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ORIGINAL ARTICLE

# Development of a Patient Decision Aid on the Choice of Diabetes Medication for Filipino Patients with Type 2 Diabetes Mellitus*

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**Abstract**

Objective. To develop a locally adapted patient decision aid (PtDA) on treatment intensification among Filipino patients with Type 2 Diabetes Mellitus and to test the feasibility of using PtDAs in a low middle-income country

Methodology. A qualitative approach and an iterative process of development of a PtDA were employed for this study. We describe the process of developing a Filipino version of the Diabetes Medication Decision Aid. This PtDA was designed to help the patient choose the appropriate treatment intensification based on his own values and preferences, in consultation with his physician. The process involved decisional needs assessment through focus group discussions and key informant interviews, systematic literature review, iterative process of the development of a PtDA with clinical encounters (pilot testing), and preliminary field testing.

Results. Decisional needs assessment revealed that Filipino patients are open to participate in shared decision-making if given the opportunity, including those with low socioeconomic status who likely have low health literacy. Physicians prefer to have visual aid tools to help them support their patient's decision-making. A PtDA prototype of a set of flash cards in Filipino was created and revised in an iterative method. We developed a more visually appealing tool after inputs from the expert panel and patient advisory group. Its use during clinical encounters provided additional insights from patients and clinicians on how to improve the PtDA. Preliminary field testing showed that its use is feasible in the target patient population.

Conclusion. Filipino patients, clinicians, and diabetes nurse educators have contributed to the creation of the first Filipino PtDA for diabetes treatment intensification.

*Key words: decision aid, decision support technique, decision support model, patient decision making, interactive health communication, risk communication*

## INTRODUCTION

The increasing array of new anti-diabetic agents and the rising uncertainty on the single "best" choice of add-on therapy to metformin has led the American Diabetes Association (ADA) and European Association for the Study of Diabetes (EASD) to emphasize the need for patient-centered care and shared decision-making (SDM).[1] Studies show only small differences between agents in terms of glucose control, which may be less likely to have a differential long-term impact on an individual patient.[1–4] The decision about the next add-on medication may not be clear cut and involves trade-offs (e.g., glucose lowering efficacy, side effects, impact on weight, cost, and patient's routine).[5] As such, SDM plays a particularly important role in this situation where the available evidence does not provide the clear "best" option for the patient. It also provides an opportunity for physicians to involve patients in a conversation about the advantages and disadvantages of the various treatment options.[6]

SDM is a patient-centered approach that engages both the physician and the patient in a discussion about reasonable treatment choices, with each one bringing in his own "expertise" into the conversation—the clinician is expected to be an expert on the clinical evidence while the patient is the expert on his illness experience, daily routine, and values. SDM also recognizes that clinical evidence alone may be inadequate to guide treatment decisions at all times.[7] In endocrinology, 60% of recommendations from current clinical practice guidelines from various societies are supported by low to very low quality of evidence whilst only 14-15% of the recommendations are based on high quality evidence.[8,9]

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On the other hand, patients and physicians may not want to nor be comfortable with patients taking part in decision making about diabetes medications.[10] In fact, impediments to SDM include patient's perceived lack of knowledge, low self-efficacy (i.e., belief that one cannot perform SDM), and the fear of making decisions about medications.[11] Thus, physicians must be provided with tools to effectively engage patients in SDM. In addition, facilitators for SDM also rely immensely on physician motivation and their perception that SDM can make an impact on patient outcomes.[10]

Patient decision aids (PtDAs) are tools used in SDM to facilitate patient participation in healthcare decision-making. They can be in the form of web-based tools, videos, treatment cards, or worksheets.[7] Unlike educational materials, PtDAs provide information in preparation for a decision to be made, which includes the various options and their corresponding advantages, disadvantages, and outcomes. In a Cochrane review of 115 trials involving 34,444 participants, PtDAs were shown to increase patient knowledge, informed patient choices, increased participation in decision making, improved decision self efficacy, and reduced decisional conflict (remained undecided).[12] However, despite the rapid pace of development in the field of SDM,[10] the impact of this approach on medication adherence, cost reduction, and clinical outcomes is still lacking.[12,13] Due to this, SDM may be more appropriate for treatment decisions in chronic care, such as diabetes, which requires more active participation and commitment to maintain medication and lifestyle regimens in the long term.[14–17] As such, different versions of PtDAs have been developed to engage patients in a conversation about decisions on initiation or intensification of diabetes treatment.[18–23] These PtDAs have been tested in RCTs and, similarly, have been found to improve patient's knowledge and increased patient involvement in SDM,[5,13,21,24] reduced decisional conflict,[5,21,24] promoted realistic expectations, and promoted autonomy in making decisions.[21]

It has been argued that SDM and the use of these PtDAs are applicable only to well-educated middle class patients and for high-income countries.[25] However, patients with lower literacy levels, when provided with well-presented information on evidence, can participate well and potentially benefit the most from increasing knowledge on medication options.[26] To date, no PtDAs have been developed and published in the field of endocrinology in the Philippines or from any other low-middle income country.

We aim to develop a locally adapted PtDA to help Filipino patients with poor glycemic control despite being on one or two medications decide on treatment intensification. We also aim to test the feasibility of using PtDAs in a low middle-income country.

## METHODOLOGY

The study was done in three-phases: 1) the creation of the PtDA prototype (including decisional needs assessment); 2) pilot testing (alpha testing); and, 3) preliminary field testing (beta testing). This process was adapted from the International Patient Decision Aids Standards (IPDAS) Collaboration and the Ottawa Decision Support Framework (ODSF).[27-28] The University of the Philippines Manila Research Ethics Board approved this study. Figure 1 shows the overall flow of the study.

