Is My Patient Overwhelmed? Determining Thresholds for Acceptable Burden of Treatment Using Data From the ComPaRe e-Cohort

Viet-Thi Tran, MD, PhD; Victor M. Montori, MD, MSc; and Philippe Ravaud, MD, PhD

Abstract

Objective: To estimate the highest burden of treatment beyond which patients with chronic conditions consider their current investments of time and effort in health care unsustainable.

Patients and Methods: We used data collected between January 1, 2017 and October 1, 2018 in the Community of Patients for Research (ComPaRe), an ongoing e-cohort of adult patients with chronic conditions in France. We matched participants’ answers to the Treatment Burden Questionnaire (TBQ) and to a Yes/No anchor question: “Think about all the things you do to care for yourself. Do you think you could continue investing the same amount of time, energy, and money in your health care lifelong?” We defined the Patient Acceptable Symptom State (PASS) for the burden of treatment as the TBQ score below which 75% of patients reported an acceptable burden state.

Results: We analyzed data for 2413 patients (1781 [73.8%] women, 1248 [51.7%] multimorbid, median age: 48 (interquartile range, 36-59] years) enrolled in ComPaRe. Of these, 38% (917 of 2413) reported that they would be unable to continue the same investment of energy, time, and money in health care lifelong. The PASS for the burden of treatment was at 39% of the maximal score (ie, TBQ score = 59/150; 95% CI, 52-64) Using these results, clinicians can detect patients at risk for becoming overwhelmed by their medical care by identifying patients with TBQ scores of 59 or higher.

Conclusion: About 40% of patients with chronic conditions report being unable to sustain current investments of energy, time, and money in health care lifelong. The PASS for treatment burden provides a practical yardstick to help clinicians and researchers interpret scores for burden of treatment.

C hronic diseases affect more than 40% of adults, and their prevalence is rapidly increasing with the aging of the population.\textsuperscript{1,2} In 2030, about 14% of the US population could have diabetes and 41% is expected to have some form of cardiovascular disease.\textsuperscript{3,4} In addition, patients are increasingly likely to have multiple chronic conditions. Today, 23% of adults have multimorbidity (ie, at least 2 chronic conditions present in the same person); half are younger than 65 years.\textsuperscript{3}

Management of patients with chronic multimorbidity is complex and entails lifelong care with medications, tests, consultations, and lifestyle changes.\textsuperscript{3} For patients, coping with all these health care tasks requires a significant amount of additional time, effort, and attention. For example, patients with type 2 diabetes are expected to spend 143 minutes, on average, every day in recommended self-care.\textsuperscript{5} For patients with multimorbidity, the amount of time required to deal with all health care tasks can be comparable to a part-time job.\textsuperscript{6}

Thus, in addition to the burden of illness, patients with chronic conditions deal with a “burden of treatment,” defined as the health
care workload associated with everything they do to care for themselves and its impact on their well-being. Whenever the work imposed on patients for health care competes with demands in their social, family, and professional lives, it may exceed patients' capacity to do it. Patients weigh the expected benefits of pursuing care against its burden and may decide to intentionally not adhere to health activities. In previous research, the burden of treatment was associated with poor adherence to medications, lower satisfaction with care, and decreased quality of life.

Multiple patient-reported outcome measures (PROMs) have been developed to assess the burden of treatment. These measures are important for both clinical practice (eg, to objectively identify patients with high treatment burden and at risk for nonadherence) and for research (eg, to serve as outcomes for developing new interventions that are both effective and minimally disruptive to patients). However, the interpretation of PROMs assessing the burden of treatment might be difficult because these measures are continuous, whereas in clinical practice, it is often helpful to label individuals as having or not having an attribute, such as being "hypertensive" or not or being "at risk for being overwhelmed by their treatment" or not. How hard should a clinician try to adapt the patient’s treatment plan if the patient has a burden of treatment score of 15 (of 150)? Similarly, if after initiating a new treatment, the patient’s reported burden of treatment increases by 10 points (of 150), how worried should caregivers be? To answer these questions, clinicians need relevant thresholds to determine what constitutes an acceptable burden of treatment for patients with chronic conditions.

