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Construction of a patient decision aid for the treatment of uncomplicated urinary tract infection in primary care

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Abstract

Background

Uncomplicated urinary tract infection (uUTI) is a frequent reason for consulting a general practitioner. The risk of pyelonephritis is low. Antibiotics are prescribed empirically for symptomatic purposes. It can induce undesirable effects and resistance. Patients sometimes wish to avoid taking antibiotics. Some European countries recommend discussing a delayed prescription with the patient and developing a shared decision. The aim of our study is to develop a patient decision aid (PtDA) that can be used in primary care to make a shared decision about whether to treat uncomplicated urinary tract infection with antibiotics or not.

Methods

We followed the steps recommended by the International Patient Decision Aids Standards, which include a design phase (focus groups, bibliography) and an alpha-testing phase. A steering group developed a draft and then final version of a prototype PtDA.

Results

The information included in the PtDA is the definition of uUTI, information on the options, their benefits, risks and consequences. The patient's values and preferences to be considered in the decision are related to the discomfort felt, the impact on daily life, the representations of the antibiotic, the position relative to the risk of adverse effect.

Conclusions

Our results confirm a need for decision making and the equilibrium in this situation. We lacked advice from outside physicians in the study. This PtDA needs to be validated in a beta-testing phase. It must then be tested in a clinical study comparing its use with the systematic prescription approach.

1. Background

Uncomplicated urinary tract infection (uUTI), or cystitis, is one of the most frequent infectious reasons for consultation in primary care [1]. Nearly half of all women report at least one episode during their lifetime [2].

Acute cystitis affects several facets of a patient's life: social and intimate relationships, self-esteem, and the ability to work. Depending on the situation, the impact can vary from being slight to very significant [3] [4].

Cystitis can spontaneously resolve favorably [5] with a rare risk of pyelonephritis [6].

Immediate probabilistic antibiotic treatment is often recommended to improve symptoms [7]. The choice of the primary antibiotic often varies from one country to another [8]. In France, the French-language infectious pathology society (*Société de pathologie infectieuse de langue française)* recommends fosfomycin as the primary therapy [9]. The antibiotic prescribed empirically is often ill-adapted to the microbiological results [10].

Antibiotic therapy is associated with adverse personal effects [11]. The resistance rate of bacteria-causing uUTI is higher in the year following an antibiotic prescription for a urinary tract infection in the primary care setting [12] [13].

Delayed treatment is the recommended strategy in some countries. In the United Kingdom and the Netherlands, guidelines for uUTI suggest that physicians discuss with the patient the option to delay antibiotic treatment [14] [15].

Patients prefer avoiding antibiotic treatment for UTIs [16] and discussing the advantages and disadvantages of antibiotics in making their decision [17]. Physicians overestimate patients' desire to take an antibiotic [16]. Patients do not always take the prescribed treatment [4]. Several authors have suggested a shared decision-making approach in uUTI [18] [19].

A Dutch study found that general practitioners who used shared decision-making with their patients prescribed fewer antibiotics in women under 40 years of age seen for UTI [20].

Patient decision aids (PtDAs) make it easier to inform patients and explore different treatment options [21]. They have a positive effect on the diffusion of information, clarifying the patients' values, risk perception, and patient involvement in the decision-making process [22]. These PtDAs are particularly relevant when linked to clinical recommendations [23].

NICE has published a decision aid to help health care professionals explain and discuss the antibiotic treatment option in the case of uUTI with the patient, in accordance with NICE's guidelines [24]. However, this decision aid does not incorporate all the dimensions recommended by the International Patient Decision Aids Standards (IPDAS) [25].

To date, a French-speaking PtDA for the treatment of uUTI is nonexistent.

The objective of this study is to develop a patient decision aid for shared decision-making in primary care, during consultation for uncomplicated urinary tract infection.

This PtDA is part of a research project that aims to compare antibiotic consumption 14 days post-randomization between current practice and the use of a PtDA in the management of uUTI.

2. Methods

The development of the PtDA was conducted according to the recommendations of the IPDAS [26]. This study focused on the first four stages of development: scoping, steering group, design (obtained with the help of focus groups and a targeted bibliography), and alpha testing. The objective was to obtain a decision aid that could be used in the field (Fig. 1).