### Phase I: Creation of the PtDA prototype

#### *Decisional needs assessment*

*Participants*

Patients were recruited from the outpatient clinics of the University of the Philippines-Philippine General Hospital (UP-PGH) General Medicine, Family Medicine, Diabetes, and Faculty Clinics through convenience sampling. Adult patients aged 18 years old and above who have a physician diagnosis of type 2 diabetes mellitus (T2DM) and were already on one or two medications for T2DM were invited to participate in the patient decisional needs assessment. Those who consented were included in the focus group discussions

Physicians recruited for the professional needs assessment included doctors from specialties directly taking care of patients with T2DM in our hospital. These were comprised of internists (IM), family medicine (FM)

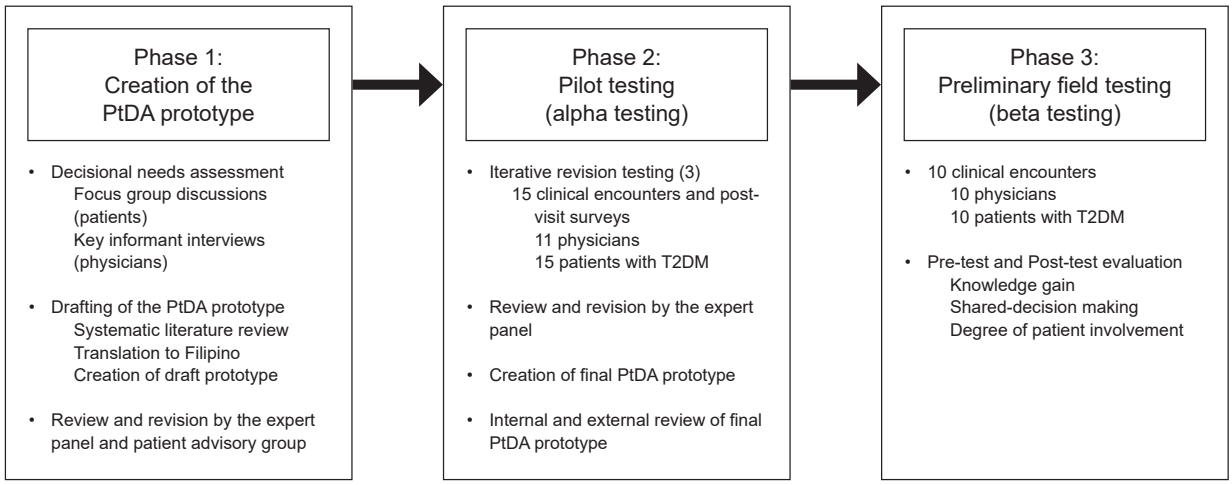


**Figure 1.** The study flow diagram.

physicians, and endocrinologists, including fellows-in-training. We recruited physicians in the spectrum of early, mid, and late career to be able to capture a wide array of perspectives on SDM.

*Methods*

Focus group discussions (FGDs) and key informant interviews (KIIs) were conducted with patients and physicians, respectively, to determine their views and perceptions on making decisions, explore the concept of SDM including barriers and facilitators to SDM, and the factors to consider when choosing diabetes medications.

Four FGDs with 5 to 9 participants each were conducted to assess patient decisional needs. Informed consent was obtained from all the participants prior to the start of the discussion. A moderator facilitated the group discussion aided by a set of guide questions. All sessions were video recorded and transcribed verbatim prior to analysis. FGDs were conducted until themes had reached point of saturation.

Ten key informant interviews (KIIs) were conducted to assess the professional needs of clinicians who will be the potential end-user of the PtDA. Semi-structured KIIs were video recorded and also transcribed verbatim.

### *Drafting of the PtDA prototype*

*Literature review and translation to Filipino*

The Diabetes Mellitus Medication Choice Decision Aid was adapted with permission from the Mayo Clinic.[29] The original English version was sent to the *Komisyon sa Wikang Filipino* (KWF [Commission on the Filipino Language]) for initial translation. The Filipino translation was revised upon the discretion of the researcher for improved comprehensibility by lay patients. The first revision of the prototype was sent back to the KWF to check for errors in grammar, spelling and translation.

To update the information presented in the PtDA, we did a systematic literature search on PubMed for evidence on the effectiveness, effects on weight, and safety including rates of hypoglycemia and adverse effects of the different medications for diabetes that are available in the Philippines. All network meta-analyses, traditional meta-analyses, RCTs, and clinical practice guidelines were critically appraised for directness, validity, and applicability prior to inclusion into the evidence base of the PtDA. Cost of medications was surveyed from local pharmacies. The range of costs was presented in the PtDA where applicable.

*Review by the expert panel and patient advisory group*

The draft prototype was presented to an expert panel composed of physicians (two endocrinologists, a family medicine physician, and an internist) and 3 diabetes nurse educators; as well as to a patient advisory group composed of 3 patients with T2DM to assess comprehensibility, clarity, and value of information. They were oriented on the scope and purpose of the study and the PtDA. Results of the decisional needs assessment were shown to them. Members of the patient advisory group were asked to role-play a clinical encounter using the PtDA prototype administered by one of the investigators. The draft of the prototype was evaluated and critiqued in two separate group discussions by the expert panel and the patient advisory group. It was then revised according to suggestions from the group discussions prior to evaluation in actual clinical encounters.

