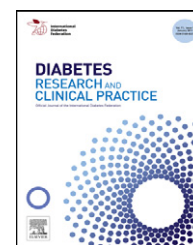


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Diabetes Attitudes Wishes and Needs 2 (DAWN2): A multinational, multi-stakeholder study of psychosocial issues in diabetes and person-centred diabetes care

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ABSTRACT

Aims: The Diabetes Attitudes Wishes and Needs 2 (DAWN2) study aims to provide a holistic assessment of diabetes care and management among people with diabetes (PWD), family members (FM), and healthcare professionals (HCPs) and explores potential drivers leading to active management.

Methods: DAWN2 survey over 16,000 individuals (~9000 PWD, ~2000 FM of PWD, and ~5000 HCPs) in 17 countries across 4 continents. Respondents complete a group-specific questionnaire; items are designed to allow cross-group comparisons on common topics. The questionnaires comprise elements from the original DAWN study (2001), as well as psychometrically validated instruments and novel questions developed for this study to assess self-management, attitudes/beliefs, disease impact/burden, psychosocial distress, health-related quality of life, healthcare provision/receipt, social support and priorities for improvement in the future. The questionnaires are completed predominantly online or by telephone interview, supplemented by face-to-face interviews in countries with low internet access. In each country, recruitment ensures representation of the diabetes population in terms of geographical distribution, age, gender, education and disease status.

Discussion: DAWN2 aims to build on the original DAWN study to identify new avenues for improving diabetes care. This paper describes the study rationale, goals and methodology.

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1. Introduction

In 2001, the Diabetes, Attitudes, Wishes and Needs (DAWN) study showed that self-management of diabetes was considered poor by people with diabetes (PWD) and healthcare professionals (HCPs). Diabetes-related distress was common amongst PWD and hampered efforts to self-manage their condition, but few received psychological treatment [1]. Although recognition by HCPs of emotional problems and diabetes-specific distress amongst PWD was low, HCPs desired a better understanding of such issues [2]. Collaboration among diabetes care providers was identified as an important factor for improving diabetes outcomes, but interdisciplinary team care was uncommon [2], and there was some resistance by PWD and HCPs to the timely initiation of effective therapies [3].

Following DAWN, patient representatives and an interdisciplinary group of diabetes care experts discussed how the DAWN findings could be translated into improved diabetes care [4]. The resulting ‘DAWN Call to Action’ [5] encouraged multiple stakeholders (HCPs, PWD and their family members [FMs]/carers, payers, policy makers, industry and non-government organisations) to implement person-centred diabetes care, and actively involve PWD in self-management with support from an interdisciplinary team of HCPs [2].

The DAWN findings support a paradigm shift from an acute care model to a person-centred, integrated chronic care model, such as the WHO Innovative Care for Chronic Conditions framework to diabetes [6]. This model involves care at three levels: micro, meso and macro, which refer to individual, healthcare organisation/community, and policy levels, respectively [6]. Optimal diabetes care is best achieved by collaboration between PWD, FM, community partners and healthcare teams that are informed, motivated, prepared, and able to work together. This collaboration is supported and influenced by the broader healthcare organisations and communities, and by the policy environment [6]. Scientific evidence provides the foundation for the approaches to care [6], but the PWD perspective is important in informing all levels of healthcare [7]. PWD have the right to be informed and educated, to have access to proper diabetes care and optimal medicine, and not to be discriminated against because of their condition [8].

It is a decade since the DAWN study highlighted the need for collaborative action across countries to improve self-management and psychosocial support. Despite major advances in collaborative care many PWD still do not achieve desirable treatment outcomes. The growing burden of diabetes calls for stronger and broader globally-coordinated efforts. As more countries recognise the effect of diabetes on population health, and the economic and personal burdens, we must expand our knowledge to include the diverse social institutions and cultures of these countries. As our knowledge has advanced, we have identified gaps in our knowledge of the role of support from family and community in living with and caring for PWD. Across nations, there is a pressing need for a new global translational research initiative that can form the foundation for measurement-guided multi-stakeholder collaboration for the advancement of person-centred diabetes care world-wide. Thus, it is time for a new DAWN.