2.1. Initial design

1. Literature Review

A preliminary literature search was conducted by two study researchers (GC and YMV). This literature search was then updated and targeted the elements gleaned from the focus groups, then adjusted according to the modifications made during the alpha-testing phase, by another researcher in the study (AF).

These searches were conducted using both national recommendations and those of the MEDLINE® database, using the following keywords:

- *urinary tract infections, low, uncomplicated OR cystitis*
- treatment
- antibiotic
- natural history
- complication
- *Decision making, shared*
- tool
- infection
- *general practice OR family practice OR primary health care*
- *patient acceptance of health care*

2.1.2. Focus groups

A qualitative method was employed by use of focus groups. The objective was to explore and clarify patients' expectations regarding the dissemination of information and the form of the patient decision aid in the context of uUTI [27].

Interview guide

A semi-structured interview guide was developed by the four study investigators exploring the following elements:

- knowledge and experience of uUTI
- the physical, emotional, and social impact of uUTI

- knowledge and expectations regarding different treatment options
- expectations on the format, terms used, and presentation of the PtDA

Participants

An initial recruitment was carried out in patient associations. This did not result in a sufficient number of patients to form focus groups. Additional recruitment was then conducted in rural and urban private practices, during consultations, or with posters. The inclusion criteria were to be an adult woman, with or without a history of uUTI, with maximum variation on socio-demographic criteria. The criteria for maximum variation were the participants' place of residence, socio-professional activity, and age. Four focus groups were created, each with between four and six women.

Ethics

Before each focus group, participants signed an informed consent agreement. They were informed of the objective of the research project. The anonymity and confidentiality of the data were ensured by anonymizing the recordings during transcription and then by deleting the recordings at the end of the study. The project received a favorable opinion from the National Commission for Data Protection (*Commission nationale de l'informatique et des libertés*) on 13 March 2018.

Implementation of focus groups

The focus groups took place in general practices outside the health care setting or on the premises of patient associations. The focus groups were recorded vocally. Prior to the focus group, the participants were asked to fill out a short questionnaire to obtain socio-demographic data, including their age and socio-professional category. Each focus group began with a brief introduction to the participants including the concept of shared decision-making and the purpose of the study. Exchanges during the focus groups were facilitated by a moderator experienced in conducting such interviews (GC and YMV, then AF and CB). The moderator was assisted by a second researcher in charge of noting non-verbal communication and ensuring that no theme or participant was overlooked by the moderator. Participants were offered a snack during the interview.

Inductive Analysis

The focus groups were entirely transcribed and anonymized. The data analysis was carried out with the R software (version 3.5.1, RQDA package). An inductive content analysis approach was used [28]. After a global reading of the verbatims, the minimum meaning units were identified. They were then coded according to the different aspects relevant to patient decision-making and were labelled using shortened titles. Double coding was carried out independently by two researchers (AF and CB). Doubts or disagreements were discussed before pooling the final analysis. These meaning units were grouped into categories that were then presented and discussed during steering meetings in order to establish the specifications of the PtDA.

2.2. Draft version of the prototype

The steering group consisted of the four researchers and three patients. The patients were recruited through patient associations and general practices. Their written consent and socio-demographic characteristics were collected.

The group used the criteria established by IPDAS [25] and examples of PtDAs. The content and form of the PtDA were then defined based on the main categories which emerged from our focus groups and further supplemented by the results of the targeted literature search. These elements were discussed steering group. The draft specifications were then defined and sent to a graphic designer who produced a draft version of the prototype.

2.3. Alpha-testing

The draft version of the prototype was presented to patients in two focus groups (composed of three and four participants), supplemented by two individual patient interviews. Three individual interviews with general practitioners independent of the study were also conducted.

The practical use of the PtDA, its content, and form were discussed. Written consent was obtained from the participants. The interviews were recorded, transcribed, and analyzed according to the methodology described above.

2.4. Final version of the prototype

The steering group met a second time to discuss and validate the adjustments suggested during the alpha-testing phase. This information was transmitted to the graphic designer.

