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Publication date:
2018

Document Version
Publisher's PDF, also known as Version of record

Development of a National Minimal Set of Patient-Important Outcome Domains for Value-Based Diabetes Care in Denmark

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Background

- The cross-regional project for Value Based Health Care (VBHC) in Diabetes in Denmark, VBS PRO-DIA, is sponsored by Northern Region Denmark and Aalborg University Hospital in partnership with the Danish Diabetes Association and Aalborg University.
- The aim is to develop and evaluate new solutions for value-based diabetes care in Denmark under the heading: Improving care by focusing on what matters most to people with diabetes (PwD).
- A key objective is to enable coordinated cross-sectorial and multi-disciplinary action to improve care through a clinical and analytical solution designed around a shared definition of "patient value".
- The first step presented here was to establish a minimal set of patient-important outcome domains, incl. PRO, to asses "value".

Value based care projects in Denmark

- Decided by the Board of Danish Regions and part of the Financial Agreement from 2016.
- Northern Denmark Region is appointed regional lead on value based *diabetes* care.

$$\text{Value} = \frac{\text{Patient-important health outcomes achieved}}{\text{Ressource use}}$$

Aims of the qualitative research

- Inform selection of a minimal set of patient-important diabetes outcome domains for VHBC by the national multi-sectorial and multi-disciplinary working group (incl. PwD).
- Using the VBHC framework (Porter et al 2010), specific aims was to gain perspective of PwD and caregivers on:
  1. The psychological, social and physical impact of diabetes.
  2. Treatment goals and priorities of PwD.
  3. Disutilities of diabetes treatment
  4. Factors affecting sustainability
- Qualitative findings were contextualized by supportive research in line with evidence-guided patient partnering methodology.

Method (1) Qualitative methodology

- Qualitative research as part of evidence-guided quality patient engagement (PFMD, NIH 2018) using 7 criteria: Shared purpose, respect, responsibility, representativeness, capacity/capability, documentation and sustainability.
- Individual semi-structured interviews and workshops were undertaken with 24 persons with diabetes and caregivers.
- Recruitment was done by a diabetes nurse at the University Hospital in collaboration with the local diabetes organization.
- An analytical selection process was applied to 1) maximize variation and 2) apply theory-driven qualitative selection for representativeness

Method (2) Qualitative methodology

Semi structured interviews:

- Participants completed open-ended questions individually.
  For example:
  - "The most important ways my diabetes affects my [physical health] / [social and psychological wellbeing] is……"
  - "My treatment is succesful when I……"
  - "The most important way diabetes affects my life as a caregiver is……"

Focus group and workshops:

- A 4 hour highly structured patient workshop consisting of focus group, consensus and co-creation sessions (see agenda below).

Qualitative analysis:

- Individual responses and group process outputs were analysed and coded separately.
- Outputs were combined in final report taking into account group dynamics, differences and analyses of coherence.
- 4 caregivers were included for hypothesis generating purposes. The results for caregivers will be presented elsewhere.

Method (3) Patient workshop agenda

Agenda overview. 4 hour workshop
Introduction and welcome by local patient organisation head and investigator.
Group discussion sessions I. 1. How does diabetes affect your physical social and psychological health/well-being? 2. What are important goals for your diabetes care? Are there commonalities? 3. How does the diabetes treatment impact life?
Group exercise II 1. Prioritise and refine most important outcome goals for diabetes care. 2. Co-create – how to use and apply in practice? E.g. use of apps to track outcome?
Plenary. Share group findings. Commonalities and differences across type & therapy? Wishes and needs for treatment and care. Requirements for sustainabilty?
Concluding exercise. • Main takeaway: What is key takeaway regarding priorities for you/ people with diabetes • Feedback to process. Anything missing. Input to next phase.

Results (1) Participants

	Type 1	Type 2	Caregiver
Total	8	13	4 (2 t1, 2 t2)
Women/men	4/4	7/6	1/3
Age 18-60 years	7	4	0
Age >60 years	1	9	4
Pen/pump	4/4	7/0	2/1
Tablet or no medication	0	6	1
Diabetes duration <10	3	6	-
Diabetes duration >10 yrs	5	7	-
Complications: 0/1/More than 1	5/1/2	11/2/0	-
Co-morbidities	2	11	-
Primary care/hospital setting	0/8	11/2	-

Results (2) Key observations

PwD and caregivers found the following of high importance for evaluation of achieved health outcomes in VBHC context:

- Blood sugar control (A1c, BGM, CGM), clinical risk factors for late stage complications, hospitalization, ketoacidosis.
- Emotional diabetes distress, impact on quality of life, burden of treatment (medication, injection, testing, lifestyle), well/being
- Key to also assess quality of care and confidence in self-care

Group level analyses further highlighted

- Outcome domains supported by individual and group-based data
- Main outcome domain differentiation was related to treatment modality (insulin/pump) and burden of complications.
- Every person has unique individual goals that shift over time. Huge heterogeneity in needs/priorities across the lifespan.

