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Treatment burden and chronic illness: Who is at most risk?

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Abstract

Background: There is a need to ascertain the type and level of treatment burden experienced by people with co-morbidities. This is important in order to identify the characteristics of participants who are at most risk of treatment burden.

Objective: The aim of this study is to identify the characteristics of participants who are at most risk of treatment burden.

Methods: This cross-sectional study was part of a larger project and recruitment was conducted across four Australian regions: rural, semi-rural and metropolitan. Participants were asked about their treatment burden using an adapted version of a measure, which included the following five dimensions: medication, time and administrative, lifestyle change, social life, and financial burden.

Results: In total, 581 participants with various chronic health conditions reported a mean global treatment burden of 56.5 out of 150 (SD = 34.5). Number of chronic conditions (β = .34, p < .01), age, (β = -.27, p < .01), the presence of an unpaid carer (β = .22, p < .001), and the presence of diabetes and other endocrine conditions (β = .13, p < .01) were significant predictors of overall treatment burden. For the five dimensions of treatment burden, social, medicine and administrative burden were predicted by the same cluster of variables: number of conditions, age, presence of an unpaid carer and diabetes. However, in addition to these variables, financial dimensions were also predicted by education level, ethnicity and health insurance. Educational level also influenced lifestyle burden.

Conclusion: A substantial proportion of community-dwelling adults with chronic conditions have considerable levels of treatment burden. Specifically, health professionals should provide greater focus on managing overall treatment burden for persons who are of young age, have an endocrine condition or an unpaid carer, or a combination of these factors.

Key Points for Decision Makers

- Healthcare systems and professionals should mostly be aware of younger adults with multiple chronic when designing interventions to reduce treatment burden.

- Although the social, medicine and administrative burden of burden are highly inter-related and could be addressed through the same changes in medical practice, further strategies are required for lifestyle and financial dimensions.

1. Background

The challenge for health professionals has shifted from treating acute illness to helping people manage chronic conditions [1, 2]. Chronic conditions or illness, such as diabetes and cardiovascular disease, are now in epidemic proportions globally, but the impact or burden of treatment on patients remains poorly understood. The 'work' of living with a chronic condition, labelled as treatment burden, can be overwhelming for many people. This can involve using medications, visiting multiple health professionals, self-monitoring, having medical and laboratory tests, and lifestyle change, e.g. physical exercise [1, 3]. The concept of treatment burden can extend to learning about treatments and their consequences, engaging with and mobilising support networks and adhering to treatment changes. Tran et al., [4] in the taxonomy of treatment burden, indicated that healthcare which imposes a burden on patients includes: management of medications, organising and performing non-pharmacological treatment, lifestyle changes, condition and treatment follow-up, organising formal caregiver care, paperwork tasks, and learning and developing an understanding of illness and treatment. More recently, Demain et al., [5] drew attention to the sociological aspect of treatment burden, suggesting that burden is not only brought about by the workload associated with treatment, but also the impact of that workload on everyday activities and patient identity.

Although the term treatment burden has been used interchangeably with the 'burden of illness', there is a fundamental difference between the two concepts. Treatment burden focuses on negative experiences resulting from the process of undertaking treatment, whereas the burden of illness refers to the impact of a chronic illness on a person [6]. Thus, treatment burden is a constructed concept that could be minimised by thoughtful intervention(s) within the healthcare system.

Despite its overarching aim to improve health and wellbeing, the healthcare system actually contributes to treatment burden through poor coordination of healthcare services, unhelpful professional-patient relationships and inadequate information [7, 8]. Furthermore, there is evidence that health professionals lack the tools to identify those people who are overwhelmed by the 'work' of being a patient and implement strategies to ease this burden [9]. As noted by Eton et al. [8], in response to poor patient outcomes health professionals can intensify therapeutic treatment (e.g. increase medication use, the provision of additional services), resulting in more work for the patient and ultimately, greater treatment burden. Therapeutic interventions should assess treatment burden and adopt strategies to minimise the 'work' of being a patient, otherwise treatment burden can lead to treatment non-adherence, side effects or worsening or recurrence of symptoms, poor quality of life and ineffective use of finite health resources [10, 11].