The DAWN2 study initiative, undertaken by Novo Nordisk in partnership with the International Diabetes Federation (IDF), the International Alliance of Patient Organisations (IAPO), the Steno Diabetes Center, and a range of other national, regional and global partners, aims to (a) improve our understanding of the unmet needs of PWD and their care-takers, (b) facilitate dialogue and collaboration among all key stakeholders to strengthen patient involvement and improve self-management and (c) establish a cross-culturally validated multi-national survey framework for assessing and benchmarking psychosocial and educational aspects of diabetes care delivery. The overall aim is to identify avenues for improvement at all three levels of care – at the meso and macro-levels for diabetes care funding and care provision, and at the micro level for delivery of care. The study explores how PWD, FMs and HCPs perceive diabetes care and investigates the value of a person-centred model of diabetes care that emphasises the needs of the individual in the context of current chronic care, self-management education and psychosocial support. This paper describes the study methodology.

2. Materials and methods

2.1. Study objectives

Within a national and international setting, the predefined objectives of the DAWN2 study are:

Primary objective:

- To assess potential barriers to and facilitators of active and successful management of diabetes among PWD, FMs, and HCPs.

Secondary objectives:

- To establish national benchmarks for health status, quality of life (QoL), access to self-management education and to self-care in diabetes.
- To assess the access to, and use and benefit of, support from healthcare teams, family and friends, communities and society.
- To explore and pinpoint the most important facilitators and barriers to person-centred chronic care for each stakeholder group.
- To identify successes, wishes, needs, preferences and priorities for change among all key stakeholders in diabetes.

2.2. Study design

DAWN2 is a multinational, interdisciplinary and multi-stakeholder study designed in February 2011 to examine the experiences and unmet needs of PWD, FMs, and HCPs (UTN No: U1111-1123-7509; NCT01507116). DAWN2 has been developed and overseen by the Global DAWN2 Study Group under the auspices of the IDF, IAPO and the Steno Diabetes Center with input from experts from: American Association of Diabetes Educators, Federation of European Nurses in Diabetes, Primary Care Diabetes Europe, Behavioral Research in Diabetes Group Exchange, Psychosocial Aspects of Diabetes Study Group of the European Association for the Study of

Diabetes, and multiple other organisations involved in person-centred diabetes care. Fieldwork began in March 2012.

2.3. Ethical considerations

In each country, the study is being conducted in accordance with the relevant ethical requirements, following regional/national/local guidelines relating to the conduct of non-interventional studies and uses guidelines of the International Chamber of Commerce/European Society for Opinion and Marketing Research [9], the Council of American Survey Research Organizations [10] and Good Pharmacoepidemiology Practices [11] as a minimum standard.

2.4. Study participants

DAWN2 is being conducted in 17 countries: Algeria, Canada, China, Denmark, France, Germany, India, Italy, Japan, Mexico, The Netherlands, Poland, Russia, Spain, Turkey, United Kingdom (UK) and United States of America (USA). Brazil was originally included in the study plan, however due to timing issues, the DAWN2 study in Brazil will be conducted separately.

The participating countries represent 4 continents – Europe, Asia, North America, and Africa. Countries volunteered for participation in DAWN2, including providing study funding, mainly to identify ways to enhance diabetes care and the lives of PWD and their FM. Other countries are currently applying or planning to apply components of the DAWN2 study design as part of the wider DAWN network; however, these research activities are not part of the 17-country DAWN2 study. Overall, the study population comprises ~16,100 participants: 9040 PWD, 2160 FMs and 4900 HCPs. Inclusion/exclusion criteria are presented in Table 1. Each country's sample is a minimum of 900 participants: 500 PWD, 120 FMs and 280 HCPs (see Fig. 1). In the USA, an additional sample of 540 PWD and 120 FMs of African-American, Hispanic and Asian ethnic origin and 140 HCPs who treat minority populations is included to obtain adequate numbers for subgroup analyses. In general, the three participant groups are independent (e.g., participants in PWD sample are not treated by participants in HCP sample). However, for the FM sample, some of the 120 participants do live in the same household as individuals who participated in the PWD survey. The data for these participants enables linkage between this subset of PWD and their FMs.

The HCP sample comprises specialist physicians (endocrinologists and diabetologists), primary care (PC) providers, general practitioners (GPs) and internal medicine physicians (with a sub-speciality in diabetes) and other HCPs (e.g., diabetes nurses, dietitians, diabetes educators, counsellors or physician's assistants, who vary by country). The sample of PWD predominantly comprises those with type 2 diabetes (with quotas for different treatment regimens), but also includes participants with type 1 diabetes.