Results (3) Thematic analysis (goals)

VBHC tier	Qualitative outcomes (PwD goals) by VBHC tiers
Achieved or desired health status	Be able to live as normal a life as possible. (Avoiding negative impacts on physical health, emotional, work, social, family, leisure life, lifestyle).
	Achieve good blood sugar control (A1c) to stay healthy and prevent complications. Staying "in range" using BGM and CGM measurements. Minimise risk of health problems and late stage complications.
	Maintain psychological wellbeing, avoid depression and emotional distress (avoiding constant fear of future complications, feeling alone, feeling that diabetes interferes in social life)
	Get attention to and care for full range of diabetes related somatic symptom distress, such as pain (neuropathic), erectile dysfunction, diabetes related sleep problems, tiredness (hyperglycemia).
Disutilities of treatment	Minimise burden and interference of diabetes treatment in daily life (social, family, mood, work, etc). Make treatment easier, more convenient. Reduce daily frustrations and need for constant attention.
	Avoid risk of and fear of mild, moderate and severe hypoglycemia. Minimise the emotional, mental, physical and behavioral consequences of hypoglycemia or the fear of hypoglycemia.
	Gastrointestinal and other side effects of diabetes medications.
Sustaina-bility factors	Have confidence, sense of security in care, reliable technology, qualified coordinated ongoing support, be treated as a "whole person", involved as partner, helped to navigate healthcare and community resources, mobilise social support and motivation, support from surroundings for diabetes.
	Feel able, informed and equipped to master and manage own diabetes care. Feel confident with own understanding, competence and motivation to take care of own diabetes while living a good life.

Results (4) PRO outcome domains

Criteria applied (desk research/expert group)	VBHC PRO domain areas
i.Importance to PwD *(qualitative & quantitative evidence)*	Self-reported health status (generic)
	Psychological well-being and risk of depression (generic)
ii.Societal/health economic importance	Somatic diabetes symptom distress (incl. neuropathic pain, erectile dysfunction, complications)
	Multi-facetted impact of diabetes on life (incl. social relations, family, work/study, leisure, quality of life)
iii.Modifiable in a systemic care context	Diabetes related emotional distress (incl fear of complications, hypoglycaemia, depressive thinking)
	Treatment burden (incl daily burden/interference, side effects, impact of and fear of all forms of hypoglycaemia (biopsychosocial/behavioural consequences)
iv.Clinically important and actionable	Confidence in and quality of care and support*
v.Measurability/theoretical foundation	Confidence in self-management, adaptation, mastery, competency*
vi.Complementary to clinical endpoints	

* Process domains included based on central importance for long-term prognosis

Conclusions and next steps

- Qualitative research and partnering with PwD informed national multi-stakeholder expert decision process regarding relevance of PRO-based outcome domains for outcomes assessment in value based diabetes care.
- Domains were supported by follow-up patient workshops, survey research in collaboration with ICHOM, and by literature review of multi-national qualitative and survey research (Nicolucci, Stucky, Young-Hyman).
- Next phases now are to further detail domains, finalise national PRO questionnaires, develop and test final VHBC PRO diabetes care solution in Northern Region of Denmark and with collaborating regions/sites.
- Our research supports use of our clinically anchored evidence-guided PwD partnering process for all steps of PRO implementation, including item selection, linking PRO to care actions and considering vulnerable groups.
- PRO item bank and branching technology is applied to address population heterogeneity and cross-sectorial use.
- International collaboration for harmonisation of PRO diabetes methods is helpful to future national PRO efforts.

Acknowledgements

Thank you to all our partners and collaborators, including:

- The PwD and caregivers, clinical teams, The Danish Diabetes Association and the Danish national VHBC working group.
- Lotte Klim and Dorthe Hinzman for contributing to planning, execution, reporting and applying results as persons with diabetes.
- Professors Sheldon Greenfield and Sherrie Kaplan, University of California Irvine, Professor Frans Pouwer, Southern Denmark University and multiple Individual members of relevant related organisations including ICHOM, PSAD, ACBRD, BRIDGE, T1D.

Abbreviations

PRO: Patient Reported Outcomes.
PWD: Person/people with diabetes.
VBHC: Value Based Health Care.
VBS PRO-DIA: Danish Project for Value Based Care and Patient Reported Outcomes in Diabetes, Northern Region, Denmark.

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