The graphic designer produced the final version of the prototype from two versions that were identical in content but different in appearance. These two versions were submitted to the members of the steering group who validated the final version.

3. Results

3.1. Initial design

1. Literature review

The literature review identified five randomized trials comparing antibiotic versus placebo in uUTI [5, 29–32]. These five trials were all included in a meta-analysis published in 2009 [6].

We selected four randomized trials comparing the use of an antibiotic to an non-steroidal anti-inflammatory drug (NSAID) in uUTI [18] [19] [33] [34] and four studies describing the natural history of uUTI simple [10, 35–37].

We selected four examples of available PtDAs. Three PtDAs concerned anti-infectious treatment decisions in outpatient settings [38–40]. A fourth PtDA was blank and could be used for any shared decision-making situation [41].

Symptom duration

Untreated uUTI healed spontaneously in 50–70% of cases. Symptoms could last up to several weeks [36]. Mild to severe symptoms improved after 4.94 days in women not taking antibiotics [37]. Symptoms in women not taking an antibiotic lasted 50–60% longer than in women treated with an antibiotic to which the bacterium was susceptible [37]. Clinical resolution of symptoms was more likely in patients treated with antibiotics, with an odds ratio of 4.67 [2.34–9.35] [6].

After three days, the proportion of complete resolution of symptoms varied across studies, from 37% in patients treated with nitrofurantoin versus 20% in patients treated with placebo [5], 44% in women treated with fosfomycin versus 24% in women treated with ibuprofen [18], and 80% in women treated with norfloxacin versus 54% in women treated with diclofenac [34].

Risk of complications

There was no significant difference associated with the risk of pyelonephritis when compared between patients taking an antibiotic and those taking a placebo (OR 0.33; CI [0.04–2.70]). The incidence of pyelonephritis was between 0 and 2.6% [6]. There were no reported cases of sepsis. The French guidelines describe the risk of pyelonephritis as very low [9].

Three of the four trials comparing antibiotic use with an NSAID in uUTI found more pyelonephritis in women taking an NSAID compared to women taking an antibiotic [18] [19] [34].

Adverse reactions

The occurrence of adverse events was significantly higher in antibiotic-treated patients compared to placebo-treated patients [6].

In the case of pivmecillinam, 5–8% of adverse events were reported [32]. In a multinational trial conducted in primary care and hospital settings, patients taking single dose fosfomycin had 6% adverse events versus 8% of patients taking nitrofurantoin. The most common adverse events were gastrointestinal (nausea, vomiting, diarrhea, abdominal pain), asthenia, headache, dizziness, and vaginal discharge [5] [42]. These studies did not report any serious allergic reactions related to antibiotics.

Recurrence

The data did not allow for a meta-analysis on the occurrence of clinical recurrence [6]. In the study comparing nitrofurantoin to placebo the clinical recurrence rate at two weeks was between 17.6–20% [5]. In the study comparing pivmecillinam to placebo the recurrence rate at one month was 12–13% [32]. We did not find study comparing the incidence of recurrence over longer time periods.

Resistance

The emergence of resistance in the randomized studies varied from 0–45.5% of women taking an antibiotic versus 0–20% of women taking a placebo, with no significant difference [6]. In a Swedish study, taking an antibiotic for a uUTI in primary care was associated with a higher rate of bacterial resistance [13].

Alternative treatments

Patients taking herbal medicine do not have a different symptom course than those taking a placebo [43–44]. There is no evidence of cranberry (*Vaccinium macrocarpon*) or hydration as treatment for cystitis simple [45–46].

3.1.2. Focus groups

Participants spoke of their personal or reported experiences with cystitis and its impact on their social and sexual lives: *"It restricts social life, because you always have to be near a toilette (laughter)"* (P3.2), *"You don't dare to have sex anymore"* (P4.4).

This experience touched on intimacy and could be perceived as taboo: *"It's a feeling of guilt, actually. Well, in a way it is, because we feel that our intimacy as women is being attacked"* (P3.4).

They feared that cystitis could be complicated by renal, gynaecological, or fertility problems: *"If there's blood in my urine it means that the kidneys must be affected" (P3.2), "It's going to make an infection maybe a bit generalized in that area, maybe causing problems to have children..."* (P1.2).