The global study sample (and subsample) sizes are sufficient to achieve more than 80% power for a 'small' effect size (e.g., Cohen's $d = 0.2$). National samples of PWD and HCP were designed to achieve 80% power for a 'medium' effect size

Table 1 – Inclusion and exclusion criteria.

Inclusion criteria

- All participants: Internet access at home or convenient location or able to attend a face-to-face or telephone interview; informed consent before the start of any study-related activities
- PWD: Adults aged ≥ 18 years diagnosed with diabetes by an HCP at least 12 months ago (type 1 or type 2; not only during pregnancy)
- FM: Adults aged ≥ 18 years who are not diagnosed with diabetes, live in the same household with an adult (≥ 18 years) with diabetes (type 1 or type 2; not only during pregnancy) and are involved in his/her care
- HCP: GPs, PC physicians and internal medicine physicians who have been in practice for ≥ 1 year and who personally treat ≥ 5 adults (≥ 18 years) with diabetes per month and initiate oral medication
- HCP: Diabetes specialists (endocrinologists/diabetologists or GP/PC physicians/internal medicine physicians with sub-speciality in diabetes) who have been in practice for ≥ 1 year, personally treat ≥ 50 adults (≥ 18 years) with diabetes per month and prescribe insulin (may also prescribe oral medication or other injectable diabetes medications). Threshold may be adjusted according to country-specific requirements
- HCP: Other HCPs (diabetes nurses/dietitians/other HCPs) who have been in their respective professions for ≥ 1 year and provide care for ≥ 5 adults (≥ 18 years) with diabetes per month

Exclusion criteria

- All participants: Inability to understand and comply with written and verbal instructions
- PWD: Individuals aged < 18 years and/or diagnosed with diabetes less than 12 months ago and/or diagnosed with diabetes only during pregnancy

FM, family members; GPs, general practitioners; HCP, healthcare professional; PC, primary care; PWD, people with diabetes.

(e.g., Cohen's $d = 0.5$). Minimum national sample size was 120 to achieve 80% power to detect a difference in proportions of 10%. Minimum national subsample size was 80 to permit effective weighting (especially important when proportional sampling would generate a smaller subsample that would not yield a reliable subsample estimate).

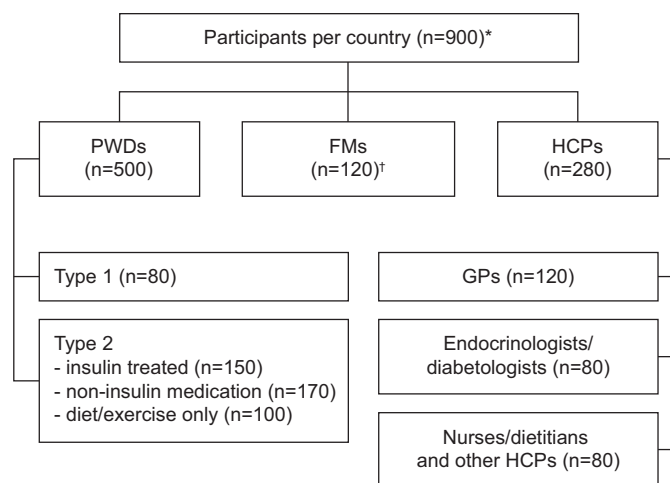
2.5. Recruitment methodology

2.5.1. HCPs

In all countries, potential participants are identified primarily from online panels and databases. When necessary, other sources such as telephone lists and physician directories are used for recruitment. All potential participants are invited to take part via email or phone. As with other DAWN2 survey groups, all participants receive a web-link to a secure server to enable them to complete the survey online.

2.5.2. PWD and FMs

Web, telephone and in-person methods relevant to each country's situation were applied while trying to maximise comparability of methodologies and survey populations across countries.



*In the USA, additional 540 PWD and 120 FMs recruited to better represent African-American, Hispanic and Asian ethnic groups, plus 140 HCPs who work with minority populations.

*Some of the 120 FMs live with PWDs, allowing linkage between this subset of PWD and their FMs.

FM: family members; GPs: general practitioners; HCP: healthcare professional; PWD: people with diabetes

Fig. 1 – Composition of DAWN2 study population in each country.

