).

Characteristic	N (%)
Gender	
Male	11 (44%)
Female	14 (56%)
Years of clinical practice experience	
0-5	2 (8%)
6-10	4 (16%)
11-15	8 (32%)
16-20	2 (8%)
21-25	2 (8%)
26-30	3 (12%)
31-35	0 (0%)
36-40	3 (12%)
41-45	1 (4%)
Specialty	
General practitioner	12 (48%)
Paediatrician	10 (40%)
Ear-nose-throat physician	3 (12%)
Practice setting	
Group practice	12 (48%)
Hospital	10 (40%)
Hospital and private practice	3 (12%)
Rurality	
Rural area	1 (4%)
Town or suburb	17 (68%)
City	4 (16%)
Combination	3 (12%)
Province	
Antwerp	6 (24%)
East Flanders	3 (12%)
Flemish Brabant	7 (28%)
Limburg	8 (32%)
West Flanders	1 (4%)

Focus group	
1	7 (28%)*
2	5 (20%)**
3	8 (32%)
4	5 (20%)***

*: One participant from the first focus group had to leave the focus group ten minutes early. This participant did not receive the transcript.
**: The transcript was returned to one participant of the second focus group to provide additional comments, since the participant had to leave the focus group midway through.
***: Three participants from the fourth focus group were working in the same general practitioner's office.

3.2. Theme analysis

3.2.1. Theme 1: Balancing support and simplicity: User-centered considerations for CDSS implementation in ambulatory care

Workability

Participating physicians mentioned that completing the CDSS should entail as little additional work as possible. The CDSS should operate seamless within the own EHR during a consultation. Workability was an important topic during the focus groups.

> *"If it is a pop-up, you do not need to dismiss with a click but with scrolling, that will make it less disturbing, yes, that is what it is about. So, it can be there all the time. But if it's something that pop ups on your screen and you think "there it is again, click" then it will become a nuisance in the end."*
> *-F1P7 (general practitioner, 11-15 years of clinical experience)*

Minimizing the number of clicks was often mentioned by physicians, as something timesaving and improving the workability of the CDSS.

> *"If you want to develop something like this and the number, well, the amount of mouse-clicks you need to do to finish something, could be measurable to determine the user-friendliness."*
> *-F1P4 (general practitioner, 11-15 years of clinical experience)*

Not only the mouse-clicks, but also a smooth integration in the existing program of the physicians was mentioned by the participants.

> *"[…] I think it is easier if it can be matched with everyone's medical file [EHR], I think that is a great challenge, because well, we will not write it on paper or open a new program online. We already have to click so much and type so much and open so many letters. It needs to be user friendly for every medical file [EHR], I think."*
> *-F2P1 (paediatrician, 11-15 years of clinical experience)*

Participants agreed that the CDSS needs to cost as little additional administration time as possible. If it would be time-consuming to use, the CDSS would not be an enrichment.

> *"No, if it is going to cost you more administration time you will … You're not going to do it. I have only been a GP for four years and I already notice a difference in what I typed in the beginning and that has decreased in four years, so if you had to add extra administration."*
> *-F4P4 (general practitioner, 6-10 years of clinical experience)*
> *"You're not going to use it."*
> *-F4P5 (general practitioner, 26-30 years of clinical experience)*

A CDSS should not have a negative influence on the contact with the patient.

> *"The most practical thing usually, because, well, if you are working with computer, you are not, not working with the patient anymore. So, if you really want to integrate that into a new program and you want to say what that looks like, very concise and clear."*
> *-F4P2 (general practitioner, 6-10 years of clinical experience)*

Activation

Both passive and active activation of the CDSS was mentioned by the participants. Different types of activation were mentioned by the participants, some mentioned word recognition based on the diagnosis.

> *"If you enter your most plausible diagnosis or sure diagnosis, that there is some sort of pop-up, at our GP out-of-hours service in Leuven that is already the case. If you enter acute otitis media for example, a frame comes on the screen, copy pasted from the BCFI or maybe from a different protocol."*
> *-F1P7 (general practitioner, 11-15 years of clinical experience)*

> *"Or if you type bronchitis, that there will be an automatic message with acute bronchitis is something that will often pass without antibiotics."*
> *-F1P1 (general practitioner, 11-15 years of clinical experience)*

> *"Yes, I think what has been said here, that it has to be extracted from the EHR automatically and that it does not have to be an additional questionnaire you have to fill in."*
> *-F4P3 (ENT physician, 0-5 years of clinical experience)*

However, they mentioned that recognition based on words, would provide unnecessary pop-ups.

> *"Yeah, and if you type 'he had a fever last week, is better now', that the system thinks: 'oh fever, child, [...], here is a pop-up, then I think, […], that it is a bad idea to have it based on typed words."*
> *-F1P1 (general practitioner, 11-15 years of clinical experience)*

Information to consider

Participants discussed several parameters to be considered by the system, including: the clinician's gut feeling, the general impression, the seriousness of the disease, the evolution of the illness, the age of the child, the clinical history, the parent's story and gut feeling, and the timing of the consultation.

> *"I think that the number of parameters you should enter should be limited."*
> *-F1P1 (general practitioner, 11-15 years of clinical experience)*

Physicians mentioned that some parameters were difficult to capture or enter in the CDSS (e.g., gut feeling, interpretation of the sick child).

> *"If you use the guidelines, there are some non-tangible parameters like a seriously ill child, what is that? A gut feeling […] if you follow the guidelines, it's often your gut feeling to start antibiotic treatment."*
> *-F1P4 (general practitioner, 11-15 years of clinical experience)*

> *"There is too much interpretation in the gut feeling if something is wrong in the seriously ill child."*
> *-F1P4 (general practitioner, 11-15 years of clinical experience)*

Way of filling it in

Different ways of filling in the CDSS were mentioned, namely automatic extraction from the EHR (e.g., age, medical history) entering information in a tree structure or via checkboxes.

> *"But then, a decision tree structure is going to be [...] much easier to say yes or no there was a fever, than an interpretation of the pattern of the fever, because how are you going to enter something like that in a computer programme?"*
> *-F1P4 (general practitioner, 11-15 years of clinical experience)*

"I do not know if parameters such as heart, saturation, breathing frequencies et cetera could be in a decision tree."
-F3P8 (paediatrician, 6-10 years of clinical experience)

"I think that […] you are going to fill it in your EHR anyway, maybe it could extract it from there. That you already have some checkboxes."
-F4P2 (general practitioner, 6-10 years of clinical experience)

Participants mentioned that the pattern of fever was a very important parameter and should be part of the CDSS.

"But it could be a question in itself right "is there an alarming pattern of fever?" with an 'i' [...]. Alarming pattern of fever 'colon', what does that mean?"
-F1P7 (general practitioner, 11-15 years of clinical experience)

Another thing mentioned by participants was the age of the child involved, they agreed that this was important for the CDSS.

"[...] Because your program takes into account the age and can adjust to: "what is normal and what is not normal anymore""
-F1P1 (general practitioner, 11-15 years of clinical experience)

Next to the age of the children, their clinical history is also important. Participants suggested that it would be an addition if the CDSS could fill this in automatically.

"It would be very good if it could extract codes from the medical history which are relevant"
-F4P2 (general practitioner, 6-10 years of clinical experience)

3.2.2. Theme 2: Clinical judgment: Physicians' expectations for diagnostic, therapeutic, and follow-up guidance from a CDSS

Diagnostics

Various forms of output were mentioned by the physicians. They mentioned the most probable diagnoses as a possible outcome of the CDSS.

"It could also suggest diagnoses, which you as a doctor might just not have thought about at the time [...]. That you actually thought too narrowly as a doctor and should have thought more broadly, but by seeing that, that makes you say "I had not thought of that now, maybe I should take that into consideration.""
-F4P2 (general practitioner, 6-10 years of clinical experience)
"Do you mean differential diagnosis and most likely diagnosis above?"
-F4P3 (ENT physician, 0-5 years of clinical experience)
"Yes, the diagnostic landscape actually."
-F4P2 (general practitioner, 6-10 years of clinical experience)

There was some disagreement over this as some physicians mentioned that a CDSS that would provide a diagnosis would need too much input from the physicians and could not include the gut feeling of the physician.

