



## Major Article

## The value of participatory development to support antimicrobial stewardship with a clinical decision support system



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**Background:** Current clinical decision support systems (CDSSs) for antimicrobial stewardship programs (ASPs) are guideline- or expert-driven. They are focused on (clinical) content, not on supporting real-time workflow. Thus, CDSSs fail to optimally support prudent antimicrobial prescribing in daily practice. Our aim was to demonstrate why and how participatory development (involving end-users and other stakeholders) can contribute to the success of CDSSs in ASPs.

**Methods:** A mixed-methods approach was applied, combining scenario-based prototype evaluations (to support verbalization of work processes and out-of-the-box thinking) among 6 medical resident physicians with an online questionnaire (to cross-reference findings of the prototype evaluations) among 54 Dutch physicians.

**Results:** The prototype evaluations resulted in insight into the end-users and their way of working, as well as their needs and expectations. The online questionnaire that was distributed among a larger group of medical specialists, including lung and infection experts, complemented the findings of the prototype evaluations. It revealed a say/do problem concerning the unrecognized need of support for selecting diagnostic tests.

**Conclusions:** Low-fidelity prototypes of a technology allow researchers to get to know the end-users, their way of working, and their work context. Involving experts allows technology developers to continuously check the fit between technology and clinical practice. The combination enables the participatory development of technology to successfully support ASPs.

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Clinical decision support systems (CDSSs) are a relatively well studied and widely used form of eHealth technology to support physicians in prudently prescribing antimicrobial agents.<sup>1</sup> This makes these systems a valuable asset for an antimicrobial stewardship program (ASP). An ASP—a multilevel program based on a theragnostic approach<sup>2</sup>—is intended to deal with the global health problem of infections with multidrug-resistant organisms by guiding prudent use of anti-

microbial agents based on adequate diagnostics.<sup>2,3</sup> Despite promising results,<sup>4</sup> the implementation of such programs remains challenging.<sup>5</sup> Implemented systems are not always used or adhered to.<sup>6,7</sup>

A recently performed scoping review<sup>1</sup> dug deeper into this phenomenon. It showed that end-users were hardly involved in the development of the CDSSs. This means that it is very likely that CDSSs are successful at reflecting clinical standards, but fail to support their users in practice.<sup>1</sup> It has been suggested that this contributes to low use and adherence rates.<sup>6,8</sup> Studies show a need for a behavioral and/or social approach to the development of interventions in ASPs.<sup>9,10</sup> This can be done by adopting a participatory development approach (ie, involving end-users and other stakeholders).

Via the description of the development process of a CDSS for ASPs, we aimed to demonstrate why a participatory development approach renders important insights to develop successful ASP-supporting technology. In addition, we describe what kind of information it yields that contributes to the success of the technology.

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This is done by applying a mixed-methods design to gain insight into the potential end-users' perceived needs and to cross-reference those perceived needs with actual needs. Perceived needs were evaluated via scenario-based prototype evaluations among medical resident physicians, with a low-fidelity prototype of a CDSS for an ASP. Actual needs were evaluated via an online questionnaire among a larger group of physicians. The questionnaire focused on clinical practice of a specific aspect of ASPs (ie, diagnostic tests and parameters) that is often overlooked, but is—in our view—a pillar of ASPs.<sup>2</sup> The approach and methodologies for participatory development that are described herein are in this case applied to prescribing antimicrobial agents. However, an ASP is more than prescribing antimicrobial agents. It also requires infection prevention and control (IPC) measures. The approach that is described in this article is also very suitable for and should also be applied to the development of supportive IPC measures.

**METHODS**

Within this section, the scenario-based prototype evaluations and online questionnaire are described.

*Scenario-based prototype evaluations*

Gaining insight into the perceived needs of potential end-users of a technology can be more difficult than it seems. Merely inquiring about needs without offering some concrete example of what the technology might look like requires great imagination. In this part of the study, physicians were presented with an example of what a CDSS might look like. In addition, they were given a real-life scenario that they could encounter in clinical practice. Offering a scenario triggers participants to think about how they make clinical decisions. Also, it makes it easier for them to imagine what it would be like to work with the technology in clinical practice.<sup>11</sup> Thus, participants can visualize and verbalize their perceived needs while researchers gain insight into the ways end-users work and think.

