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ORIGINAL RESEARCH

Breaking Barriers to Effective Type 2 Diabetes Management: Findings from the use of the OPTIMA© Questionnaire in Clinical Practice

André Grimaldi · Alfred Penfornis · Silla Consoli · Bruno Falissard ·

Elisabeth Eymard · Paul Williams · Sylvie Dejager

ABSTRACT

Background: The OPTIMA© (MSD, Courbevoie, France) questionnaire was developed to promote shared decisions and the set-up of specific micro-objectives in clinical practice by optimizing communication between type 2 diabetes (T2DM) patients and their physicians. The present study aimed to assess OPTIMA in clinical practice.

Methods: A cross-sectional multicenter observational study was conducted in France from 2012 to 2014. During routine consultation, patients completed one of the five modules of the OPTIMA questionnaire (Physical activity, Diet, Treatment, Knowledge of the disease or Self-monitoring of blood glucose). The rate of SMART (specific, measurable, acceptable, realistic, timely) micro-objective set-up following the use of the questionnaire was assessed. Data on how patients felt about their diabetes management (beliefs concerning actions, how easy they were to do and how often they were done in practice) were gathered. Finally, patients' and physicians' opinions on OPTIMA were assessed using the PRAgmatic Content and face validity Test

A. Grimaldi
Service de diabétologie, Institut E3M, Hôpital Pitié-Salpêtrière, Paris, France

A. Penfornis
Service d'endocrinologie, diabétologie et maladies métaboliques, Centre Hospitalier Sud-Francilien de Corbeil-Essonnes, Université Paris-Sud, Orsay, France

S. Consoli
Université Paris Descartes, Service de Psychiatrie de l'Adulte et du Sujet Agé, Hôpitaux Universitaires Paris Ouest, Paris, France

B. Falissard
Université de Médecine Paris-Sud, Ecole de Santé Publique Paris-Sud, INSERM U669, Paris, France

E. Eymard · S. Dejager (✉)
MSD, Medical Department, Courbevoie, France
e-mail: sylvie.dejager@merck.com

P. Williams
Mapi, Patient-Centered Outcomes, Lyon, France

(PRAC-Test© (Mapi, Lyon, France) evaluation questionnaire.

Results: Overall, 807 patients were included by 186 physicians. While 92.7 % of consultations led to the set-up of a micro-objective, only 22.3 % were SMART micro-objectives: Physical activity module (34.3 %), Diet module (9.6 %), Treatment module (16.4 %), Knowledge of the disease module (25.2 %), and Self-monitoring of blood glucose module (29.5 %). Among patients completing the Physical activity module, 79.0 % reported that they believed physical activity was useful, 35.0 % that it was easy, and 25.8 % that they regularly practised it. PRAC-Test results showed that OPTIMA was a useful and easy-to-use questionnaire that promotes communication between physicians and their patients according to 92.8 % of patients and 69.4 % of physicians.

Conclusion: The OPTIMA questionnaire facilitates communication between patients and their physicians and promotes the set-up of micro-objectives concerning T2DM management. The Physical activity module was the most likely of the five modules in the questionnaire to lead to the set-up of SMART micro-objectives.

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Keywords: Clinical practice; OPTIMA questionnaire; Shared decision-making; SMART micro-objective; Type 2 diabetes

INTRODUCTION

Regular physical activity, healthy eating, and medications to lower blood sugar levels are vital in the treatment and management of type 2 diabetes mellitus (T2DM) [1]. Increasing adherence to lifestyle recommendations and medications for diabetes is a public health priority both economically [2] and medically to avoid complications [3]. Lifestyle recommendations regarding the management of diabetes are primarily conveyed via the patient's physician (general practitioner—GP—or diabetologist) during routine consultations. However, current evidence reveals a lack of quality communication between patients and their physicians [3]. Patients with T2DM have expressed difficulties when asking for emotional support or for a more personalized way of managing their diabetes [3]. One possible reason for this may be the lack of physicians encouraging their T2DM patients to ask questions and to express concerns [4], perhaps due to difficulties talking about sensitive issues [5].

Furthermore, physicians tend to give vague lifestyle goals during consultations [6]. Patients may misunderstand these goals, because they find them difficult to achieve. They may also be uncertain of the extent to which they need to follow their physician's recommendations to achieve the goals given to them [6]. Eventually, these issues are likely to lead to a lack of patient adherence [7]. To make these goals easier to implement for physicians and patients, the concept of SMART (specific, measurable, achievable, realistic and timely) micro-objectives has been proposed [8, 9]. The use of SMART micro-objectives in practice has led to improvements in the micro-objective writing skills of physicians [7] and patients' perception of being well informed [10].