"[...] But I do not know if that is possible now. I think it is very complex. Is there enough data about likelihood ratios if you choose a specific symptom? Because you are going to translate it to a computer program, and a computer does not work with gut feeling. It works with the data it is given with what the positive predictive value and the negative predictive value of fever is."
-F1P4 (general practitioner, 11-15 years of clinical experience)

Advice on technical examinations

Another valuable function of a CDSS could be to assist physicians in determining which additional technical examinations to perform or avoid. Multiple options were mentioned, such as C-reactive protein (CRP) measurement, white blood cell count, screening for sepsis, urinalysis, X-rays, throat swabs and lumbar punctions. However, GPs mentioned that they do not have easy access to these additional tests. They mentioned that it could lead to unnecessary referrals to a specialist or the opposite, to not refer to them soon enough.

"[...] I do not know if a flowchart is going to help me or maybe mislead me. Maybe I will ask for an X-ray too soon and bypass you [...]."*
-F1P4 (general practitioner, 11-15 years of clinical experience)
**Referring to the paediatricians*

"I do not think it is useful, because you are going to ask for too many."*
-F1P5 (paediatrician, 16-20 years of clinical experience)
**Referring to the amount of X-rays*

"Maybe something that could be useful, so, you have the history, clinical examination, the only thing that you have not actually been able to check at the end of history and clinical examination is the urine. Everything else you can actually check clinically, but urine, you do not really know that, so maybe there is some guideline somewhere as to when I should examine a urine sample? Should I do that on every child with a fever? From when should I do that? Should I do it immediately? Can I wait? In what way should I do it? That might be a little too much, because I agree with you, you are not going to examine the urine in every child."
-F1P6 (paediatrician, 36-40 years of clinical experience)

They discussed that it would be useful to add advice on technical examinations to a CDSS but agreed that technical examination was not a main factor for decision making. They mentioned a CRP point-of-care test (POCT) as an example.

"We have had it for a year in the in the hospital now, on the outpatient practice and it is an absolute ... it has to be seen very well in the context of when fever is going on and it is never going to replace the clinic it is never just a CRP to go fully decided and done. So, it depends on many more factors. But we have had surprises in the sense that yes, a child who had a fever for four days still looks clinically quite okay and you think okay I am going to do a finger prick just to be sure. Apart from for example some upper respiratory infection no clear explanation of the fever and that you can still sometimes pick out a sepsis based on a high CRP. And the other way around as well, children from which you think that are seriously ill for four-five days of fever and then with a low CRP, that you do get reassured and that you can follow up on an outpatient basis and see if more is needed. So, totally agree that it cannot be the main chunk in a decision tree but I do think it is a useful value to include provided the fever or the clinical picture is going on long enough to be able to trust it."
-F2P5 (paediatrician, 11-15 years of clinical experience)

Advice on treatment

Another helpful aspect of a CDSS could be advice on treatment, especially advice on antibiotic use. They noted that this was most helpful if there was a clear diagnosis. If there was no clear diagnosis, physicians often referred to their gut feeling.

"[...] I would like an algorithm that could help me when I say, "I do not know". Like the guidelines for traumatic head injury, a risk percentage, which can help you decide – and not let the computer decide if you give antibiotics, but you can weigh the percentage against your gut feeling."
-F3P7 (paediatrician, 21-25 years of clinical experience)

"That is the hardest, the insecurity we have to deal with. [...] fever without a focus is often the parameter which decides if you should start antibiotic treatment. I think we need to remember that."
-F3P7 (paediatrician, 21-25 years of clinical experience)

When talking about rational antibiotic use, some physicians thought that including advice on treatment with or without an antibiotic would help to promote rational antibiotic use.

> *"If you want to reduce people getting antibiotics inappropriately then the best thing to do is to overwhelm doctors as much as possible with the message [laughs] that they really should not prescribe that for viral infections."*
> *-F4P2 (general practitioner, 6-10 years of clinical experience)*

Advice on referral

Some participants felt that the CDSS could aid with the decision when a referral to a specialist or a non-ambulatory setting should be necessary. The need for a specific diagnosis was mentioned as important.

> *"[…] If you have a diagnosis, it should say what you need to do. Should it be a referral or can you treat it yourself. If you do not have a diagnosis, you have to work more shall I say empirical, that is important."*
> *-F4P2 (general practitioner, 6-10 years of clinical experience)*

Advice on ambulatory follow up

Ambulatory advice and advice to the parents should also be included in the CDSS. The message generated by the CDSS should be clear, concise, unambiguous and able to be interpreted by both clinicians and non-medically trained people.

> *"What I also think is quite important, is to communicate specifically [...] about measurable things as much as possible. I am not really comfortable with a recommendation, for example, that "when the child urinates less". [...] I think [...] the description we use, that they must be as measurable, visible, tangible and open to little or no interpretation. If you say, fever above 38.5 in a sick child and you give an antipyretic at a correct dose then after 1.5 to 2 hours [...] the fever should have dropped below 38.5 and the child should revive. You can measure that sort of thing. That is measurable, people have a clock, people have a thermometer, and people have a dosing pipette for their antipyretic."*
> *-F2P3 (paediatrician, 36-40 years of clinical experience)*

This should be easily accessible for the physician and could be information to print for parents.

> *"No, but let's just say it is nice to have it available in an easy way if you ever want to give them [the parents] something, so you do not have to Google it [...]. You could put links to patient letters in the Evidence Linker."*
> *-F4P2 (general practitioner, 6-10 years of clinical experience)*

Lay-out

Also mentioned by the participants were different ways the layout of the CDSS should be designed. They mentioned pop-ups, boxes with information or additional text. The use of colour was mentioned for extra visualisation. An important, re-occurring theme for physicians was alert fatigue from the program.

> *"I think if there are a lot of pop-ups then you will have, you are used to close them with a click because if with every file there is a pop-up, you will think, ah yes, well okay, enter, enter, and you will not read them anymore in the long run. That is the danger of pop-ups I think personally."*
> *-F3P5 (general practitioner, 16-20 years of clinical experience)*

Next to alert fatigue, the danger of trusting a system with pop-ups too much was also mentioned by participants.

"In this hospital we do not work with pop-ups yet. In the hospital where I did my medical training there were [pop ups], and I realized that the pop-ups got clicked away […]. That is also the danger of pop-ups, if for example, an allergy is not registered and there is no pop-up you might think it is okay"
-F3P4 (paediatrician, 11-15 years of clinical experience)

They mentioned that if it was a message appearing on the screen, it would be more useful and lead to less of the previous mentioned alert-fatigue.

"But that […] your screen is so disturbing, right? If I look now when I take an example of the GP out-of-hours service, it is not disturbing that it is there, but it is there and it is only there when you type in a diagnosis, right?
-F4P2 (general practitioner, 6-10 years of clinical experience)

"Maybe it should be at the bottom, something small that becomes visible, but you do not need to actively click it away, otherwise you will be clicking all the time"
-F4P3 (ENT physician, 0-5 years of clinical experience)

Physicians agreed that the CDSS should be part of the existing EHR and mentioned that if it was a stand-alone program, they would not use it as much.

"Yes, I think if it is a stand-alone, that it will be used less."
-F4P5 (general practitioner, 26-30 years of clinical experience)

Standardization

There was an understanding under physicians that there is a vast array of current guidelines for treating infections in ambulatory care. The CDSS could help with standardization among physicians to create a uniform use of guidelines.

