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Treatment Burden and Treatment Fatigue as Barriers to Health

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Abstract

Effective management of chronic diseases involves sustained changes in health behavior, which often requires substantial effort and patient burden. As treatment burden is associated with reduced adherence across several chronic conditions, its assessment and treatment are important clinical priorities. The balance between patient demands and capacity (e.g., coping resources) may be indexed by patients' subjective experience of treatment fatigue. We present a modified workload-capacity model that incorporates evidence that treatment fatigue may 1) be caused by increased workload due to treatment burden (e.g., intensity, complications) and 2) undermine adherence. Emerging technology-based interventions may be well-suited to reduce treatment burden, prevent treatment fatigue, and increase treatment adherence.

Chronic Disease and Health Behaviors

The leading causes of chronic disease and preventable death are attributed to modifiable risk behaviors [1], such as minimal physical activity, poor nutrition, tobacco use, and overconsumption of alcohol. Although numerous interventions have been found to promote health behaviors within clinical trials, these often fail to translate into sustained, real world effectiveness. This disconnect has been attributed, in part, to poor adherence to self-administered treatments (e.g., medication, behavioral strategies). Despite 182 randomized controlled trials (RCTs) of interventions designed to increase medication adherence, there is no clear solution [2]. To further complicate matters, medication adherence is typically only one component of an extensive set of treatment recommendations. For example, proper management of diabetes can require approximately two hours of daily care activities [3]. Similar levels of effort, sustained over time, are a necessary component of chronic care management for most health behaviors. Thus, treatment adherence in and of itself is a major health behavior.

Recognizing the substantial costs of developing treatments that patients will not adopt, clinical researchers have proposed frameworks to evaluate optimal dosing parameters (e.g.,

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duration, frequency, amount) for behavioral interventions [4, 5]. Behavioral interventions that are too burdensome, required too frequently, or incur too much effort will result in non-compliance. More is not always better, and increases in patient burden are a primary determinant of reduced adherence and effectiveness. Thus, the optimal dose for any behavioral intervention is that which results in maximum adherence. Adaptive treatment strategies (also called dynamic treatment regimens) are innovative personalized medicine approaches that tailor treatment delivery dynamically, to meet patients' changing needs [6, 7]. Guided by the assumption that optimal dosing may change over time, and unnecessary treatment provision can lead to patient overburden and treatment fatigue, one simulation study demonstrated that adaptive interventions can enhance effectiveness through *less* treatment [8].

The aforementioned studies suggest that treatment burden and treatment fatigue must be better understood and incorporated into healthcare if we hope to realize the full potential of rigorously tested interventions, and the future of behavioral medicine. Unfortunately, how best to conceptualize and quantify these constructs is unclear. Though the literature on adherence is vast, we herein review recent studies (since 2012) that address newer concepts that underlie adherence: treatment burden and treatment fatigue. We aim to characterize how these constructs are defined, measured, and influence health behaviors. Findings are integrated within an adapted model that views treatment adherence to depend on the balance between patient workload and capacity (Figure 1, discussed further below) [9]. Demands associated with disease management represent treatment burden. Together with general life demands (e.g., job, family), they comprise overall patient workload. When workload exceeds capacity (e.g., resources, abilities, readiness, and disease symptoms or illness burden), this potentiates treatment fatigue, and ultimately disengagement from recommended health behaviors (i.e., non-adherence).

Treatment Burden

The science of treatment burden has advanced substantially since 2012. Several qualitative studies have been conducted to conceptualize patient concerns [10, 11], and examine how well these are addressed by primary care providers [12]. These studies are complemented by systematic reviews of studies that examined treatment burden both qualitatively [13, 14] and quantitatively [15, 16]. Studies reviewed rarely focused on treatment burden specifically, but a priori definitions of burden were used to identify relevant patient responses. As indicated in Table 1, these studies are inclusive of different patient populations and assessment methods, but several common themes were observed. There is clear evidence that treatment burden is experienced by patients with at least one chronic health condition, and this affects many aspects of their lives.