*Participants*

The prototype evaluations took place at an 800-bed teaching hospital. Participants were selected via convenience and snowball sampling and were invited via e-mail. Six medical resident physicians were invited and participated in the study.

*Procedure and materials*

First, participants were asked about their background and work processes to gain insight into the context within which the results should be interpreted. Specifically, questions focused on experience with prescribing antimicrobial agents and on support systems that are currently being used for that purpose.

Then, participants were presented with a low-fidelity prototype of a CDSS. The prototype of a CDSS to support the prudent prescribing of antimicrobial agents was created based on what we learned from prior research about existing CDSSs.<sup>1</sup> The prototype (see Fig 1) was created using Balsamiq software Version 2.0 (Balsamiq Studios, LLC, Sacramento, CA), allowing the physicians to click through the screens of the prototype. To guide them in doing so, a real-life scenario was developed in cooperation with a clinical microbiologist:

A patient is referred to you by his general practitioner. He has a high fever and an increased respiratory rate. You suspect that the patient has pneumonia.

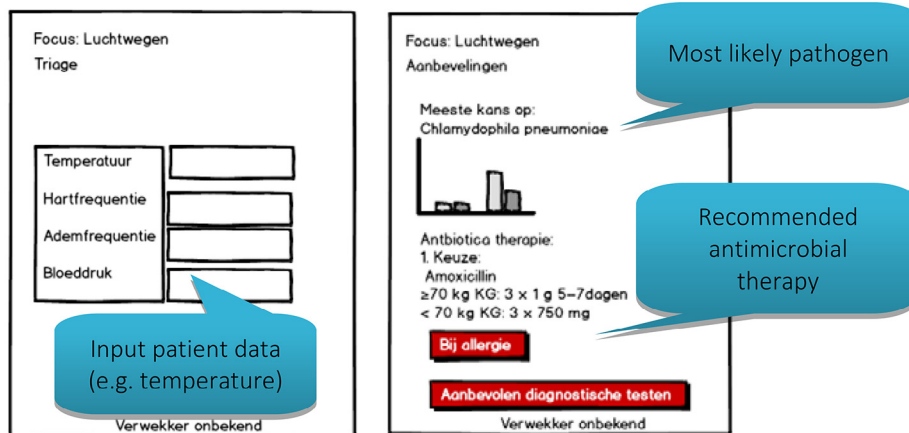
Participants were asked what kind of support they would like to receive in the given situation and why. The individual prototype evaluations took about 45 minutes each. With permission of the participants, all prototype evaluations were audiorecorded.

*Data analysis*

Verbatim transcripts of the audiorecordings were analyzed using a codebook. To do so, the coder (NBdJ) read and reread all transcripts to familiarize herself with the data. Based on these data a codebook was developed. It contained codes related to the various topics of interest; that is, experience with support systems, need for a CDSS, type of support needed, and the evaluation of the low-fidelity prototype CDSS. Two researchers (NBdJ and JW) independently coded 10% of the dataset to check the reliability of the codebook. This resulted in a Cohen's kappa of 0.807, indicating very good reliability. For data analysis, the codes were grouped and quotes were summarized. Descriptive statistics were calculated for all codes.

*Online questionnaire to gain insight in current ASP practice*

An online questionnaire was used to cross-reference some of the findings of the prototype evaluations. This was done to disclose potential say/do problems,<sup>12</sup> to investigate the use context and the prototype's fit with it, and to show why one should not only ask



**Fig 1.** Example screens of the prototype (in Dutch) of a clinical decision support system for antimicrobial agent prescribing.

end-users what they think they need, but also should validate this with practice and other stakeholders (in this example: specialists in the field of the given case—lung disease—or in the field of infections and/or antimicrobial prescribing).