"I think it is an important thing to mention, if you work together with a lot of different people and those protocols actually make sure you all more or less work in the same way, that can actually be a very important point."
-F2P2 (general practitioner, 36-40 years of clinical experience)

3.2.3. Theme 3: Reducing uncertainty and enhancing safety: CDSS support in the evaluation and triage of acutely ill children

Severity of the illness

When assessing the severity of the condition of an acutely ill child, physicians are confronted with a lot of uncertainty. The majority of the focus group participants concurred with the fact that a CDSS could be helpful in cases with non-specific findings (i.e., "the grey zone"), and where the physician is undecided on what to do next (i.e., diagnostics, prescribing an antibiotic, or referral to secondary care).

In order for the CDSS to be able to be helpful in evaluating the severity of the illness, the system should take into account the most prognostic factors for severe illness (i.e., "alarm symptoms"), like: respiratory rate, characteristics of breathing, oxygen saturation, capillary refill, dehydration, heart rate, colour of the child, fever, fever pattern, vomiting, and neurological symptoms.

"It is the pattern of the fever that should worry you about whether it is an uncomplicated, normal course of an infection and there are 3 things that I know of that I always tell parents to talk about a reassuring versus a worrying pattern. A reassuring pattern is a pattern that they can wait with, and a worrying pattern is a pattern that they should seek medical help with. And the first thing is that they may have a high fever, they may have 40°, they may be flat on their backs, no problem, but you give paracetamol or ibuprofen or spontaneously and 2 hours later you have an okay child again, so clear ups between the fever peaks are incredibly important. […] Secondly, after 72 hours the worst of the fever is behind you […], but after 72 hours it is less high in absolute value less high, less frequent and the worst must clearly be over. […] And the third is after a week the fever must be gone that is really the extreme limit. […] I personally have found that interesting advice to give to parents for years, it

is also practically manageable they know that it is easy to see 72 hours, 7 days, clear up yes or no, but still, that is something they can interpret."
-F1P6 (paediatrician, 36-40 years of clinical experience)

"I would say first check the warning signs, for example, do we have a dehydration condition? Okay, do we have a child with tachypnoea or are there retractions or something like that? First, check the warning signs, if they are not already present, and then see if we have done a clinical examination."
-F1P7 (general practitioner, 11-15 years of clinical experience)

"Yes, I think that we, that such a decision support has to look at whether there are warning signs during history taking or clinical examination to do something now or whether there are things again where we say, okay, we can wait here for a while and see how, what it is like."
-F2P1 (paediatrician, 11-15 years of clinical experience)

Reducing diagnostic uncertainty

Various approaches were suggested by the participants in which way the CDSS could help reduce diagnostic uncertainty. First off, the CDSS could be of help by making a lineup of points of attention during history taking and/or clinical examination, as to help gather relevant information from the patient.

"What can be interesting and what could be a guideline is that you explicitly list everything you need to pay attention to, because the most important thing is in fact, and they told us that during semiology training, namely collecting your clinical data. You can perfectly know the differential diagnosis of hepatomegaly or splenomegaly, but if you cannot diagnose them then you are nowhere. And finally, such a flowchart, at that moment you have all your data but of course you still have to be able to get it out of the patient. And when you then list those things look, have you looked at that, have you, then say still look at that again carefully have you not overlooked that so in that sense that can help to someone who may be doing careless clinical examination or history taking to do that adequately enough."
-F1P6 (paediatrician, 36-40 years of clinical experience)

"Those alarm symptoms are going to be very useful, certainly for novice doctors, if they are all listed and you also have something like, I have checked them all off in your history taking and clinical examination, that that could be a priority of what could be included, right?"
-F1P7 (general practitioner, 11-15 years of clinical experience)

"And then I thought, because you asked yes, how do you see that best, I think that the main pitfalls or red flags for me really have to be clearly listed."
-F2P1 (paediatrician, 11-15 years of clinical experience)

Secondly, interpretation of alarm symptoms by physicians can be aided by the CDSS by showing normal or cut-off values for these alarm symptoms (e.g., respiratory rate).

"But that would already be useful for me in the decision aid, how old is your child, what are the normal values. You have learned those, useful to have them there again."
-F1P3 (general practitioner, 0-5 years of clinical experience)

"Because it changes so much with children. And I have them somewhere in tables, because I think, if I have doubts, then I can look it up again, but indeed, if that were in your EHR, that would be ideal."
-F1P1 (general practitioner, 11-15 years of clinical experience)

Third, by providing percentages on the risk of serious infection or whether an infection is more likely to be bacterial or viral the CDSS could play another role in aiding clinicians in their decision making. It is important that this function is based on inclusion and exclusion criteria and that it considers the baseline likelihood in a specific context (i.e., primary care vs. secondary care vs. tertiary care).

"Age-related fever under 28 days, the risk of an SBI [severe bacterial infection] is somewhere between twelve and eighteen percent […], but, then I always think, well, statistics do not really take into account that, that child of 29 days, but, but those are the kind of things that can be put into an algorithm and this is something very easy, but, but I can imagine that, if you start working with models, with different parameters, that a computer model can get slightly purer numbers out of that."
-F3P7 (paediatrician, 21-25 years of clinical experience)

"Rather, rather yes, rather for diagnostics or risk assessment, that you actually, like you say, you fill out, the temperature, you do your clinical examination […] or a number of fixed characteristics and that those actually, which are the most predictive of serious illness also? Is fever important? Is respiratory rate important? What is the one here that most predicts that the child that I have in front of me is seriously ill yes or no?"
-F4P2 (general practitioner, 6-10 years of clinical experience)

Finally, by displaying the incidence rates of various pathologies, the CDSS can help physicians to gauge the expected number of serious infections in their clinical setting, which in its turn could help physicians to not miss certain diagnoses by revealing their blind spots if they notice they do not meet certain incidence rates in their clinical practice.

"Yes absolutely, but we are talking about a very heterogeneous group of sick children. We are talking about newborns, children under the year, then you have older children, and about a whole variety of pathologies, so I think as a GP I would find it interesting to have such incidences of different pathologies and that you are indeed confronted with your blind spots. When you see, look that diagnosis you would have to make 1 in 100 and you have seen 500 children in 2 years for example and you do not pick-up those diagnoses, then you know that you are missing things."
-F1P4 (general practitioner, 11-15 years of clinical experience)

Safety

Missing severe illnesses is something that physicians try to avoid at all costs. The participants argued that a CDSS could offer safety and assistance in backing up their clinical judgment.

"I think decision trees give an enormous sense of security somewhere. If you follow a decision tree, you can always deviate on your own feeling where you want to do a little more because you […] still have the gut feeling that something is wrong. But if you have then reassured yourself and you can then do the decision tree again and it gives you security once more, then you feel very reassured."
-F2P1 (paediatrician, 11-15 years of clinical experience)

Triaging of patients

By implementing a triage function in the CDSS, it will be able to provide end-users with advice on referral and thus help refer patients to the appropriate line of care (primary vs. secondary). By extension this could decrease the burden on the healthcare system and thus be a cost-effective measure.

"It can also have a triage function, right? If it works to support decisions, […], refer or not, and the burden on the health care system can possibly be influenced by it. So, I think it is important that such a function can immediately [give] a supported decision for reassurance or for referral as to separate the wheat from the chaff."
-F1P4 (general practitioner, 11-15 years of clinical experience)

3.2.4. Theme 4: Defining the boundaries: Scope, usability, and real-world integration of CDSS in primary care

Scope

The participants emphasised the need to define the system's scope in advance, including the target patient group, end-users, and the intended purpose. The participating physicians noted that 'acutely

ill children' represent a highly diverse group, varying in symptoms, diseases, severity of the disease, and age.