2.5.3. Hybrid online and telephone methodology

In 11 DAWN2 countries with high internet penetration (USA, Canada, UK, France, Germany, Italy, Spain, Denmark, Netherlands, Poland, Japan) a hybrid online and telephone methodology is used to recruit PWD and FMs. In these groups, participants are enrolled using web-based recruitment or by telephone. This recruitment methodology is intended to ensure the study population in these countries is as representative as possible of the wider diabetes community and to address concerns regarding potential bias if the entire sample were obtained through web-based recruitment.

For the online sample, potential participants are identified from multiple online panels and databases per country. Individuals identified from these sources are contacted by email and invited to participate in the study. Participants recruited by telephone may complete the survey either by telephone or online. Depending on their preference, participants are either sent a web-link via email to complete the survey online or are interviewed by telephone.

For the telephone sample, potential participants are identified from a variety of sources (general telephone lists, proprietary databases, lists from past research, patient association lists). They are contacted by telephone and, if eligible, invited to participate in the study. Procedural details for non-web-based recruitment are country-specific and comply with local logistics and ethical regulations.

2.5.4. Face-to-face methodology

In the remaining six DAWN2 countries with lower internet access (Algeria, China, India, Mexico, Russia and Turkey) participants are recruited by telephone or face-to-face using telephone lists, patient association lists, proprietary databases, and hospital and physician directories. Participants complete the questionnaire via a face-to-face interview.

2.6. Questionnaires

The multi-dimensional scientific survey design for DAWN2 was developed by the Global DAWN2 Survey Working Group according to a person-centred model for chronic illness care with input from multi-national, multi-disciplinary meetings involving representatives of all the countries participating in DAWN2, and patient advocacy and scientific experts from the collaborating organisations. A summary of the main topics and subtopics covered by the PWD, FM, and HCP questionnaires is presented in Table 2. The questionnaires were designed to permit comparison across respondent types where possible.

The questionnaires incorporate several elements, including: items from the original DAWN study (to enable evaluation of trends in diabetes care over the past decade); newly developed questions (to investigate areas such as discrimination and the needs and preferences for better education and support); and open-ended questions (to capture the individual stories of the respondents). Some new questions were developed with inspiration from, or adapted/modified from existing validated instruments, as relevant in each case with the originators of the questionnaires, including the Diabetes Empowerment Scale-short form (DES-SF) [12,13]; Diabetes Family Behavior Checklist (DFBC) [14] and the Health Care Climate Questionnaire (HCC) [15]. In addition, several standardised instruments were incorporated into the questionnaires in original or shortened forms, including: the Problem Areas in Diabetes-short form (PAID-5) [12–20]; Patient Assessment of Chronic Illness Care (PACIC) [16,17]; Summary of Diabetes Self-Care Activities Measure (SDSCA) [21]; WHOQOL-BREF [22]; EuroQol (EQ-5D) [23]; and the WHO Well-Being Index (WHO-5) [24].

Table 2 – Summary of main topics and subtopics covered by the PWD, FM, and HCP questionnaires.