Our research does not intend to fully and in detail describe the development of a CDSS, but rather to illustrate some of the challenges and possible ways to deal with them. Therefore, we zoom in on a single type of support (ie, the selection of appropriate diagnostic tests) that we know from literature is first and foremost necessary,<sup>2</sup> but also available,<sup>1</sup> and from scenario-based prototype evaluations that the perceived need for this kind of support is limited. The aim of the questionnaire was to investigate whether this kind of support should be a need. We assumed that for such support not to be needed, it would require representatives from clinical practice and experts to agree on a clear vision about what actions should be taken. In this case, that means they should concur on what diagnostic tests should be used for a given scenario. The scenario matched the one that was used in user testing.

### Participants

The scenario-based user tests demonstrated that among the most important reasons for experiencing a need for support was that clinicians often treat patients with infections caused by pathogens outside of their own medical specialty. Thus, it was decided to send e-mail invitations via hospital clinical microbiologists to clinicians from any kind of medical specialty to participate in the online questionnaire. A total of 75 physicians started filling out the online questionnaire, 54 of whom actually completed it.

### Procedure and materials

The real-life scenario that was used in the prototype evaluation was also used in the online questionnaire. It aided the participants in determining what diagnostic tests they considered important. Physicians were asked to indicate (on a 5-point Likert scale) how important they consider different diagnostic parameters and tests. For that purpose, they were presented with a list of possibilities:

- |                            |                                  |  |
|----------------------------|----------------------------------|--|
| • Temperature              | • Respiratory rate               | • X-ray of the abdomen                     |
| • C-reactive protein       | • Differentiation                | • Rapid test for Pneumococcal colonization |
| • Venous oxygen saturation | • Ultrasound abdomen             | • <i>Clostridium</i> rapid test            |
| • Heart rate               | • Blood culture                  | • Feces culture                            |
| • Procalcitonin            | • Erythrocyte sedimentation rate | • Intravenous pyelogram                    |
| • Creatinine               | • Lumbar Puncture                | • Urine sediment                           |
| • Blood pressure           | • Sputum culture                 | • Lactate                                  |
| • Leukocyte count          | • X-ray of the thorax            | • Other                                    |
| • Urea test                | • Urine culture                  |  |

This list was developed in cooperation with a clinical microbiologist and was based on scientific literature and medical guidelines.<sup>13-15</sup> The potentially relevant parameters were supplemented with less relevant parameters to provide additional options. Questions were included to gain insight into demographic characteristics of the participants and into their motivation for their rating of the diagnostic parameters and tests.

### Data analysis

SPSS version 20.0 (IBM-SPSS Statistics, Armonk, NY) was used to analyze data. The frequencies with which physicians indicated a certain parameter or test was (very) important, neutrally important, or (very) unimportant were analyzed using descriptive statistics. The aim of this part of the study was to measure consensus. In the existing literature, different thresholds for consensus are applied.<sup>16,17</sup> In striving toward strong consensus, the rather conservative threshold of 80% agreement was set for the current study.

## RESULTS

Within this section, the results of both the scenario-based prototype evaluations and the online questionnaire are described.

### Scenario-based prototype evaluations

Six medical resident physicians (4 women) were invited and participated in the scenario-based prototype evaluations. Their average age was 26.7 years (range, 26-28 years), with work experience of on average 11.7 months (range, 4-22 months) at different departments (ie, surgery, gastroenterology, cardiology, pediatrics, and neurology).

### Current clinical practice

All 6 participating medical resident physicians indicated having experience with prescribing antimicrobial agents. Additionally, they all had experience with using some kind of support system. Most of the systems that participants reported working with were digital support systems (eg, online guidelines of the Dutch Working Party on Antibiotic Policy). Interpersonal support systems (eg, consultations with medical microbiologists or other medical specialists) and paper-based support systems (eg, hospital protocols) were less often mentioned.

Quote 1. "For more complicated cases . . . we regularly consult a medical microbiologist. Because it is his everyday work, he knows exactly what should be used for what, and has all the test results at hand."

Surgery, male respondent

Mostly, patients were initially treated with a broad-spectrum antibiotic. Some participants pro-actively explained the triggers to start any antimicrobial therapy. Triggers that were mentioned were anamnesis, the patient's history (ie, prior infections, prior lab test results, prior health care institution stay, recent time spent abroad, and recent stays in an environment with a risk of extraordinary bacteria), estimation of severity or mortality scores, most likely pathogen, lung imaging, and whether infection is community- or hospital-acquired.