Their knowledge about the risk factors and treatment of cystitis was part of a lay knowledge shared amongst women: *"I told my mother about it and she said: don't worry, drink lots of water, it will pass, this antibiotic works well; because she often had it"* (P2.2).

Some participants described a feeling of infantilization and guilt during the consultation with the physician: *"The doctor or the ones I saw, made me feel like it was my fault because I didn't wash (myself) well. Afterwards, we are told once we hold it back! We don't have to be told every time"* (P3.2).

They wanted a personalized exchange, where they could express their experiences: *"What is important with cystitis, I learned from the doctor who took the time to explain it to me. [...] We are not in a normal state when we are sick. So he really needs to listen to us"* (P2.5).

The participants wished to clearly define cystitis and its risk factors, with a vocabulary accessible to all, without medical jargon: *"And in rather simple terms, so that everyone can understand it... Not in doctor's language"* (P1.3). They suggested a pictorial presentation: *"The more graphic, the more people are affected"* (P1.3), accompanied by the doctor: *"The diagram is nice, but if the doctor doesn't explain it to you, [...] she won't understand anything"* (P3.3).

Their expectations of treatment could be the rapid relief of symptoms, or the prevention of recurrence in the longer term: *"Isn't there something more effective and long-lasting, [...] rather than just immediately stopping the pain?"* (P1.2).

Some patients have expressed an interest in being involved in the decision related to the antibiotic: *"Do you have something to offer me that is not antibiotics? I have time now, I can stay at home, if it's really not going well we'll switch to antibiotics, but why don't we test something else? Maybe there should be a second option"* (P4.4).

The action of the antibiotic was seen as magical, but could lead to side effects and resistance: *"This antibiotic was really a miracle"* (P6.1), *"Every antibiotic [...] that we swallow, we know that there are side-effects"* (P1.1).

The participants considered alternative treatments, described as natural, such as cranberry or hydration: *"Having the choice between a chemical molecule and something a bit more natural, something less harsh, I'll take what is less harsh"* (P2.3).

3.2. Draft version of prototype

The draft version of the prototype (Fig. 2) included the following elements.

The title explicitly described the decision whether to take an antibiotic or not. The elements of the PtDA were then arranged according to these two choices.

The common symptoms and etiology of uUTI were briefly described and illustrated with a diagram of the bladder.

The treatment options that were presented included antibiotic treatment, hydration, and cranberry. The practical modality of a single-dose antibiotic therapy was specified.

The average duration of symptoms, the risks of recurrence, resistance and complications were detailed according to whether the antibiotic was taken or not.

Colored pictograms numerically represented the evolution of symptoms after three days according to the choice of treatment and the incidence of adverse effects.

The patient values to be explained were physical discomfort, the impact on their daily life (professional, social, sexual), their general opinion on antibiotics and their adverse effects. A free space allowed for the collection of additional value.

Deliberation was facilitated by sliders polarized according to the two options, for each value expressed. A final slider helped in the decision-making process.

The chosen format of the PtDA was a double-sided A4 sheet of paper. It was intended to be used during discussion with the physician during the consultation and not for use by the patient alone.

3.3. Alpha-testing and final version of prototype

The results of the alpha-testing phase and the second meeting of the steering group are presented in Table 1. The final prototype of the PtDA is shown in Fig. 3.

Table I : Results of the alpha-testing phase and 2nd steering group

 elements to improve ✓ elements validated FG = focus group II = individual interview

