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

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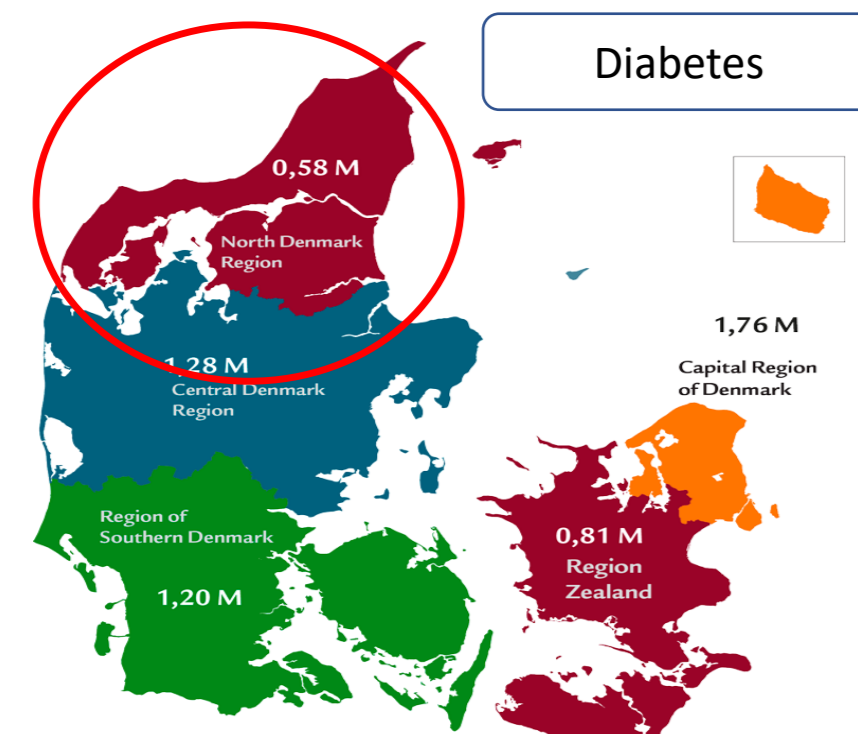
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## Background

- 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 assess "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.



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

## Aims of the qualitative research

- Inform selection of a minimal set of patient-important diabetes outcome domains for VBHC 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:
  - The psychological, social and physical impact of diabetes.
  - Treatment goals and priorities of PwD.
  - Disutilities of diabetes treatment
  - 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 successful 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.	<ol style="list-style-type: none"> <li>How does diabetes affect your physical social and psychological health/well-being?</li> <li>What are important goals for your diabetes care? Are there commonalities?</li> <li>How does the diabetes treatment impact life?</li> </ol>
Group exercise II	<ol style="list-style-type: none"> <li>Prioritise and refine most important outcome goals for diabetes care.</li> <li>Co-create – how to use and apply in practice? E.g. use of apps to track outcome?</li> </ol>
Plenary. Share group findings. Commonalities and differences across type & therapy? Wishes and needs for treatment and care. Requirements for sustainability?	
Concluding exercise.	<ul style="list-style-type: none"> <li>Main takeaway: What is key takeaway regarding priorities for you/ people with diabetes</li> <li>Feedback to process. Anything missing. Input to next phase.</li> </ul>

## 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	<p>Be able to live as normal a life as possible. (Avoiding negative impacts on physical health, emotional, work, social, family, leisure life, lifestyle).</p> <p>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.</p> <p>Maintain psychological wellbeing, avoid depression and emotional distress (avoiding constant fear of future complications, feeling alone, feeling that diabetes interferes in social life)</p> <p>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).</p>
Disutilities of treatment	<p>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.</p> <p>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.</p> <p>Gastrointestinal and other side effects of diabetes medications.</p>
Sustainability factors	<p>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.</p> <p>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.</p>

## Results (4) PRO outcome domains

	VBHC PRO domain areas
<b>Criteria applied (desk research/expert group)</b>	Self-reported health status (generic)
	Psychological well-being and risk of depression (generic)
	Somatic diabetes symptom distress (incl. neuropathic pain, erectile dysfunction, complications)
	Multi-faceted impact of diabetes on life (incl. social relations, family, work/study, leisure, quality of life)
	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)
<i>i.Importance to PwD (qualitative &amp; quantitative evidence)</i>	Confidence in and quality of care and support*
<i>ii.Societal/health economic importance</i>	Confidence in self-management, adaptation, mastery, competency*
<i>iii.Modifiable in a systemic care context</i>	
<i>iv.Clinically important and actionable</i>	
<i>v.Measurability/theoretical foundation</i>	
<i>vi.Complementary to clinical endpoints</i>	

\* 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 VBHC 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.

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## 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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