Quote 2. "And whether the patient went to a sauna or something like that, because of which he would be at risk for other bacteria than the ones that you would find in normal open air. Those are things you keep in mind."

Gastroenterology, female respondent

Ideally, upon initiating an antimicrobial therapy, diagnostic tests should be requested. Although not explicitly asked for, 5 respondents proactively indicated what kind of diagnostic tests they would request. Diagnostic tests that they mentioned were sputum culture, blood culture, lung imaging, temperature, blood pressure, and heart rate. Some tests were each mentioned by 1 participant: respiratory frequency, anamnesis, physical examination, saturation, Early Warning System score (a measure for severity of septic shock), *Legionella* rapid test, leukocyte count, and C-reactive protein.

One participant (surgery, female respondent) mentioned almost all tests (79%) and another (gastroenterology, female respondent) also mentioned relatively many tests (57%). The others each mentioned significantly fewer laboratory tests (21%-29%).

### Perceived need for a CDSS

All participants believed that having a CDSS available would improve their work. However, their reasons differed. Participants mentioned that a CDSS would help them select the right kind, dosage, and duration of antimicrobial agents for rare pathogens or in case of organ (eg, kidney) failure; save them time, because it

automatically integrates a lot of scientific literature into a single advice; be especially helpful for treating patients who have an infection that does not lie within their own specialty; help to avoid unnecessary use of broad-spectrum antimicrobial agents; and help to alert physicians about possible allergies that a patient has, if the CDSS is linked to an electronic health record.

Quote 3. "We encounter all kinds of infections that are not always related to neurology. (...) And basically, we do want to treat all our patients ourselves."

Neurology, male respondent

On the other hand, barriers were mentioned that would prevent participants from using a CDSS for prescribing antimicrobial agents. Prerequisites for a CDSS to deal with perceived barriers are that the advice should not be restrictive; it should not discard any antimicrobial agents that would not be harmful if they were used; the participants still want to see alternative antimicrobial agents so that they can have a final say in which they select; and the system should not prevent physicians from thinking for themselves, because they may come to rely on it too much.

#### Perceived system needs

The CDSS should be offered on smartphone, or a combination of smartphone with personal computer (which is available in the clinic) and tablet. The CDSS should be available 24 hours a day, 7 days a week. It would mainly be used during rounds or when starting empiric antimicrobial therapy for newly admitted patients.

#### Perceived service needs

Participants appreciated the fact that the prototype was concise. However, some challenges arose concerning its user-friendliness. For example, the term *MDRO* (ie, multidrug-resistant organism) was unclear, and participants were unfamiliar with the AMBU-65 score (a severity index for pneumonia), preventing them from adequately using that part of the prototype.

A CDSS should use and provide references to the reliable guidelines that it was based on, for the users to be able to work with and trust the system. Also, 2 participants explicitly mentioned that a CDSS should not be restrictive, meaning that it should suggest courses of action, but not compel physicians to do as it says.

Quote 4: "I think you should really see it as guidance and not as something binding. Of course, protocols are really nice and in many cases you can work with them, but there are also plenty of reasons why you would deviate from them. ... There are numerous factors that can change your choice: previous lab test results or previous experiences."

Surgery, male respondent

Participants indicated that the CDSS should highlight a preferred antimicrobial agent and provide others as alternatives, based on degree of illness or other input data. They believed this would help them to quickly select the correct agent. Finally, 1 participant stated that it is necessary for users to have insight in the reasoning; that is, the algorithms behind the system.

#### Perceived content needs

Existing CDSSs mainly offer decision support on 3 aspects of prescribing antimicrobial agents: selecting adequate microbiologic laboratory tests, selecting a correct diagnosis, and/or selecting an appropriate antibiotic. Some of the existing CDSSs combine these with other support; for example, patient information and easy access to scientific literature.

#### Lab test selection

Participants mentioned that recommendations of appropriate lab tests might be useful as a reminder for physicians. However, other participants explicitly stated that this feature is not needed. This is the only feature respondents explicitly mentioned not appreciating or needing.

Quote 5. "Actually, I think every doctor knows what to do."