SUNDAE Check-list	*Alpha-testing Results*		Pilot group
	Participants (FG + II)	**Physicians (II)**	**Changes made**
Explicit description of the decision	▯ Reformulate the title in interrogative form ✓ No need to specify the revocable nature of the decision and the possibility of re-consultation, which must be clarified orally by the doctor		⇨ Modified title ⇨ Polarized distribution of information according to the decision
Description of the health problem	▯ Need for a clearer definition of uUTI ▯ Diagram of bladder not very useful and difficult to identify	✓ Validation of symptoms description	⇨ Improved definition of uUTI, addition of the term inflammation ⇨ Removed the bladder diagram
Information on options, their benefits, risks, and consequences	✓ Overall positive to help in making decision ✓ Layout validation ▯ Improving the visibility of adverse events and their link to antibiotics ▯ Term "several weeks" not precise enough	✓ Suitable information ✓ Information on the risk of pyelonephritis is relevant because it is not well known ✓ Interest of the precision on the absence of risk on fertility ▯ Provide information on alternative treatments to antibiotics ▯ Improve the reading of information by changing the formatting of the text	⇨ Adjusting for recurrence, complication, and adverse event rates using data from the literature ⇨ Improved description of adverse reactions ⇨ Clarification on the low level of evidence for alternative treatments (cranberry, hydration) ⇨ Improved, more spacious page layout
Numerical probabilities	✓ Validation of the pictograms used ✓ Good understanding of adverse reaction data	✓ Validation of the pictograms used	⇨ Adjustment using data from the literature ⇨ Addition of bibliographical references ⇨ Adding the PtDA update date

SUNDAE Check-list	*Alpha-testing Results*		Pilot group
	Participants (FG + II)	Physicians (II)	Changes made
Clarification of values (implicit and explicit)	✓ Validation of the values explored ✓ Validation of the concept of slider left blank but use to be explained		⇨ Legend for the blank slider
Guidance in deliberation	▯ Add a color gradient to the sliders, and don't put the slider in the center by default ✓ Slider format and polarization validation ▯ Non-contributing final slider ▯ Make it clear that the patient's decision is made orally with her doctor	▯ Coloring the sliders	⇨ Changing the slider graphics ⇨ Final slider replaced by a sentence encouraging deliberation with the doctor
Guidance in communication	▯ Reading of the PtDA to be accompanied by the doctor	▯ Fear of a difficulty of use due to lack of time, in particular to use the sliders	⇨ Elements to be included in training to use the PtDA
Reading and comprehension level	✓ Understandable slider terms ▯ Prefer the term "drinking water" to "hydration"		⇨ Clarification of the definition of resistance ⇨ Replacing the term hydration
Other	▯ Enhance contrast, favor a uniform background ✓ Pink color validation	▯ Enhance contrast	⇨ Improved contrast

4. Discussion

We have developed a PtDA that allows the physician and the patient to make a shared decision regarding antibiotic treatment for uUTI. This PtDA is to be used as support during consultation. It is used in addition to the information delivered orally by the doctor (diagnosis, risk factors, monitoring, advice for further consultation, etc.). Our PtDA was created in line with international standards [25, 26].

We recruited more patients face-to-face during medical consultations than through patient associations. Recent changes in French regions have led to the need for the reorganization of associations. This may have hindered their participation despite a strong willingness to be involved in the project. The ease of face-to-face recruitment has also been described elsewhere [47].

A focus group of four to six participants has previously been documented to facilitate communication [47]. The medium-sized focus groups in our study allowed for rich and varied exchanges, including those involving intimate topics. The age and socio-professional category criteria and place of residence were varied, which contributed to the expression of diverse points of view.

An important limitation to the development of this PtDA is the lack of a medical perspective from the exterior of the study. The number of interviews with physicians during the alpha-testing phase was low. A Cochrane review noted that when developing PtDAs, the patients' views are more often collected than those of physicians [48].

Our study confirmed that there is a need for increased involvement of the patient in the decision-making process about the treatment of uUTI [16, 17]. No evidence was found in the literature elements that divide the equipoise between the two options proposed.

Some elements collected from the focus groups corresponded with the existing literature, such as representations of uUTI and its risk factors [16], representations and opinions on antibiotics [16] [17], and the impact on social or professional life [3]. Patients mentioned numerous representations relating to the gynaecological sphere, intimacy, sexuality, and fertility. Such representations are rarely found in articles concerning uUTI. Their evocation was facilitated during focus groups composed solely of women, including the observer and the investigator. The importance of representations around femininity was integrated into the PtDA using a pink/purple color. Some members of the focus group expressed the desire to have a more gender-neutral representation. The pink color was widely validated by the patients during the alpha-testing phase and was consequently retained.