"It is very important that you define the correct field of applicability of the system that you are going to set up. So, for which patient group, for which complaints, that it actually applies, so that it is not too broad. I have a bit of the impression that if you are talking about all types of infection, that it is starting to become so broad that it is going to be difficult to do that part well, so we are going to have to define well which patient group is it actually for here and for which symptoms."
-F1P6 (paediatrician, 36-40 years of clinical experience)

"So, I think that the normal child with a blank medical history and who does not have, like you just said, who does not have a clear cut diagnosis, a slightly red ear, a slightly red throat, […] and a fever, yes, it is just those gray ones that I think pose the greatest challenge for doctors, whether we are going to wait, whether we are not going to wait, whether we are going to start, […], whether we are not going to start, and that a decision tree might be able to help with that."
-F2P1 (paediatrician, 11-15 years of clinical experience)

Some participants stated that the CDSS will not be used for every child, such as in cases where the child appears visibly healthy and alert.

"But for yeah, just a kid first day of fever, where that you already, that is breaking down your cabinet, I am not going to click on that and fill all that in. That is probably not going to happen."
-F1P3 (general practitioner, 0-5 years of clinical experience)

"If the little one really comes in very lively, then my history taking will also be a bit more dry. Then I do not have to know all the details 100%, because I can already see at a glance that the little one is okay. […] Then I do not have to ask God-knows-what exactly, then I am honestly never going to fill that in if that is in my system."
-F1P3 (general practitioner, 0-5 years of clinical experience)

"For example, general appearance, yes, if that child is hopping around there very much alive, yes, then I actually should not be ticking off a lot of red flags, because the child already looked so good."
-F2P1 (paediatrician, 11-15 years of clinical experience)

Participants also discussed the system's end-users, considering both their professional roles (i.e., only physicians or also secretaries) and their level of clinical experience (e.g., novice physicians).

"Well, then you do have that distinction between first and second line, because in statistics, with us a fever, the chance that something serious will come out of that as a GP is much smaller than a child with a fever in the emergency room. The chance that something serious will come out of that is much greater and behind that, those statistics that are in your program and in that flowch-, what has to be included in that, that is then a difference simply because a selection has already been made, and that skill, those programs take that into account with that probability [prevalence] I think if you are going to work like that."
-F1P1 (general practitioner, 11-15 years of clinical experience)

"Now it also depends on who the decision tree is for, is it for the paediatrician, is it for a family doctor, is it for the secretary, is it for a medical secretary? Yes, I think that we need a lot of different types of decision trees for that."
-F2P4 (general practitioner, 11-15 years of clinical experience)

"A novice doctor who actually has little to no experience, certainly in paediatrics, would it not be better to first look in such a decision tree […], are there any warning signs, then for a novice doctor it is useful to look there first and then make the distinction. So that fewer things are missed, to eliminate that disadvantage a little for the inexperienced doctor."
-F1P7 (general practitioner, 11-15 years of clinical experience)

The physicians highlighted the distinction between primary and secondary care, as well as the distinction between a GP's office and an out-of-hours service.

> *"I think that in such a flowchart you actually have to distinguish between first and second line, because you have a different prevalence profile."*
> *-F1P4 (general practitioner, 11-15 years of clinical experience)*

> *"Well, I think that we see fewer sick children, we also see children with an ear infection, but we do not prescribe antibiotics for most of them, but that is usually not necessary, that is also been very clearly proven. […] I think that we see a completely different spectrum, or a different spectrum of children than you, and that is why it is difficult from one to the other, so I think that is why different decision trees are needed."*
> *-F2P2 (general practitioner, 36-40 years of clinical experience)*

> *"As a GP, we see a lot of children, we see different children than the paediatrician sees, I hope anyway. So, I hope that the general paediatrician sees slightly sicker children than we see. And that if we have the feeling that something is wrong, that we refer them to the paediatrician, or to the ENT specialist or whoever."*
> *-F3P5 (general practitioner, 16-20 years of clinical experience)*

> *"Well, I also think that the setting plays a role. In the GP's office, you know your own patients, but at the GP out-of-hours service you do not know anyone [...]. So, then you have to make a different assessment and then you also give antibiotics more quickly because you simply do not know those people and you want to be on the safe side."*
> *-F3P5 (general practitioner, 16-20 years of clinical experience)*

Regarding the system's intended purpose – whether it is meant to assist in diagnostics or provide treatment recommendations – physicians noted that once a diagnosis is confirmed, consulting guidelines is straightforward.

> *"It is still a bit unclear to me whether we should really talk about a child who already has a certain clinical diagnosis in the decision tree or whether it is mainly about fever without focus, because I think that is a very important first thing, because I do not think that a child with a fever without focus should be given antibiotics blindly, actually, never, without any further technical research having been done."*
> *-F2P5 (paediatrician, 11-15 years of clinical experience)*

> *"For me it also makes a big difference, do you really have a clear diagnosis, [...] you see a clear acute otitis media, yes, if you have a clear diagnosis and the context, then I think yes, the antibiotics are very clear for some conditions. [...] What are you going to do if it is a bit vague, sometimes you do not have a diagnosis, then I think yes, you always have a working diagnosis? If you do not have a diagnosis, then you are in the fever without focus and then it is a completely different story, but you always have a working diagnosis, even if it is an acute bronchitis in a young child, well, you never have no diagnosis, or then you can call it a fever without focus, you know?"*
> *-F2P1 (paediatrician, 11-15 years of clinical experience)*

All participants agreed that the CDSS should function as a support tool rather than a decision-making system and emphasised the importance of preventing physicians from developing tunnel vision or blindly following its recommendations.

> *"And I think the more that everything is standardised or when there are too many aids, that sometimes people forget to also think of course. [...] It is of course, I think that you have to be very careful that thinking is not forgotten, [...]. It is an aid, but once it is there, it sometimes becomes self-evident."*
> *-F3P4 (paediatrician, 11-15 years of clinical experience)*

> *"That is the same with aids around the dose of medication, there will often be a standard dose or a maximum dose for adults, but yes, for children it depends on so much more than just age, that it really is not that obvious to introduce such things in your EHR I think. So, there we are already running into a lot of problems, and we*

notice that you then have to build in 101 exceptions for when it is a premature baby or, depending on the postnatal age and ... Yes, we are very afraid of using too many things there, if you stop thinking about it over time or if people who have less experience rely on it too much and instead of asking a supervisor or something, they would just follow the computer system almost blindly of course."
-F3P4 (paediatrician, 11-15 years of clinical experience)

"It really should be something that is truly decision-supporting and not decision-making."
-F3P6 (ENT physician, 11-15 years of clinical experience)

In conclusion, the physicians agreed that the system should be a complimentary tool to the indispensable history taking and clinical examination.

"Indeed, I think on one hand it has to be clear, convenient, well-organised and not complex, but in my opinion, you will never be able to grasp the complexity in that, so I think it really has to be complementary. […] You have your own history taking, clinical examination, gut feeling, your own idea, with then the support of a decision tree, but it cannot purely be just a decision tree, […], then people can also fill that in on Google at home. It is and-and."
-F2P1 (paediatrician, 11-15 years of clinical experience)

Reliability

Participants stressed that the system should be grounded in established and trustworthy sources, including existing guidelines (e.g., BCFI, BAPCOC, NHG-Guidelines, hospital protocols) and high-quality clinical research and methodologies.

"I suppose it is the intention to actually feed the decision tree with what already exists, or at least that is how I imagine it?"
-F2P2 (general practitioner, 36-40 years of clinical experience)

"Well, of course we would assume that the decision tree is indeed well-founded, that you can trust them, that I also think is very important. Very important is the way in which they are developed. You use them quickly at the moment you need them, then you do not go and check everything, but you do want to know that the source where they [the information] come [comes] from, that that is really based on research. To indeed prevent calamities."
-F2P2 (general practitioner, 36-40 years of clinical experience)

Balancing the thoroughness of the system and the practical usability was a point of discussion for the participants, as a very thorough and complete system might no longer be practical or workable.

"The question is whether such a system remains workable, either it is very complete and very extensive, and the system is perhaps no longer useful or no longer workable, […], either it is too limited and is again not complete and there is too much interpretation in it."
-F1P4 (general practitioner, 11-15 years of clinical experience)

Technical aspects

The physicians identified various technical obstacles that must be overcome, such as integrating the system into different medical software, relying on accurate, complete, and properly coded data from the EHR, and ensuring ongoing maintenance so that the recommendations always align with current guidelines.