Gastroenterology, female respondent

#### Diagnosis selection

Participants want a CDSS system to provide the most likely pathogen, and information about whether the infection is most likely community- or hospital-acquired. The prototype version of a CDSS made use of the AMBU-65 score<sup>18</sup> to calculate a severity score for pneumonia. Not all participants were familiar with this specific score, but it was acknowledged as a useful feature for a CDSS.

#### Antimicrobial selection

Antimicrobial selection was the most appreciated type of support of the prototype CDSS. Participants saw value in recommendations about the kind of antimicrobial agent. This also goes for the feature of the prototype where alternative antimicrobial agents were suggested in case a patient has an allergy.

Quote 6. "That is what makes it difficult: In case of an allergy. That's a practical example that I experienced, and it made me realize that I could not find it anywhere."

Surgery, female respondent

Participants appreciated recommendations about the dosage and duration of the antimicrobial therapy. They mentioned that especially the optimal duration of a therapy is often unclear.

Quote 7. "It is often decided like: 'Well, let's make it 7 days, or actually, make it 10. Even though 5 days might have sufficed.'"

Gastroenterology, female respondent

Participants also find possible drug-drug interactions and possible side effects to be useful information. Finally, some aspects of the antimicrobial selection support were mentioned by a single participant (ie, dosage in the case of kidney failure, alternative administration routes, when to switch from intravenous to oral administration, and contraindications).

#### Other support

Participants appreciated the link to an information database that was provided with the prototype. It referred to a Web-based app for administering antimicrobial agents in clinical practice that was previously developed for, and greatly appreciated by, nurses.<sup>19,20</sup> They especially liked the combination of a concise CDSS with optional further (in-depth) reading in an additional database.

Quote 8. "I do not think you should strive to incorporate everything in this system. That would make it too cluttered. And it remains to be seen whether you always need to know everything. In 9 out of 10 cases this would suffice."

Surgery, male respondent

#### Online questionnaire

In the prototype evaluations, participants indicated that they would know what diagnostic tests to perform in the given scenario. Thus, this kind of support was not needed by some of them. This finding was subsequently cross-checked through an online questionnaire.

A total of 75 physicians started filling out the online questionnaire, 54 of whom (33 men) actually completed it. Their mean age



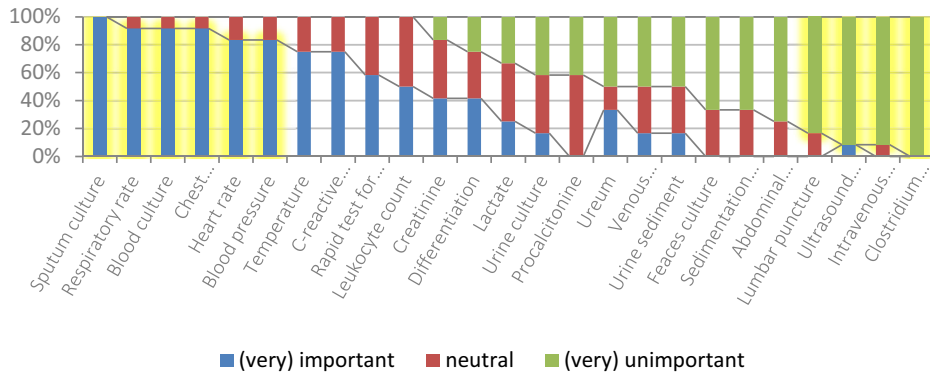


Fig 2. Consensus among lung and infection specialists regarding the usefulness of parameters or tests.