Topic	Subtopic		
	PWD	FM	HCP
Sociodemographics	Age; gender; height; weight; ethnic origin; country-specific education and income; country-specific socioeconomic questions; work situation; geographical location; country-specific region questions	Age; gender; ethnic origin; country-specific education and income; country-specific socioeconomic questions; work situation; geographical location; country-specific region questions	Age; gender; geographical location; years in practice/profession; area of speciality/subspecialty
Diabetes profile	Diagnosis; time of diagnosis; type of treatment received at diagnosis and currently; medication/treatment status (current diabetes treatment, types of pills, mode of insulin administration, number of insulin injections); hypoglycaemia (self-treated, severe, hypoglycaemia awareness); existing comorbidities/complications	Diagnosis; time of diagnosis; type of treatment received at diagnosis and currently; medication/treatment status (current diabetes treatment, types of pills, mode of insulin administration, number of insulin injections); hypoglycaemia (self-treated, severe, number of times received medical assistance, awareness); type of diabetes	Patients (%) with type 1/type 2 diabetes; medication/treatment status (current diabetes treatment, types of pills, mode of insulin administration, number of insulin injections)
Health and QoL	QoL (WHOQOL-BREF); health status (EQ-5D mobility, self-care, usual activities, pain/discomfort, anxiety depression, VAS Scale); emotional well-being/mental health (WHO-5); BMI; weight	QoL (self – WHOQOL-BREF); emotional well-being/mental health (self – WHO-5); weight	Patients (%) with clinical depression
Diabetes impact and burden	Diabetes distress (PAID); overall impact; impact on physical health; personal relationships; financial impact; productivity/work/leisure activities; impact on emotional well-being; depression related to diabetes; dietary restrictions	Diabetes distress (PAID Family Versions); overall impact; physical health; impact on personal relationships; financial impact; productivity/work/leisure activities; impact on emotional well-being; depression related to diabetes; dietary restrictions; burden of caring	Need for improvement in dealing with emotions around diabetes; societal burden of diabetes
Diabetes control	Perceived control; improvements needed in HbA1c; blood pressure; lipid profile/cholesterol; weight	Perceived control; improvements needed in HbA1c; weight	HbA1c levels; improvements needed in weight
Diabetes management	Self-management behaviours (SDSCA including diet, exercise, blood sugar testing, feet checking, taking medication, smoking); improvements needed	Self-management behaviours (improvements needed in diet, exercise, blood sugar testing/control, taking medication, dealing with emotions around diabetes, weight)	Self-management behaviours (improvements needed in: diet, exercise, blood sugar testing, taking medication, dealing with emotions around diabetes, weight, taking responsibility)
Family and social support	Non-HCP support behaviours (modified DFBC); non-HCP involvement; reasons for non-involvement; living situation; family conflict; overall social support	Non-HCP support behaviours (modified DFBC); non-HCP involvement; reasons for non-involvement; living situation; family conflict; split of responsibilities; overall social support; assistance with hypoglycaemia	Importance of family involvement

Table 2 (Continued)

Topic	Subtopic		
	PWD	FM	HCP
Healthcare support	<p>Person-Centred Chronic Illness Care: (modified PACIC/HCC: asking about QoL and medication problems, patient activation, listening, goal-setting, problem-solving, giving confidence, planning on-going family/community support, group interventions, pro-active follow-up, care organisation)</p> <p>Access to medical care/ medical supplies; accessibility; HCP assessments (HbA1c, blood pressure, lipid profile/ cholesterol, weight, feet, anxiety/depression, diet, exercise); early diagnosis</p>	<p>Accessing medical care; discussion/improvement of prevention activities; early diagnosis</p>	<p>Person-Centred Chronic Illness Care (HCPPACIC items/HCC version: asking about QoL and medication problems, patient activation, listening, goal-setting, problem-solving, giving confidence, planning on-going family and community support, group interventions, pro-active follow-up, overall care organisation); team care</p> <p>Access to medical care/ medical supplies; accessibility; HCP assessments (HbA1c, blood pressure, lipid profile/ cholesterol, weight, feet, depression, eyes)</p> <p>Practice/provision around: screening/early detection, diabetes prevention, HbA1c lab tests, emotional distress, structured education</p> <p>Clinic resources for: Care for vulnerable groups, individual counselling, IT-systems for quality monitoring/ improvement and coordinated care, involvement of patients to improve local care; healthcare remuneration system</p> <p>Role of dietitians/educators</p>
Education and information	<p>Education attended and helpfulness; education, information and support relied on, desired; understanding of medications</p>	<p>Education attended and helpfulness; education, information and support relied on, desired</p>	<p>Education attended, resources and referral options for HCPs; desired future training; role of educators and dietitians; information and support methods</p>
Workplace, community and wider environment	<p>Community/societal improvements (acceptance healthy eating, exercising, workplaces, early diagnosis and treatment)</p> <p>Discrimination; community support/activities; virtual support</p>	<p>Community/societal improvements (acceptance healthy eating, exercising, workplaces, early diagnosis and treatment, public awareness, prevention, good medical care)</p> <p>Discrimination; community support/activities; virtual support; tolerance; diabetes in the media</p>	<p>Community/societal improvements (acceptance healthy eating, exercising, workplaces, early diagnosis and treatment, public awareness, prevention)</p> <p>Discrimination; Community support, collaboration, prevention programmes; virtual support; reimbursement</p>
Attitudes and beliefs	<p>Illness and treatment beliefs and attitudes, activation and empowerment; intentions to improve self-management; medication beliefs; insulin beliefs; willingness to start medication; fear of hypoglycaemia; diet and exercise beliefs</p>	<p>Illness and treatment beliefs and attitudes, activation and empowerment, intentions to improve self-management; fear of hypoglycaemia; confidence in dealing with hypoglycaemia; inspiration from PWD; understanding of diabetes</p>	<p>Empathy, perceived influence on patient self-management; advocacy for patients; attitudes to patient responsibility; role of FMs; attitudes towards medications</p>