### Phase 2: Pilot testing (Alpha testing)

#### *Participants*

A convenience sample of clinicians (IM and FM residents and endocrinology fellows), and patients from the UP-PGH General Medicine, Family Medicine, Diabetes, and Faculty Clinics were invited to participate in the study. Eligible patients included adult Filipino patients age ≥18 years of age, with a physician diagnosis of T2DM, currently on mono- or dual therapy of oral anti-diabetic medication/s, with an HbA1c within the past 3-6 months of greater than or equal to 7.5%, and were advised by their physician to consider additional anti-diabetic medication to achieve glycemic targets. Subjects were identified through chart review of patients who were scheduled to undergo a check up on that clinic day or were referred for inclusion by their respective physicians. Informed consent was obtained prior to enrolment into the study.

We excluded patients who were pregnant and those who cannot speak or understand Filipino. Other patients excluded were those who require very complex care or with poor health status, i.e., requiring long-term care, with severe cognitive impairment, or with end stage chronic illness that will impair them from fully participating in a discussion and significantly limit medication choices. End stage chronic illness included the presence of stage III-IV congestive heart failure (CHF), oxygen dependent lung disease, end stage renal disease requiring dialysis, or metastatic cancer.

Clinicians recruited for the pilot testing included physicians who provide consultations for patients with T2DM in our hospital such as those from IM, FM, and Endocrinology. However during the recruitment process, only IM residents and Endocrinology fellows-in training consented to participate in the study.

A convenience sample of 3 to 5 clinicians and 6 to 7 patients participated in each iteration.

#### *Procedure*

An iterative process was utilized in developing the final prototype PtDA. Prior to the use of the prototype during an actual clinical encounter, clinicians were oriented about the nature of the study, the purpose of the PtDA, and how to use it. When the patient agrees to participate, the physician administered the PtDA prototype. Each clinical encounter was expected to last for 5 to 30 minutes. During the actual clinical encounter, the physicians encouraged the patient to participate in deciding what medication will be added to his current regimen. At the end of the consult, the physician and the patient were expected to arrive at a decision on treatment intensification. Aside from choosing an add-on medication, patients were also allowed to choose not to intensify treatment as long as she/he understood the risks of such an option. This was followed by a semi-structured interview of the patient and physician to gather insights on the usability, acceptability,

comprehensibility, and visual appeal of the PtDA, as well as other suggestions on how to improve it. All clinical encounters were recorded through video recording. The video recordings were reviewed to see if and how the PtDA facilitated discussion on medication choice and how well it was utilized.

After each iteration, the PtDA prototype was revised according to the feedback obtained from the clinical encounters as discussed with the expert panel. The revised prototype was then used in the next iteration. These iterations were repeated until an acceptable version of the PtDA for field testing was made.

The final prototype of the PtDA was reviewed by a group of 4 practicing endocrinologists from our hospital who were not included in the development of the PtDA. The reviewers assessed content including accuracy and completeness of information. The PtDA was revised further to reflect comments from the external review prior to preliminary field testing. An investigator also evaluated adherence to the IPDAS checklist to ensure the quality of the PtDA.

### Phase 3: Preliminary field testing (Beta testing)

The aim of this phase of the study was to test the feasibility of a study formally evaluating the effectiveness of the final version of the PtDA.

#### *Participants*

A convenience sample of 10 sets of patients and clinicians who met the selection criteria used in the pilot testing were recruited for this phase.

#### *Procedure*

Pre-test and post-test evaluations were performed for each clinical encounter. To evaluate knowledge gained among patients, we administered a 10-item multiple-choice test containing questions related to the diabetes medications discussed in the PtDA. The Filipino version of the Shared Decision Making Questionnaire (SDM-Q9)[30] was used to evaluate whether the final PtDA was able to facilitate SDM among the participants. The SDM-Q9 is a tool used to investigate the effectiveness of PtDAs as an intervention aimed at the implementation of SDM.[31] It is a 9-item questionnaire with a 6-point Likert scale (*completely disagree* to *completely agree*) with a total score that ranges from 0 to 54 transformed into a 100-point scale. Patients were asked to answer the SDM-Q9 questionnaire during a pre-test (evaluating their most recent consultation for their diabetes) and a post-test (pertaining to the consultation using the PtDA).

The degree of patient involvement during each clinical encounter was evaluated by two physician raters using the OPTION scale, a 12-item questionnaire that measures what degree clinicians involve patients in decision-making.[32-33] The primary investigator and another physician not involved in the development of the PtDA observed the video recordings of the clinical encounters. The card selection, medication choice, and duration of encounter were also recorded. Both physician raters used the OPTION Manual to guide the rating process.

## RESULTS

### Phase I: Creation of the PtDA prototype

#### *Decisional needs assessment: Patients*

Four FGDs were conducted to elicit patients' views on their decisional needs in relation to their DM medications. The data analysis and results of the FGDs will be discussed in detail in a separate paper. Table 1 shows the characteristics of patients that were included in the FGDs.

Briefly, the points that emerged which were relevant to the development of the PtDA included the following:

1. Patients are willing to participate in decision-making for their own care if given the opportunity.
2. There is a subset of patients who prefer to leave the decision-making to their doctors who they perceived to be the expert in their illness.
3. Some of the patients find it difficult to grasp the concept of decision-making for their own care.
4. The most difficult decisions to make were those that involve the transition to an insulin-based regimen or the addition of an expensive medication.
5. Aside from cost and method of administration, other factors that they consider when choosing or agreeing to a medication include side effects such as hypoglycemia, allergy and gastrointestinal effects.
6. Only some physicians spend time to discuss medication choice with their patients.
7. Few physicians ask for their patient's opinion regarding treatment options.
8. Activities that help reduce decisional conflict include facilitation of external sources of free or cheap medicines and educational activities at the outpatient clinic.
9. Factors that facilitate decision-making include availability of information from their doctors that patients can understand, more time spent by their clinician explaining their condition, and clarification of risks and benefits of treatment. They consider family members, fellow patients, and their doctors as allies in decision making.

