

## Appendix 3

### Stage 1 Literature Review and Stakeholder Consultation

#### Appendix 3.1 – Concept Analysis of Treatment Burden

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# Burden of treatment for chronic illness: a concept analysis and review of the literature

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## Abstract

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**Keywords:** chronic illness, concept analysis, health professional, medication burden, treatment burden

**Context** Treatment burden, the burden associated with the treatment and management of chronic illness, has not yet been well articulated.

**Objective** Using Rodgers' (1989, *Journal of Advanced Nursing*, 14, 330–335) method of concept analysis, this review describes the ways in which treatment burden has been conceptualized to define the concept and to develop a framework for understanding its attributes, antecedents and consequences.

**Methods** Leading databases were searched electronically between the years 2002 and 2011. To ensure the review focused on actual observations of the concept of interest, articles that did not measure treatment burden (either qualitatively or quantitatively) were excluded. An inductive approach was used to identify themes related to the concept of treatment burden.

**Main results** Thirty articles, identified from 1557 abstracts, were included in the review. The attributes of treatment burden include burden as a dynamic process, as a multidimensional concept, and comprising of both subjective and objective elements. Prominent predisposing factors (antecedents) include the person's age and gender, their family circumstances, possible comorbidity, high use of medications, characteristics of treatment and their relationship with their health-care provider. The most dominant consequences are poor health and well-being, non-adherence to treatment, ineffective resource use and burden on significant others. Furthermore, many of these consequences can also become antecedents, reflecting the cyclic and dynamic nature of treatment burden.

**Conclusion** The findings underscore the need for researchers and health-care professionals to engage in collaborative discussions and make cooperative efforts to help alleviate treatment burden and tailor treatment regimens to the realities of people's daily lives.

## Introduction

Chronic diseases are the leading cause of death in the world, largely associated with 63% of the 57 million deaths that occurred in 2008.<sup>1</sup> The majority of these deaths are attributed to cardiovascular diseases, cancers, chronic respiratory diseases and diabetes.<sup>1</sup> Although the burden associated with chronic illness is well documented, the burden associated with the treatment and management of chronic illness has not been well defined. Related terms such as disease burden and symptom burden have been well articulated,<sup>2,3</sup> but the definition of treatment burden has remained elusive and confusing. Although treatment burden is often inseparable from disease burden, it is not based on the natural history of the disease, but on the need to treat the disease in order to change its course or ameliorate its effects. Treatment burden is, therefore, an important concept that is distinct from disease burden, symptom burden and other related terms.

Treatment of chronic illness comes in many forms including surgery, physical therapy, psychological therapy and radiotherapy. However, one of the most common treatment forms is the use of medication. In Australia, as in many developed nations, the use of medications represents one of the largest components of health expenditure; accounting for 13% of the total health expenditure in 2006–07.<sup>4</sup> There were 262 million prescriptions filled in 2008,<sup>4</sup> many of which were used to treat chronic illness. The prevention and treatment of chronic illness, especially when involving multiple medications, can become burdensome.

Few validated instruments have been developed to assess the experiences of treatment burden on patients.<sup>5–16</sup> In some cases however, the concept of treatment burden has been included as one domain within a multidimensional instrument designed to assess health-related quality of life or treatment satisfaction.<sup>5–12,17,18</sup> These measures reflect wide variation in terms of the dimensions of treatment burden and its definition. One team of researchers explored the experience of treatment burden with the

purpose of identifying its core components.<sup>19</sup> These researchers identified four main tasks that contributed to the sense of burden, namely learning about treatments and their consequences, engaging with others and mobilizing support, adhering to treatment and lifestyle changes and monitoring treatments. Although the most useful conceptualization of treatment burden in the literature, this analysis was not intended to provide a concept analysis. Instead, it was focused on the utility of an existing theoretical framework as a tool for identifying burden. Thus, it is important to conduct further empirical investigation of this concept to enhance our knowledge and draw coherent conclusions about its prevalence and impact.

The lack of a clear conceptual model of treatment burden has contributed to our inability to measure its impact or identify people most at risk, thereby obscuring the health professional's role in assisting people to alleviate this burden. It has generated confusion and misinterpretation that detracts from appropriate and timely management or prevention. A crucial first step in assessing treatment burden and articulating the role of health professionals is defining the concept itself and developing a framework for understanding its occurrence and impact.

The purpose of this review is to comprehensively analyse the concept of treatment burden to enable informed recommendations for health professionals who wish to alleviate its impact. This analysis aims to outline the ways in which treatment burden has been conceptualized and operationalized, by identifying and discussing the critical attributes of treatment burden, exploring the factors that can lead to treatment burden (antecedents) and highlighting its consequences. Antecedents are predisposing events that occur prior to the concept, whereas consequences are events that occur as a result of the concept.<sup>20</sup> Furthermore, attributes are at the heart of a concept, providing insight into its occurrence.<sup>20</sup> A thorough knowledge of the attributes, antecedents and consequences of treatment burden is important from a health practice perspective because



without such knowledge, health professionals will not be able to provide services that alleviate such burden among people with chronic illness.

## Methods

Rodgers<sup>21</sup> evolutionary method of concept analysis was used to comprehensively analyse the concept of treatment burden. This particular method is well suited to the concept of treatment burden because of its changing and dynamic nature (e.g. the emergence of new health technologies leading to possible burden). The evolutionary view of concept analysis indicates that concepts are influenced by contextual factors and may change over time.<sup>22</sup>

### Data sources and search strategy

A systematic search was conducted using the terms 'treatment burden', 'burden of treatment', 'medication burden' and 'burden of medication' as keywords in the following databases: Medline, PsychINFO, Cinahl, Cochrane, Scopus, Health Reference Centre (HRC), PsychEXTRA, Informat, the System for Information on Grey Literature in Europe (SIGLE) and National Technical Information Service USA (NTIS). A sensitivity analysis conducted prior to the search suggested that these key search terms encompassed most of the research within the field. In particular, the sensitivity analysis confirmed that medication was the most prominent form of treatment for chronic illness, necessitating the inclusion of this search term. Although the use of broader terminology may have identified other bodies of literature, restricting the search to these specific terms ensured that the overlap with other forms of burden was minimized.

To ensure a contemporary exploration of this concept, the search was limited to articles published from 2002 to 2011 with human subjects and a focus on the major chronic illnesses that have been named as priorities in Australia: asthma, diabetes, cardiovascular disease, musculoskeletal illness, cancer and mental health.

According to the World Health Organization, these conditions contribute a significant burden in terms of mortality and/or morbidity globally.<sup>1</sup> After this search, 1157 abstracts were identified.