Most validated measures of treatment burden have been developed for specific chronic conditions, such as diabetes and asthma [12, 13]. Even within some of these studies, treatment burden has generally been included as one component within a multidimensional instrument, specifically designed to measure overall quality of life and treatment satisfaction [10]. Yet, chronic conditions rarely occur in isolation, with many people experiencing co-morbidity of at least two or more conditions [14]. In Australia, 20% of the population experience multiple chronic conditions [15]. Not surprisingly, there is evidence that treatment burden increases with co-morbidity [1], suggesting that the experiences of people with multiple and more complex conditions may be different from those people with only one condition [10]. There is clearly a need to ascertain the type and level of treatment burden experienced by people with co-morbidities.

The aim of this study was to identify the characteristics of participants who are at most risk of treatment burden. The findings will inform the way in which healthcare systems can target and respond to the needs of those people experiencing treatment burden. An understanding of the predictors of treatment burden will increase the ability of health professionals to identify whether patients are feeling overburdened by their treatment, thereby tailoring appropriate treatment strategies to meet their individual needs.

2. Methods

2.1. *Design and Recruitment*

This cross-sectional study was part of a larger project, which explored the experiences and expectations of people with chronic conditions and/or their carers of health professionals and health services. Ethical approval was obtained from a tertiary institution and from one state Government Health Department). To participate in the study, participants needed to have one or more chronic condition(s), or be an unpaid carer of someone with a chronic condition, or both (a carer who personally had a chronic condition). Recruitment was conducted across four Australian regions: Logan-Beaudesert and Mount Isa/North West regions of Queensland, the Northern Rivers area of New South Wales and the greater Perth area of Western Australia. These regions reflected significant diversity in geography (e.g. metropolitan versus rural), accessibility, socioeconomic status and culture.

Recruitment for the study involved an intensive campaign conducted through Non-Government consumer organisations (e.g. Diabetes Australia), community pharmacies and local area health services. Advertisements were placed in suburban and regional newspapers, promotional flyers were distributed in public places and email

distributions were sent through membership/client lists of key health and professional organisations and services. Recruitment occurred in places likely to be visited by people with chronic conditions, such as hospital clinics, cardiac rehabilitation units, and community pharmacies. Face-to-face recruitment was conducted at various shopping centres, malls and markets to access those who may not be regular health service users. To ensure diversity, Aboriginal and Torres Strait Islander peoples and those from culturally and linguistically diverse backgrounds were recruited from community groups and Non-Government organisations servicing these communities.

2.2 Measures

The survey incorporated measures of treatment burden, self-reported health status, health service utilisation, and socio-demographics. It also included a discrete choice experiment to elicit healthcare preferences, which has been reported elsewhere [16]. Further details on these measures are provided below.

2.2.1 Treatment burden

Participants were asked about their treatment burden using an adapted version of a measure developed and validated by Tran et al. [1] in France in 2012, called Treatment Burden Questionnaire© (TBQ). This measure was chosen as it was, at the time, the most comprehensive generic measure (i.e. not specific to a single condition) of treatment burden identified in the literature. Additionally, the TBQ© was rigorously developed and validated by Tran et al. [1]. For example, the authors conducted factor analysis, construct validity and the test-retest method to ensure appropriate psychometric development of the instrument. Tran et al. [4] subsequently validated the measure in an English speaking population in 2015, which was unavailable during the data collection stage of this study. In their most recent version, Tran et al included a question about relationships with healthcare providers and a question about financial burden. We had already included a question measuring financial burden and an additional question about side effects of treatment, which was not asked by Tran et al in [1]. The inclusion of financial burden and the subsequent validation of the original TBQ© measure in an English speaking, community based population strengthens the use of this tool in the present study.

Initially, Tran et al. [1] developed a measure to assess treatment burden "associated with the following four categories: (i) taking medicines, (ii) self-surveillance, laboratory tests, doctor visits, need for organization and, administrative tasks, (iii) following advice on diet and physical exercise and (iv) social impact of the treatment" (p.

2). Recently, Tran et al. [4] found that the themes identified in their study complemented their treatment burden questionnaire they developed three years earlier.