Measures of treatment burden are often specific to a single medical condition, although patients are often diagnosed with several. The Treatment Burden Questionnaire was designed to capture a broader assessment of burden across any medical condition, or set of conditions [17, 18]. A global score is derived by summing 0 (not a problem/not applicable) to 10 (large problem) ratings for 15 items. Four items address taking medicine, and the remaining assess self-monitoring, laboratory tests, doctor visits, need for organization, administrative tasks, following advice on diet and physical activity, social impact of treatment, and financial burden. Global treatment scores are negatively correlated with adherence and quality of life. However, this measure fails to address the emotional distress that is so often associated with treatment adherence directly.

Treatment Fatigue

Beyond assessment of treatment burden (i.e., how much effort is required for a given health behavior), a growing area of interest focuses on the impact of that burden. There is extensive research on physical fatigue caused by specific interventions (e.g., chemotherapy among cancer patients), but we focus on the psychological fatigue associated with treatment engagement, herein called treatment fatigue. This nascent literature is mostly restricted to diabetes and human immunodeficiency virus (HIV) management.

In a qualitative study of adults with type 1 diabetes patients attributed non-adherence to treatment fatigue [19]. Known also as “diabetes overwhelmus,” “diabetes emotional distress,” and “diabetes burnout” [20], patients describe treatment fatigue as feeling overwhelmed by the cumulative effort of disease management. Such themes are consistent with item content within diabetes-specific questionnaires that assess burden of disease management. For example, the emotional burden subscale of the Diabetes Distress Scale includes items such as “feelings that diabetes is taking too much of my mental and physical energy” and “feeling overwhelmed by the demands of living with diabetes” [21]. Elevated fatigue is observed among those who experienced complications or had more intensive regimens. Even in cases where patients engage in proper disease management, fatigue may still result if such patients perceive negligible benefits (e.g., “I’m doing all the right things, but it isn’t doing any good”).

A systematic review identified 17 studies that addressed fatigue associated with chronic disease management among people living with HIV [22]. To consolidate the vast terminology (e.g., pill-, medication-, treatment-, regimen-, dosing-, drug-, and injection-fatigue), the authors recommended future use of treatment regimen fatigue, which they defined as decreased desire and motivation to maintain vigilance adhering to prescribed treatment regimens. Consistent with the diabetes literature, fatigue was positively associated with treatment intensity and complications (e.g., side effects), and negatively associated with adherence.

Integrative Model and Clinical Implications

The treatment fatigue literature within diabetes and HIV both point toward the need for common terminology, definition, and measurement tools. A broader conceptualization of fatigue, across a range of chronic health behaviors, would facilitate a transdiagnostic understanding. Our workload-capacity model (Figure 1) incorporates the evidence that treatment fatigue may 1) be caused by increased workload due to treatment burden (e.g., intensity, complications) and 2) undermine adherence. This is consistent with limited resource models, such that expending effort on a task can lead to subjective fatigue and diminished performance on subsequent tasks [23]. However, limited resource theory cannot address why fatigue occurs, for example, among diabetic patients whose workload remains constant, who experience minimal treatment benefits. This observation is better explained by motivational control theories of fatigue [24–28], where fatigue serves as an indicator of inefficient resource allocation. In other words, without tangible benefits (i.e., symptom reduction), the patient is likely to decrease adherence and allocate capacity elsewhere, even when demands are unchanged.

We could only find one study to examine the temporal dynamics of treatment fatigue, but results support the importance of noticeable benefits from adherence. Within a clinical trial of 1504 daily smokers (each randomized to placebo, monotherapy, or combination therapy) [29], a single-item measure of cessation fatigue ("I am tired of trying to quit smoking") was assessed daily for two weeks post-quit. Fatigue increased across time, was negatively associated with abstinence at 6-month follow-up, and was positively correlated with daily ratings of nicotine withdrawal (craving and negative affect). As treatment dose/intensity increased, both withdrawal symptoms and treatment fatigue were reduced. This suggests active treatments increased capacity (e.g., via withdrawal reduction) to a greater degree than they increased treatment burden, which created a balance in favor of abstinence.

The integrated model makes clear predictions that fatigue (and subsequently non-adherence), can result from at least one of four pathways: 1. increased workload, via general demands; 2. increased workload, via treatment burden; 3. decreased capacity, via general resources; and 4. decreased capacity, via illness burden. This model is in need of further testing, especially given the recency of studies that address fatigue/burden. There are many unanswered questions within this model, including the threshold of burden or fatigue that has bearing on clinical outcome, the longitudinal course of fatigue, and the degree to which these constructs are disease-specific vs. general. As treatment fatigue assessments are further developed, they could serve as triage tools, with elevated fatigue indicating the need for a comprehensive evaluation of workload and capacity, and specifically the four pathways noted above. Fortunately, these pathways also offer potential intervention targets when fatigue is observed.