These abstracts were reviewed by two members of the research team. Abstracts without a substantial focus on treatment burden were excluded, along with those that emphasized disease or symptom burden. If both researchers were uncertain about whether the abstract met the inclusion criteria or were not in agreement, the full article was retrieved and reviewed. As a result of this process, 170 articles were thoroughly reviewed by two researchers, leading to the exclusion of a further 140 articles (Fig. 1). Further exclusions were applied to ensure the review focused on articles that actually measured a person's experience of treatment burden. Specifically, articles that did not measure treatment burden (either qualitatively or quantitatively) were excluded (i.e. opinion pieces or theoretical articles). Thirty articles met the inclusion criteria and were included in the concept analysis (Table 1). Most of these studies

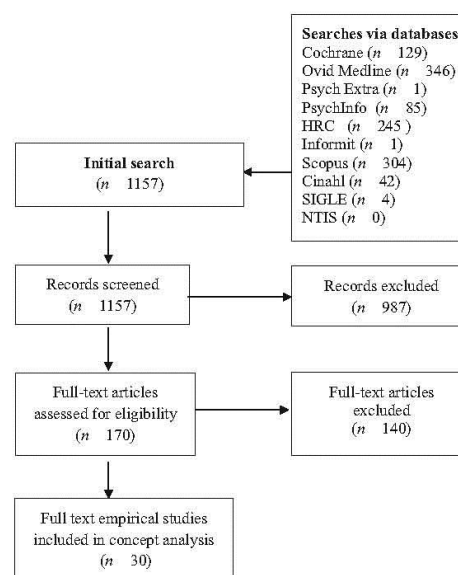


Figure 1 Selection process for concept analysis



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**Table 1** Articles included in the concept analysis

Reference	Country	Participants	Data collection methods
Anderson <i>et al.</i> <sup>5</sup>	USA	<i>n</i> = 170 and <i>n</i> = 402, people with diabetes	Mixed methods
Fried <i>et al.</i> <sup>51</sup>	USA	<i>n</i> = 125, 65 years or older with a limited life expectancy	Quantitative survey
Kim <i>et al.</i> <sup>27</sup>	USA	<i>n</i> = 1083, male and female with schizophrenia	Quantitative survey
Brod <i>et al.</i> <sup>8</sup>	Multination	<i>n</i> = 17,488 with type 2 diabetes	Quantitative survey
Gallacher <i>et al.</i> <sup>19</sup>	UK	<i>n</i> = 47 patients with chronic heart failure	Qualitative interview
Henry <i>et al.</i> <sup>40</sup>	USA	<i>n</i> = 15,532 people with cancer	Quantitative survey
Campbell <i>et al.</i> <sup>9</sup>	UK	<i>n</i> = 19 with asthma for focus groups, <i>n</i> = 131 for questionnaire	Mixed methods
Vijan <i>et al.</i> <sup>37</sup>	USA	<i>n</i> = 1,653 Veteran patients with type 2 diabetes	Quantitative survey
Benner <i>et al.</i> <sup>45</sup>	USA	<i>n</i> = 5759 patients with initiated antihypertensive lipid-lowering therapy	Quantitative survey
Bernhard <i>et al.</i> <sup>13</sup>	Switzerland/ Italy	<i>n</i> = 249 patients in a trial for the prophylaxis for delayed emesis	Quantitative survey and diary cards
Ribi <i>et al.</i> <sup>16</sup>	Switzerland	<i>n</i> = 373 women with early or advanced breast cancer	Quantitative survey
Yoon <i>et al.</i> <sup>47</sup>	USA	<i>n</i> = 1,219 women with breast cancer	Quantitative survey
Ow <sup>33</sup>	Singapore	<i>n</i> = 22 parents from 20 families with children with childhood cancer	Quantitative survey
Zucca <i>et al.</i> <sup>35</sup>	Australia	<i>n</i> = 1410 adults with cancer	Quantitative survey
Graves <i>et al.</i> <sup>24</sup>	USA	<i>n</i> = 101 primary caregivers of children with asthma	Quantitative survey
Olinder <i>et al.</i> <sup>48</sup>	Sweden	<i>n</i> = 90 adolescents aged 12–18 years with diabetes	Diary records and survey
Haugstvedt <i>et al.</i> <sup>41</sup>	Norway	<i>n</i> = 103 (mothers) and <i>n</i> = 97 (fathers) of 115 children with type 1 diabetes	Quantitative survey and medical records
Thomas <sup>31</sup>	USA/France	<i>n</i> = 1500 patients with schizophrenia (Study 1) and <i>n</i> = 284 (Study 2)	Quantitative survey
Wysocki & Gavin <sup>44</sup>	USA	<i>n</i> = 190 adult couple caregivers of a child with a chronic condition	Quantitative survey
Martire <i>et al.</i> <sup>42</sup>	USA	<i>n</i> = 244 dyads with a major depressive disorder	Quantitative survey
Longo <i>et al.</i> <sup>34</sup>	Canada	<i>n</i> = 282 patients with cancer	Quantitative survey
Rodbard <i>et al.</i> <sup>26</sup>	USA	<i>n</i> = 3551 individuals with type 2 diabetes mellitus	Quantitative survey
Brod <i>et al.</i> <sup>23</sup>	Australia/NZ	<i>n</i> = 299 male or female with type 1 diabetes	Quantitative survey
Fiese <i>et al.</i> <sup>25</sup>	USA	<i>n</i> = 153 families of a child with asthma.	Quantitative survey
Nicholl <i>et al.</i> <sup>36</sup>	USA	<i>n</i> = 970 with recent schizophrenia and 2996 with ongoing schizophrenia.	Medical claims
Tija <i>et al.</i> <sup>32</sup>	USA	<i>n</i> = 457 women (60–65 years) eligible for breast cancer chemotherapy	Quantitative survey
de Kraker <i>et al.</i> <sup>43</sup>	Multination	<i>n</i> = 410 patients between ages 6 months and 18 years with Wilms' tumour	Medical outcomes
Gutierrez-Maldonado <i>et al.</i> <sup>28</sup>	Chile	<i>n</i> = 45 caregivers of people with schizophrenia	Quantitative survey
Moss & Crane <sup>29</sup>	USA	<i>n</i> = 86 older women with post-myocardial infarction	Quantitative survey
Ziaian <i>et al.</i> <sup>38</sup>	Australia	<i>n</i> = 160 children aged 10–16 years with a chronic illness	Quantitative survey

were conducted in the United States of America (USA) and included self-report survey questionnaires to assess the level of treatment burden among patients and their carers. A number of inter-related themes were identified from the review relating to the antecedents, attributes and consequences of treatment burden.

#### Data extraction and analysis

An initial coding framework was developed based on the questions in Table 2. These questions reflected Rodgers' method of concept analysis, which involves a multidisciplinary literature review to identify the common attributes, antecedents and consequences of the concept.<sup>3</sup>

**Table 2** Review questions for data extraction

Number	Review questions
1	What are the key attributes of the concept?
2	Which factors (antecedents) are proposed to precede treatment burden?
3	What are the consequences of treatment burden?

Five researchers independently extracted data from the selected articles in accordance with the review questions in Table 2 and coded the data within the initial framework, expanding the subthemes as required. Each coding framework was then reviewed by two researchers for recurring themes, which were placed into categories (attributes, antecedents, and consequences).

## Results

### Attributes of treatment burden

The defining attributes of treatment burden were chosen due to their frequent occurrence in the literature. Treatment burden emerged as a dynamic multidimensional concept that comprised of both subjective and objective elements.

#### *A dynamic process*

Treatment burden changed over time<sup>23</sup> in response to disease severity and control<sup>24,25</sup> and the development of comorbidities.<sup>26,27</sup> It is possible that that either familiarity with, or acceptance of, treatment lessens the experience of burden through a process of adjustment. In patients with diabetes, longer duration of disease was associated with less burden.<sup>8</sup> Despite changing over time, some degree of burden appeared to persist.<sup>28</sup> Treatment burden also had a cyclic aspect, with many of the consequences of treatment burden also being antecedents. For example, increased burden could result in non-adherence to medication which may then lead to further burden.<sup>29</sup>

#### *A multidimensional concept*

Treatment burden emerged as a multidimensional concept, including physical, financial, temporal, and psychosocial time demands.