Some of these representations correspond to known risk factors (i.e. sexual intercourse). Others were beliefs (risk of infertility) that were absent in the literature. Some patients wanted to be able to discuss them. The steering group decided not to mention risk factors because they were not directly involved in the decision-making process. This information could be added in a leaflet handed over to the patient.

Most of the patients' values expressed in the focus groups could be integrated into the PtDA, particularly in the slider. An empty slider allows the patient to express additional values, like her expectations regarding treatment (reduction of recurrence, rapid symptom relief, etc.).

One concern expressed among the patients and doctors interviewed was the risk of pyelonephritis. There is little data on the natural course of uUTI without antibiotics. The meta-analysis comparing antibiotics to placebos did not show a significant increased risk [6]. Patients treated with an anti-inflammatory drug have a higher risk of pyelonephritis than those treated with an antibiotic [18, 19] [34]. This increased risk could be explained by the harmful role that anti-inflammatory drugs can play in infectious diseases [34].

Some of the physicians interviewed were concerned that the use of the PtDA would increase the length of the consultation. There is little evidence documented on the impact of the shared decision on the length

of consultations [49]. A study comparing a standard approach to the use of an PtDAs in the management of depression in primary care did not show a difference in the length of visit [50].

The steering group chose to present the probability of symptoms after three days. This time frame made it possible to present data in the PtDAs concerning the first-line antibiotic in France (fosfomycin) and placebo. This short delay aligns with the French guidelines which recommend another consultation in case of failure after three days, as well as with the British guidelines which propose a delay of 48 hours for the delayed prescription.

Our PtDA proposes to not prescribe antibiotics immediately, which is not currently recommended in France [9], unlike the United Kingdom and the Netherlands [14, 15]. PtDAs obtain credibility when they are developed simultaneously with national guidelines [23], as NICE has been able to do [24].

Delayed prescribing could reduce antibiotic use [51]. This is an option which resembles immediate non-prescription and a close re-evaluation in case symptoms persist. Delaying the prescription can therefore be integrated with the use of the PtDA.

Compared to NICE's PtDA, the information on the options, their benefits, risks, and consequences is similar to our PtDA and is based on the same bibliographical references. On the other hand, NICE's PtDA does not include a schema to facilitate an appropriate understanding of numerical probabilities. It does not allow the patient to clarify her values nor foster deliberation, as recommended by the IPDAS [25].

5. Conclusion

We developed one of the first PtDA for uUTI treatment in primary care, in line with international standards.

A beta-testing phase is necessary to finalize our PtDA. The purpose of this phase is to investigate the feasibility of the PtDA from both patient and physician perspectives. This step is important because the PtDA requires the physician’s commitment, who must accompany the patient in its use. Furthermore, the positive attitude displayed by physicians towards the natural course of the infection is associated with faster resolution of symptoms [37].

The impact of our PtDA’s usage on patients satisfaction and antibiotic prescription remains to be evaluated.

Abbreviations

IPDAS
International Patient Decision Aids Standards
PtDAs
Patient decision aids
NSAID

non-steroidal anti-inflammatory drug
uUTI
Uncomplicated urinary tract infection

Declarations

Ethics approval and consent to participate

We have the agree of the French CNIL (Commission Nationale de l'Informatique et des Libertés) for our work.

Our Referent was Chantal Durand from the CHU of Bordeaux

Consent for publication

Not applicable

Availability of data and materials

The datasets analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

YMV and GC were in charge of the methodology part, while AF and CB led the focus groups. All authors participated drafting the manuscript.