Over the past few years, patients have started to play a larger role in healthcare decision-making, in particular, when it comes to diabetes management [11, 12]. In parallel, the American Diabetes Association and the European Association for the Study of Diabetes released a position statement recommending that diabetes care be individualized and

consider the needs, preferences, and tolerances of each patient [11]. The two associations further noted that decision-making tools may help physicians gauge their therapeutic choices [11]. The ability of such tools to encourage the active involvement of patients in the decision-making process is well established, especially in regard to detail-oriented tools [13, 14]. To date, however, there are no validated tools designed to help patients with T2DM communicate with their physician to establish effective diabetes management plans.

The OPTIMA© (MSD, Courbevoie, France) questionnaire has been developed to fill this gap. Its purpose is to enable patients to recall personal beliefs and lifestyle behaviors, a process which "optimizes" communication between the patients and their physicians during the consultation. Patient responses to the questionnaire are used to facilitate the set-up of personalized and agreed-upon SMART micro-objectives. The questionnaire is made up of five modules, each specifically focused on one key area in T2DM management, either (1) physical activity, (2) diet, (3) treatment, (4) knowledge of the disease, or (5) self-monitoring of blood glucose.

The aim of this study was to assess the use of the OPTIMA questionnaire in routine clinical settings to assist physicians in identifying and setting up appropriate SMART micro-objectives (1) by analyzing the rate of set-up of SMART micro-objectives following the use of different OPTIMA modules by physicians during consultations; (2) by analyzing data from patients' responses to the OPTIMA modules compared to how patients' beliefs about the usefulness of an action, how easy they thought it was to perform, and how often they actually did it in their everyday lives; (3) by examining the opinions of patients and physicians on the use of the OPTIMA questionnaire.

METHODS

Study Design and Setting

The study was a cross-sectional multicenter observational study conducted in France from 2012 to 2014 involving patients presenting at their general practitioners (GPs) and diabetologists for a routine consultation.

Physicians who agreed to participate were given guidance on the study as part of their onboarding pack. Within this pack, general information about the study was given including recommendations on the administration of the OPTIMA questionnaire and the completion of The PRAgmatic Content and face validity Test [PRAC-Test© (Mapi, Lyon, France)]. Each physician had to recruit five patients consecutively over a 5-day period in the following order: the first two patients were to be randomly assigned to one of four OPTIMA modules (either Physical activity, Diet, Treatment or Knowledge of the disease). A predefined randomization process at the physician level was used to ensure a minimum of 100 patients for each of these modules. The third patient was to be assigned to the Self-monitoring of blood glucose module of OPTIMA. The fourth and fifth patients could choose which of the five OPTIMA modules they wanted to fill out. Patients were asked to complete the module alone in the waiting room or the consultation room. The physician could eventually finish the completion of the questionnaire with the patient during the consultation. Based on patient responses to the module, and discussion with their patients, physicians identified and set up a micro-objective. Then, the physician informed the patients about the study and invited them to participate. Upon patient's agreement and after verification of patient's eligibility, the

physician then attributed an identification number to each of their patients and completed the study documents including the PRAC-Test evaluation form, patient medical form, and a form on which they noted whether they had set up a micro-objective with their patient and if so, described the micro-objective in depth. Patients completed the PRAC-Test (version for patient). In case the patient refused to participate, the physician had to destroy all the documents completed by the patient.

To recreate real world settings, physicians were not given any specific guidance before the study began on how to set up SMART micro-objectives with their patients after the latter had finished the OPTIMA module.

To minimize bias in the completion of the questionnaire and the set-up of SMART micro-objectives, patients were given the module of the OPTIMA questionnaire to complete before being informed of the study.

A scientific committee was established at the onset of the project to provide methodological, scientific and clinical support and expertise at the milestones of the project. The scientific committee included four members, two diabetologist specialists working in clinical practice, one expert methodologist in questionnaire development and validation, and one psychiatrist.

Population

Physicians
Diabetologists and GPs were recruited from the network of the contract research organization in charge of fieldwork. They were randomly selected. Participation in the study was voluntary, after having been informed about the study objectives, process, and their role.

Patients
Patients were recruited by the diabetologists and GPs during a routine, spontaneous consultation. T2DM patients aged 35 years or above, with glycated hemoglobin (HbA1c) between 6.5% and 9.5%, and who had not achieved their HbA1c target set-up with their physician were eligible for study inclusion. They must have been receiving oral hypoglycemic agents (OHAs) for at least 1 year, without glucagon-like peptide-1 (GLP-1) analogs and without insulin.

Sample Size

The sample size was calculated to estimate the rate of consultations ending with the set-up of a micro-objective within a given confidence interval (CI). Assuming a rate of between 50% and 95%, a sample of 100 patients per module would be needed to estimate the rate with half-length of the CI less than or equal to 9.8%. The type 1 error rate was set at 5%.