Tran et al. [17] suggested that new items could arise in different contexts, and the measure was adapted to suit the social and cultural context of Australia. For example, because of the financial circumstances of the French public health system (free healthcare for patients with chronic conditions), Tran et al. [1] did not measure the financial burden of treatment. Hence, we included the following item to measure the financial burden of treatment: *the financial impact of your medication and treatment (e.g. paying for medication and healthcare professional fees, paying private health insurance premiums, losing your income, etc.).* Furthermore, the original measure did not incorporate side-effects of treatment, particularly medication. However, our research and a review of the literature indicated that the side-effects of medication were a common burden for people. Hence, we included the item: *the side-effects of your medication, treatment and medical tests.*

Other minor grammatical changes were made to the original measure to suit the Australian context. Overall, treatment burden was measured via 15 items in our survey (Table 1). Our adapted measure included the following five dimensions: medication burden (5 items on the burden associated with medicine use and its side effects), time and administrative burden (5 items on the burden associated with self-surveillance, doctor visits, need for organization, administrative tasks, etc.), lifestyle change burden (2 items on the burden associated with changing lifestyle, i.e., diet, exercise, sleep), social life burden (2 items on the burden associated with social life, i.e., family and relationships), and financial burden (1 item on the burden of costs of treatment and/or out of pocket expenses). For each item, participants were asked: *when thinking about your treatment(s), how would you rate the following? (select one number only).* Each item was measured using a scale of 0 to 10, (0 = no burden, 5 = some burden, 10 = considerable burden), with higher scores indicating higher levels of burden. In the current study, the Cronbach alpha coefficient for the 15 item treatment burden measure was 0.93, indicating good levels of internal consistency.

Table 1

2.2.2 Self-reported health status

Participants self-reported the number, type and duration of diagnosed chronic condition(s). Researchers clustered the responses into the following categories: diabetes and other endocrine conditions, cardiovascular conditions, mental

illness, musculoskeletal conditions, respiratory conditions and cancer. We also measured participants' experiences of their chronic condition(s), and their frequency of medication and health and pharmacy services use.

2.2.3 Socio-demographic characteristics

A range of socio-demographic characteristics including age, gender, income, level of education, employment status, marital status, ethnic or cultural background, receipt of a government concession (i.e. increased or basic subsidies for healthcare costs), possession of private health insurance, and presence of an unpaid carer (i.e. a person who is not an employed carer, such as a family member) were collected.

2.3 Procedure

Data collection was mostly conducted by an independent Computer Assisted Telephone Internet (CATI) provider. The survey was first sent to an English language consultant with substantial experience working with health consumers to ensure that it was written in 'plain English.' The survey was then pilot tested by the CATI provider with a convenience sample of 36 participants (recruited from the personal contacts of all researchers) and minor amendments were made. Data collection was conducted between October 2013 and January 2014. The CATI provider sent surveys to participants for pre-reading approximately one to two weeks prior to conducting the survey. A CATI representative then contacted each participant via telephone to undertake the survey. Method and time of contact was based on each participant's personal circumstances. For example, some participants were contacted via landline and others via cell (mobile) phone. A small number of interviews were conducted face-to-face by the research team ($n = 54$) to ensure inclusion of participants who were considered difficult to reach by telephone or who might have preferred face-to-face discussion. This included Aboriginal and Torres Strait Islander peoples, culturally and linguistically diverse participants and younger employed men. Participants were offered a supermarket gift voucher (AU$50) as reimbursement for their time.

2.4 Data analysis

Analyses were conducted using SPSS Version 22.0 and Stata 13 software. Data were initially analysed descriptively. For each participant, the individual treatment burden item scores were summed to give a global score out of 150 indicating total treatment burden; higher scores represented a higher level of burden.

Treatment burden and chronic illness

Stepwise multiple regression was used to test the ability of independent variables to predict overall levels of treatment burden (primary analysis) and treatment burden for each of the five dimensions (secondary analyses). The predictors were separated into two groups: (a) personal characteristics, and (b) disease characteristics. Groups of predictors were entered into the model simultaneously and then removed individually in a stepwise approach. The beta coefficients (β) were inspected to assess the unique contribution of each variable in predicting overall treatment burden. A $\beta = .10$ was considered to be a small effect, $\beta = .30$ was a medium effect, and $\beta = .50$ was a large effect (Cohen, 1988).