"I think that… concerning the decision tree, concerning the question of yes, what should that look like, I think that, we all work with different medical systems [EHRs], that in itself is a huge challenge of do you have a tree or something visual in front of you somewhere, then I think that it is useful for everyone if it can be matched with everyone's medical file [EHR]."
-F2P1 (paediatrician, 11-15 years of clinical experience)

"What I think is also important is the validation of the content. If you register an allergy for every red pimple you get on amoxicillin, right? Yes then, and that will remain there for the rest of their lives, yes then you will probably treat patients for a very long time with second-choice medication, because someone once thought: "Gosh, that person might have been allergic or reacted," while in more than 90% of the cases that has nothing to do with allergy."
-F3P7 (paediatrician, 21-25 years of clinical experience)

"The misery is mainly that, yes, it is good to link to coded diagnoses, but the codes themselves are very, very outdated. If we want to do something with those computer programs, then we should actually work daily to thoroughly revise those codes."
-F4P2 (general practitioner, 6-10 years of clinical experience)

"Then it has to be updated very actively, right? Of course there is someone who keeps those guidelines up to date, or several people, but then it also has to be translated, yes, almost simultaneously into what you do there, otherwise it is pointless."
-F4P2 (general practitioner, 6-10 years of clinical experience)

Future prospects

Some physicians stated the possibility of the framework of this CDSS being used as an early template for other CDSSs down the line since facilitators and barriers have already been discussed.

"We have done it for a sick child now. We might as well do something for chest pain or something or whatever. There are still a lot of things I think you can do, yes, useful work around."
-F4P2 (general practitioner, 6-10 years of clinical experience)

4. DISCUSSION

4.1. Main findings

This focus group study was designed to build an explanatory framework to reveal and understand the preferences physicians have regarding the use of the CDSS. In four focus groups, a clear image of the content and use of the CDSS for assessing acutely ill children in ambulatory care was formed. The following characteristics were identified for the CDSS.

1. To be regarded effective and user-friendly, the CDSS should impose minimal additional workload to the physician with seamless integration in the clinical workflow.
2. The information presented by the CDSS must be concise, precise and unambiguous; and the CDSS should provide guidance on diagnosing and treatment of disease.
3. The CDSS can help reduce diagnostic uncertainty through highlighting alarm symptoms indicating serious illness, help gauge the expected number of serious infections in their clinical setting and help triage patients to the appropriate line of care.
4. Existing and reliable sources of evidence-based information, the scope of the system, and technical barriers should be considered during implementation of the CDSS.

4.2. Strengths and limitations

4.2.1. Strengths

To determine and identify how a CDSS can help assist GPs in Belgium to prevent overprescription of antibiotics in acutely ill children, this focus group study was conducted. This study was therefore able to attain valuable information and give a comprehensive and detailed understanding of what physicians would prefer.

In this study, the participants where physicians from a diverse range of specialties. They worked in different areas of Belgium and had different levels of clinical experience. This gave room for discussion, interaction between participants, and ensured different opinions.

The coding process and theme generation was done by a group of researchers with different expertise and different backgrounds. The coding process and theme generation was first done separately and discussed by the complete group afterwards. This approach enhances the reliability of the findings by minimizing individual biases and ensuring a more comprehensive interpretation of the data. Independent analysis allows for diverse perspectives, while subsequent discussion facilitates the resolution of discrepancies and the development of a more nuanced understanding of the data.

The research group conducting the research and analysing the data, with HD as a coordinator, had different experience in research, focus groups and experience in working with EHRs and CDSSs. All researchers were mindful of their own biases and assumptions and made sure these did not influence the study.

4.2.2. Limitations

The participants of this study were limited to only Flanders. All five Flemish provinces were included, and efforts were made to ensure diversity among physicians in terms of relevant demographic and professional characteristics.

The recruitment process for this study may have resulted in a selective group of participants who had a particular interest in CDSS and were more motivated to engage in the study, leading to possible selection bias.

Participant responses may be influenced by recall bias, which involves inaccurate recollection of past experiences. For participants in the focus groups there could also be social desirability bias, wherein participants may alter their responses to conform to perceived social expectations.

There was a lower number of participants than anticipated in the protocol recruited to participate in the study. The focus groups were however planned with a diversity of participants in each group.

Some physicians were willing to participate, but only online. Two focus groups were performed via an online medium. These focus groups resulted in interesting perspectives but there were less discussions and more monologues by participants.

4.3. Comparison with the existing literature

Previous studies have demonstrated that seamless integration of a CDSS into the existing EHR and daily clinical workflow is essential for uptake. When implementation does not extend consultation time or adversely affect the physician-patient relationship and when the CDSS is incorporated directly into the EHR interface, physicians report greater willingness to use the tool (62,70–72). Our findings align with these studies, proving workflow integration as a critical facilitator of adoption.

Efficiency – or the perception that a CDSS saves time rather than adding to consultation length – merges as the most frequently cited factor influencing uptake (73). Both developers and clinicians emphasise that ensuring the system is timesaving is a primary objective when designing and deploying a CDSS (73). In our study, physicians repeatedly highlighted efficiency as a decisive determinant of success, echoing past research on barriers and facilitators.

Closely related to efficiency are usability and relevance of the information provided. Prior research emphasises the importance of minimising clinician effort, delivering actionable recommendations, and providing timely, context-specific support at the point of decision-making (74). Features such as automatic in-context prompts, periodic performance feedback, and the capability to generate patient-facing documentation further enhance utility and encourage ongoing use of the CDSS (72,74).

Conversely, several interrelated barriers have been shown to undermine CDSS adoption. Poor usability, lack of integration into the EHR or existing workflow, limited applicability to diverse patient populations, and irrelevant or excessive alerts (often termed “alert fatigue”) discourage physicians from following recommendations (62,67,70,72,75,76). Additional obstacles include mistrust of the information provided and perceived threats to clinical autonomy (77). While automatic generation of recommendations can streamline decision-making, participants in our study expressed mixed views on this feature. Some worried that too many automatic alerts could exacerbate alert fatigue, a concern that contrasts with findings suggesting that context-specific, actionable automation supports rather than hinders CDSS use (74).

In our study both active and passive activation of the CDSS was mentioned by the participants, in addition, different types of activation were also mentioned by the participants, like word recognition based on the diagnosis, however, they also mentioned that recognition based on words, could provide unnecessary pop-ups. These results correspond with the existing literature where previous studies have described the need for balance between the potential risk of less effective clinical outcomes in passive systems and the potential risk of overalerting the end-users in active systems (78,79).

4.4. Implications for clinical practice and future research

CDSSs can play a crucial role in supporting physicians in reducing unnecessary antibiotic prescriptions, thereby helping to combat AMR. Effective implementation of a CDSS in daily clinical workflow can aid in optimising antibiotic stewardship by providing evidence-based recommendations. Ensuring seamless integration into the EHR and minimising disruptions to consultation time should be prioritised to enhance use of the CDSS by physicians. Additionally, developers should focus on optimising CDSS efficiency, as time constraints remain a key barrier to adoption. Providing actionable, context-specific recommendations while mitigating alert fatigue is essential for improving usability. Also, physicians trust these systems, by being grounded in evidence-based sources.

Future research should explore strategies to further refine CDSS design, particularly in addressing concerns related to automation, practicality and efficiency. Investigating the long-term impact of CDSS use on antibiotic prescribing patterns and patient outcomes is critical in assessing its effectiveness in reducing AMR. Additionally, research on tailored CDSS interventions across different medical specialties may provide insights into discipline-specific adoption barriers and facilitators. Lastly, evaluating the role of periodic performance feedback and patient-directed documentation in increasing CDSS utilisation warrants further investigation.