Also, 100 patients were assigned to the Self-monitoring of blood glucose module to sharpen the estimation in this particular module, and 400 patients could freely choose which module they wished to complete. Two hundred physicians were targeted to recruit these 1000 patients.

Measures

Socio-demographic, clinical and biological data were collected for all patients from their patient records. Basic demographic data were collected for physicians.

OPTIMA Questionnaire
The OPTIMA questionnaire has been developed following a robust qualitative methodology involving patients with T2DM, GPs and diabetologists [The questionnaire has been

provided (in French) as supplementary material] [15, 16]. The qualitative analysis identified five well-known key areas for T2DM patients and physicians: physical activity, diet, treatment, knowledge of the disease and self-monitoring of blood glucose [15, 16]. A specific module containing between 8 and 21 items was developed around each of these key area (Fig. 1). Each item focused on a specific activity, for example, 'Moving as much as possible in the house'. Based upon an existing framework for patient-physician communication highlighting the importance of 'beliefs' and 'skills' [17], each item were designed around domains so that patients were able to describe their 'beliefs' about the activity's utility for controlling their T2DM, how 'easy' they thought the activity was to do and, where applicable, their 'actions' in their day-to-day lives in relation to each activity.

PRAC-Test and Patient-adapted PRAC-Test

The PRAC-Test was used to assess physicians' opinions about the OPTIMA questionnaire [18].

The PRAC-Test included 33 items that aimed to evaluate physicians' interest in the tool, the limitations they thought it had, how useful they thought it was, how long it took them to complete, how easy it was for them to use it and their intentions for using OPTIMA in their clinical practice in the future.

A version of the PRAC-Test was adapted for use with patients. It included the following three items: (1) 'easiness of understanding of the questionnaire', (2) 'usefulness of the questionnaire' and (3) 'whether the questionnaire facilitates communication between the patient and the physician'.

Analysis

All patients who met inclusion criteria and for whom a completed micro-objective form was available were included in the analysis. Patients were divided into two analysis sets: the Imposed OPTIMA Analysis Set (IOAS) included patients who had been assigned the module; the Free

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1.A. Moving as much as possible in the house is:

Very difficult for me	Difficult for me	Neither difficult nor easy for me	Easy for me	Very easy for me
$\square_1$	$\square_2$	$\square_3$	$\square_4$	$\square_5$

1.B. Moving as much as possible in the house is:

Completely useless for controlling my diabetes	Useless for controlling my diabetes	Neither useless nor useful for controlling my diabetes	Useful for controlling my diabetes	Very useful for controlling my diabetes
$\square_1$	$\square_2$	$\square_3$	$\square_4$	$\square_5$

1.C. Moving as much as possible in the house:

I never do	I do rarely	I do sometimes	I do often	I do always
$\square_1$	$\square_2$	$\square_3$	$\square_4$	$\square_5$

Note: Taken from the French version of the OPTIMA questionnaire. English translations for examples only. Linguistic validation of the questionnaire has not been conducted.

Fig. 1 OPTIMA questionnaire item example (Physical activity module, item 1)

OPTIMA Analysis Set (FOAS) included patients who freely chose their OPTIMA module.

The scientific committee reviewed all the micro-objectives reported by physicians to distinguish SMART micro-objectives from non-SMART micro-objectives.

The rate of consultations leading to the set-up of a SMART micro-objective was calculated by analysis set and by module, and a two-sided 95% CI was estimated using a normal distribution approximation. Univariate logistic regression models were used to estimate the odds of establishing SMART micro-objectives between modules and between analysis sets. The type 1 error rate of statistical tests was set to 5%.

Patient data were described according to the analysis sets and overall. Responses to the OPTIMA items were described using frequencies and percentages for all positive response options: for the 'easiness' domain, positive responses were 'easy' or 'very easy'; for the 'beliefs' domain, positive responses were 'useful' or 'very useful'; and for the 'actions' domain, positive responses were 'often' or 'always'.

PRAC-Test items were described for patients and physicians, and also according to physician specialty (GPs or diabetologists) using frequencies and percentages for all positive response options.

All analyses were performed using SAS® software, version 9.4 of the SAS System for Windows, SAS Institute Inc., Cary, NC, USA.

RESULTS

Study Population

A total of 186 active physicians recruited 829 patients. Out of these 829 patients, 807 (97.3%) patients met study inclusion/exclusion criteria and had complete data for the OPTIMA questionnaire and the micro-objective form, and were included in the analysis. Of these 807 patients, 511 (63.3%) were assigned an OPTIMA module, and 296 (36.7%) freely chose their module. The proportions of patients assigned to each OPTIMA module as well the proportions of patients freely choosing their module reflected the sampling design. The proportions of patients who freely chose each OPTIMA module were distributed unevenly, with a higher number completing Diet (35.8%) and Physical activity (31.4%) modules compared to the other modules (all <15%).