There is only limited published data available in Australia about the demographic characteristic of individuals with chronic condition(s). We compared our sample to participants from the (Australian) National Health Survey 2007-8 [18] that reported one or more chronic conditions (i.e. cardiovascular conditions, diabetes, cancer, asthma, arthritis, osteoarthritis and mental health conditions; Table 3). There were no significant differences in age, the proportion identifying as being from an Australian background, those reporting two or more conditions, or reporting a cardiovascular condition. However, females, those with a higher educational qualification, lower income or in receipt of government concession benefits, were over-represented in our sample whereas the employed and those with private health insurance were under-represented. Participants with diabetes and other endocrine, respiratory, or musculoskeletal conditions, cancer, or mental illness were over-represented in our sample.

3. Results

3.1 Sample characteristics

Of 600 participants who consented to participate, 581 completed the surveys (Table 2). Participants had a mean age of 57.28 years (SD = 15.64) and the majority ($n = 407$; 70.0%) were female. Nearly one quarter ($n = 139$; 23.9%) experienced a chronic condition and also provided unpaid care for someone else. Although 59.7% ($n = 359$) of participants reported being from an Australian (non-indigenous) background, other participants were from diverse

cultural backgrounds, including Chinese, Filipino, Pacific Islander people, German, Italian, and New Zealanders. Furthermore, 8.7% ($n = 52$) of participants identified as being from an Aboriginal or Torres Strait Islander background. All participants had at least one chronic condition, but the majority ($n = 501$; 86.2%) reported having two or more chronic conditions. The most prevalent conditions were musculoskeletal conditions (e.g. arthritis, osteoporosis, chronic neck/back pain), cardiovascular conditions (e.g. heart disease, high blood pressure) and mental illness (e.g. anxiety, depression).

3.2 Description of treatment burden

Participants reported a mean global treatment burden of 56.5 (SD = 34.5) out of a possible score of 150 (where higher scores represent higher burden). When analysed individually for the five dimensions of treatment burden (highest possible score of 10), the highest levels of burden were reported in the financial (mean=5.4, SD = 3.6), lifestyle (mean=4.1, SD = 3.0), and social (mean = 4.0, SD = 3.1) dimensions, followed administrative (mean= 3.5, SD=2.4) and medicine (mean= 3.5, SD= 2.5).

For treatment burden specifically, significant univariate positive relationships (Table 4) were found for the number of co-morbidities (.30, $p < .01$), mental illness (.25, $p < .01$), presence of an unpaid carer (.23, $p < .01$), diabetes-related conditions (.15, $p < .01$), and musculoskeletal conditions (.12, $p < .01$). The only significant negative relationship for treatment burden was with age (-.16, $p < .01$). Number of co-morbidities was found to have strong positive relationships with various types of chronic disease categories: mental illness (.51, $p < .01$), musculoskeletal conditions (.50, $p < .01$), respiratory conditions (.49, $p < .01$), cancer related conditions (.42, $p < .01$), and cardiovascular conditions (.40, $p < .01$). Number of co-morbidities showed a weaker relationship with diabetes-related conditions (.21, $p < .01$), compared to other disease categories. Age also showed significant relationships (in terms of size and statistically) with a number of variables, including income (-.27, $p < .01$), reaching the Pharmaceutical Benefits Scheme (PBS) Safety Net[1] (.33, $p < .01$), number of co-morbidities (.27, $p < .01$), cardiovascular conditions (.46, $p < .01$), and musculoskeletal conditions (.28, $p < .01$).