#### *Decisional needs assessment: Physicians*

Ten physicians were interviewed to assess decisional needs of clinicians treating patients with T2DM. Table 2 shows the characteristics of physicians included.

The following is a summary of findings from the KIIs that helped inform the PtDA development.

1. Some patients prefer that their doctors make the decision for them. On the other hand, more empowered patients, usually the younger ones, prefer to participate in SDM.
2. Some physicians prefer to choose the medications for their patients especially if it is an oral medication. In contrast, initiating insulin requires a more detailed explanation from the physician.
3. The most difficult type of decision for patients to make is transitioning to an insulin-based regimen or the addition of a more expensive medication
4. Family members help facilitate decision-making of patients. Elderly patients who rely on their children for financial support most often need help from them to decide on an add-on medication.

**Table 1.** Demographic and clinical characteristics of patients included in the focus group discussions for decisional needs assessment

| Characteristic | n=24 |
|---|---|
| Age, n (%) | |
| ≤ 40 years | 4 (17) |
| 41-60 years | 14 (58) |
| 60 year | 6 (25) |
| Mean (SD) | 53 (9.1) |
| Sex, n(%) | |
| Male | 8 (33) |
| Female | 16 (67) |
| Education, n (%) | |
| At least elementary school graduate | |
| At least high school graduate | 11 (46) |
| At least college graduate | 9 (37) |
| Postgraduate | 4 (17) |
| Employment, n (%) | |
| Retired | 6 (25) |
| Unemployed | 9 (37.5) |
| Employed | 9(37.5) |
| Physician, n (%) | |
| Consultant | 9 (37) |
| Fellow | 14 (58) |
| Resident | 1 (4) |
| Duration of Type 2 DM, n (%) | |
| <10 years | 12 (50) |
| 10-20 years | 8 (33) |
| >20 years | 4 (17) |
| Number of DM meds, n (%) | |
| 1 | 9 (38) |
| 2 | 7 (29) |
| ≥3 | 8 (33) |
| mean (SD) | 1 (0.3) |
| Type of DM medication, n (%) | |
| Oral agent/s only | 10 (42) |
| Insulin only | 2 (8) |
| Both oral agent and insulin | 12 (50) |
| History of hypoglycemia, n (%) | |
| No | 8 (33) |
| Yes | 16 (67) |

**Table 2.** Characteristics of key informants

| Characteristic | n=10 |
|---|---|
| Age | |
| <40 year old | 4 |
| 40-60 years old | 5 |
| >60 years old | 1 |
| Area of practice | |
| Metro Manila | 8 |
| Outside of Metro Manila | 2 |
| Specialty | |
| Family Medicine | 2 |
| Internal Medicine | 1 |
| Endocrinology | 7 |
| Type of physician | |
| Consultant | 8 |
| Fellow-in-training | 2 |
| Years in practice[a] | |
| <10 years | 4 |
| 10-20 years | 4 |
| >20 years | 2 |

[a] including years in training

5. Barriers to SDM include lack of time, skills, knowledge (on the different options), resources (materials to aid SDM), and motivation to use SDM or to change one's habits.
6. Patients who are not receptive to new treatment options, i.e., being close-minded, is also an important barrier to SDM.
7. All the physicians prefer to have visual aid tools to help them support their patient's decision-making.
8. Aspects of medications that are important to consider when choosing medications include side effects, cost, and efficacy. Size of tablet is also important to consider but to a lesser degree.
9. The PtDA will not only help educate patients but also help doctors be informed about treatment options and the evidence base to support them.
10. The PtDA is a potential tool that can correct patient's misconceptions and misinformation about medications.

### *Scope and design of the PtDA*

This Diabetes Medication decision aid for Filipino patients with T2DM aims to facilitate a patient's participation in decision-making during a consultation with his physician. This PtDA was designed to help the patient choose the appropriate treatment intensification to his existing diabetes treatment regimen based on his own values and preferences. It is a set of flash cards comparing different drugs based on domains that are important to consider when choosing medications. It is intended for use during a clinical encounter if add-on therapy is being considered.

### *Literature review*

Information on the rate of hypoglycemia and magnitude of HbA1c reduction was extracted from two network meta-analyses.[2,34] Information on the daily routine for the use of the medications was gathered from the Full Prescribing Information from the US Food and Drug Administration or from the manufacturer. Data for weight change were collected from three network meta-analyses[2,35] for metformin, sulfonylureas, pioglitazone, DPP4 inhibitors, and SGLT-2 inhibitors, while data for liraglutide and insulin (Insulin glargine and Neutral Protamine Hagedorn, NPH) were from two randomized controlled trials (RCTs). Information on side effects were extracted from several meta-analyses for pioglitazone (edema, heart failure, fractures),[36–38] DPP4 inhibitors (headache and dizziness),[39] and SGLT-2 inhibitors (polyuria, orthostatic dizziness, urinary tract infection, and genital yeast infection),[40] while those for liraglutide (nausea and vomiting, diarrhea, and nasopharyngitis)[41] and insulin (local skin reaction, worsening of retinopathy)[42] were from two RCTs. Information on daily sugar testing was based on one meta-analysis[43] and a consensus guideline from the International Diabetes Federation[44] except for liraglutide which was gathered from a European expert recommendation.[45]