The consecutive recruitment of patients over a 5-day period for each physician proved to be difficult for many physicians, either due to patients' refusal, or patients not meeting the eligibility criteria in this timeframe. Therefore, the recruitment period had to be extended. However, the target sample size was still not reached at the end of the extended inclusion period.

Patient and Physician Characteristics

Patient socio-demographics and clinical characteristics are described in Table 1. There were no substantial differences between the IOAS and the FOAS samples. Overall, patients were representative of a T2DM population orally treated in France. Patients were mostly male (60.5%) with a mean age of 63.9 years. A majority of patients (62.0%) were retired, and 30.0% were employed. The mean duration of diabetes was 10 years. Cardiovascular risk factors were: hypertension (140/90 mmHg): 66.8%, obesity: 44.5%, and smoking: 13.6%. The majority of patients were being treated with either one (35.2%) or two (42.3%) OHAs and by design, no patients were being treated with insulin or GLP-1 analogs. Metformin was the

Table 1 Patient socio-demographics and clinical characteristics

	Total (N = 807)	IOAS (N = 511)	FOAS (N = 296)
OPTIMA module completed (%)			
Physical activity module	22.6	17.4	31.4
Diet module	25.0	18.8	35.8
Treatment module	17.5	19.0	14.9
Knowledge of the disease module	14.4	16.2	11.1
Self-monitoring of blood glucose module	19.6	28.0	5.1
Several modules	1.0	0.6	1.7
Age [mean years, (SD)]	63.9 (10.4)	64.3 (10.5)	63.2 (10.1)
Male (%)	60.5	61.4	58.8
Education level (%)			
Vocational certificate (≤CAP/BEP)	62.9	64.0	61.1
Professional certificate (≥BAC)	36.8	35.6	38.9
Missing	0.2	0.4	0.0
Professional status (%)			
Employed	30.0	27.8	33.8
Unemployed	4.7	4.5	5.1
Retired	62.0	64.4	57.8
Disabled	3.2	3.1	3.4
Missing	0.1	0.2	0.0
Time since diabetes diagnosis in years (%)			
<5 years	22.2	22.5	21.6
5–10 years	35.2	34.8	35.8
>10 years	40.9	40.7	41.2
Time since diabetes diagnosis [mean years, (SD)]	10.0 (6.8)	10.0 (6.8)	10.1 (6.7)
BMI (%)			
Underweight (<25)	16.2	17.0	14.9
Normal (25–30)	39.3	39.9	38.2
Obese (≥ 30)	44.5	43.1	47.0
Smoking status (%)			
Non-smoker	65.1	65.4	64.5
Smoker	13.6	12.7	15.2
Former smoker	21.3	21.9	20.3

Table 1 continued

	Total (N = 807)	IOAS (N = 511)	FOAS (N = 296)
Blood pressure in mmHg (%)			
≥130/80	84.9	84.0	86.5
≥140/90	66.8	67.3	65.9
HbA1c, [mean %, (SD)]	7.8 (0.6)	7.8 (0.6)	7.8 (0.6)
Total cholesterol [mean g/L, (SD)]	1.9 (0.4)	1.9 (0.4)	1.9 (0.4)
LDL [mean g/L, (SD)]	1.1 (0.4)	1.1 (0.4)	1.1 (0.3)
HDL [mean g/L, (SD)]	0.5 (0.2)	0.5 (0.2)	0.5 (0.2)
Triglycerides [mean g/L, (SD)]	1.6 (0.9)	1.6 (0.9)	1.7 (0.9)

IOAS Imposed OPTIMA Analysis Set, *FOAS* Free OPTIMA Analysis Set, *SD* standard deviation, *BMI* Body Mass index, *HbA1c* glycated hemoglobin, *LDL* low-density lipoprotein, *HDL* high-density lipoprotein, *CAP* Certificat d'Aptitude Professionnelle (Youth Training (NVQ Level 1,2), *BEP* Brevet d'Etudes Professionnelles (vocational high school), *BAC* Baccalauréat (bachelor degree)

most prescribed drug (82.7%), followed by sulfonylureas (49.6%), DPP4 inhibitors (40.4%), glinides (10.8%), and α-glucosidase inhibitors (2.9%).

Physicians were mostly male (65.6%) with a mean age of 53 years. The majority were GPs (78.5%), and 16.7% were diabetologists, seeing an average of 15 diabetic patients per week (GPs) and 28 diabetic patients per week (diabetologists).