5. CONCLUSION

Physicians prefer a CDSS that is pragmatic by integrating seamlessly into the existing EHR of the physician, requiring minimal extra time during consultations. The CDSS should offer concise outputs–such as symptom checklists and probable diagnoses based on inputted data–along with specific guidance on technical examinations, treatment, referral, or ambulatory follow-up. By interpreting red flags, non-specific findings, quantified risks, and incidence rates, the CDSS can

reduce uncertainty about the seriousness of the illness. The advice generated by the CDSS should be unambiguous, so that is understandable both to clinicians and non-medically trained people. It must be based on reliable sources, include a defining scope, and addresses technicalities. The implementation of a CDSS can play a role in reducing unnecessary antibiotic prescriptions in acutely ill children.

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7. ADDENDA

7.1. Addendum I - COREQ checklist

Consolidated criteria for reporting qualitative research (COREQ): 32-item checklist

Developed from:
Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. International Journal for Quality in Health Care. 2007. Volume 19, Number 6: pp. 349 – 357

No. Item	Guide questions/description	Reported on Page #
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Interviewer/facilitator	Which author/s conducted the interview or focus group?	6
2. Credentials	What were the researcher's credentials? E.g., PhD, MD	7-8
3. Occupation	What was their occupation at the time of the study?	7-8
4. Gender	Was the researcher male or female?	7-8
5. Experience and training	What experience or training did the researcher have?	8
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	8
7. Participant knowledge of the interviewer	What did the participants know about the researcher? E.g., personal goals, reasons for doing the research	6
8. Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? E.g., Bias, assumptions, reasons and interests in the research topic	7-8
Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? E.g., grounded theory, discourse analysis, ethnography, phenomenology, content analysis	7
Participant selection		
10. Sampling	How were participants selected? E.g., purposive, convenience, consecutive, snowball	5-6
11. Method of approach	How were participants approached? E.g., face-to-face, telephone, mail, email	5-6
12. Sample size	How many participants were in the study?	8
13. Non-participation	How many people refused to participate or dropped out? Reasons?	8
Setting		
14. Setting of data collection	Where was the data collected? E.g., home, clinic, workplace	6

15. Presence of non-participants	Was anyone else present besides the participants and researchers?	6
16. Description of sample	What are the important characteristics of the sample? E.g., demographic data, date	6; 8-9
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	6; Suppl. M.
18. Repeat interviews	Were repeat interviews carried out? If yes, how many?	6
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	7
20. Field notes	Were field notes made during and/or after the interview or focus group?	7
21. Duration	What was the duration of the interviews or focus group?	6
22. Data saturation	Was data saturation discussed?	NR
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	9
Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	7
25. Description of the coding tree	Did authors provide a description of the coding tree?	11; Suppl. M.
26. Derivation of themes	Were themes identified in advance or derived from the data?	7
27. Software	What software, if applicable, was used to manage the data?	7
28. Participant checking	Did participants provide feedback on the findings?	7
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? E.g., participant number	12-20
30. Data and findings consistent	Was there consistency between the data presented and the findings?	12-20
31. Clarity of major themes	Were major themes clearly presented in the findings?	11-20
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	12-20

NR: not reported; Suppl. M.: Supplementary Material

7.2. Addendum II – Research protocol

MASTERPAPER PROTOCOL: PROSPECTIVE STUDY USING OTHER NON-SPECIFIED RESEARCH DESIGN

Approved by EC Research UZ Leuven / KU Leuven - MP022375

1. APPLICANTS

Protocol - full title	Physicians' preferences for the use of clinical decision support systems in the context of acutely ill children presenting to ambulatory care: A focus group study
Version 1: Date submission	Date: 27/12/2022
Principal Investigator – Promotor	**Name: Jan Y Verbakel**
	Telephone: 016 37 72 86
	E-mail: jan.verbakel@kuleuven.be
Following both questions should be answered:	
The principal investigator is a health professional according to the Law of 10 May 2015. YES ☒ NO □	
The supervisor has read and approved the submission for ethics approval. YES ☒	
Co-Investigator – Co-Promoter	**Name: Tine De Burghgraeve**
	Telephone: 016 37 72 76
	E-mail: tine.deburghgraeve@kuleuven.be
The co- investigator is a health professional according to the Law of 10 May 2015. YES □ NO ☒	
Supervisor	**Name: Hannelore Dillen**
	Telephone: 016 37 64 61
	E-mail: hannelore.dillen@kuleuven.be
Sub-investigator – Student(s)	**Name: Annelien Dankaerts**
	Student number: r0759712
	E-mail: annelien.dankaerts@student.kuleuven.be
	Name: Daan Pauwels
	Student number: r0675705

	E-mail: daan.pauwels@student.kuleuven.be
	Name: Danielle Snijders
	Student number: r0874779
	E-mail: danielle.snijders@student.kuleuven.be

2. BACKGROUND AND RATIONALE

The desired effects of antibiotics are being compromised by the rapid escalation of **antimicrobial resistance (AMR)**, which is considered a major global health threat (1). In 2019, there were an estimated 1.27 million deaths attributable to bacterial AMR globally (2).

Diagnostic uncertainty is a main driver of **antibiotic over-prescribing** by GPs (3). **Children** are particularly at risk for unnecessary antibiotic prescribing. Childhood infections are often self-limiting and caused by viruses (4). Only 1% of acutely ill children attending primary care will be diagnosed with a serious infection needing antibiotic treatment (for example pneumonia, urinary tract infection, meningitis, or sepsis) (5). Distinguishing non-severe from serious infections is difficult, especially in the early stages of the disease where signs and symptoms are unspecific (5). Early recognition and adequate referral of a serious disease could prevent unnecessary investigations, referrals, treatments (including antibiotic prescriptions) and hospitalisations in children without a serious illness, avoiding traumatic experiences for the child, parental concerns and health care expenditures (6).

A **clinical decision support system (CDSS)** is intended to improve healthcare delivery by enhancing medical decisions with targeted clinical knowledge, patient information, and other health information (7). Despite its potential to improve the clinical decision-making process, clinicians do not always use CDSSs in such a way that their potential can be fully realized (7). Insight into barriers and facilitators, preferably in a specific context, is needed to improve the acceptance of CDSSs (7). Factors are most often related to (a lack of) usefulness and relevance of information, ease of use and efficiency of the system (7).

A widely used CDSS is the French system: Antibioclic. It is a publicly funded CDSS for antibiotic prescribing in primary care that provides personalized antibiotic recommendations for 37 infectious diseases (8). Antibioclic is freely available on the web and as a smartphone app (8). The number of users of Antibioclic has been steadily increasing over time, with no saturation effect (8). However, no CDSS has been introduced at a large scale in Belgium. With this focus group study, we aim to investigate the barriers and facilitators and the preferred manner of delivery of a CDSS, in the context of acutely ill children presenting to ambulatory care in Belgium.

3. STUDY OBJECTIVES

Primary objective: To investigate the preferred manner of delivery of a CDSS in the context of acutely ill children presenting to ambulatory care in Belgium.

Secondary objective: To investigate barriers and facilitators for the use of a CDSS in the context of acutely ill children presenting to ambulatory care in Belgium.

4. RESEARCH METHOD

We will perform synchronous focus group discussions among ambulatory care physicians treating acutely ill children. We will perform the discussions in person, unless COVID-19 measures do not allow for this. We will pilot the content and design of the focus group discussions with one physician who also has some research experience, if this is deemed necessary at the time. During the discussions at least one moderator and at least one observer from the research team will be present. The moderator will begin the interview with providing some general information of the principle of clinical decision support systems, so that all participants have a shared basic idea. The topics to be explored or open-ended questions that will be posed during the focus group discussions are listed in the ‘Interview Guide’ as annex.

Adhering to the principles of grounded theory, the researchers will reflect after each interview in order to come up with ways to improve the next interview in any way possible, including methods to obtain data that better answers the research question(s).

Since the participants will also have the opportunity to submit comments via email up to a week after the focus group, there will also be an asynchronous aspect.