Physical side-effects<sup>30</sup> were a significant source of treatment burden,<sup>13,24,29,31</sup> arising in particular from medications or drug interactions.<sup>29</sup> Side-effects could occur at any stage of treatment. For example, they could be more acute at the commencement of therapy, they could be ongoing or they may result from cumulative toxicity in the later stages of treatment.<sup>29</sup> Side-effects varied in nature and severity, from minor hypoglycaemic events and weight gain,<sup>8</sup> to those that are so unpleasant that the possibility of experiencing them frightened some patients.<sup>8</sup> Experiencing more than one side-effect contributed to overall treatment burden.<sup>13</sup> Some side-effects may be preventable especially those related to the use of medications that were no longer required.<sup>32</sup>

The cost of treatment could be high,<sup>24</sup> contributing to overall treatment burden.<sup>28,29,33</sup> Even when treatment was subsidized, the out-of-pocket costs could be intolerable.<sup>34</sup> The cost of travel was one of the greatest out-of-pocket expenses, especially for patients from non-metropolitan areas,<sup>35</sup> although this was often obscured by the rhetoric of 'free' hospital care. Inpatient treatment was also associated with financial burden.<sup>36</sup> Personal medical costs competed with other living expenses, such as, food, clothing and housing.<sup>26</sup>

The time required to plan and organize travel for treatment,<sup>37</sup> receive treatment,<sup>19,35,38</sup> learn about treatments and their potential outcomes,<sup>19</sup> monitor treatment<sup>37,39</sup> and manage side-effects<sup>40</sup> was related to treatment burden. As well as consuming financial resources, travel required a great deal of time, especially for patients who lived in outer regional areas.<sup>35</sup> A substantial time burden for family and carers as well as for patients themselves was evident.<sup>40</sup> One study reported families of children with chronic illnesses may already be under considerable time pressure, and the increased use of long-term home-based care for these children adds to this burden over time.<sup>38</sup>

The psychological and social aspects of treatment burden were closely linked, often because additional support is needed to manage treatment<sup>28</sup> or day-to-day tasks or both. Some



patients had difficulties managing home responsibilities as a consequence of treatment,<sup>33,35,40</sup> and often, household and personal tasks, normally completed by the patient, were carried out by other family members.<sup>34</sup> Parents needed to accompany, administer medication to and monitor a child receiving treatment. However, many families seemed to adapt well to treatment tasks.<sup>41</sup> When children attended school, the burden of administering medications was likely to be borne by the child or a staff member, which may explain why some children experience more burden than their parents.<sup>38</sup> Older adults generally relied on family for assistance and support.<sup>42</sup> Family members or carers also at times needed to accompany or support patients receiving invasive or lengthy treatments such as cancer treatment.<sup>40</sup> The impact of treatment on significant others added to the burden experienced by the patient.<sup>43</sup> Family members could perceive themselves as being incompetent or not able to care for the patient due to a lack of personal or economic resources.<sup>28</sup> These perceptions could also add to the patient's sense of burden.<sup>28</sup> Thus, there is a need for adequate information to be provided by health-care professionals about treatment and its consequences in order to address these perceptions.<sup>33</sup>

Treatment tasks that interfered with daily activities<sup>24</sup> or lifestyle<sup>5,41,43</sup> also contributed to treatment burden.<sup>36,41</sup> For instance, it was inconvenient to transport treatment equipment or medications (e.g. insulin injections or metered dose inhalers) and embarrassing to use (medication) in public.<sup>9</sup> More invasive treatments such as dialysis were even more inconvenient and restrictive.<sup>5,9</sup> Interestingly, new technologies (e.g. new forms of blood glucose monitoring) did not emerge as a significant source of distress or burden,<sup>44</sup> but this area requires further investigation.

#### *Both subjective and objective burden*

Some elements of treatment burden such as the number of medications,<sup>19,24,29,32,36,45,46</sup> and time to administer or monitor treatment,<sup>19</sup> could be measured objectively. Patients and carers,

however, were not homogenous and therefore could have different perceptions concerning the burden related to similar tasks.<sup>38</sup> This subjective aspect of treatment burden was associated with a number of factors<sup>13,24,43</sup> and therefore may be predictable. However, as it includes elements of an intangible nature, for example, guilt, hopelessness, and fear,<sup>33</sup> its quantification could be difficult. Subjective aspects, such as fear of medication supply running out, the meaning attributed to side-effects,<sup>16</sup> beliefs about a medication's effectiveness<sup>31,32</sup> and beliefs about the impact of medication on health and well-being (e.g. believing that medication is harmful and addictive), were associated with increased levels of treatment burden.<sup>9</sup>

#### *Antecedents of treatment burden*

Although a large number of antecedents of treatment burden were identified, there was minimal information about their particular influence on treatment burden, reflecting the lack of theoretical development within the research field. Antecedents were associated with characteristics of the patient, the disease, the treatment, the family or support network and the health-care system.

##### *Patient characteristics*

Gender seemed to be a key antecedent of burden because men and women experienced treatment burden differently. Women experienced more treatment burden than men and also reported more caregiver burden when their children were sick, possibly as a result of their traditional homemaker roles.<sup>13,40,41</sup> A strong positive correlation was apparent between unemployment and treatment burden.<sup>35,40</sup> A strong relationship between age and treatment burden also emerged.<sup>16,40,47</sup> Elderly people seemed to experience more treatment burden than young people, as might be expected given the likelihood of illness and multiple conditions.

##### *Disease conditions*

As expected, comorbidity was associated with increased burden.<sup>26</sup> The presence of particular



comorbidities,<sup>27,36</sup> especially psychological illnesses such as anxiety or depression,<sup>40</sup> was associated with high levels of treatment burden.<sup>28,36,37</sup> Particular chronic conditions such as diabetes<sup>37</sup> and schizophrenia<sup>36</sup> were associated with greater levels of treatment burden. Finally, functional capacity, poor symptom control<sup>24</sup> and longer duration of illness<sup>8</sup> could also lead to treatment burden.<sup>39</sup>

#### *Treatment characteristics*

Treatment characteristics, particularly medications,<sup>8,13,31</sup> were an important antecedent of burden. Using a high number of medications<sup>19,24,29,32,45,46</sup> emerged as the most common antecedent in the literature. Particular dosage forms (e.g. injections as opposed to oral tablets) were also considered to be burdensome. Finally, changes to medication regimens were also a key antecedent of burden and have been attributed to a lack of continuity of health care.<sup>19</sup>

#### *Family support and engagement*

Availability of extended family networks and support from an appropriate social network could lead to lower treatment burden.<sup>33</sup> However, the support and assistance provided by a caregiver could also result in treatment burden for both the patient and the carer.<sup>28</sup> One way of reducing burden, particularly for carers, was to introduce an intervention designed to support family members to understand, communicate and participate in treatment decisions.<sup>28</sup>

#### *Health-care systems*

An aspect of health care that emerged frequently was the health practitioner–patient relationship.<sup>29,37</sup> Failure of health-care practitioners to provide adequate information regarding treatment was associated with treatment burden.<sup>37</sup> Poor communication between patients and health-care providers about medication adherence was likely to result in the use of multiple medications (polypharmacy), which was associated with treatment burden.<sup>29</sup> The location of the health-care centre also emerged as an antecedent of financial and time burden,

caused by long travel distances.<sup>35</sup> This issue was further complicated by a lack of financial reimbursement for travel of this kind.<sup>35</sup>

#### *Consequences of treatment burden*

The concept analysis identified a number of consequences of treatment burden including poor adherence, reduced health and well-being, ineffective use of health resources, reduced employment and low productivity, and negative health impacts on family and carers.