Rates of SMART Micro-Objective set-up after using the OPTIMA Questionnaire

The rates of SMART micro-objectives set-up after using the OPTIMA questionnaire are reported in Table 2. Table 3 provides some examples of SMART micro-objectives per module that were established after OPTIMA completion. While the vast majority of visits (92.7% with a 95% CI: 90.9–94.5) ended with the set-up of a micro-objective, the rate of SMART micro-objective set-up was only 22.3% overall. The rates of SMART micro-objective set-up were similar for the IOAS and FOAS (21.2% and

24.2%, respectively; OR = 1.19, $p = 0.34$). Among the patients of the FOAS and IOAS, rates of SMART micro-objective set-up were highest in the FOAS for the Physical activity module (42.5% and 25.6%, respectively) and the Self-monitoring of blood glucose module (42.9% and 28.1%, respectively); rates were the lowest for the Treatment module (11.4% and 18.8%, respectively) and Diet module (10.7% and 8.4%, respectively). Regardless of whether patients were assigned to their module or freely chose it, patients completing the Physical activity module were five times more likely to establish a SMART micro-objective with their physician compared to those completing the Diet module (OR = 5.00, $p < 0.001$) and about three-times more than those completing the Treatment module (OR = 2.63, $p < 0.001$).

Responses to the OPTIMA Questionnaire

Median percentages of patient positive responses to the domains of the OPTIMA items per module are reported in Fig. 2.

Table 2 Rate of SMART micro-objective set-up

OPTIMA module	Total (N = 807)		IOAS (N = 511)		FOAS (N = 296)	
	n	% [95% CI]	n	% [95% CI]	n	% [95% CI]
All modules	173	22.3 (19.4; 25.3)	104	21.2 (17.6; 24.8)	69	24.2 (19.2; 29.2)
Physical activity module	58	34.3 (27.2; 41.5)	21	25.6 (16.2; 35.1)	37	42.5 (32.1; 52.9)
Diet module	19	9.6 (5.5; 13.7)	8	8.4 (2.8; 14.0)	11	10.7 (4.7; 16.6)
Treatment module	23	16.4 (10.3; 22.6)	18	18.8 (10.9; 26.6)	5	11.4 (2.0; 20.7)
Knowledge of the disease module	28	25.2 (17.1; 33.3)	18	22.8 (13.5; 32.0)	10	31.3 (15.2; 47.3)
Self-monitoring of blood glucose module	44	29.5 (22.2; 36.9)	38	28.1 (20.6; 35.7)	6	42.9 (16.9; 68.8)

IOAS imposed OPTIMA analysis set, *FOAS* free OPTIMA analysis set

Table 3 Examples of established SMART micro-objectives

Physical activity module

  Do 30 min using the exercise bike every day

  Walk for 30 min per day

Diet module

  Reduce alcohol intake to two glasses per day

  Reduce from 4 to 2 pastries per week

Treatment module

  Know the role of your medicines and the times to take them

  Take your medicines without forgetting any

Knowledge of the disease module

  Know your Hba1c level and your blood sugar target

  Know your blood pressure

Self-monitoring of blood glucose module

  Measure you blood sugar after lunchtime meals

  Measure your blood sugar every morning for 15 days

Hba1c Glycated hemoglobin

Physical Activity Module

A large majority of patients reported positive beliefs for all 13 activities of the Physical activity module, ranging from 65.4% for 'Gardening' to 85.7% for 'Going for walks on foot or bicycle rides'. Indications of 'easiness'

for these activities were less often reported, ranging from 23.1% for 'Doing a sports activity' to 52.7% for 'Moving as much as possible in the house'. Indications of actually performing these activities, 'actions', were less often reported and ranged from 8.2% for 'Using an exercise bike' to 47.3% for 'Moving as much as possible in the house'.

Diet Module

A majority of patients indicated positive beliefs for most activities of the Diet module, ranging from 32.2% for 'Accepting to eat without pleasure' to 95.5% for 'Managing my diet'. Indications of 'easiness' for these activities were reported by a minority of patients, ranging from 6.9% for 'Losing weight' to 71.8% for 'Reducing alcohol with meals'. Indications of actually performing these activities, 'actions', were also infrequently reported, ranging from 21.8% for 'Declining non recommended food for my diabetes when I am invited' to 73.8% for 'Reducing alcohol with meals'.