### *First PtDA prototype*

The original English version of the Diabetes Medication Choice decision from the Mayo Clinic was composed of 6 domains: hypoglycemia, daily routine, weight change, HbA1c reduction, daily sugar testing, and side effects. After the initial translation, the phrase "blood sugar" which was translated to "*asukal sa dugo*" (blood in the sugar) by KWF was revised back to "blood sugar" since the latter is more readily understood by Filipino patients. After the translation to Filipino, the first prototype was redesigned to include cost (Figure 2). All figures were updated to reflect the most current information based on literature review. DPP4 inhibitors and SGLT2 inhibitors were included in the list of medications, as they have become more widely available since the time of the original decision aid. Liraglutide was not included because albeit locally available, it is not widely used in the country due

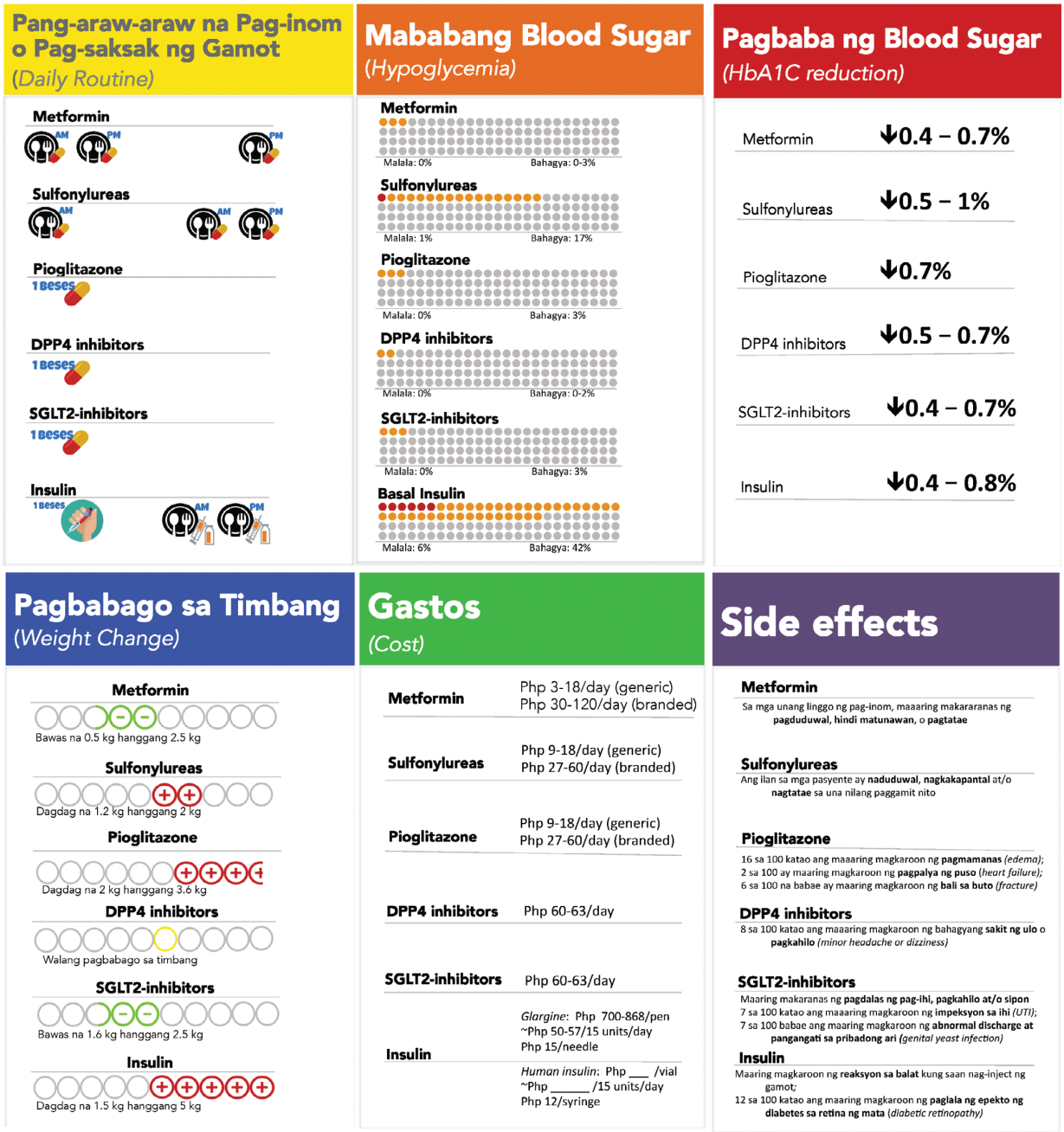


**Figure 2.** The first prototype of the Filipino Diabetes Medication Decision Aid.

to limited accessibility and high cost. Data on side effects were presented as frequencies ($x$ in 100 patients) rather than percentages to represent absolute risk.

*Review by the expert panel and patient advisory group*

The following revisions were made to the first prototype of the PtDA based on the recommendations of the expert panel:

1. Included liraglutide in the list of medications because it is an available option for patients that should be offered to patients.
2. Revised the icons in the daily routine card to reflect the relation of tablet intake or medication injection to a meal and the interval between intake instead of just indicating "once a day."
3. Used a single color in the weight change card to indicate that a particular weight change (i.e., weight gain) may not always have a negative impact on the patient.
4. Presented HbA1c reduction as a vertical bar graph instead of plain numbers to better illustrate differences in efficacy of glucose lowering.
5. Used photographs of coins and bills for the prices to better illustrate the differences in total projected expenditure per day.
6. Presented prices for generics drugs for simplification.
7. Added the cost for sugar testing in the cost for insulin.
8. Presented side effects as illustrations to improve comprehensibility for the patients.
9. Added a card on daily sugar testing to reflect recent expert consensus recommendations.[43,44]

10. Included a clinician's guide to serve as general instructions for use during a clinic consultation.

Further revisions were made based on the issues raised by the patient advisory group. They suggested using 2 colors to differentiate weight gain or loss because it was not quickly understood despite the use of "+/-" signs. To simplify further, they suggested using the same icons for the same side effects. They also emphasized the importance of the skill of the clinician explaining the cards. Additional inputs included use of more appropriate terms such as "*pagturok*" (to prick or inject) instead of "*pagsaksak*" (to stab)(Figure 3).