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Figures

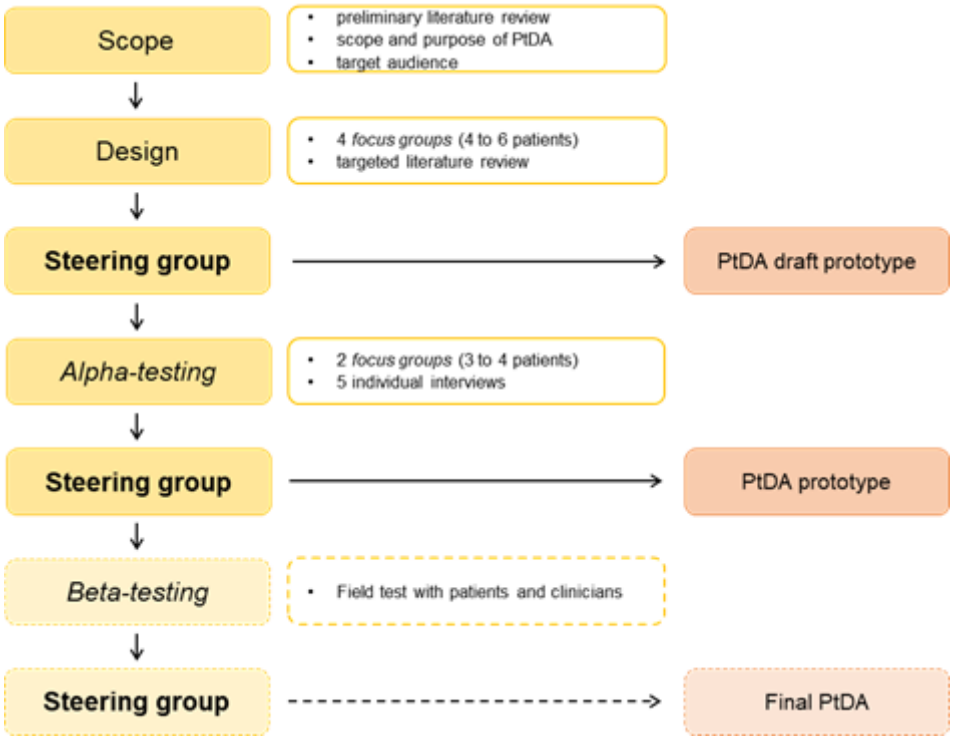

Figure 1

Development process; adapted from IPDAS