Treatment Module

A large majority of patients reported positive beliefs for most activities of the Treatment module, ranging from 52.5% for 'Understanding how each medicine works for
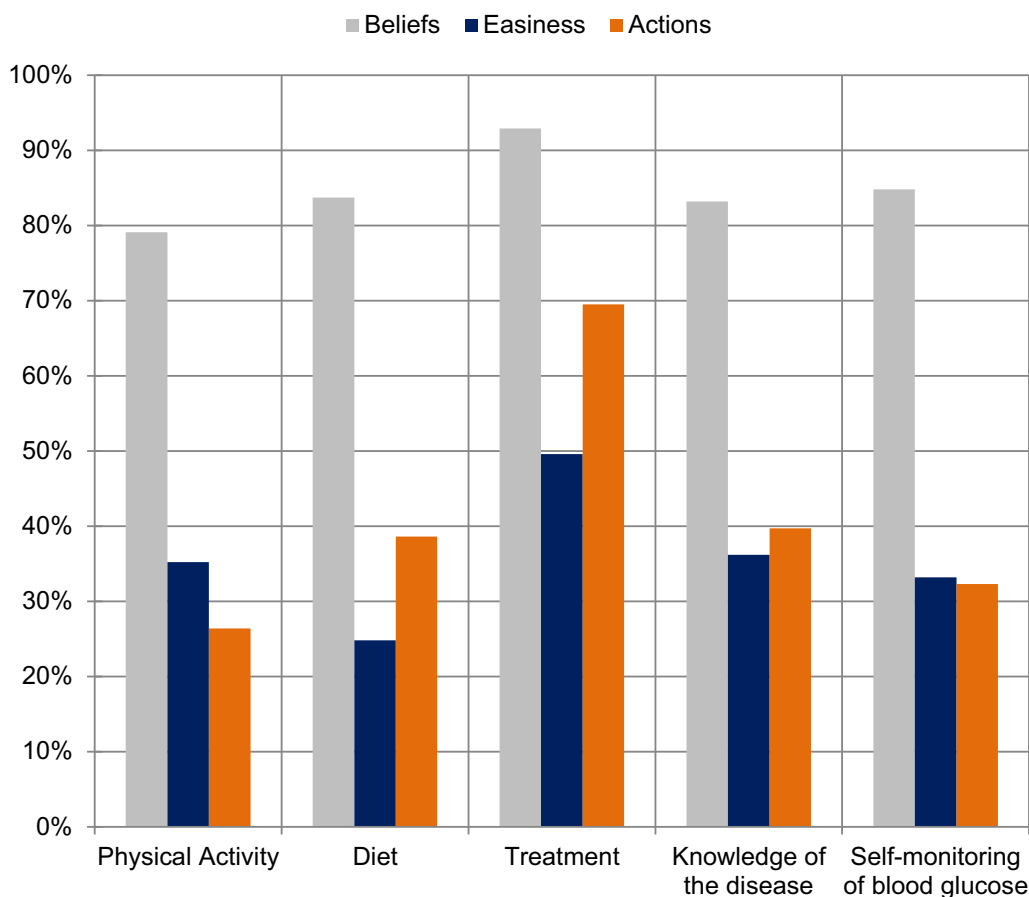
Fig. 2 Median percentage of patients responding positively to domains of OPTIMA questions per module

my diabetes' to 95.0% for 'Taking my medicines everyday'. Indications of 'easiness' for these activities were less often reported and ranged from 29.8% for 'Understanding how each medicine works for my diabetes' to 70.2% for 'Remembering to take my medicines'. Indications of actually performing these activities, 'actions', were reported by a majority of patients, ranging from 42.6% for 'Finding the answers to questions I have about my medicines' to 93.6% for 'Taking my medicine every day'.

Knowledge Module

A large majority of patients reported positive beliefs for all activities of the Knowledge module, ranging from 57.8% for 'Knowing my

target blood pressure' to 97.4% for 'Bringing down my level of sugar in the blood'. Indications of 'easiness' for these activities were less often reported and ranged from 12.1% for 'Bringing down my level of sugar in the blood' to 72.4% for 'Knowing my blood pressure'. 'Actions' were reported by 39.7% of patients in response to the question 'Bringing down my level of sugar in the blood'.

Self-Monitoring of Blood Glucose Module

A large majority of patients reported positive beliefs for all activities of the self-monitoring of blood glucose module, ranging from 62.0% for 'Withstanding pain when I prick my fingertip' to 96.2% for 'Changing my diet to correct my high blood sugar'. Indications of 'easiness' for

these activities were reported less often, ranging from 24.7% for 'Changing my diet to correct my high blood sugar' to 63.9% for 'Withstanding pain when I prick my fingertip'. Indications of actually performing these activities, 'actions', were also reported less often, ranging from 20.3% for 'Increasing my physical activity to correct my high blood sugar' to 65.8% for 'Withstanding pain when I prick my fingertip'.

Opinions About the OPTIMA Questionnaire

Patients' Opinions

The OPTIMA questionnaire was considered 'easy to understand' (responses 'yes' or 'mostly yes') by a large majority of patients (91.2%); this was similar across all modules. In decreasing order, these were: physical activity (96.2%), diet (92.6%), treatment (91.5%), self-monitoring of blood glucose (89.9%), and knowledge of the disease (81.9%).