The objective of this work was to ascertain the highest burden of treatment beyond which patients with chronic conditions consider their current investments of time and effort in health care unsustainable over time.

For that, we repurposed the Patient Acceptable Symptom State (PASS) for the burden of treatment. The PASS is the level of a continuous treatment outcome measure below which patients consider themselves well. For example, most patients with knee osteoarthritis consider their pain acceptable when their score is less than 27 mm on a 0- to 100-mm visual analogue scale, thus defining a PASS of 27 mm for pain. By analogy, the PASS for burden of treatment represents the threshold above which patients perceive their burden of treatment as unsustainable over time.

With the PASS, continuous measures of the burden of treatment obtained from clinical research or practice can be categorized to express how many patients “feel well.” This categorization may help physicians communicate research results to their patients and improve shared decision making. For example, the statement “As compared with treatment B, treatment A reduces the average burden of treatment for patients by 10 points (of 150) on the Treatment Burden Questionnaire (TBQ),” which may be difficult to envision for patients and clinicians, can be expressed as “Among 100 people like you, 40 using treatment A will consider an acceptable/sustainable burden of treatment as compared with only 20 people using treatment B.”

**PATIENTS AND METHODS**

**Data Sources**

We analyzed data from the Community of Patients for Research (ComPaRe; www.compare.aphp.fr), an ongoing e-cohort of adult patients who report having at least 1 chronic condition (defined as a condition requiring health care for at least 6 months). Patients join ComPaRe to donate time to accelerate research on their conditions. They can do this by completing regular PROM and patient-reported experience measure instruments, suggesting ideas for new research, or participating in the setup or analysis of research projects. Recruitment in ComPaRe involves direct outreach to potential participants through widespread advertising in general and social media and partner patient associations, similar to other initiatives such as All of Us, the UK Biobank,
or the Nutrinet-Santé study. ComPaRe was approved by the Institutional Review Board at the Hôtel-Dieu Hospital (0008367).

To determine the PASS for the burden of treatment, we matched participants’ answers to the TBQ and their answers to an anchor question used to determine the PASS in rheumatology. The TBQ is a self-reported questionnaire assessing the burden of treatment without restricting its scope to a single condition or treatment context. It is composed of 15 items rated on a Likert scale ranging from 0 (not a problem) to 10 (big problem) related to the burden associated with taking medicine, self-monitoring, laboratory tests, physician visits, need for organization, administrative tasks, following advice on diet and physical activity, and social impact of the treatment. The total score is 150. The anchor question used to determine patients’ current state of burden of treatment was a Yes/No question inspired from the question used by Outcome Measures in Rheumatology to determine the PASS in rheumatology: “Coping with all health tasks imposed on you (visits, tests, medication, lifestyle changes, administrative tasks, etc) can sometimes take a lot of time, effort, money and sacrifice. Think about all the things you do to care for yourself. Do you think you could continue investing the same amount of time, energy and money in your health care lifelong?”

Statistical Analyses
To enhance the representativeness of our estimates, we used a weighted data set obtained by calibration on margins of our data that included sex-specific weights for age and educational level derived from National Census data describing the French population reporting at least 1 chronic condition. The main study results are presented using the recalibrated data. Raw results are provided in appendices.

First, we described the proportion of patients who answered the anchor question by reporting an unacceptable burden of treatment state. To better understand the underlying factors of this feeling, we compared how the different aspects of the burden of treatment (burden associated with medications, visits, tests, lifestyle changes, etc) varied between patients reporting an acceptable and unacceptable burden of treatment. In addition, we investigated whether depressive and anxiety symptoms, measured using the Patient Health Questionnaire-9 (PHQ-9) and Generalized Anxiety Disorder 7-item (GAD-7) scales, affected the feeling of having an unacceptable burden of treatment state.

Second, we calculated the PASS for the burden of treatment, which is the cutoff score of the TBQ that classifies patients in an acceptable or unacceptable burden-of-treatment state. Similar to other studies, this cutoff was defined as the TBQ score below which 75% of patients reported an acceptable burden state. CIs were obtained by using percentile bootstrap with 2000 replications.