Our adapted model also recognizes that treatment adherence results in reciprocal feedback that adjusts both workload and capacity, and this too may determine sustainability of health behaviors. Intuitively, treatment recommendations will have direct effects on treatment and illness burden, but they can also influence general demands and capacity. For example, practicing cognitive-behavioral techniques to help curb smoking (e.g., cognitive restructuring, relaxation, problem solving) may generalize and build capacity in other areas of patients' lives. Therefore, interventions that improve capacity broadly may be more sustainable than those of equivalent workload that focus on illness alone.

Potential Applications

With the exception of one study [29], the concepts of treatment burden and fatigue have not been applied to understand the most common sources of morbidity and mortality: obesity, nicotine dependence, or alcohol dependence. These are chronic and relapsing conditions that require substantial effort to change, and may be susceptible to the same patterns described above. It is unclear if burden and fatigue will manifest differently when attempting to change behaviors that are hard to reduce (e.g., smoking), hard to sustain (e.g., exercise, medication adherence), or both (e.g., diet) [30].

Additionally, the burden and fatigue associated with adhering to psychosocial therapies has yet to be explored. Patients report the use of psychosocial skills to overcome treatment burden, for example: problem-focused strategies (e.g., routines, planning, using technology); emotion-focused coping strategies (e.g., positive attitude, focusing on other life priorities, and spirituality/faith); and cognitive restructuring (e.g., recognizing and challenging beliefs about treatment burden) [31]. Use of these strategies to overcome other forms of treatment burden suggests they enhance capacity and impose minimal burden, but this remains an empirical question.

We are now at the forefront of a new wave of behavioral health care [32], one that encompasses technological innovation, to meet and treat patients at times and places where they are most susceptible to treatment fatigue. Such technologic strategies could ultimately have a very large impact on adherence behaviors, thereby augmenting chronic care treatment for health. Predictions from the workload-capacity model presented herein (Figure 1) could help guide how these technologies are applied to meet their full potential.

Future of Chronic Care

Behavioral intervention technologies offer scalable approaches to reduce patient efforts [33–36], and are evolving rapidly [37–39]. Mobile phones are owned by 90% of American adults [40], representing a platform to increase accessibility to chronic care. Mobile health interventions (mHealth) can facilitate communication between health care providers and patients, thereby reducing burden associated with travel (e.g., transportation costs, time). Although mHealth has typically been limited to those that deploy static messages at fixed schedules [41, 42], recent applications have been more interactive and may allow for treatment delivery when capacity is compromised [43]. Patients can self-report the need for treatment delivery in real time, and patient history can even be used to proactively offer interventions [44].

The next generation of mHealth is working towards automatic treatment delivery by leveraging sensors that are part of smartphones (e.g., global positioning system [GPS], Bluetooth, accelerometers, magnetometers, gyroscopes, cameras and microphones) or can be integrated with phones (e.g., biosensors) [43]. Data from these sensors can be paired with self-report to predict contextual factors that undermine or promote health behaviors (e.g., location, physical activity, driving, social interaction, stress). This information can be used to inform machine learner models, such that sensor data alone can predict contexts and trigger intervention delivery. Patients may be willing to train models early in treatment, when fatigue is low, which would facilitate automatic treatment delivery at later times when fatigue increases, ultimately preventing burden and optimizing treatment effectiveness.

Context sensing technologies are also beginning to show potential. For example, one study demonstrated that a smartphone application incorporated with GPS prevented relapse among alcohol dependent patients leaving residential treatment [45]. Patients registered locations where they previously obtained or consumed alcohol, and were provided treatment support when they approached high-risk locations. This automatic yet personalized treatment component allows patients to prepare for high-risk situations before they arise, or to avoid them altogether. That is, it can reduce the amount of effort typically needed to monitor high-risk situations, and to resist them. These are but a few examples of the many innovative strategies that might sustain patient engagement (i.e., protect against fatigue) over the long term.