Table 2 (Continued)

Topic	Subtopic		
	PWD	FM	HCP
Wishes and future needs	Desired future family and social support; improvement areas in country/region; improvements in self-management	Desired future family and social support; improvement areas in country/region	Desired future family and social support; desired improvements of medications; improvement areas in country/region; improvements needed in medical care and psychosocial support
Personal experiences	Open-ended questions (impactful story about how to manage diabetes, challenges, successes, wishes)	Open-ended questions (impactful story about living with someone with diabetes/ involvement in diabetes care of PWD, challenges, successes, wishes)	Open-ended questions (challenges, successes, wishes)

DFBC, Diabetes Family Behavior Checklist; EQ-5D, EuroQol; FM, family members; HbA1c, glycated haemoglobin; HCC, Health Care Climate Questionnaire; HCPs, healthcare professions; PACIC, Patient Assessment of Chronic Illness Care; PAID, Problem Areas in Diabetes scale; PWD, people with diabetes; SDSCA, Summary of Diabetes Self-Care Activities Measure; WHOQOL-BREF, World Health Organization Quality of Life questionnaire; WHO-5, WHO (five) Well-Being Index.

All surveys were reviewed and approved in the original English version by leading experts from all participating countries. The three survey questionnaires in English were tested further with 16 participants (7 PWD, 3 FMs and 6 HCPs) from India, Canada, USA, and the UK, to assess whether the questionnaire content was unambiguous and understandable and to ensure face validity and acceptability. Questionnaires were subjected to additional written reviews by people with type 1 and type 2 diabetes prior to finalisation.

Questionnaires for the three surveys were translated into the primary language(s) of each participating country by at least two independent local professional translators who were native speakers in the relevant local language. These translations were reviewed by national diabetes experts in each country to confirm the accuracy and cross-cultural equivalence of the translations. A subset of selected psychometrically validated scales and items intended for scientific benchmarking within and across countries were back translated into English by a third independent professional translator and a review and harmonisation process was undertaken. This involved the approval by academic experts and originators of the original scientific scales, as well as PWD, where feasible. This process also involved multi-national harmonisation of previously published local language versions of scientific instruments, including the PAID-5, the WHO-5, the WHOQOL-Bref and the SDSCA.

2.7. Research questions

The DAWN2 surveys were designed to provide data-driven guidance relevant for all stakeholders in diabetes and chronic illness management regarding how diabetes care may be optimised locally, nationally or internationally at the micro, meso or macro level within a holistic person-centred chronic care framework. Key research questions include:

1. How do the participating countries compare in terms of healthcare processes and outcomes based on the measures

that are proposed as suitable for benchmarking (e.g., established validity and reliability of source measures)?

2. What are the determinants of QoL and psychosocial adaptation of PWD?
3. What are the determinants of self-management behaviour by PWD?
4. What are the determinants of HCP delivery of person-centred diabetes care/support (especially those forms of care/support that are found to have a major impact on patient outcomes)?
5. What are the determinants of burden for FMs and family support for PWD, especially those forms of support that are found to have a major impact on patient outcomes?
6. What is the current level of access to diabetes education, how is it provided, and what are the benefits to PWD? What are the roles of nurses, dietitians and other HCP providers?
7. What are the determinants of medication initiation, adherence, persistence and intensification?
8. What changes have occurred in the period between DAWN and DAWN2?
9. What are the key events that have created turning-points in how people live with and manage diabetes? What individual and societal changes do survey respondents want?

Numerous additional topics will be addressed, but a full listing of questions is beyond the scope of this paper.