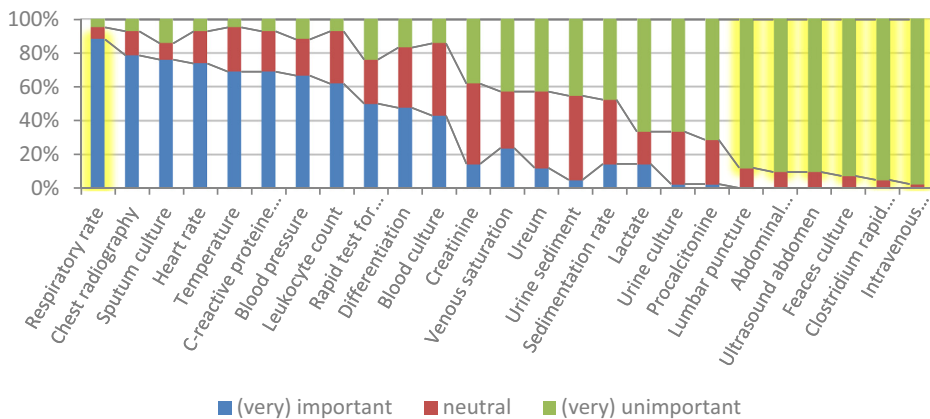


Fig 3. Consensus among other medical specialties regarding the usefulness of parameters or tests.

was 46.3 years (range, 32-64 years), with on average 12.7 years of work experience (range, <1-32 years).

These 54 physicians represent 26 different medical specialties. Among them were experts in the field of infections (ie, clinical microbiologists and specialists in internal medicine) and experts in the field of the case in the scenario (ie, lung specialists). The other participating medical specialists do not prescribe antimicrobial agents or treat lung diseases as their core clinical task (eg, cardiologists and gynecologists). It might be that the judgments of infection or lung experts (n = 12) and those from other specialties (n = 42) differ.

Expert consensus

When focusing on the lung and/or infection experts, 10 (40%) parameters reached consensus: sputum culture, respiratory rate, blood culture, chest radiography, heart rate, and blood pressure were all 6 (24%) considered (very) important by this subgroup. The experts also consented about the unimportance of 4 (16%) of the tests: lumbar puncture, ultrasound abdomen, intravenous pyelogram, and Clostridium rapid test (see Fig 2). This automatically means that experts differed in opinion about 60% (n = 15) of the diagnostic tests.

Consensus among other specialties

The other medical specialties representatives reached consensus on a total of 7 (28%) of the parameters or tests (see Fig 3). One of these (4%) was considered important: respiratory rate. The others (24%) were found (very) unimportant: lumbar puncture, abdominal radiography, ultrasound abdomen, feces culture, Clostridium rapid test, and intravenous pyelogram. Thus, their opinions differed for 18 (72%) of the diagnostic tests.

Comparing lung and infection experts with other medical specialties

Neither lung and infection experts nor other medical specialties reached consensus very often (both far less than half of the time). Experts did reach consensus more often than the other specialties. However, considering the number of times that no consensus was reached, there is clearly a broad range in preferences and opinions among all medical specialties. Additionally, more than half (59%) of the times that consensus was reached, a diagnostic test was found to be unimportant. Rather than agreeing on what should be done in clinical practice, physicians in these cases just agree on what should not or does not have to be done.

DISCUSSION

Existing CDSSs for ASPs are medically based and clinically focused. They are expert- or guideline-driven. This myopic view leads to CDSSs that do not support the actual processes in patient care and their supportiveness remains limited. At the same time, supportiveness is pivotal to be able to provide stewardship within an ASP, especially in an integrated stewardship model where many and complex (intertwined) decisions and considerations must be made. The aim of the current article is to demonstrate how participatory development stewardship can be provided by developing technology (such as a CDSS) via a participatory development process.

Lessons learned

The main lessons learned, concerning the added value of participatory development of eHealth technology for ASPs, are discussed in this section.

### The technology

In the current study, end-users and other stakeholders were very much involved. The scenario-based prototype evaluations allowed users to experience what it would be like to work with such a technology and to verbalize clear notions of what the technology should or should not do. Participants were integral in stating that it should not be restrictive, because they find it crucial to still be able to use their tacit knowledge (ie, clinical eye) in treating patients. This was noted in other studies<sup>21–23</sup> and confirmed in the current online questionnaire. This helped to bring to the surface clear differences in opinions—both among experts and among other medical specialties—about the importance of certain diagnostic tests. The discordance in the opinions of experts is an indication that it is undesirable or even impossible for a CDSS in ASP-related diagnostics to provide directive instructions about what to do. Rather, it should provide support, motivate, and remind physicians to take all the necessary steps for antimicrobial stewardship. This requires for a CDSS to be flexible; that is, to be able to adapt to changing settings and conditions.