Table 4

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[1] A government concession whereby the cost of prescription medicines for individuals and families is reduced once the PBS Safety Net threshold has been reached

3.3 Multivariate regression

3.3.1 Total treatment burden

Following stepwise multiple regression, the final model specification had statistically significant predictive capability ($F(4, 558) = 38.78$, $p < .001$). Twenty-one per cent of the variation in overall treatment burden was explained by the set of independent variables ($R^2 = .22$; adjusted $R^2 = .21$). Table 5 shows the raw and standardized regression coefficients of the predictors along with their correlations with treatment burden and their squared semi-partial correlations. The following four variables made significant ($p < .001$) contributions to the prediction of overall treatment burden: age, presence of an unpaid carer, number of chronic conditions, and the presence of diabetes and other endocrine conditions.

Number of chronic conditions received the strongest weight in the model (standardised coefficient, $\beta = .34$, p < .01), followed by age, ($\beta = -.27$, p < .01), the presence of an unpaid carer ($\beta = .22$, p < .001), and the presence of diabetes and other endocrine conditions ($\beta = .13$, p < .01). The remaining variables did not have a significant impact (p ≤ 0.1) on the prediction of treatment burden: gender, being a carer or consumer, marital status, income, employment status, educational background, ethnic or cultural background, government concession, private health insurance, cardiovascular conditions, mental illness, musculoskeletal conditions, respiratory conditions, and cancer.

Table 5

The raw beta coefficients from the model suggest that the mean treatment burden for participants with one chronic condition other than an endocrine condition (including diabetes) and no unpaid carer was 62.8 (SE 5.0) out of a possible score of 150. The presence of an unpaid carer was associated with an increase in treatment burden of 17.6 units, each additional chronic condition with an increase of 4.8 units, and the presence of an endocrine condition with a further 9.7 unit increase in treatment burden. Conversely, each additional year of age was associated with a reduction of 0.6 units in treatment burden.

3.3.2 Treatment social burden

The final model specification (following stepwise multiple regression) had statistically significant predictive capability ($F(4, 518) = 29.60$, $p < .001$). Eighteen per cent of the variation in overall social burden was explained by the set of independent variables ($R^2 = .19$; adjusted $R^2 = .18$). Only the number of chronic conditions (standardised coefficient, $\beta = .27$, $p < .001$), the presence of an unpaid carer ($\beta = .26$, $p < .001$), age ($\beta = -.21$, $p < .001$), and the presence of diabetes and other endocrine conditions ($\beta = .11$, $p < .001$) were significant predictors.

3.3.3 Treatment medicine burden

The final model specification (following stepwise multiple regression) had statistically significant predictive capability ($F(4, 517) = 26.14$, $p < .001$). Sixteen per cent of the variation in overall medicine burden was explained by the following set of independent variables ($R^2 = .17$; adjusted $R^2 = .16$): number of chronic conditions (standardised coefficient, $\beta = .32$, $p < .001$), age ($\beta = -.24$, $p < .001$), the presence of an unpaid carer ($\beta = .17$, $p < .001$), and the presence of diabetes and other endocrine conditions ($\beta = .09$, $p < .050$).

3.3.4 Treatment administrative burden

The final model specification (following stepwise multiple regression) had statistically significant predictive capability ($F(4, 516) = 24.77$, $p < .001$). Sixteen per cent of the variation in overall administrative burden was explained by the following set of independent variables ($R^2 = .16$; adjusted $R^2 = .16$): number of chronic conditions (standardised coefficient, $\beta = .25$, $p < .001$), age ($\beta = -.21$, $p < .001$), the presence of an unpaid carer ($\beta = .19$, $p < .001$), and the presence of diabetes and other endocrine conditions ($\beta = .18$, $p < .001$).

3.3.5 Treatment lifestyle burden

The final model specification (following stepwise multiple regression) had statistically significant predictive capability ($F(4, 518) = 18.80$, $p < .001$). Fifteen per cent of the variation in overall lifestyle burden was explained by the set of following independent variables ($R^2 = .16$; adjusted $R^2 = .15$): number of chronic conditions (standardised coefficient, $\beta = .30$, $p < .001$), the presence of diabetes and other endocrine conditions ($\beta = .18$, $p < .001$), age ($\beta = -.15$, $p < .001$), the presence of an unpaid carer ($\beta = .10$, $p < .001$), and educational background ($\beta = .10$, $p < .05$).