2.8. Supplementary research

In parallel with the three main surveys, a separate situational assessment is being performed in each country, comprising literature research on national guidelines, policies and activities related to person-centred diabetes care, supplemented by interviews with a range of different national stakeholders. These are designed to provide an assessment of the existing diabetes and chronic care delivery systems in each country, against which the perceptions of survey respondents can be compared. Representatives of patient associations,

policy-makers and thought leaders in each country are key contributors to this study component. The situational assessment allows each country to benchmark itself relative to other countries in relation to health policies, guidelines, healthcare infrastructures, national programmes, and community structures related to person-centred chronic illness care, and to identify concrete opportunities for national improvement from the DAWN2 survey results.

2.9. Analysis

Survey data are provided to the Principal Investigators of each country's national advisory or survey group as descriptive statistics for all variables for each participant group. To permit generalisation from the sample to larger populations, individual weights are provided. These weights are based on population proportions for each country, as provided by each country's survey advisory group, and on publicly available epidemiological data.

Furthermore, the subset of FMs who live in the same household as individuals who complete the PWD questionnaire are linked to one another for analysis. This enables comparison of the perceptions of provision of practical and emotional care and support from both members of the dyad and assessment of the association between the behaviour of support givers and the impact on support recipients. For non-linked samples, concordance between respondents can be assessed statistically for items that are identical, but other items can only be compared numerically (e.g., the percentage of PWD who report engaging in a behaviour and the percentage of PWD that physicians estimate to engage in that behaviour).

Publications will use the appropriate statistical tests for a particular hypothesis and type of data. These include nonparametric bivariate statistics (e.g., chi-squared test, Kendall correlation coefficient, Mann–Whitney test, Kruskal–Wallis test), parametric bivariate statistics (e.g., analysis of variance, Pearson correlation) and multivariate tests (e.g., logistic regression, ordinary least squares regression, analysis of covariance).

In addition, psychometric validation of multi-item measures in each country will be performed to confirm cross-cultural validity and suitability for clinical and benchmarking purposes.

3. Discussion

The 'DAWN Call to Action' [5] identified strategic areas for the improvement of diabetes care by focusing on the psychosocial issues attached to living with diabetes [2,5]. Strategies for national action to improve access to person-centred diabetes care, as guided by the first DAWN study, included: (1) raising awareness of the PWD perspective, (2) empowerment of PWD through information and education, (3) training of HCPs, (4) development of innovative tools to deliver PWD support, (5) improvement of guidelines/policies for person-centred care, and (6) translational research into delivery of person-centred diabetes care.

Evidence suggests that substantial progress has been made within these areas, but there is a need for continued

implementation of these strategies, including training of HCPs in person-centred chronic illness care [25,26], new tools and intervention strategies for improving the psychosocial care of PWD [2,27], revision of guidelines to include sections on the self-management and psychosocial aspects of diabetes care [28–39], and research on psychosocial and person-centred diabetes care [40].

DAWN2 builds upon a decade of multi-nationally coordinated actions and efforts to improve person-centred care. Following DAWN, other diabetes surveys have been initiated to explore psychosocial issues in diabetes, but predominantly in relation to medical therapy and not addressing FM, community, or patient organisation perspectives.

The scope of DAWN2 is broad and should further our understanding of issues in diabetes and person-centred care, over and above that provided by other diabetes surveys. By surveying the attitudes, wishes and needs of over 16,000 people from the three stakeholder groups involved in day-to-day living with and management of diabetes, DAWN2 aims to provide a unique, comprehensive, systematic perspective on the facilitators and barriers to achieving optimal person-centred diabetes care.

The design of the DAWN2 questionnaires should enable identification of discrepancies between the 'felt needs' of PWD and their 'perceived needs' by FMs and HCPs. Comparisons of the results across countries, within the context of differing national guidelines, policies and care delivery models, may identify optimal and sub-optimal national and local models of care, education and community support. Through the cross-cultural validation of the multiple scientific measurement instruments incorporated into the DAWN2 survey, each country can incorporate mini-DAWN2 surveys into clinic, local, and regional quality improvement programmes, to allow for within-country benchmarking.

Comparison of DAWN2 data with those from DAWN allows for the determination of temporal trends in the profile of diabetes care and, possibly, whether differences between these data in countries that participated in both studies reflect a growing recognition and acceptance of the psychosocial aspects of diabetes care in the past 10 years.