#### *Adherence*

One of the most widely cited consequences of treatment burden was non-adherence to treatment. Non-adherence<sup>19,27,37,48</sup> was then related to sub-optimal health outcomes,<sup>29,37</sup> including disease relapse,<sup>31,36</sup> decreased quality of life<sup>24</sup> and the unscheduled use of more expensive health-care resources, such as increased emergency department visits and hospitalization.<sup>31</sup> Non-adherence was also associated with increased school absences.<sup>24</sup>

Non-adherence was most often linked to treatment burden resulting from medication characteristics, including the number of medications, their frequency of administration,<sup>45</sup> side-effects<sup>24</sup> and perceived lack of efficacy.<sup>24</sup> As the number of medications being used increased, the rate of non-adherence associated with the addition of each additional medication decreased.<sup>45</sup> Hence, there appeared to be a threshold of treatment burden where additional medications did not add further burden. However, the addition of each additional medication did nevertheless add to the financial cost of treatment.<sup>27</sup> This was a concerning finding given that the elderly and welfare recipients were found to reduce their use of medications in response to the introduction of prescription co-payments and subsequently experienced an increase in serious adverse events.<sup>34</sup>

#### *Health and well-being*

The health and well-being consequences of treatment burden were many and varied. Treatment burden affected patient choices about

treatment,<sup>37</sup> with some patients who were recommended insulin refusing this therapy.<sup>37</sup> Such a choice was associated with poor glycemic control.<sup>37</sup> However, opting for a less-efficacious alternative treatment could be a reasonable course of action given that ‘...difficult or demanding treatment regimens may appreciably lower treatment effectiveness, which may be possible to achieve with less burdensome treatment’.<sup>5:573</sup> In other words, while a treatment might appear to have superior efficacy in the controlled setting of a clinical trial, in reality, the interaction between treatment regimen and treatment burden could create difficulties. Thus, patients may choose to select a less effective, but less burdensome treatment to suit their daily lives, which ultimately may result in better health outcomes.

Treatment burden was associated with a number of negative health outcomes including specific symptoms,<sup>16,29</sup> recurrence of disease,<sup>28,36,43</sup> decline in health,<sup>29,36</sup> reduced survival,<sup>43</sup> decreased treatment satisfaction<sup>23</sup> and reduced quality of life.<sup>25,40</sup> Treatment-related side-effects were often found to have a marked impact on quality of life,<sup>16</sup> which was also affected by perceived treatment burden, disease severity<sup>25</sup> and disruption of lifestyle.<sup>48</sup> Finally, as well as increasing the risk of adverse outcomes, which was mediated by non-adherence, greater prescription co-payment burden was associated with increased self-reported psychological distress and attempted suicide in patients with schizophrenia.<sup>27</sup>

#### *Resource use*

Ineffective use of resources has been attributed to treatment burden.<sup>19</sup> Unfortunately, a reduction in scheduled care (i.e. non-adherence) may result in a demand for unscheduled care (i.e. hospital admission), creating avoidable resource use.<sup>24,31</sup> Perceived financial burden caused by prescription co-payments resulted in the increased self-reported use of unscheduled care, such as emergency room visits and hospitalization.<sup>27</sup> Polypharmacy complicated therapy and health-care delivery,<sup>29</sup> which added to unnecessary use of resources. Moreover, poly-

pharmacy was accompanied by an increased risk that medications included in the treatment regimen were unnecessary and therefore a waste of resources.<sup>32</sup>

#### *Employment*

The burden of treatment had a marked impact on the patient’s ability to attend work and maintain productivity. In a cancer clinic, patients who were still employed were absent for an average of 12.6 days during the month.<sup>34</sup> Absences from work were related to prescription co-payment burden,<sup>27</sup> the need to travel<sup>35</sup> and side-effects,<sup>34,40</sup> including fatigue associated with chemotherapy. The latter resulted in the loss of 4.2 sick or vacation days per month.<sup>40</sup> In some instances, patients needed to change employment status in order to manage treatment burden.<sup>34,40</sup> Caregivers also needed to take time off work to care for cancer patients.<sup>34</sup> Unfortunately, work absences could lead to feelings of guilt among patients about burdening their co-workers and lost productivity,<sup>40</sup> which added to burden.

#### *Family and carers*

Treatment burden was related to carer burden and fatigue,<sup>43</sup> causing patients to forgo caregiver support.<sup>34</sup> The distress caused by treatment burden was found to flow in both directions in that seeing a significant other (i.e. patient or carer) suffer could lead to further burden and distress,<sup>42</sup> especially in the case of parents.<sup>25,41</sup> There was evidence that effective treatment of a loved one resulted in significant benefits for carers.<sup>42</sup>

### **Discussion**

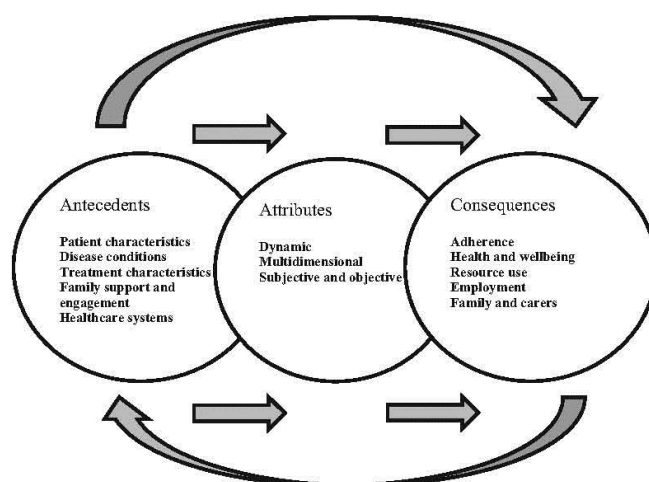
This concept analysis provides a much needed theoretical framework for understanding the dynamic, multidimensional and cyclic nature of treatment burden. We found that treatment burden is a dynamic process, evolving with the emergence of new treatment options and symptoms. It persisted over time, but perhaps reached a subjective threshold beyond which perceptions of burden no longer increase. The



dimensions of treatment burden include undesirable physical effects of treatment (side-effects), the economic burden imposed by treatment (financial burden), time required to obtain, administer and manage treatment (time burden), and the psychosocial aspects of burden including the impact on family and lifestyle (personal burden). Treatment burden has both subjective and objective elements including number of medications, time to administer and monitor treatment (objective) vs. feelings of guilt, hopelessness and fear relating to treatment (subjective). A range of antecedents and consequences were identified, although many of the consequences could also become antecedents, reflecting the cyclic nature of treatment burden. The attributes, antecedents and consequences emerging from the review of treatment burden are summarized in Fig. 2, which also highlights the cyclic nature of the concept. As an outcome of this concept analysis, we define treatment burden as a person's subjective and objective overall estimation of the dynamic and multidimensional burden that their treatment regimen for chronic illness has imposed on them and on their family members. It is influenced by a person's characteristics, disease duration/severity, treatment circum-

stances, level of family support and engagement and also the overall health-care systems, in which the person obtains treatment.

The health consequences of treatment burden are particularly concerning given that treatment burden has been associated with specific symptoms, recurrence of disease, decline in health, reduced survival, decreased treatment satisfaction and reduced quality of life. There is a clear need to implement services that help alleviate the burden of treatment experienced by patients in order to improve their health and well-being. Another alarming consequence of treatment burden, particularly from a public health perspective, was the ineffective use of resources. In an era of cost efficiency, poor use of health resources is particularly undesirable. By addressing poor adherence and consequently, treatment burden, it may be possible to identify ways of minimizing the use of more costly resources such as hospital admissions. The World Health Organization indicates that poor adherence to the treatment of chronic illness is a global problem averaging almost 50% in developed countries.<sup>49</sup> Strategies that increase adherence are urgently needed if we are to optimize health outcomes. However, these strategies must take into account the



**Figure 2** Attributes, antecedents and consequences of treatment burden.



subjective aspect of treatment burden and its important cyclic nature.