Conclusions

Chronic disease management requires substantial effort, and is associated with both positive and negative consequences. The balance between patient demands and capacity may be indexed by treatment fatigue, and will determine the sustainability of the behavioral change (i.e., adherence). This suggests the need for ongoing efforts to reduce treatment burden and/or increase patient capacity to undertake necessary health behaviors. Innovations in technology-based interventions (e.g., mHealth) are well positioned to meet this need.

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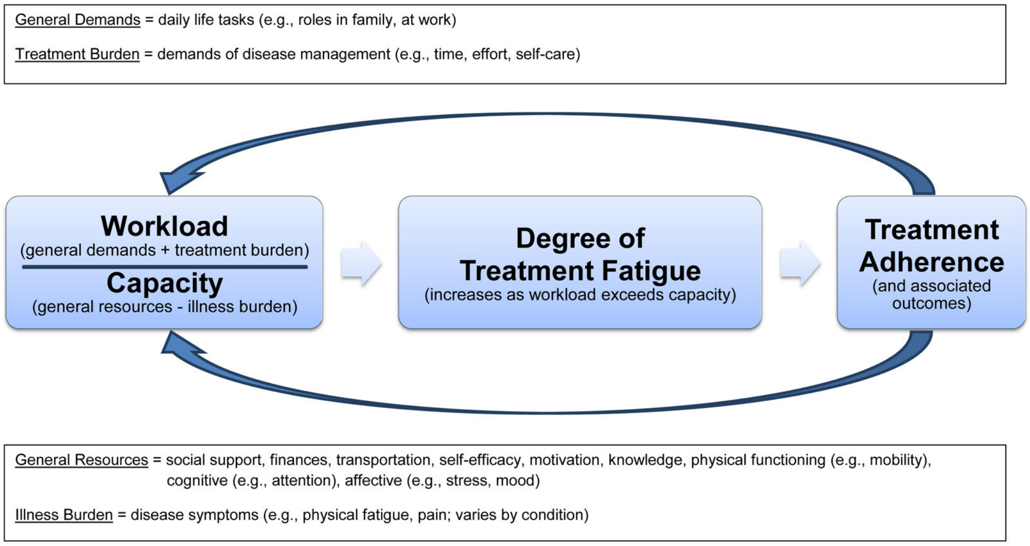
Highlights

1. Burden associated with chronic care management may undermine treatment adherence.
2. Treatment fatigue may index when patient demands exceed coping capacity.
3. Treatments should aim to minimize treatment burden and increase patient capacity.
4. Technological innovations offer promising tools to reduce patient burden.
5. Additional research is needed to better understand treatment burden and fatigue.



General Demands = daily life tasks (e.g., roles in family, at work)

Treatment Burden = demands of disease management (e.g., time, effort, self-care)

General Resources = social support, finances, transportation, self-efficacy, motivation, knowledge, physical functioning (e.g., mobility), cognitive (e.g., attention), affective (e.g., stress, mood)

Illness Burden = disease symptoms (e.g., physical fatigue, pain; varies by condition)

Figure 1.

Modified workload-capacity model.

Table 1

Characteristics of treatment burden reviews.

First Author	Publication Year	Chronic Condition(s)	Type of Studies	Number of Studies	Themes Identified
Eton	2013	diabetes, kidney disease, heart failure	quantitative	98	emotional impact/regimen-related distress, family conflict/unsupportive behavior, treatment convenience, self-care convenience, monitoring burden, lifestyle impact (social, work interference), scheduling flexibility, medication side effects, diet/food-related problems, device function/bother, economic burden, and overall treatment burden
Gallacher	2013	stroke	qualitative	54	making sense of treatment and planning care, interacting with others, enacting management strategies (institutional admissions, managing stroke in the community, reintegrating into society, adjusting to life after stroke), and reflecting on management
Gallacher	2013	stroke	qualitative	69	making sense of treatments, planning recovery and care, interacting with others, institutional admissions, managing stroke in the community, reintegrating into society, adjusting to life after diagnosis, and reflecting on management
Sav	2013	asthma, diabetes, cardiovascular disease, musculoskeletal illness, cancer, and mental health	qualitative and quantitative	30	physical (side effects), financial (care/travel), temporal, and psychosocial time demands (roles, caregiving)