3.3.6 Treatment financial burden

The final model specification (following stepwise multiple regression) had statistically significant predictive capability ($F(7, 518) = 15.72$, $p < .001$). Seventeen per cent of the variation in overall financial burden was explained by the following set of independent variables ($R^2 = .18$; adjusted $R^2 = .17$): number of chronic conditions (standardised coefficient, $\beta = .29$, $p < .001$), ethnic background ($\beta = .19$, $p < .001$), age ($\beta = -.18$, $p < .001$), presence of private health insurance ($\beta = .16$, $p < .001$), the presence of an unpaid carer ($\beta = .15$, $p < .001$), and educational background ($\beta = .09$, $p < .05$).

4. Discussion

Despite recent popularity, the description and measurement of treatment burden is an area in need of substantial development and research. This is the first study to attempt to describe overall treatment burden in a large sample of Australians with multiple chronic conditions. There is little data against which we can compare the mean global treatment burden in our sample. In developing this instrument, Tran et al. [1] divided their sample into three clusters with mean global scores of low = 11.3 (SD = 9.2), moderate = 34.6 (SD = 11.1) and high = 65.8 (SD 18.1) out of 130; these clusters were defined as low, moderate and high treatment burden respectively. Although their sample was not comparable to ours as over half were hospital inpatients, our community sample reported at least a moderate level of treatment burden (mean = 56.5, SD = 34.5 out of 150) using these cut-off points. However, what was notable in our sample was the substantially greater variation in burden than found in the original hospitalised sample used by Tran et al. [1] suggesting a more heterogeneous experience following discharge, as would be expected. Our study has indicated that a substantial proportion of community-dwelling adults with chronic conditions have considerable levels of treatment burden. Importantly, these levels of burden may be amenable to prevention through the provision of adequate support and/or different professional practices. The impact of these high levels of treatment burden remains unknown and often undetected.

As expected, treatment burden increased with an increasing number of chronic conditions. However, treatment burden also decreased with increasing age, which appeared counter-intuitive, given that illness and medication use increases with age. Age was also a significant predictor of all domains of treatment burden. For example, age showed significant relationships (in terms of size and statistically) with income (-.27, $p < 0.001$), reaching the Pharmaceutical Benefits Scheme (PBS) Safety Net (.33, $p < .001$), number of co-morbidities (.27, $p < .001$), cardiovascular conditions (.46, $p < .001$), and musculoskeletal conditions (.28, $p < .001$). This may be explained in the context of the significant

relationship between age and employment. For instance, younger individuals are more likely to be in employment, and therefore, in the Australian health system, less likely to have a concession card that reduces the co-payment cost associated with obtaining medicines and other treatments. Indeed, existing research suggests that some participants prioritise their medications according to cost and their capacity to pay, and at times, decide not to purchase medications that are not covered by pharmaceutical concession [6]. However, this effect may also be associated with the fact that burden of this kind is more socially sanctioned in older people and may be perceived as having greater impact on lifestyle for younger people. Alternatively, it may suggest that people become accustomed to what they have to do and see it as less burdensome or have more time when they retire. Clearly, the reasons why younger age was associated with increased burden is worthy of further research.

Although having more chronic conditions predicted increased treatment burden, a self-reported presence of diabetes or another endocrine condition was associated with a substantial increase beyond that associated with number of conditions. The presence of diabetes, which is a growing chronic condition in developed nations, was associated with an increase in treatment burden three times that observed in other conditions and appeared to be particularly relevant to social, medical and administrative burden rather than lifestyle and financial burden. Previous research has identified the extensive treatment burden in patients with diabetes associated with continual monitoring, medication administration, access to services and treatment side-effects [19]. Importantly, this finding confirms that simplifying the management of diabetes represents an opportunity to minimise treatment burden. The only dimension of treatment burden not impacted by diabetes was financial burden, perhaps reflecting the assistance that is available through the national diabetes program in Australia.

Having an unpaid carer predicted a substantial increase in treatment burden. However, it is possible that when health deteriorates to the point that one's relatives or friends are imposed upon to provide care, one's sense of burden increases as a result of guilt and shame. Interestingly, treatment burden was not associated with being both a consumer and a carer, suggesting that being forced to receive care may be perceived as a greater source of treatment burden than having to provide care. We believe this may reflect the possible psychological states of some carers and carer-recipients. For example, carer-recipients may experience feelings of guilt and shame for burdening a family member to care for them while carers may feel a sense of self-worth and satisfaction for caring for a loved one.