### Research implications

The attributes, antecedents and consequences identified in this review also have clear implications for all health-care professionals to alleviate the burden of treatment for patients. As the perception of treatment burden could be subjective, strategies to alleviate its impact need to be individualized, reflecting the individual's circumstances and preferences. This review has reinforced the fact that it is not only just health outcomes that are important for patients and their family, but also the way in which how health professionals achieve those outcomes for patients. Further, the dynamic nature of treatment burden means that for any one individual patient, their capacity to manage new and multiple treatments may vary over time. The complexity of this concept can best be managed through individualized and holistic care and ongoing evaluation that is responsive to the needs of each person.

The analysis has highlighted the fact that burden can also be a result of interactions with health-care professionals. Poor health professional–patient relationships and a lack of adequate information regarding treatment were associated with high levels of treatment burden. As Moss and Crane<sup>29</sup> argued, poor communication between patients and health-care providers about medication use may result in the provision of multiple medications, which could then lead to treatment burden. Health-care professionals need to develop a relationship that is sensitive to patient's preferences and offer explanations of treatment options that include their potential side-effects. This type of relationship will enable patients to become more actively involved in decision making and integrate treatment with their daily lives, ultimately improving adherence and treatment outcomes.

Despite the variety of settings and methods used in the studies included in this concept analysis, treatment burden resulting from

medication use emerged as a key theme. This finding is not surprising given that medication is one of the most common forms of treatment for chronic conditions. In Australia, reports indicate that Australians between the ages of 65 and 75 were taking an average of four medications in 2009 and will be taking, on average, six medications by 2019.<sup>50</sup> The findings present clear opportunities for health professionals who are prescribing or dispensing medications to engage in greater discussions and improve medication management among patients. Community pharmacists, in particular, are accessible and well placed to support medication management, so that patients with chronic conditions receive the maximum benefit from their treatment.

Interestingly, the tasks of self-management (e.g. organizing treatment, monitoring symptoms, changing lifestyle) were identified as a major source of treatment burden. Similar to the findings of Gallacher *et al.*,<sup>19</sup> our study revealed a set of tasks associated with learning about treatments, engaging with and organizing the treatment, altering routines and monitoring symptoms and progress. It is ironic that these core tasks of self-management represent a significant burden for patients despite being seen as a solution for the long-term management of chronic illness in society. Gallacher *et al.*,<sup>19</sup> were able to clearly distinguish between treatment burden and illness or disease burden, suggesting that our response to chronic illness generates a great deal of distress that is independent of that which might be experienced otherwise. It is not surprising that Gallacher *et al.* refer to treatment burden as the 'work' of chronic disease management. Our study has confirmed the important role this 'work' plays in generating a sense of burden. This review identified many negative consequences of treatment burden some of which may result in the continued escalation of burden over time because they also act as antecedents. Breaking this cycle is important, as is the identification of the factors that have the greatest impact on treatment burden and those that can be most easily modified. Clearly, health professionals

have a major role alongside patients and their families in alleviating the burden associated with the treatment of chronic illness.

### Research limitations

Like any research, this review also has limitations that must be considered. Only research published in the decade between 2002 and 2011 was included in the analysis. These dates were chosen because treatment burden is a relatively new and evolving concept and therefore research conducted prior to this date was deemed inappropriate for the purposes of this review. Furthermore, the articles used in the concept analysis focused on selected chronic illnesses known to be associated with high burden of disease. We acknowledge that there may be high levels of treatment burden associated with other ongoing health conditions. Given the importance of treatment burden for patients and their family and lack of clarification of the concept to date, the insights from this review provide a valuable foundation on which to further develop this concept.

### Conclusion

Given the potential negative impacts of treating a chronic illness(s), researchers and health-care professionals need to engage in collaborative discussions and make cooperative efforts to help alleviate treatment burden in order to optimize health outcomes. Continued research into treatment burden, its definition, assessment and impact, is needed to understand people's burden experience and implement treatment that suits the realities of daily life.

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### Conflicts of interest

The authors confirm that there is no conflict of interest.

### References

- 1 Alwan A, Armstrong T, Cowan M, Riley L. *Noncommunicable Diseases Country Profiles 2011*. Geneva, Switzerland: World Health Organization, 2011.
- 2 Mathers CD, Vos ET, Stevenson CE, Begg SJ. The burden of disease and injury in Australia. *Bulletin of the World Health Organization*, 2001; **79**: 1076–1084.
- 3 Gapstur RL. Symptom burden: a concept analysis and implications for oncology nurses. *Oncology Nursing Forum*, 2007; **34**: 673–680.
- 4 Australian Institute of Health and Welfare. *Australia's Health, 2010. Australia's Health Series No. 12. Cat. No. AUS 122*. In: Australian Institute of Health and Welfare, ed. Canberra: Commonwealth of Australia, 2010.
- 5 Anderson RT, Skovlund SE, Marrero D *et al.* Development and validation of the insulin treatment satisfaction questionnaire. *Clinical Therapeutics*, 2004; **26**: 565–578.
- 6 B  chet  ille A, Arnould B, Bron A *et al.* Measurement of health-related quality of life with glaucoma: validation of the Glau-QoL    36-item questionnaire. *Acta Ophthalmologica*, 2008; **86**: 71–80.
- 7 Brod M, Hammer M, Kragh N, Lessard S, Bushnell DM. Development and validation of the treatment related impact measure of weight (TRIM-weight). *Health and Quality of Life Outcomes*, 2010; **8**: 19–30.
- 8 Brod M, Valensi P, Shaban JA, Bushnell DM, Christensen TL. Patient treatment satisfaction after switching to NovoMixReg. 30 (BIAsp 30) in the IMPROVETM study: an analysis of the influence of prior and current treatment factors. *Quality of Life Research: An International Journal of Quality of Life Aspects of Treatment, Care & Rehabilitation*, 2010; **19**: 1285–1293.
- 9 Campbell JL, Kiebert GM, Partridge MR. Development of the satisfaction with inhaled asthma treatment questionnaire. *European Respiratory Journal*, 2003; **22**: 127–134.
- 10 Chen H, Cisternas MG, Katz PP *et al.* Evaluating quality of life in patients with asthma and rhinitis: English adaptation of the Rhinasthma