5. SELECTION AND WITHDRAWAL OF PARTICIPANTS

5.1 Inclusion and exclusion criteria

We will recruit Belgian ambulatory care physicians treating acutely ill children (i.e., general practitioners, paediatricians, and ear/nose/throat physicians). A condition for participation in the study is the use of an electronic medical record. Physicians will be purposively sampled to obtain variation in gender (i.e., male and female), experience (i.e., number of years active as a doctor), specialty (i.e., general practitioner, paediatrician, ear/nose/throat physician), practice setting (i.e., solo and group practice), and rurality (i.e., urban and rural).

5.2 Sample size and population

]We will perform focus group discussions until theoretical saturation is reached. We will include 5 to 10 participants per group, based on previous studies on CDSS use in primary care (9-12). The exact number of sessions cannot be determined in advance, but based on previous research we expect to perform three to four interviews (9-12). The physicians in the focus groups are representative for physicians working in Belgium. Sufficient variety is ensured among the physicians.

5.3 Recruitment

The investigators will invite participants by mail or phone to participate in the study that will take place at the Academic Centre for General Practice (Leuven), Onderwijs en Navorsing (campus Gasthuisberg, Leuven), or at a practice near the participants. Physicians will be recruited from across Flanders (i.e., the Dutch-speaking part of Belgium). A wide network of physicians was already built up from previously conducted studies by the research centre. Physicians will only be contacted if they gave approval for this in previous studies. We will ask physicians to participate according to the principles of purposive sampling. If needed, we will recruit physicians by advertising the study on relevant websites (i.e., epi-centre.be, facebook.com/achgkuleuven/, vvkindergeneeskunde.be, https://orl-nko.be/nl) and newsletters (i.e., contactblad Academisch Centrum voor Huisartsgeneeskunde, newsletter Corilus, newsletter Vlaamse Vereniging voor Kindergeneeskunde, newsletter Koninklijke Belgische Vereniging Voor Oto-Rhino-Laryngologie, Gelaat- En Halschirurgie).

When these people consent, a time will be scheduled when the study will take place. The informed consent form (ICF) will be delivered to the participant by mail in advance. This ICF clarifies the purpose, method, and implications of the study; the possible benefits, risks, and disadvantages associated with participation; the possible external funding of the study, the processing of personal data, as well as the retention period and storage of these data. It also explicitly states that audio recordings will be made during the study. This ICF will be reviewed with the participant at the beginning of the focus group. Only when the participant agrees to the research and returns the signed ICF to the researcher, the research will start. The research will proceed as follows: we will investigate the preferred manner of delivery and barriers and facilitators of a CDSS in the context of acutely ill children presenting to ambulatory care in Belgium by performing focus groups with 5-10 participants. Each participant will attend one focus group with an estimated duration of 2 hours.

Both in the ICF and at the start of the focus group, it will be clearly stated that the person is not obliged to participate. Both for participating and not participating, as well as for ending the study early, there are no negative consequences for the person in question. Thereby, the research can be terminated at any time at the request of the participant. The data (including any audio clips) of uncompleted studies will not be included in the data analysis and will be destroyed.

There is an incentive in place for participating physicians: a coupon of 40 euros of Standaard Boekhandel. This will not be explicitly mentioned in the recruitment materials, as per the guidelines of the UZ Leuven Ethics Committee (13).

5.4 Expected duration

The study will begin January 2023. The end of the study is scheduled for June 2023. Each participant will attend one focus group with an estimated duration of 2 hours (travel time not included). Before the focus group, each participant will need some time to become familiar with the topic of the focus group, to schedule the moment of the

focus group (i.e., having contact with the investigator), and to read the informed consent form. After the focus group, the participants have the opportunity to submit comments via mail up to a week after the focus group. In total, participants will take 3 hours to participate in this study.

6. ANALYSIS

After transcribing the focus group discussions, we will perform qualitative data analysis (14) using the latest version of QSR NVivo software. Following constructivist grounded theory, memos will be written before the coding starts. Coding will be done independently by two researchers (15). Cases of discrepancy will be solved by discussion or a third researcher if consensus cannot be reached. A codebook will be developed. The coding process will happen in three phases: open, focused, and axial coding. During initial (open) coding, we will focus on small units of analysis, coding line-by-line. During focused coding, we will look at frequent earlier codes to navigate through the data, and will discern initial codes with the most analytical strength. During axial coding, we will examine the relations between categories and subcategories of codes (16). Findings will be reported using the consolidated criteria for reporting qualitative research (COREQ) checklist (17).

7. DATA HANDLING AND MANAGEMENT

7.1 Data storage and management

For the collection and storage of the data, we use OneDrive for Business, provided by KU Leuven. All data will be treated confidentially and with due care during the project. In function of our research question, preferences for the use of a CDSS for acutely ill children in ambulatory care will be collected by means of focus groups. Only relevant information will be collected and this will be limited to what is necessary for the purposes of the research question. The information obtained through the research will be collected in a structured manner in a secured computer document. If possible, this file will be stored in a project- or team-based storage location on a KU Leuven or UZ Leuven server, in OneDrive for Business, provided by KU Leuven. Otherwise, a personal computer secured by password, two-step verification or specialized program such as 7-Zip or AEScrypt will be used.

Data allowing identification of participants will be pseudonymized. This means that personal data will be processed in such a way that it can no longer be attributed to a specific person without the use of additional information. However, the direct link between the data subject and the dataset will not be broken, but will be encoded using a code. This code contains neither the name, nor initials, nor elements that could lead to identification (e.g., date of birth or place of birth). The codes will be kept in a separate and encrypted file, only in the possession of the supervisor(s) and the students involved. This file will not be kept on the same laptop or desktop as the data files.

Anything said by the participants during the study will be recorded via audio recordings. The audio recordings will only be listened to and transcribed by the researchers. Immediately after transcription, the audio recordings, the diary entries, the interviewer's personal notes will be destroyed. Transcripts of the interviews will not include names or any other data that will allow identification. In the actual master's thesis, some excerpts from the interviews will be quoted in an anonymous manner and in such a way that it is not possible to trace the statement back to a particular participant. The transcripts will be kept in a secure computer document that is only in the possession of the supervisor(s) and the students involved. If possible, this file will be kept in a project- or team-based storage location on a KU Leuven or UZ Leuven server, in OneDrive for Business, offered by KU Leuven. Otherwise, a personal computer secured by password, two-step verification or specialized program such as 7-Zip or AEScrypt is used. GROUP BIOMEDICAL SCIENCE HERESTRAAT 49, O&N II - BUS 700 BE-3000 LEUVEN 2020.10 When sending a copy of confidential information or documents, they will always be encrypted with a password or unique code. For sending large files, Belnet Filesender will be used. Applications such as Google Drive, a personal OneDrive (with the exception of OneDrive for Business, offered by KU Leuven) or WeTransfer will be avoided at all times. Upon completion of the project, files will be delivered to the supervisor who will further ensure their safe keeping. In accordance with KU Leuven policy, these files will be kept for 10 years, after which it will be reassessed whether it is considered useful to keep the data any longer.

7.2 Declaration of Confidentiality and Careful Management of Information and Personal Data

In the framework of his / her Master's thesis, the student(s) will have access to all kinds of data, information, results and documents. In order to ensure the confidentiality of this Information and the privacy of those involved, within the framework of his / her Master's thesis the student(s) should always deal with the Information with the greatest care and discretion. In particular research related to patients and including the collection and analysis of personal data requires the utmost of care and discretion. Therefore, at all times the student must observe complete confidentiality with respect to the Information he / she has collected during the course of his / her Master's thesis.