RESULTS
We analyzed data from 2413 patients (1781 [73.8%] women) enrolled in ComPaRe between January 1, 2017, and October 1, 2018. Median age was 48 (interquartile range, 36-59) years. Participants’ diseases included diabetes (n=217), hypertension (n=231), cancer (n=147), rheumatologic conditions (n=653), and depression (n=152). In total, 1248 (51.7%) patients were multimorbid (Table).

After statistical calibration, 917 of 2413 (38%) participants found their treatment burden unacceptable. This figure ranged from 19% (50 of 266) for patients with cardiac conditions to 50% (69 of 137) for those with asthma.

All TBQ item scores were higher on average for patients who considered their burden of treatment unacceptable, with larger differences for items related to: (1) regular health care reminding patients of their health problems, (2) the financial burden of treatment, (3) the burden of arranging and adapting to medical appointments (physician visits, laboratory tests, and other examinations), and (4) difficulties in relationships with health care providers.
Among patients with available PHQ-9 and GAD-7 scores (n = 1753; 72.6%), levels of depression and anxiety symptoms were higher for patients with unacceptable vs acceptable burden of treatment (PHQ-9 mean score: 12.1 vs 8.0; \( P < .0001 \); GAD-7 mean score: 9.2 vs 6.4; \( P < .0001 \)).

The PASS for the burden of treatment assessed using the TBQ was 39.3% of the maximal score (TBQ score = 45; 95% CI, 26-77) to 58% for those with asthma (TBQ score = 87; 95% CI, 37-103; Figure 3, Supplemental Figure 3, available online at http://www.mayoclinicproceedings.org). The proposed PASS estimate (TBQ score = 59) was adequately discriminative in all subgroups tested (Supplemental Tables 1 and 2, available online at http://www.mayoclinicproceedings.org).

### DISCUSSION

In our study, about 40% of patients with chronic conditions considered their treatment burden unsustainable. Patients carry unsustainable burdens because of the imbalance between the high health care workloads, which add to the competing demands of life, and their limited capacity

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<td>Considered their burden of treatment unacceptable, n (%)</td>
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<td>TBQ scores, median [interquartile range]</td>
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aTBQ = Treatment Burden Questionnaire.

bWeighted data were obtained after calibration on margins for sex-specific age categories and educational level using data from a national census describing the French population self-reporting at least 1 chronic condition.

cTotal may exceed 100% because participants can have multiple chronic conditions.
to shoulder this burden and access, use, and perform health care tasks. The high proportion of patients reporting an unsustainable burden, across a broad range of conditions and treatment contexts, suggests that a considerable part of the burden is structural and results from how health care is organized rather than by specific patient, condition, or treatment factors.

To help clinicians identify patients at risk for or already overwhelmed by the health care tasks imposed on them, we defined and estimated the PASS for the burden of treatment, which represents the threshold of burden-of-treatment score above which patients believed that their burden of treatment was unsustainable over time. The PASS can help clinicians, patients, and researchers interpret and put into context burden-of-treatment scores in research, quality evaluations, and care.

Of note, there is no direct correspondence between the PASS value and the proportion of patients reporting that they
would not be able to continue the same investments of time and effort in health care over time. For example, both approximately 25% (41 of 162) of patients with cancer and with thyroid disorders (60 of 228) considered their treatment burden unacceptable, but the TBQ score above which most patients reported an unacceptable burden of treatment was higher for patients with thyroid disorders (70 vs 45). This finding may be explained in some situations by patients being willing to accept a higher burden of treatment due, for example, to differential perceptions, beliefs, or expectations in their treatments.

Our study has limitations. First, we provided a “global” value of the PASS, derived from a large but heterogeneous population of patients with a broad range of conditions, treatments, and context. Thus, the PASS may be nonoptimal in some specific subgroups of patients. However, our analyses showed that a TBQ score cutoff of 59 remained adequately discriminative in all subgroups tested. Second, despite the use of methods to enhance the representativeness of estimates, the generalization of our findings is cautioned because primary data were based on volunteers enrolled in an e-cohort who may be more likely to have reasons for dissatisfaction with their care. However, (1) estimates from the TBQ in ComPaRe were similar to those obtained from epidemiologic studies recruiting consecutive patients from both hospital and outpatient settings,9,10,14 and (2) the number of patients considering their treatment burden unacceptable was similar when analyzing raw and weighted data, which suggests that age, sex, and educational level do not play a major role in patients’ perceptions of being overwhelmed by care. Nonetheless, given the impact of health care organization on the workload transferred to patients, our findings may need to be reproduced in other health care systems.

