Evaluation of healthcare products in diabetes: what are the most important domains for patients?

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CONTEXT & OBJECTIVES

Patients' perspectives (quality of life and unmet needs) are more and more considered to evaluate new drugs, medical devices and digital health solutions. In clinical and medical researches, patient's experiences are collected using dedicated instruments (PROs: Patient-Reported-Outcomes).

This research aimed at identifying the most important domains for people with diabetes to optimise and facilitate the selection and development of PROs used for healthcare product evaluation.

METHODS

Patient-Driven Outcome Selection (PDOS) method, a patient-focused approach for selecting outcomes using patient-generated data was used.

Given the variety of products and the importance of digital solutions (DHS) for diabetes management (health apps, internet resources, wearable devices, …), patients' assessment was done by types of healthcare products.

PATIENT-DRIVEN OUTCOMES SELECTION (PDOS) METHOD

STEP 1: STATE-OF-THE-ART
Identification of **PROs most frequently used** in diabetes medical & clinical research

STEP 2: MEDICAL & REGULATORY RECOMMENDATIONS
Identification of **PROs & outcomes recommended** by Health Authorities (HA) and/or expert groups on diabetes.

LIST OF OUTCOMES COVERED BY PROs AND RECOMMENDED BY EXPERTS AND AUTHORITIES

STEP 3: ASSESSMENT OF PATIENTS' PERPECTIVES
Direct-to-patient survey to determine the **most important domains** for people living with diabetes and identify potential **new important domains.**

LIST OF MOST IMPORTANT OUTCOMES FOR PATIENTS

STEP 4: GAP ANALYSIS between outcomes covered by PROs, recommended by experts' & authorities' and important for patients

SELECTION of PROs ADAPTED TO THE CONTEXT AND PATIENTS' PREFERENCES

RESULTS

Steps 1 & 2: Bibliography & Recommendations

Comparative review of medical and clinical researches in diabetes (clinicaltrial.gov, pubmed, …) and HA guidelines (see table 1):

- 7 diabetes specific major PROs identified[2]: DTSQ, DDS, PAID, SDSCA, DES, DQOL, DHP-1
- Guidelines for Medicines and Digital Health Solutions from France (Haute Autorité de Santé) [3, 4], US (Food and Drug Administration)[5]
- Some domains recommended by authorities are covered by PROs, some others are not or poorly covered
- Recommendations differs for medicines and for digital health solutions

Recommended by authorities and covered by PROs

Recommended by authorities and poorly or NOT covered by PROs

NOT recommended and not covered by PROs

DOMAIN	TREATMENT FOR DIABETES	DHS (web sites, apps, devices…)
Quality of Life (personal, professional, social, physical and emotional well-being)	■	■
User satisfaction / efficacy perception	■	■
Patient empowerment in daily diabetes management	■	■
Patient autonomy in diabetes management		
User experience / easy-of-use		
Copying with illness-related difficulties		
Side effects		
Adherence		
Health litteracy		

Table 1 : Comparison of domains covered by PROs and recommended by experts and HA

Step 3: Direct-to-patient Survey

Survey design:
- **Online questionnaire on Carenity platform: 20 questions** (socio-demographic & medical profile, VAS, ranking questions, open-ended questions)
- **Inclusion criteria:** Adult ($\geq$ 18y/o) people with diabetes living in France
- **Data Collection:** 10 to 31 May 2023
- **Number of respondents: 249 patients**

Profile of respondents:
- **Gender:** 49% men, 50% women, 1% non-binary
- **Mean age:** 64.8 years old
- **Diabetes type:** 24.5% Type 1, 73.9% Type 2, 1.2% Type 1.5, 0.4% other
- **Comorbidities:** 22% none, 78% with one or several comorbidities
- **Median time from diagnosis:** 20% $\leq$ 10 years, 80% >10 years
- **Treatments for diabetes:** 53 % one treatment, 47% several treatments

Most important domains for patients (ranking questions):

Mean rank	Ranked in 1st position	TREATMENTS	DIGITAL HEALTH SOLUTIONS	Ranked in 1st position	Mean rank
2.7	34%*	61% — User satisfaction / Efficacy perception	37%	14%	4.0
4.0	11%	36% — Patient empowerment in daily diabetes management	37%	14%	4.0
4.3	12%	31% — Quality of Life	33%	14%	4.2
4.1	12%	33% — User experience / Ease of use	37%	15%	4.0
4.3	8%	30% — Patient autonomy in diabetes management	36%	12%	4.1
5.3	4%	18% — Adherence / Trust / Compatibility with lifestyle	27%	8%	4.8
5.9	5%	16% — Health litteracy / Diabetes understanding	23%	8%	5.3
5.3	4%	19% — Copying	23%	7%	4.9
5.0	10%	29% — Side-effects / Life privacy	21%	8%	5.4

■ Ranked in top 3

*: these patients ranked in top 3 for DHS: efficacy (48%), user experience (38%) and empowerment (35%)

Figure 2: Most important domains for patients with diabetes for the evaluation of treatment and DHS (n= 249 respondents)