Also, across all modules, a large majority of patients (92.8%) responded positively in regard to whether the module 'promoted communication with [their] physician'. In decreasing order, these were: physical activity (97.8%), diet (94.6%), self-monitoring of blood glucose (91.1%), knowledge of the disease (89.7%), and treatment (88.7%).

Last, across all modules, a large majority of patients (88.7%) responded positively in terms of the 'usefulness' of the module. In decreasing order, these were: physical activity (95.1%), diet (91.6%), knowledge of the disease (85.3%), self-monitoring of blood glucose (84.8%), and treatment (83.0%).

Physicians' Opinions

The OPTIMA questionnaire was considered 'easy to understand' (responses 'yes' or 'mostly yes') by a majority of GPs and diabetologists (69.2% and 77.4%, respectively). A majority of GPs and diabetologists responded positively in regard to whether the questionnaire 'promoted communication with [their] patients' (70.5% and 67.7%, respectively). Just over half of all GPs and diabetologists responded positively in regard to whether the questionnaire was 'useful' (66.4% and 54.8%, respectively).

A majority of GPs and diabetologists reported that the tool would be of benefit to patients (69.9% and 67.7%, respectively) and to physicians (54.1% and 58.1%, respectively). The most frequently reported uses of the tool were to 'help or follow observance or adherence' (71.2% of GPs and 80.6% of diabetologists) and to 'help adapt treatment' (41.8% of GPs and 32.3% of diabetologists).

Intention to use the OPTIMA questionnaire to any extent was highly reported by both GPs (95.5%) and diabetologists (92.5%). Intention of use for 'a majority' or 'all' of patients was reported as 55.4% for GPs, and 23.1% for diabetologists.

Most physicians (41.9%) reported that the questionnaire required an additional 15–30 min of consultation time (including explanation, administration of the questionnaire, dialogue, and micro-objective set-up). The remaining physicians reported either requiring less than 15 additional minutes (33.9%) or more than 30 additional minutes (0.5%) (23.7% did not answer this question). Physicians expressed that the required additional time was quick (45.2%) or not quick (26.3%) (23.1% did not answer this question).

DISCUSSION

This study aimed to assess the use of the OPTIMA questionnaire in routine clinical settings as well as the set-up of SMART micro-objectives following its use. Prior to the

analysis, an in-depth review of all micro-objectives by the scientific committee ensured that clinically meaningful SMART micro-objectives were distinguished from non-SMART micro-objectives. For example, a SMART micro-objective for the Physical activity module could be to walk for 30 min every day, or for the Diet module to reduce alcohol intake to two glasses per day. The rate of SMART micro-objective set-up was 22.3% overall. This rate of SMART micro-objective set-up was observed without any specific training given to physicians on the setting of SMART micro-objectives, which explains why the rate of SMART micro-objective set-up was much lower than the rate of any type of micro-objective being set up, whether SMART or not (92.7%). In fact, the micro-objectives recorded in the study varied considerably in terms of their content and specificity. The difference between the rates of any type of micro-objective set-up and SMART micro-objective set-up reveals a potential for improvement on the rate of SMART micro-objective set-up after having administered specific training for physicians [19]. Educational interventions for physicians and nurses have been shown to increase the setting of SMART collaborative goals [7, 10].

The rates of SMART micro-objective set-up were generally higher for patients who completed a module of their choice than for patients who had been assigned a specific module. Although the difference was not significant, the trends of higher rates of SMART micro-objective set-up among patients who choose their module may suggest increased success when patients are able to play an active role at an early stage of the clinical decision-making process. The difference between rates of SMART micro-objective set-up was especially apparent for the Physical activity module.

The OPTIMA questionnaire exposed specific gaps in T2DM management in regard to key activities that are important to patients and physicians. These gaps were characterized by a high report of patient beliefs that specific activities were useful in controlling their diabetes in contrast to the low reports that these activities were easy to perform and of actually implementing them in day-to-day life. For example, in terms of how easy it was for patients to perform activities, the maximum percentage of patients reporting that an activity was easy was never more than 72.4%. This was the case throughout all modules. In other words, for every activity described within the OPTIMA questionnaire, at least 27.6% of patients expressed that it was not easy to perform. These reports may highlight the presence of specific barriers that affect a large proportion of T2DM patients and inhibit them from performing particular activities. If this is the case, the identification of these barriers may lead to more effective T2DM management [20].

Report of implementing activities was low for the majority of modules. Physical activities appeared to be the least implemented of all with no more than half (47.3%) of all patients reporting often implementing any type of physical activity. In contrast, actions reported in the Treatment module in regard to taking medicines were more frequently reported. These results are consistent with a previous large study of diabetic patients which found that patients adhered to medications and dietary plans but failed to adhere to exercise recommendations [3].