- Questionnaire. *Annals of Allergy, Asthma, & Immunology*, 2011; **106**: 110–118.
- 11 Henry B, Aussage P, Grosskopf C, Goehrs JM. Development of the Cystic Fibrosis Questionnaire (CFQ) for assessing quality of life in pediatric and adult patients. *Quality of Life Research: An International Journal of Quality of Life Aspects of Treatment, Care & Rehabilitation*, 2003; **12**: 63–76.
- 12 Modi AC, Quittner AL. Validation of a disease-specific measure of health-related quality of life for children with cystic fibrosis. *Journal of Pediatric Psychology*, 2003; **28**: 535–546.
- 13 Bernhard J, Maibach R, Thurlimann B, Sessa C, Aapro MS, Swiss Group for Clinical Cancer Research. Patients' estimation of overall treatment burden: why not ask the obvious? *Journal of Clinical Oncology*, 2002; **20**: 65–72.
- 14 Oude Elberink JNG, van der Heide S, Guyatt GH, Dubois AEJ. Analysis of the burden of treatment in patients receiving an EpiPen for yellow jacket anaphylaxis. *Journal of Allergy and Clinical Immunology*, 2006; **118**: 699–704.
- 15 Wilcox AR, Dragnev MCC, Darcey CJ, Siegel CA. A new tool to measure the burden of Crohn's disease and its treatment: do patient and physician perceptions match? *Inflammatory Bowel Diseases*, 2010; **16**: 645–650.
- 16 Ribi K, Bernhard J, Bohme C *et al.* Endocrine symptom assessment in women with breast cancer: what a simple "yes" means. *Supportive Care in Cancer*, 2007; **15**: 1349–1356.
- 17 Bailie GR, Cardone KE, Grabe DW, Hoy CD, Manley HJ, Meola S. Quantifying home medication regimen changes and quality of life in patients receiving nocturnal home hemodialysis. *Hemodialysis International*, 2011; **15**: 234–242.
- 18 Corona J, Matsumoto H, Roye DP, Vitale MG. Measuring quality of life in children with early onset scoliosis: development and initial validation of the early onset scoliosis questionnaire. *Journal of Pediatric Orthopedics*, 2011; **31**: 180–185.
- 19 Gallacher K, May CR, Montori VM, Mair FS. Understanding patients' experiences of treatment burden in chronic heart failure using normalization process theory. *Annals of Family Medicine*, 2011; **9**: 235–243.
- 20 Walker LO, Avant KC. *Strategies for Theory Construction in Nursing*. Upper Saddle River, NJ: Pearson Prentice Hall, 2005.
- 21 Rodgers BL. Concepts, analysis and the development of nursing knowledge: the evolutionary cycle. *Journal of Advanced Nursing*, 1989; **14**: 330–335.
- 22 Rodgers BL, ed. *Concept Analysis: An Evolutionary View*. Philadelphia, PA: Saunders, 2000.
- 23 Brod M, Christensen T, Bushnell D. Maximizing the value of validation findings to better understand treatment satisfaction issues for diabetes. *Quality of Life Research*, 2007; **16**: 1053–1063.
- 24 Graves MM, Adams CD, Bender JA, Simons S, Portnoy JM. Volitional nonadherence in pediatric asthma: parental report of motivating factors. *Current Allergy and Asthma Reports*, 2007; **7**: 427–432.
- 25 Fiese BH, Wamboldt FS, Anbar RD. Family asthma management routines: connections to medical adherence and quality of life. *Journal of Pediatrics*, 2005; **146**: 171–176.
- 26 Rodbard HW, Green AJ, Fox KM, Grandy S, Shield Study Group. Impact of type 2 diabetes mellitus on prescription medication burden and out-of-pocket healthcare expenses. *Diabetes Research & Clinical Practice*, 2010; **87**: 360–365.
- 27 Kim E, Gupta S, Bolge S, Chen CC, Whitehead R, Bates JA. Adherence and outcomes associated with copayment burden in schizophrenia: a cross-sectional survey. *Journal of Medical Economics*, 2010; **13**: 185–192.
- 28 Gutierrez-Maldonado J, Caqueo-Urizar A. Effectiveness of a psycho-educational intervention for reducing burden in Latin American families of patients with schizophrenia. *Quality of Life Research: An International Journal of Quality of Life Aspects of Treatment, Care & Rehabilitation*, 2007; **16**: 739–747.
- 29 Moss L, Crane PB. Exploring polypharmacy in elderly women after myocardial infarction. *Journal of Women and Aging*, 2010; **22**: 22–33.
- 30 World Health Organization. *Diagnosis and Management of Adverse Drug Reactions*. Geneva: World Alliance for Patient Safety, 2007.
- 31 Thomas P. The stable patient with schizophrenia – from antipsychotic effectiveness to adherence. *European Neuropsychopharmacology*, 2007; **17**: 115–122.
- 32 Tjia J, Micco E, Armstrong K. Interest in breast cancer chemoprevention among older women. *Breast Cancer Research and Treatment*, 2008; **108**: 435–453.
- 33 Ow R. Burden of care and childhood cancer: experiences of parents in an Asian context. *Health and Social Work*, 2003; **28**: 232–240.
- 34 Longo CJ, Fitch M, Deber RB, Williams AP. Financial and family burden associated with cancer treatment in Ontario, Canada. *Supportive Care in Cancer*, 2006; **14**: 1077–1085.
- 35 Zucca A, Boyes A, Girgis A, Hall A, Newling G. Travelling all over the countryside: travel-related burden and financial difficulties reported by cancer patients in New South Wales and Victoria. *Australian Journal of Rural Health*, 2011; **19**: 298–305.
- 36 Nicholl D, Akhras KS, Diels J, Schadrack J. Burden of schizophrenia in recently diagnosed



- patients: healthcare utilisation and cost perspective. *Current Medical Research and Opinion*, 2010; **26**: 943–955.
- 37 Vijan S, Hayward RA, Ronis DL, Hofer TP. Brief report: the burden of diabetes therapy: implications for the design of effective patient-centered treatment regimens. *Journal of General Internal Medicine*, 2005; **20**: 479–482.
  - 38 Ziaian T, Sawyer MG, Reynolds KE *et al.* Treatment burden and health-related quality of life of children with diabetes, cystic fibrosis and asthma. *Journal of Paediatrics and Child Health*, 2006; **42**: 596–600.
  - 39 Brod M, Cobden D, Lammert M, Bushnell D, Raskin P. Examining correlates of treatment satisfaction for injectable insulin in type 2 diabetes: lessons learned from a clinical trial comparing biphasic and basal analogues. *Health & Quality of Life Outcomes*, 2007; **5**: 8.
  - 40 Henry DH, Viswanathan HN, Elkin EP, Traina S, Wade S, Cella D. Symptoms and treatment burden associated with cancer treatment: results from a cross-sectional national survey in the U.S. *Supportive Care in Cancer*, 2008; **16**: 791–801.
  - 41 Haugstvedt A, Graue M, Rokne B, Wentzel-Larsen T. Perceived family burden and emotional distress: similarities and differences between mothers and fathers of children with type 1 diabetes in a population-based study. *Pediatric Diabetes*, 2011; **12**: 107–114.
  - 42 Martire LM, Gildengers AG, Karp JF, Reynolds CF, Schulz R, Whyte EM. Treatment of late-life depression alleviates caregiver burden. *Journal of the American Geriatrics Society*, 2010; **58**: 23–29.
  - 43 de Kraker J, Graf N, Van Tinteren H *et al.* Reduction of postoperative chemotherapy in children with stage I intermediate-risk and anaplastic Wilms' tumour (SIOP 93–01 trial): a randomised controlled trial. *Lancet*, 2004; **364**: 1229–1235.
  - 44 Wysocki T, Gavin L. Paternal involvement in the management of pediatric chronic diseases: associations with adherence, quality of life, and health status. *Journal of Pediatric Psychology*, 2006; **31**: 501–511.
  - 45 Benner JS, Chapman RH, Petrilla AA, Tang SSK, Rosenberg N, Schwartz JS. Association between prescription burden and medication adherence in patients initiating antihypertensive and lipid-lowering therapy. *American Journal of Health-System Pharmacy*, 2009; **66**: 1471–1477.
  - 46 Robertson TA, Cooke CE, Wang J, Shaya FT, Lee HY. Effect of medication burden on persistent use of lipid-lowering drugs among patients with hypertension. *American Journal of Managed Care*, 2008; **14**: 710–716.
  - 47 Yoon J, Adams JL, Ganz PA *et al.* Symptoms after breast cancer treatment: are they influenced by patient characteristics? *Breast Cancer Research and Treatment*, 2008; **108**: 69–77.
  - 48 Olinder AL, Kernell A, Smide B. Missed bolus doses: devastating for metabolic control in CSII-treated adolescents with type 1 diabetes. *Pediatric Diabetes*, 2009; **10**: 142–148.
  - 49 World Health Organization. Adherence to long-term therapies: evidence for action. 2003. Available at: [http://www.who.int/chp/knowledge/publications/adherence\\_full\\_report.pdf](http://www.who.int/chp/knowledge/publications/adherence_full_report.pdf) (accessed 11 May 2012).
  - 50 Australian Department of Health and Ageing. Evaluation of the DAA/PMP Programs. 2010. Available at: [http://www.health.gov.au/internet/main/publishing.nsf/Content/5B1B138DA00B B9C7CA2578150083984E/\\$File/DAA%20PMP%20Report.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/5B1B138DA00B B9C7CA2578150083984E/$File/DAA%20PMP%20Report.pdf) (accessed 11 May 2012).
  - 51 Fried TR, Bradley EH, Towle VR. Assessment of patient preferences: integrating treatments and outcomes. *The Journals of Gerontology: Series B: Psychological Sciences and Social Sciences*, 2002; **57B**: S348–S354.