Other domains important for patients (open-ended question):
- **For treatments:** Financial impact & health insurance coverage (n=15); Information on disease and treatments (n=11) ; Psychological impact (n=10)
- **For digital health solutions:** Information qualitative and reliable on disease and treatment by websites (n=15), Communication between patients (n=13)
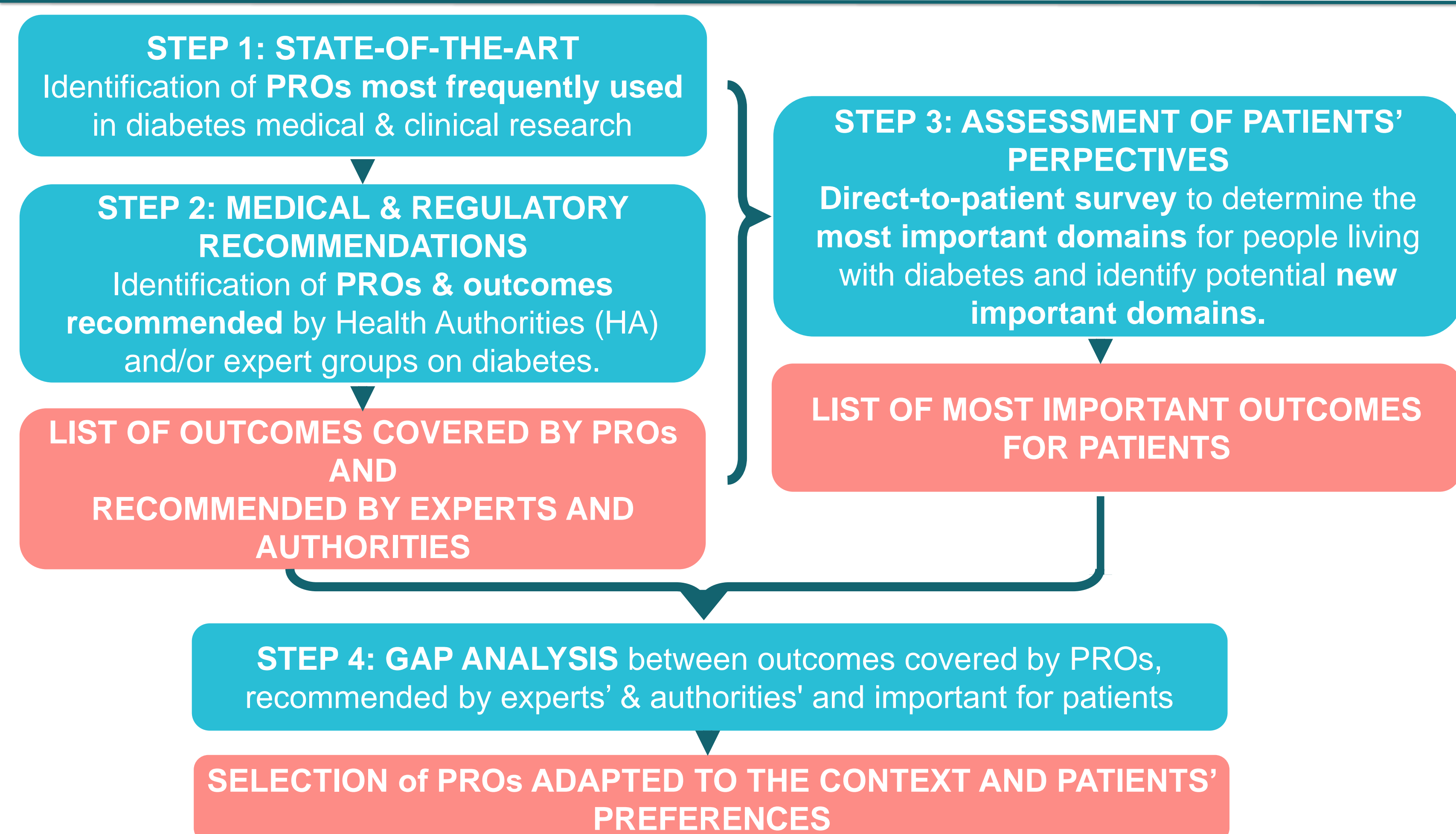
Step 4: Gap Analysis
- Domains recommended by HA to assess patient's perspectives, covered by PROs and important for patients: **User satisfaction, patient empowerment & Quality-of-life**
- Domains important for patients but not recommended by HA and/or covered by existing PROs: **financial impact** and **information** provided by HCPs, websites and social networks
- Domains of importance reported by patients differs between treatments & DHS

CONCLUSIONS

This research shows the relevance of PDOS method applied to diabetes area, that integrates patients' perspectives into the PRO selection process.
It confirms that the most important domains for patients are those recommended by HA and well covered by existing PROs. Other patients-important domains that are partially covered by commonly used PROs should also be addressed during health products development.
Moreover, patient's perspectives can differ for a treatment than for a digital health solutions. It is thus important to adapt the PROs and domains selection to the health product considered.

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