The relationship between the report of 'easiness' and the report of actually implementing activities suggests an interesting tradeoff in the eyes of patients. For all the modules except Physical activity, patients often implemented 'actions' despite expressing a

degree of difficulty. In contrast, patients in the Physical activity module reported often not doing tasks even if these were perceived as relatively easy (see Fig. 2). Such reports may indicate that patients were transitioning through earlier stages of behavioral change when they completed the OPTIMA Physical activity module, as previously postulated in the Prochaska and DiClemente's stages of change model [21]. The role of physicians who exercise in informing and promoting behavioral change is likely to be key in successfully engaging patient motivation and involvement [22]. Future qualitative research could look deeper into this perceived tradeoff between 'easiness' and 'actions' concerning the implementation of healthy lifestyle behaviors.

According to the PRAC-Test, GPs and diabetologists found the OPTIMA questionnaire useful for monitoring compliance or adherence and for adapting treatment. They believed that it was an easy questionnaire to implement, that it was useful in their clinical practice and that it promoted communication with their patients. Patients' opinions regarding these three aspects were overall more positive than those of physicians. Patient opinions were the highest toward the Physical activity and Diet modules.

Results suggest that the Physical activity module is the most likely module to be of benefit to patients. First, the success of setting up SMART micro-objectives in the Physical activity module suggests that physicians and patients can, together, set up meaningful goals. Second, the gap between 'easiness' and 'actions' in the Physical activity module suggests that this is a fruitful area in which physicians and patients can set up feasible SMART micro-objectives. Third, the choice of this module by a large proportion of patients may indicate patient demand to focus on this area. Last, this appeared to be the most

well-received module, as indicated by the highest percentage of patients' reporting of usefulness on the PRAC-Test. Successful implementation of SMART micro-objectives may not only have benefit in one specific area. It has been suggested that because of increased patient empowerment, patients may actively engage in other healthy lifestyle behaviors in a virtuous cycle of improvements [23].

The study presents some limitations. As the study was conducted in a single country only, the findings are likely to not be generalizable as diabetes management, and patient attitude might differ from one country to another. Also, following the study design, physicians used more than one OPTIMA module, so physician opinions collected using the PRAC-Test could not be differentiated by module. Also, one could not tell from the current study whether the rate of SMART micro-objective set-up would have been different without the OPTIMA questionnaire. Finally, we acknowledge that the method of convenience sampling may have introduced bias in study results, but was the method ensuring minimal additional study related procedures into the real world setting. The method was also adapted for physicians seeing only a few diabetic patients, for whom it would have been difficult to generate lists of patients and randomize at that level.

The results of this study call for the prioritization of promoting physical activities for the management of T2DM. We propose that a decision-making tool such as the OPTIMA questionnaire be used in combination with the establishment of SMART micro-objectives. Evidence suggests that shared decisions lead to increased patient adherence to recommendations across different disease areas [14]. Furthermore, patients' desire for active involvement in their own healthcare has been

shown to be positively associated with control of their diabetes [24]. Future interventional research is now needed to provide evidence that the use of OPTIMA questionnaire increases set-up, retention, and completion of SMART micro-objectives and eventually leads to improved health outcomes.

CONCLUSION

The OPTIMA questionnaire is a useful and easy tool that could facilitate the communication between patients and their physicians, and promote the set-up of micro-objectives for T2DM management following consultations. In particular, the Physical activity module of the questionnaire was the most likely to lead to the set-up of SMART micro-objectives. Patients had high beliefs regarding the importance of specific activities for the management of their diabetes, yet they found activities difficult to perform, and consequently, did not perform them often. This was particularly the case for patients completing the Physical activity module. Future studies may consider giving specific guidance to physicians on how to formulate SMART micro-objectives to increase the set-up of SMART micro-objectives.

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Disclosures. AG, AP, SC and BF were involved in the development of the OPTIMA questionnaire. EE and SD are employees of MSD France, which owns the copyright of the OPTIMA questionnaire. PW is an employee of Mapi, the company commissioned by MSD to conduct the project. The OPTIMA questionnaire is protected by international copyright with all rights reserved to Merck Sharp and Dohme. For more information on, or permission to use the OPTIMA questionnaire and/or its translations, please contact Dr. Sylvie Dejager, MSD France, Tel: 00 33 1 80 46 41 88, email: sylvie.dejager@merck.com.

Compliance with ethics guidelines. The present observational study was conducted in accordance with the Helsinki Declaration of 1975, as revised in 2000 and 2008 and in accordance with the rules of the French Order of Physicians and Good Practices for Epidemiological Studies. Candidates for inclusion were provided with full written information about the study. All data processing was carried out in compliance with French Information Technology and Privacy Law.

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