Our findings have several implications. For clinicians, our results highlight a between-person variability of the burden of treatment and of how it could be accepted by patients, which calls for assessing the burden of treatment in each patient regularly. Regular assessments are necessary because treatment burden results from the

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**FIGURE 2.** Empirical cumulative distribution function for the burden of treatment scores. The cumulative distribution of scores is shown for the 2413 patients, including 1496 who considered their treatment burden acceptable (blue line) and 917 (green line) who considered it unacceptable. Estimates were obtained from the weighted data set after calibration on margins for sex-specific age categories and educational level using data from a national census describing the French population self-reporting at least 1 chronic condition. PASS = Patient Acceptable Symptom State.
dynamic interaction of workload and capacity. The perceived burden is likely to change as new challenges and opportunities appear in a person’s life or as new complications of disease or treatment emerge. Previously tolerated programs may become infeasible or, when obligatory, disrupt desirable life routines. We support efforts to care for all patients in ways that advance their health goals while minimizing the burden of treatment, a practice sometimes called minimally disruptive medicine. However, particular
efforts may need to be directed toward patients with a burden of treatment above the PASS. Efforts to minimize the burden of treatment include tactics to reduce workload (eg, ease access to and convenience of care, stop unnecessary or unwanted care, and fit the situation to the values and preferences of patients) and increase the ability to bear it (eg, capacity coaching, palliation of debilitating physical and mental symptoms, functional and occupational rehabilitation, financial support, and social integration).28

Second, on a research level, several recent trials aimed at testing new care models for multimorbid patients failed to demonstrate improvement in quality of life.29-31 Among potential explanations that investigators invoked were the broad inclusion criteria that may have selected patients not likely to benefit from the interventions, which in turn may have “diluted the potential effectiveness of the approach.”32(p11)

With the PASS, we offer the ability for researchers to develop interventions targeted at high-risk patients (ie, patients with burden-of-treatment levels above the PASS). These interventions could, for example, have components that adapt over time to patients’ responses and burdens of treatment, thus mimicking the “dance” of minimally disruptive medicine.33

Finally, for health care organizations, integrating burden-of-treatment measures as quality indicators for evaluating long-term care will support the transition from models of care focused on performance and disease control toward new patient-centered models of care focused on optimal care for these patients.34 In particular, analysis of patients’ profiles with burden-of-treatment levels remaining above the PASS could help care organizations identify priority populations for improvement and modify how they organize their provision of care.

CONCLUSION
About 40% of patients with chronic conditions report that they would not be able to sustain the same investment of energy, time, and money in health care lifelong. To help clinicians and researchers identify these patients, we provide the PASS for the burden of treatment.

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SUPPLEMENTAL ONLINE MATERIAL
Supplemental material can be found online at http://www.mayoclinicproceedings.org.

Abbreviations and Acronyms: ComPaRe = Community of Patients for Research; GAD-7 = Generalized Anxiety Disorder 7-item scale; PASS = Patient Acceptable Symptom State; PHQ-9 = Patient Health Questionnaire-9; PROM = patient-reported outcome measure; TBQ = Treatment Burden Questionnaire

Affiliations (Continued from the first page of this article.). Policy Research, Department of Health Sciences Research and Knowledge and Evaluation Research Unit, Mayo Clinic, Rochester, MN (V.M.M.); and Department of Epidemiology, Columbia University Mailman School of Public Health, New York, NY (P.R.).

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Correspondence: Address to Viet-Thi Tran, MD, PhD, Hôpital Hôtel Dieu, Centre d’Épidémiologie Clinique, Paris, France, 1 place du Parvis Notre-Dame, Paris 75181, France (thi.tran-viet@aphp.fr).

REFERENCES