3.1. Study limitations

Many challenges are associated with conducting DAWN2, the largest multi-national study of its kind in diabetes, including how to represent the population within each country accurately. Since DAWN2 aims to study variations in access to and consequences of diabetes care, community support and education within and between countries, samples needed to be geographically and socio-demographically dispersed in each country. Therefore, recruiting through a limited number of centres or clinics, as often done in diabetes surveys for practical reasons, would not be appropriate for DAWN2 as results would be biased towards well-resourced clinics.

While populations with internet access may be generally representative of the total population in some countries, internet methodology may not be fully representative. Phone recruitment was used to some extent in all countries to minimise a systematic bias related to internet use only. Moreover, weighting of the data from each country to national

proportions should help minimise such biases. However, in some countries, telephone penetration is poor. While the use of face-to-face recruitment and interviewing in the DAWN2 study helps overcome this barrier to representativeness, the expense associated with outreach to rural areas in countries with broad geographic dispersion makes sampling of all areas of the country infeasible. In addition, some countries and regions are not represented, e.g., Indonesia, Thailand, the Arab countries, sub-Saharan Africa and South America. Thus, results cannot be generalised to the entire global population of the three key diabetes stakeholder groups.

4. Conclusions

The original DAWN study identified a major gap between the psychosocial and educational support needs of PWD, and the care and support available in developed and less developed countries. However, despite developments in the field of self-management education and psychosocial care during the past decade, too many PWD receive inadequate care and support to enable them to achieve optimal health and well-being. In response, DAWN2 seeks to identify possible areas for improvement and determine the drivers of change to achieve optimal person-centred diabetes care. DAWN2 has been designed to facilitate easy translation of the study findings, including involvement of a broad foundation of multiple national and international diabetes stakeholders.

As the first major survey of the opinions of FMs of PWD, DAWN2 aims to achieve a broader humanistic and societal perspective on the needs of PWD and those caring for them. Responding to the IDF declaration on patients' rights and responsibilities, and including all areas of life with diabetes, it is hoped that DAWN2 will promote improvements in conditions for PWD. Ultimately, DAWN2 aspires to provide a voice for PWD and those caring for them, which reflects their unmet needs.

The DAWN2 study should enable new opportunities for improving diabetes self-management and QoL, and for ascertaining the critical drivers of active management as well as improvement in person-centred diabetes care. These findings may facilitate innovative efforts by all stakeholders to improve self-management and psychosocial support in diabetes.

Conflict of interest

Melanie Davies has acted as consultant, advisory board member and speaker for Novartis, Novo Nordisk, Sanofi-Aventis, Lilly, Merck Sharp and Dohme, and Roche, and as a speaker for Servier. She has received grants in support of investigator and investigator-initiated trials from Novartis, Novo Nordisk, Sanofi-Aventis, Lilly, Pfizer, Merck Sharp and Dohme, GlaxoSmithKline and Servier.

Richard Holt has received funding for travel and accommodation to attend DAWN2 International Publication Planning Committee meetings, but has not received any fee for this work from Novo Nordisk. He has acted as an advisory board member and speaker for Novo Nordisk, and as a speaker for

Sanofi-Aventis, Eli Lilly, Otsuka and Bristol Myers Squibb. He has received grants in support of investigator trials from Novo Nordisk.

Norbert Hermanns is a member of the International DAWN2 Advisory Board. He has received research grants in the last year from Roche, Berlin Chemie, Eli Lilly and Sanofi Aventis. He also received speaking honoraria from Novo, Germany, Lilly, Berlin Chemie, Lifescan, Sanofi Aventis and Menarini Diagnostics.

Antonio Nicolucci has received research grants in the last year from Novo Nordisk, Eli Lilly, Sanofi Aventis, Merck Sharp and Dohme, Bristol Myers Squibb-Astra Zeneca and Bayer.

Mark Peyrot has recently received research grants and/or consulting fees from Amylin, Genentech, Lilly, MannKind, Medtronic, and Novo Nordisk. He has received speaking honoraria from Novo Nordisk and has participated in advisory panels for Novo Nordisk and Roche. He has received financial support from Novo Nordisk for his participation as Principal Investigator for the DAWN2 study.

Johan Wens has acted as an advisory board member for Eli-Lilly, Bristol Myers Squibb-AstraZeneca and Novo Nordisk.

Søren Skovlund is an employee of Novo Nordisk A/S, Copenhagen, Denmark.

Angus Forbes, Ingrid Willaing, Sanjay Kalra and Katharina Kovacs Burns have no conflicts of interest to disclose.

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