## Appendix 3.2 – Systematic Review of Patient Centred Care

This is the post-print (final draft post-refereeing) version of the following manuscript:

McMillan SS, Kendall E, Sav A, King MA, Whitty JA, Kelly F, Wheeler AJ. Patient-centred approaches to health care: a systematic review of randomised controlled trials. The final, definitive version of this paper has been published in *Medical Care Research and Review* 2013; 70(6):567-96. DOI: 10.1177/1077558713496318 by Sage Publications. All rights reserved. © [McMillan SS., et al 2013.]

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## Patient centred approaches to health care: A systematic review of randomized controlled trials

### Abstract

There is growing interest in patient centred care, but there is little guidance about the interventions required for its delivery and whether it leads to better health outcomes. This systematic review evaluates the efficacy of patient centred care interventions for people with chronic conditions. Thirty randomised controlled trials were identified from health-related databases. The findings indicated that most interventions were based on the notion of empowering care and included attempts to educate consumers or prompt them about how to manage a health consultation. Other common interventions focused on training providers in delivering empowering care. Although it was difficult to draw firm conclusions because of the moderate to high risk of bias of the research designs, this review has shown some promising findings from implementing a patient centred care approach. There appeared to be benefits associated with this model of care in terms of patient satisfaction and perceived quality of care.

Keywords: Systematic review; patient centred care; chronic disease; intervention



## Patient Centred approaches to Health Care: A systematic review of randomized controlled trials

The notion of patient-centred care (PCC) has been a feature in the healthcare sector since the 1950s (Bauman, Fardy, and Harris 2003). However, there has been a significant rise in its popularity over the last fifteen years, presumably as health systems seek solutions to the challenges they face in contemporary society. Although many definitions of PCC exist in the literature (Little et al. 2001; Mead and Bower 2002; Institute of Medicine (2001)), it is generally described as an approach to care that meets the specific needs, values and beliefs of patients. This approach is now acknowledged as a requirement for the delivery of safe and high-quality health care that can address the demands created by an ageing population and increasing rates of chronic conditions (Luxford, Piper, Dunbar, and Poole 2010; Institute of Medicine (2001); Department of Health (2010)). However, it remains poorly understood and is described using a range of terminology that has different meanings for different professionals (Bauman, Fardy, and Harris 2003; Stewart 2001; Mead and Bower 2002). Terms such as person-centred, client-centred, consumer-centred, user-centred, individual-centred or family-centred care are often used interchangeably, leading to confusion and barriers to practice.

In an attempt to synthesise the literature and address this confusion, several conceptual analyses have been conducted over the last decade or so (Leplege et al. 2007; McCormack and McCance 2006; Mead and Bower 2000; Hughes, Bamford, and May 2008), each resulting in frameworks or typologies that aim to inform practitioners about the key elements of PCC and its expected outcomes. Although useful, most reviews have failed to draw solid conclusions about whether or not PCC positively impacts on health outcomes for people with chronic conditions. This situation is likely to be associated with the multitude of

ways in which PCC has been operationalized and the predominance of empirical studies in this complex area. In a recent review of PCC (Rathert, Wyrwich, & Boren, 2012), it was concluded that future research should examine the specific dimensions of PCC and how they each relate to outcomes. Our review applies an existing framework (Morgan & Yoder, 2012) to categorize the domains of PCC and relate them to the expected outcomes. We have also classified PCC interventions by the type of activity that was implemented to address variability in the operationalization of PCC. Finally, to clarify the outcomes associated with PCC interventions, our review has focused only on randomized controlled trials (RCTs). Although less well controlled studies, i.e. non-RCTs, are equally valuable, RCTs are considered more rigorous as they are able to test whether a cause-effect relationship exists between variables (Sibbald and Roland 1998). The findings of this review will support health professionals to develop effective and targeted PCC strategies that can better assist people with chronic conditions in the future.

#### New Contribution

Although there are a considerable number of concept analyses (Hughes, Bamford, and May 2008; Leplege et al. 2007; McCormack and McCance 2006; Mead and Bower 2000; Morgan and Yoder 2012) and reviews of PCC (Mead and Bower 2002; Lewin, Skea, Entwistle, Zwarenstein, and Dick 2001; Amati, McDonald, Majeed, Dubois, and Rawaf 2012; Rathert, Wyrwich, and Boren 2012), there is no systematic review to our knowledge that focuses on the benefits of PCC for people with chronic conditions. Furthermore, despite a vast amount of literature on the topic of PCC, little is known about which elements of this complex intervention are effective, under what conditions and in relation to which outcomes. Therefore, the purpose of this review was to synthesize the RCTs that have been conducted in

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this area, with specific reference to the intervention type, the attributes of PCC that have been operationalized and the types of outcomes that have been achieved.

### Conceptual Framework

The model used to guide this systematic review was based on the most recent concept analysis of PCC conducted by Morgan and Yoder (2012). By examining all preceding descriptions of PCC across a range of contexts, Morgan and Yoder (2012) developed a higher-order model of PCC consisting of four key attributes:

- Holistic care: Recognises and values the whole person and responds to his or her complete needs in context, i.e. simultaneous assessment of physical, cognitive and psycho-social functioning, addressing situational, family, cultural and/or religious needs.
- Individualized care: Considers the individual's unique needs, preferences, personality and specific health concerns, i.e. development of an individual care plan.
- Respectful care: Recognises individuals as active health consumers and supports their strengths, abilities and preferences, i.e. listening to and supporting people's wishes or goals.
- Empowering care: Encourages autonomy, self-confidence and self-determination, facilitates a person's participation in decision-making through effective communication and negotiation, i.e. development of an action plan, assisting people to monitor their condition(s) and make changes to their treatment plan.

Although Morgan and Yoder (2012) provided a useful framework for describing the attributes of PCC, the importance of each element in improving consumer outcomes is not known. Indeed, Morgan and Yoder (2012) commented on the lack of clarity in the literature



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about whether the implementation of PCC was actually beneficial to consumers. In discussing this lack of evidence, Rathert et al. (2012) noted that the way in which PCC was delivered could influence the efficacy of the intervention, irrespective of which dimension was applied. For instance, they speculated that interventions involving direct personal contact with patients through emotionally supportive interactions may be associated with better outcomes. Methodologically, interventions in which a “direct contact” intervention is systematically designed and delivered are likely to offer higher levels of implementation fidelity. In contrast, interventions that involve general training of the existing workforce rely solely on the ability and willingness of that workforce to actually translate the learned changes into new practices.

Thus, our framework included a distinction between direct contact interventions and training interventions. However, direct interventions can be either complex, i.e. involving multiple components, or simple, i.e. involving only one new tool or process. Thus, our framework included three main categories of intervention type, i.e. complex and direct, simple and direct or training and indirect. As RCTs may not involve an actual manipulation of behaviour, a fourth category was included, i.e. observational study. The four categories were defined as:

- Complex intervention: consisted of a number of components, i.e. provision of a tailored action plan, service referrals, follow-ups and feedback, possibly by a new service provider.
- Simple intervention: the manipulation of one environmental condition to facilitate a different style of interaction between patients and existing health care providers, i.e. provision of medical record and treatment plan for discussion, lists of questions for patients to ask providers.