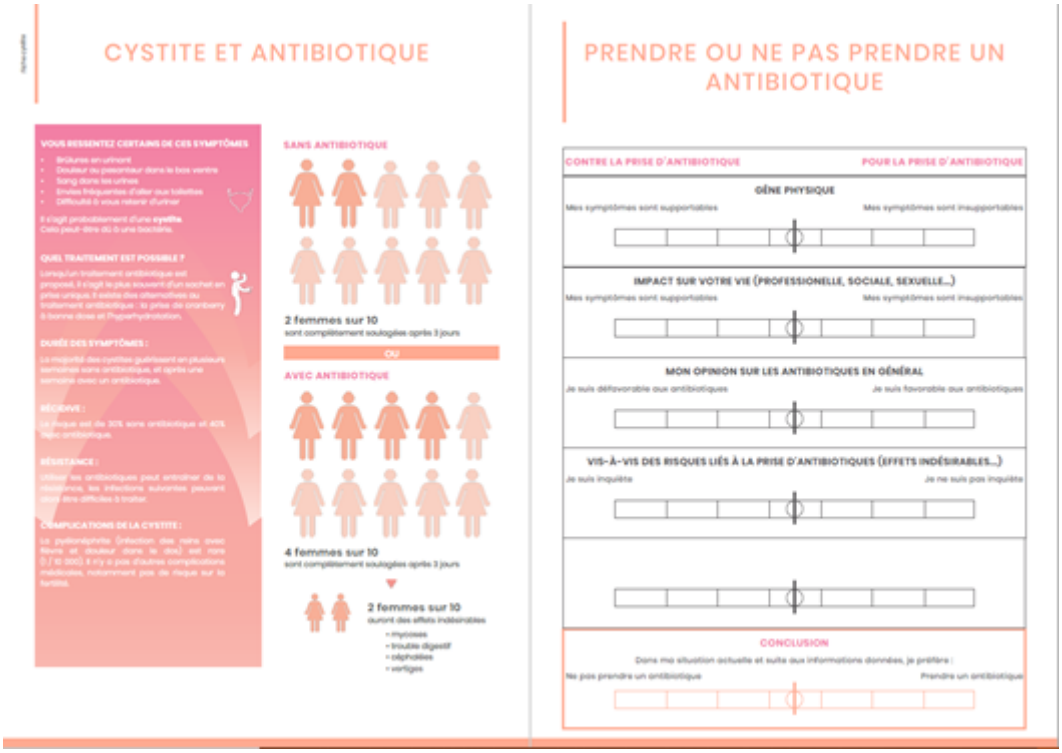

Figure 2

Draft version of the prototype

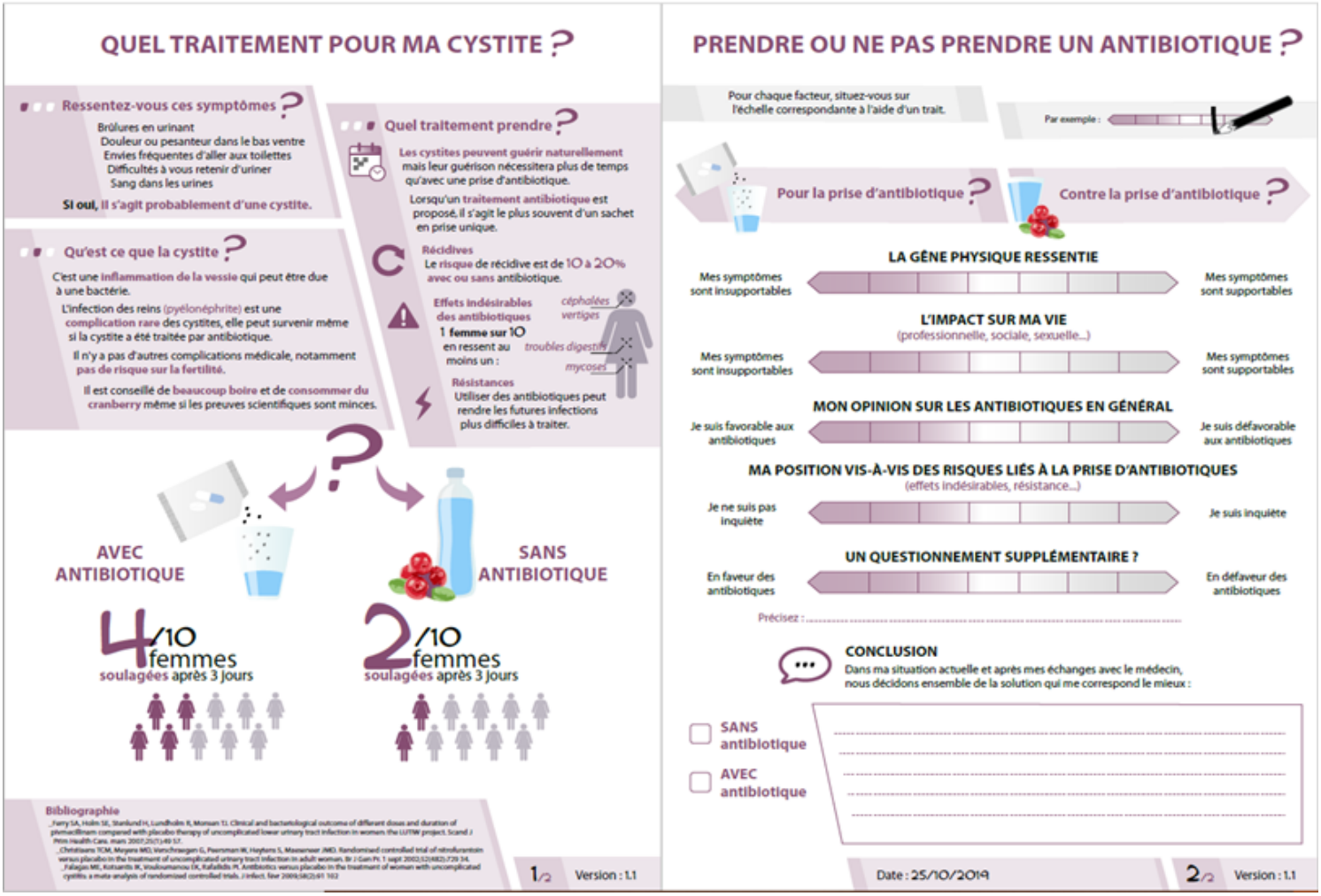

Figure 3

Final version of the prototype