**Phase 2: Pilot testing (Alpha testing)**

Three iterations composed of 15 clinical encounters were conducted after the initial revision of the prototype. Duration of use ranged from 3 to 12 minutes with a median time of 5 minutes. Seven internal medicine residents and 4 endocrinology fellows participated in the clinical encounters.

During the actual clinical encounters, we observed that some patients did not know what hypoglycemia was, hence an infographic on the symptoms of hypoglycemia was incorporated at the back of the hypoglycemia card. In the original HbA1c reduction card, one patient and one physician did not clearly recognize that the colored horizontal bars were actually a horizontal bar graph. Hence, the degree of HbA1c reduction was revised into a downward vertical bar graph to reflect decrease in HbA1c. We also added a section in this card on "Target HbA1c: ____" and "*Ang inyong* HbA1c:_____" (Your HbA1c) to emphasize individualization of glycemic target. Some patients had difficulty reading the graphics hence some of the physicians and patients requested for bigger size cards.

All of the patients found the PtDA helpful and easy to understand. They related that it was easier for them to understand and know what to expect with the use of a new medication. They emphasized the importance of the clinician guiding them through the decision-making process. They were able to ask questions and clarify aspects of their medications. All of the patients would like to be involved in decision-making related to their health.

In one of the clinical encounters, one of the patients could not read or write. With a skilled clinician explaining the PtDA, the patient was able to successfully maneuver the cards and eventually decide which medication he preferred. During the post-visit interview, we found that he indeed understood the contents clearly and was satisfied with the decision he made despite his limitations with literacy and numeracy. In contrast, we observed that elderly patients who had low literacy had more difficulty understanding the PtDA, needed more time going through the cards, and would frequently veer away from the conversation.

On the other hand, all of the physicians found the PtDA comprehensible and easy to administer for willing patients. Most of the physicians found that the use of a PtDA in the form of a visual aid made it easier for them to explain aspects of the medications to the patients. The PtDA was most helpful in patients who have decisional conflict and those who are willing to be involved in decision-making. For patients who still had decisional conflict after administration of the PtDA, it was suggested that a copy of the cards be given to the patient to be reviewed at home. One of the physicians related that the PtDA served as a reminder that as physicians, we also needed to take into account what is also important to the patient, including their values and preferences. All of the physicians were interested in incorporating SDM in their practice. Likewise, they found the PtDA to be potentially useful in their practice if such a tool was readily available. Both patients and clinicians expressed satisfaction and positive reception of their experience on the use of the PtDA.

**Phase 3: Preliminary field testing**

Nine residents and one endocrinology fellow-in-training participated in the preliminary field testing. Table 3 shows the characteristics of patients included in the preliminary field testing with their decision patterns.

Clinical encounters had a median duration of 8.5 minutes (range 5 to 25 minutes). Drug efficacy as shown through degree of HbA1c reduction was the primary concern of most of the patients (5/10) having been the first choice card of most patients and the most frequently picked card overall. Cost was the secondary consideration of majority of the patients (5/10). Other cards that were commonly picked were daily routine, weight change, daily sugar testing, and side effects. Although none of the patients chose the hypoglycemia card, we decided to retain this card because this aspect was important to bring into the conversation on diabetes medication. In terms of medication choice, SGLT2 inhibitor was the most commonly preferred medication, followed by DPP4 inhibitor and sulfonylurea. One of the patients decided to maximize his dose of metformin instead, before deciding whether to add a medication at the next consultation.

Majority of the patients (9/10) exhibited gain in knowledge and improvement in SDM Q9 scores (6/10). The PtDA was also able to promote patient involvement by clinicians with a median OPTION score of 47 points (range 32 to 53 points, possible minimum and maximum score 0 and 100 points, respectively).

## DISCUSSION

In this paper, we described the development of a locally adapted Filipino version of the Diabetes Medication decision aid, which aims to facilitate SDM between the Filipino patient and his physician. The Filipino Diabetes Medication decision aid is a user-centered tool that involved the target users (i.e., both health care professionals and Filipino patients) in every step of its development. It was created in accordance with the standards set by the IPDAS. The content is based on the current available evidence on the benefits and risks of the different treatment options for diabetes. It is visually comprehensible to the Filipino patient, and was well-received by both clinicians and patients, who expressed enthusiasm and satisfaction with its use.