When the five components of treatment burden were examined separately, social, medicine and administrative burden were predicted by the same cluster of variables (i.e., number of conditions, presence of an unpaid carer, age

and presence of diabetes). This finding suggests that these elements of burden are highly inter-related and could be addressed through the same changes in practice. However, unlike these dimensions of burden, lifestyle and financial dimensions of burden were predicted by education level. Thus, lifestyle and financial burden appeared to be experienced more by people with higher levels of education. This finding could reflect the possibility that those with higher levels of education were engaged in activities that were significantly disrupted by treatment activities (e.g., employment, studying). Financial burden was predicted by a number of additional variables, namely; ethnicity and health insurance. Those who had private health insurance and those from a non-Caucasian background experienced higher levels of financial burden. Increasing rates of premiums individuals must pay to maintain private health insurance and the low levels of English literacy among non-Caucasian backgrounds (who may be less able to navigate the health care system or understand their treatment) may offer a possible explanation for these findings.

Strengths of this study include the use of face-to-face interviews to involve those unable to use the telephone or who preferred this interaction, and the large and diverse sample, with a strong representation from Aboriginal or Torres Strait Islander Australians and ethnic minority groups. To our knowledge this is the first study that has combined the analysis of patient treatment burden with that of unpaid carers. Including unpaid carers to the study sample represents a significant contribution to the literature on treatment burden because unpaid carers may be managing their own illnesses, in addition to doing the "work" of alleviating a family member's treatment burden. Whilst there were some differences in the characteristic of our sample and this of the general Australian population who report chronic condition(s), this does not limit our analyses, which sought to identify predictors of treatment burden in those with chronic condition(s). Further, whilst this survey was undertaken in an Australian population, it would be reasonable to consider that the predictors of treatment burden might be similar in other high-income countries where the health system is similar, such as the United Kingdom, Canada, and some parts of Europe – although this would need confirmation with further studies. Our study aimed to access the opinions of individuals who were regular users of pharmacy and healthcare services, as well as those who were not. Thus, the conclusions drawn from our study require confirmation in other samples before they can be generalised to the Australian population, or indeed other populations, more widely. We also acknowledge the benefits and limitations of self-reported health status and the low possibility of our findings being due to chance. Finally, the TBQ©, used to measure treatment burden in this study is relatively new and further validation of this instrument in the study sample would have been beneficial before this study took

place. Nevertheless, our study makes strong contributions towards conceptualising treatment burden and the identification of those for whom this is most problematic.

5. Conclusion

Although our study has not addressed the question of how we can improve treatment burden, it has identified some people who could benefit from targeted strategies aimed at reducing burden. In particular, health professionals should be aware that younger adults with multiple chronic conditions, particularly diabetes or endocrine conditions and those with an unpaid carer may be at particular risk of treatment burden. In addition, those with health insurance, higher levels of education and ethnic backgrounds may be at risk of financial burden. The routine inclusion of treatment burden measures in clinical trials has been suggested as an important consideration to improve the evaluation of the treatment burden associated with health care interventions and management strategies [20]. Importantly, the development and application of appropriate measures in this context would also expand our understanding of this under-researched concept and the extent of the problem.

Author's contributions AS drafted the manuscript. AW, MK, JW, FK, and EK participated in the design of the main study. SM, AS, MK, AW, EK, and FK were involved in designing and facilitating the surveys. AS, SM and FK analysed the data. All authors read and approved the final manuscript.

Compliance with Ethical Standards

Competing interests   AS, JAW, SM, EK, FK, MAK, and AJW declare that they have no competing interests.

Ethical approval   Approval for this study was obtained from a University Human Ethics Committee (PHM/12/11/HREC), and from one state Government Health Department. Informed consent was obtained from all individuals who participated in the study. Thus study was conducted in accordance with the World Medical Association's (WMA) Declaration of Helsinki.

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