### The users

A previous scoping review<sup>1</sup> demonstrated that CDSSs for ASPs generally offer support on 1 or more aspects of an ASP (eg, selecting lab tests, selecting a diagnosis, or selecting an antimicrobial therapy). Of these, the selection of lab tests was least often supported. In the current study, the participatory development approach provided insight into the CDSS's end-users and their support needs. The end-users' needs inhabit different levels: the need for a CDSS as a whole, but also the need for the different kinds of support such a system can provide. However, only inquiring end-users about their needs does not suffice. This article has revealed some so-called say/do problems<sup>12</sup> and has also provided an example of how researchers can forestall such problems, such as by including other stakeholders. In this case, end-users indicated not appreciating a certain kind of support (ie, selecting diagnostic tests) provided in the CDSS prototype, whereas the online questionnaire demonstrated that this kind of support would nevertheless be necessary for optimal clinical practice. Experts can and should be involved to cross-reference the perceived needs of end-users, to make sure their needs fit clinical practice. However, some challenges remain: If users do not think they need (a certain kind of) support, then how can we get them to use the technology? We suggest, also based on prior research,<sup>24</sup> making sure that using the system is made an integral part of physicians' work processes. Thus, the work process itself must be a trigger for physicians to use the CDSS. Second, we advocate applying persuasive systems design<sup>25</sup> elements to persuade users (eg, via reminders) to use the system at a time when they might not know they need it. In doing so, it is very important to provide reminders prudently to prevent alert-blindness in the users.<sup>26</sup>

### The context

In the scoping review,<sup>1</sup> hardly any information was found (and if so, information was scarce) about the context within which the CDSSs were to be used. Working with the low-fidelity prototype of a CDSS for an ASP allowed end-users to clearly indicate how they would like the proposed system to be integrated with existing systems and work processes. They mainly appreciated integration of the CDSS with electronic health records because that could save them valuable time related to inputting patient data. Additionally, they wanted the system to be linked to an information database. This enables the CDSS itself to be kept concise while its users can still easily and quickly find additional information when necessary.

### Implications for clinical practice

For any kind of technology to have a positive influence on clinical practice, it is of paramount importance that technology developers must gain insight into its use. Not only in who is involved in clinical practice, but also their context, work relations, beliefs, needs, likes, and dislikes. This article offers insights into factors that can contribute to making a CDSS for an ASP successful. But more importantly, rather than just providing rules for what a CDSS should be like, it offers a means of revealing such information; specifically, via methods for participatory development. The participatory development approach that is described in the current article can be applied to the development of CDSSs for physicians, but it has also already been shown to be useful for other kinds of technology and other health care professionals in ASPs.<sup>20</sup>

### Future work

Based on this and prior research,<sup>1,5,24,27–29</sup> we are convinced that the greatest added value of technology in an ASP lies in creating a network of technologies to support an integral approach to antimicrobial stewardship.<sup>2</sup> Adequate and timely diagnostics are the basis for this type of integrated approach to stewardship, so this should be supported through technology (eg, via CDSSs). It also requires prudent prescribing of antimicrobial agents (also supported via CDSSs), adequate administration and monitoring of antimicrobial therapy (supported via an information app<sup>19</sup>), and applying infection control measures (supported via plain language translations of and easy access to protocols and guidelines<sup>28</sup>). Such a network of technologies has a value that is greater than the sum of its parts because the connection between such technologies allows for a smart system to be developed that draws data from numerous sources (eg, protocols and patient data). In doing so, it can use big datasets to model and predict outbreaks and provide tailored advice for the treatment of individual patients.

### CONCLUSIONS

Participatory development is of great added value for the development of successful ASPs. Low-fidelity prototypes of a technology allow researchers to get to know a system's end-users, their way of working, and their work context. Additionally, it helps potential end-users to visualize what it would be like to work with the system, and to indicate their needs. Involving experts allows technology developers to continuously check the fit between needs and clinical practice. The combination enables the development of technology that is not only user-friendly and successful in terms of uptake, but also successful in terms of influence and clinical outcomes.

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