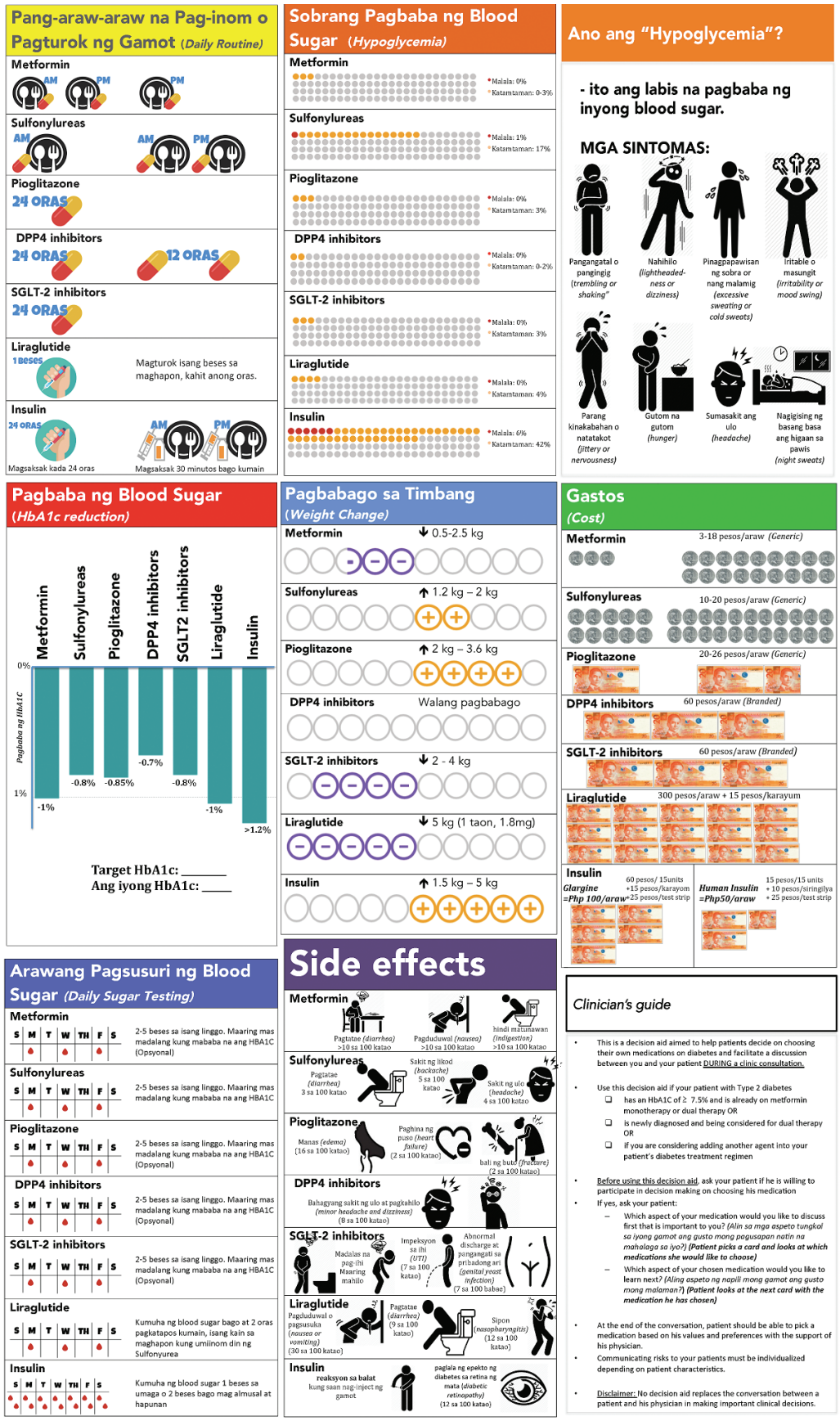


**Figure 3.** The final prototype of the patient decision aid for Filipino patients with diabetes mellitus©.

**Table 3.** Characteristics of patients and their corresponding choices of domain cards and medication (Preliminary field testing)

| Pt | Age/ Sex | Location | Education | Type of MD | Duration of Consult (mins) | HbA1C | Hypo-glycemia | DM duration (yrs) | Number of DM meds | Medication choice | Card choice 1 | Card choice 2 | Card choice 3 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 51/F | Urban | College | Resident | 25 | 7.9 | Yes | 1 | 1 | SU | sugar testing | cost | daily routine |
| 2 | 48/F | Urban | High School | Fellow | 16 | 9.3 | No | 7 | 2 | Pioglitazone | HbA1C reduction | cost | N/A |
| 3 | 44/F | Rural | Vocational | Resident | 24 | 8.1 | No | 4 | 2 | SGLT2i | HbA1C reduction | cost | weight change |
| 4 | 56/F | Rural | High School | Resident | 7 | 10.9 | Yes | 1 | 1 | SU | HbA1C reduction | cost | side effects |
| 5 | 73/F | Urban | Grade School | Resident | 7 | 10.1 | No | 4 | 1 | DPP4i | daily routine | cost | HbA1C reduction |
| 6 | 51/F | Rural | College undergrad | Resident | 7 | 8.3 | Yes | 8 | 2 | Insulin | HbA1C reduction | side effects | N/A |
| 7 | 56/F | Urban | High School | Resident | 16 | 8.3 | No | 8 | 2 | DPP4i | sugar testing | HbA1C reduction | weight change |
| 8 | 66/M | Rural | Vocational | Resident | 7 | 9.5 | No | 18 | 1 | SGLT2i | weight change | HbA1C reduction | cost |
| 9 | 50/F | Rural | College | Resident | 5 | 10.8 | No | new | 1 | SGLT2i | weight change | sugar testing | N/A |
| 10 | 61/M | Urban | College undergrad | Resident | 10 | 7.7 | No | 0.5 | 1 | Increased Metformin dose | HbA1C reduction | daily routine | Side effects |

N/A – not applicable; SU- Sulfonylurea; SGLT2i – SGLT2 inhibitor; DPP4i – DPP4 inhibitor

During the development process, we also incorporated elements of the approach to development of PtDAs by Mayo Clinic, which was used in the creation of the original Diabetes Medication Choice PtDA.[29] The patient advisory group was asked to role-play as if they were in a diabetes consultation and then provided reflections of their experience collectively. Compared to the original PtDA, the Filipino version was very graphic, with less textual information. We also incorporated a card containing brief instructions for the clinician on how to use the PtDA. A reminder to individualize HbA1c targets and compare it with the patient's present level was also included in the HbA1c reduction card. A similar decision aid on diabetes treatment intensification, the PANDAs decision aid, is an online interactive multimedia PtDA that requires at least 25 minutes to view.[18] Since access to the Internet by our patients and in the clinic is limited in our setting, we opted to focus on paper-based cards to be used during a clinical consultation.