In performing this research, the student(s) commit(s) him/herself to the following confidentiality obligations:

- He / she accepts, during and after the completion of the Master's thesis, the obligation to strictly observe the confidentiality of the Information he / she has collected and the activities to which he / she has participated, and regarding the patients, healthy volunteers and the staff members with whom he / she comes into contact;
- He / she will only process and collect data that is relevant and necessary for his / her Master's thesis;
- He / she will not share information with persons not directly involved within the framework of his / her research; only the investigator, possible group members and his/her supervisor will have access to the data
- He / she will take all necessary steps to protect the confidentiality of Information and the privacy of those involved;
- He / she will handle with care and responsibility the Information and the access granted to him/her to information systems and digital media.
- He/ she will discuss the confidentiality, storage and sharing of files with his/her supervisor. He/she will use anonymisation or pseudonymisation in order to limit the risks of data leaks and data loss.
- If pseudonymisation is used, he/she will treat the pseudonymisation key or the encryption table containing the pseudonyms and the identifiable information fields with the same confidentiality as the original data. He/she will never store the key or encryption table at the same device (e.g. laptop or desktop) as the work file or database containing the pseudonymised data.
- Wherever possible, he/she will use a project based or team based storage location for storing and exchanging data. He/she will contact his/her supervisor to discuss the possibility of using an internal or external service of KU Leuven or UZ Leuven to save data. If not possible, he/she will use OneDrive for Business, provided by KU Leuven, or a password protected device for storing collected data. Applications such as Google Drive, a personal OneDrive (except OneDrive for Business, provided by KU Leuven) or WeTransfer will be avoided at all times.
- He/she will always encrypt confidential information and files with a password, two-step verification or specialized program such as 7-Zip or AEScrypt.
- When sharing a copy of strictly confidential data, he/she will always encrypt the data with a secure password or unique code. For sharing large files, a secure application such as Belnet Filesender will be used.
- In the event of a data breach he/she will immediately contact his/her supervisor

As this research is conducted in the context of a Master's Thesis, the legal basis for the processing of personal data is the public interest. This research will generate knowledge and new insights that (directly or indirectly) will benefit society.

All investigators shall treat all information and data relating to the study as confidential and shall not disclose such information to third parties or use such information for any purpose other than the performance of the study. The collection, processing and disclosure of personal data, such as participants' contact information, health information and medical information, is subject to compliance with the General Data Protection Regulation (GDPR).

When approval is given by the Ethics Committee, it is confirmed that the proposed processing of personal data meets the requirements of the GDPR. Consequently, from a GDPR perspective, there is no objection to start the processing operations. When approval is given, this application will, In accordance with the GDPR, become included in KU Leuven's register of processing activities in the context of research and public service. No separate privacy application should be submitted for this type of studies.

8. ASSESSMENT OF RISKS AND SAFETY

This study poses very little to no physical safety risks to the participants.
If the focus group discussions take place online, we will use Microsoft Teams software. Consequentially, participants

are not anonymous and may be visually recognized by one another. Additionally, this software provides user privacy protection. Although highly improbable, a breach in software security remains possible. Data that might be visible to other participants can include a participant's email address, IP-address, message content, and chat dialogues. These data may all be traceable and accessible at various times during and after the research effort. The researchers will make attempts at enabling anonymity (e.g., advising participants not to use their name or email address as a visible username in MS Teams), but they want to stress that full anonymity is not guaranteed.
In the case of in-person focus group discussions, the probability of participants recognising each other is slightly higher. Although unlikely to occur, interviewees could be involved in traffic accidents on the way to or from the interview. All researchers involved have an up-to-date GCP certificate. The name of the Principal Investigator and other relevant point of contacts have been integrated in the ICF.

9. APPROVAL

Hereby we confirm that data collection is performed with approval of the head of the respective unit(s) or department(s) where data collecting is taking place.

Contact details Jan Verbakel:
Academisch Centrum voor Huisartsgeneeskunde
Kapucijnenvoer 7 blok h – bus 7001
3000 Leuven
Mail: jan.verbakel@kuleuven.be
Tel.: +32 16 37 72 86

10. PUBLICATION POLICY

Publications will be coordinated by the Principal Investigator. Authorship to publications will be determined in accordance with the KU Leuven policy on authorship.

11. DIRECT ACCESS TO SOURCE DATA AND DOCUMENTS

The investigator(s) and the institution(s) will permit study-related monitoring, audits, ethical review and regulatory inspections (where appropriate) by providing direct access to source data.

12. REFERENCES

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13. ANNEXES

1. *A template of the **ICF** has been developed and is available on https://med.kuleuven.be/nl/obc/Documenten or https://med.kuleuven.be/nl/obc/Documents_en. This must be used as a basis and adapted where necessary.*

   In case an alternative template is being used, a motivation should be provided here. Please copy your information letter here.
2. *All relevant information and documents regarding your research design*
3. *Every **advertisement, flyer, poster**, etc. that will be used in the study should be added. If recruitment will be done through **social media** or by **mail**, please also add the text or illustration that will be used.*
4. *Other (if applicable)*

7.3. Addendum III – Poster



7.4. Addendum IV – Interview guide

- Do you have any experience with clinical decision support?
  - If yes, what was that experience like?
  - If no, what do you think of the idea of 'clinical decision support'?
- What are the benefits of clinical decision support? Or What do you like about clinical decision support?
- What are the disadvantages of clinical decision support? Or What factors hinder the use of clinical decision support?
- Suppose an acutely ill child presents to you, what information would you like to see provided in clinical decision support?
  - What advice should the decision support provide?
  - When should this information be provided?
  - If the decision support recommends antibiotics, what information is essential?
  - Do you think that too much information could be provided? How could this be resolved?
  - In which way would you prefer to see the information appear?

    - Should there be an option to pass on the information to the patient as well?
- How does clinical decision support fit into your consultation?
    - Do you think decision support is best integrated into software already available to physicians or is it better to remain separate?
    - In what way do you think the system would be best activated?
    - Does the complexity of the case or diagnosis play a role in the amount of notifications you wish to receive? Possibility of temporarily turning off notifications?
- Other questions (if time is left - taking into account the final question)
    - What is your opinion on audit and feedback? Should completed data and decisions be made traceable? Can quality assessment (feedback) be part the discussion within the local quality group?
    - Would it be an option for someone other than the physician to already fill in some of the information?
    - Would you like to receive training on the use of clinical decision support? What would this training ideally look like?
    - Would you like access to calculations or quantitative information, e.g. calculating the right dose of antibiotics for the child, calculating the probability of a particular diagnosis?
    - What is preferred: recognition based on free text (coding required) or completion of a multiple-choice questionnaire?
- Case (if time is left – taking into account the final question)
  Bart is 5 years old. For a week now, he has a cough. For the last two days he has started to get a fever, reaching 38.5° in the evening. He feels unwell and lies on the sofa. He looks pale. His parents report that he was breathing very fast last night.
  Clinical examination: throat inspection: slightly red throat; nose inspection: normal; ears: normal; lung auscultation is normal, heart: regular, 100/min. Respiratory rate is currently 36/min.
    - How can clinical decision support help you in the case study?
    - Which elements from this case can help you make a decision? Or Which elements can be integrated into clinical decision support?
- Is there anything we should have discussed but did not? Or Of all the characteristics of clinical decision support we discussed, which one is most important to you? (Question for each participant)

7.5. Addendum V – Participant agreement

Participant agreement with the themes was defined in three independent ways: (1) a median score ≥5; (2) an agreement proportion (score of at least 4) ≥75%; (3) a coefficient of variation (i.e., standard deviation divided by mean) ≤0.5. Consensus between participants was defined as an interquartile range (IQR) ≤1.75.

Reference: von der Gracht HA. Consensus measurement in Delphi studies: review and implications for future quality assurance. Technol Forecast Soc Change 2012;79:1525–36.

		Theme 1	Theme 2	Theme 3	Theme 4
Agreement	Median (at least 5)	5	6	5	5
	Agreement proportion (at least 75%)	100.00%	100.00%	100.00%	100.00%
	Coefficient of variation (at most 0.5)	0.093	0.11	0.13	0.12
Consensus	IQR ≤1.75	1.00	1.00	1.00	0.00