The pilot testing and the preliminary field testing showed that PtDA is feasible to use in a low middle income country, since both Filipino physicians and patients found it acceptable and satisfactory to use. In all the clinical encounters, patients were able to arrive at a decision without significantly increasing consultation time. There were also other perceived benefits of the PtDA that were not commonly cited in development of diabetes PtDAs. The PtDA served as a reminder to physicians not accustomed to SDM—to involve patients in decision-making and facilitate a conversation between doctors and patients instead of having a one-way discussion. In addition, it not only informed patients on treatment options but also updated physicians as well.

In this study, the patients' most important considerations when choosing a medication were method of administration (injectable versus oral agent), cost, rate of hypoglycemia, and side effects. Facilitators of SDM included increasing time spent, providing more information, and support from family, fellow patients, and their doctors. From the clinician's point of view, physicians were not able to incorporate SDM in their practice due to lack of time, skills, resources, motivation to use SDM and to change one's habits. Similarly, in a systematic review[10] on the barriers and facilitators to implement SDM in clinical practice as perceived by health care professionals, the most common barriers were time pressure, lack of applicability due to patient profile, and lack of applicability due to the clinical situation. On the other hand, the most commonly identified facilitators included motivation of the health care professional, perception of a positive impact on patient outcomes and on the clinical process.

In a RCT evaluating the effects of skills development workshop and the use of risk communication aids on SDM, clinicians significantly increased their involvement of patients with a 12.9- and 10.6-point increase in OPTION score from baseline with the use of these tools, respectively.[46] Furthermore, the addition of skills development in SDM to the use of risk communication aids, increased patient involvement incrementally. Using such aids coupled with skills in SDM resulted in perceived higher patient and clinician agreement on treatment, patient satisfaction with information, clinician satisfaction with decision, and overall satisfaction with the consultation.[46] As such, the use of PtDAs in our setting, where this concept is relatively new to both patients and physicians in actual clinical practice, warrants not only its introduction but also accompanying skills training on SDM and the use PtDAs in order to maximize its benefits.

The population where the PtDA was tested included patients who had low socioeconomic status and who were more likely to have lower health literacy. Lower health literacy has been associated with higher decision uncertainty and regret. Adults with low health literacy have also been shown to have less desire for participation and question-asking.[47] Despite the low health literacy in our population, most preferred to participate in decision-making and were able to satisfactorily use the PtDA. On the other hand, some patients prefer to leave the decision

to the doctor, who they perceive as the expert. As such, this PtDA may not be used in patients who are not engaged.

A person's ability to effectively use a PtDA is determined by both their health literacy skills and the quality and suitability of the PtDA.[48] Creators of PtDAs are encouraged to design tools that can be accessed and understood by patients across the health literacy spectrum.[47] One of the intentions of this study was to create a tool that could cater to Filipinos with low literacy levels. In a systematic review looking at health literacy in PtDAs,[47] some of the specific features that improved comprehension for low literacy individuals included presenting numerical information in tables or pictographs, using the same denominator, and using natural frequencies (1 out of 100) to help patients understand probabilities. We incorporated these features in the present PtDA with a simple graphic display with less textual information as compared to the original. In the study evaluating the Greek version of the Diabetes Medication Choice Decision Aid,[49] majority of the patients (72%) recruited were high school graduates or undergraduates. Likewise, they were able to implement the Greek PtDA with a positive reception from both patients and clinicians. Supporting patients with low literacy by providing well designed tools favorably change the inequity in health care, as the average patient with low socioeconomic status and limited education appear to be at a disadvantage when handling seemingly complex information.[50] The present PtDA may mitigate the effects of low literacy among Filipino patients but this needs to be confirmed in a formal evaluation study.

We observed that elderly patients who had low literacy took longer, had poor comprehension, and would frequently deviate from the topic. Use of PtDAs among older people had similar benefits with improved risk perception, knowledge, and patient involvement. However, the evidence supporting effectiveness of PtDAs in older adults are still limited, as most studies are small and heterogenous.[51] In a study on the impact of cognitive aging on decision making, older adults were found to rely on simpler strategies and took longer to process information.[52] In the study, despite the challenges observed among the older patients, there was no trend towards a difference in knowledge gain, degree of patient involvement, and expressed satisfaction towards its use despite the challenges. Although the PtDA may have some limitations in the older population because it was not specifically designed for them, there may still be evidence to support its use, but the conversation may need participation from a family member or companion who knows the patient's routine and preferences.

The limitation of this study is its external applicability to patients of higher income and higher literacy levels including those who go for consultations in private clinics.

We recommend the introduction of the Filipino Diabetes Medication decision aid among health care professionals caring for people with T2DM to promote awareness and integration of SDM in clinical practice. A formal evaluation of the impact of this PtDA in a large and broader Filipino population is recommended. Skills training on SDM and on the use of PtDAs is of paramount importance in order to achieve its benefits, improve patient and doctor satisfaction, increase uptake among physicians, without undue disruption in the overall clinic workflow of a busy practice.

## CONCLUSION

Using a qualitative method and an iterative process of tool development, patients, clinicians, and diabetes nurse educators have contributed to the creation of the first Filipino patient decision aid on diabetes treatment intensification. This patient decision aid will help generate a conversation on shared decision-making between patients and clinicians on medication options for diabetes.

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**Statement of Authorship**
All authors certified fulfilment of ICMJE authorship criteria.

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*To avail of the high resolution version of the patient decision aid, kindly email the corresponding author at apmacalaladjosue@up.edu.ph.

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