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- Training: the delivery of skills or knowledge to existing health care providers about PCC to apply within their usual practice, i.e. communication workshops to develop listening skills, presentations on shared-decision making and cultural competency.
- Observational: patients or health professionals view interactions between patients and health providers that either occur naturally or involve scripted vignettes and then rate the quality of the interactions or care provided to the patients.

In terms of outcomes, Morgan and Yoder (2012) reported frequent anecdotal reference in the literature to three major outcomes of PCC: (1) increased satisfaction with health care, (2) greater perceived quality of care and (3) improved health outcomes. Thus, the framework adopted in this study included four attributes of PCC, four intervention types and three main outcomes (Figure 1). As will be described in the method section, we used this framework as a classification system for the RCTs to facilitate our analysis.

[INSERT FIGURE 1 APPROXIMATELY HERE]

## Method

An initial search of the literature was conducted using all terminological variants of patient-centred care, i.e. client-, person-, relationship- and family-. We noted that different terminology tended to reflect different sectors, i.e. healthcare, education and disability studies. In the healthcare arena, the term patient-centred care was most commonly used and was therefore selected for this review.

A systematic search was conducted in March 2013 using the following search terms: [chronic disease (OR chronic illness)] AND [patient centred care (OR patient centered care)]. Primary health sector databases were searched: Ovid Medline, PsychExtra, PsychInfo, Health

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Reference Centre Academic, Cochrane, Informit, Scopus, Embase and Cinahl. No other inclusion criteria were used for the initial search to ensure broad capture of all potentially relevant articles. However, only studies with abstracts printed in English were included, which resulted in 1555 abstracts. All steps in the exclusion, inclusion and analysis of these abstracts were conducted by at least two independent researchers (SM, MK or AS) and checked by a senior researcher (EK). A large number of abstracts were initially excluded because they did not appear to be related to healthcare or human participants. Following initial exclusion, 259 articles were read, leading to the exclusion of a further 230 articles because they were not based on data and not RCTs, i.e. anecdotal, observational, opinion, did not measure relevant outcomes for patients or did not operationalize any of the PCC domains.

The 29 remaining articles resulted in 30 RCTs as one of the articles contained two RCTs, both of which were included in the analysis. Five of these articles reported different sub-studies drawn from two major studies, but as they focused on different variables, all were included in the analysis. The RCTs focused on a range of populations and disease states and were conducted in a range of countries between 1985 and 2012.

Given the small number of RCTs identified, no further attempt was made to restrict the sample on the basis of quality. However, the studies were graded in terms of “risk of bias” using the Cochrane Risk of Bias tool (Liberati et al. 2009), referred to in the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines (Moher, Liberati, Tetzlaff, and Altman 2009). As there is considerable debate about the process of assessing study quality (Juni, Altman, & Eggar, 2001), our approach was to focus on the most tangible features of the studies that could bias the findings. Specifically, the RCTs were checked for sequence generation, i.e. how randomisation occurred, allocation concealment, finding, incomplete outcome data, i.e. significant loss to follow up, and selective outcome reporting. Other potential sources of bias were also considered in our interpretation of the



findings, but a bias score, i.e. high, moderate or low risk, was allocated on the basis of these major dimensions. For example, a study with a small sample size and significant drop out rate was classified as having a high risk of bias. A limited number of low risk ( $n=5$ ) to moderate risk ( $n=8$ ) studies were identified, with the majority of RCTs being evaluated as having high risk of bias ( $n=17$ ). This situation is not unexpected in this complex area where the ability to control research environments is restricted.

The studies were then categorized according to the PCC dimensions that featured in the intervention, the type of intervention and the nature of the outcomes that were measured in the study, i.e. satisfaction, perceived quality of care or health outcomes. Nine interventions demonstrated only one attribute of PCC, ten contained two attributes, five contained three attributes and six interventions contained all four attributes. The most common attribute of PCC was empowerment ( $n=25$ ). Fifteen interventions featured respect, 16 individualized care, and 12 holistic care. In terms of type of PCC intervention, the studies were coded as complex interventions ( $n=16$ ); simple interventions ( $n=7$ ); training interventions ( $n=12$ ; 6 of which were embedded within a complex intervention and were therefore coded twice) or observational studies ( $n=1$ ). The outcomes were well represented across the studies, with 22 RCTs providing only one of the three outcomes, six containing two outcomes and two containing all three outcomes.

Although the RCTs provided sufficient data to support the application of statistical meta-analysis, they were too heterogeneous in their focus, methods and outcome measures to ensure a reliable analysis. Thus, the review was conducted using a narrative synthesis. Table 1 summarizes key features of the RCTs identified in this study. The discussion below is organized around the three outcome categories that were of interest to this study (patient satisfaction, perceived quality of care and health outcomes).

[INSERT TABLE 1 APPROXIMATELY HERE]

## Results

### Patient Satisfaction

Fourteen studies focused on patient satisfaction, with either treatment or the outcomes of treatment, following a PCC intervention. Improved patient satisfaction was demonstrated in seven of these studies, the majority ( $n=6$ ) of which involved an empowering intervention (Egan, Kessler, Laporte, Metcalfe, and Carter 2007; Maly, Bourque, and Engelhardt 1999; Woodcock, Kinmonth, Campbell, Griffin, and Spiegel 1999; Saha and Beach 2011; Evans, Kiellerup, Stanley, Burrows, and Sweet 1987; Thompson, Nanni, and Schwankovsky 1990; Kinmonth, Woodcock, Griffin, Spiegel, and Campbell 1998). Three of these studies contained interventions that focused on training existing health professionals to deliver PCC (Evans, Kiellerup, Stanley, Burrows, and Sweet 1987; Woodcock, Kinmonth, Campbell, Griffin, and Spiegel 1999; Kinmonth, Woodcock, Griffin, Spiegel, and Campbell 1998), but many studies included training as part of a broader intervention, either directly training providers or indirectly influencing providers by training patients. One other non-training study, Saha and Beach (2011), randomized participants to watch either high or low patient-centred vignettes that portrayed different styles of doctor behavior. Doctors portrayed as being highly patient-centred were considered by patients to be more trustworthy than those who were low in patient-centredness. Participants stated that they were more likely to follow recommendations given by the patient-centred doctors and reported that they would be more satisfied and comfortable with the interaction.

Only two of the studies had a minimal risk of bias (Kinmonth, Woodcock, Griffin, Spiegel, and Campbell 1998; Woodcock, Kinmonth, Campbell, Griffin, and Spiegel 1999), both finding that intervention patients reported better communication with their doctor and

increased treatment satisfaction compared to the control group. Intervention patients rated their care more positively than control group participants.

The remaining five studies with higher risk of bias all found statistically significant improvements in satisfaction. Two studies, Maly et al. (1999) and Thompson et al.'s (1990) study 2 used a simple intervention designed to enhance patient ability to communicate actively with the doctor. Given that complete blinding of experimental conditions was not possible, there was a potential that doctors were inadvertently “coached” to treat intervention clients differently. Nevertheless, these studies confirmed that altering provider behaviour to support empowerment of patients was a successful PCC strategy that resulted in enhanced patient satisfaction. Study 2 by Thompson et al. (1990) also found that patients were more satisfied with their consultation when they were less anxious, more confident in their ability to remember the information they received, and more familiar with the doctor, all of which are characteristic of a state of empowerment. The only complex intervention (Egan, Kessler, Laporte, Metcalfe, and Carter 2007), which contained all four dimensions of PCC, also resulted in increased patient satisfaction. However, study findings discussed above suggest that less complex interventions can achieve the same result, presumably at much less expense.

The seven studies that failed to find significant changes in patient satisfaction for intervention groups relative to control groups included four complex interventions and three simple interventions, all focused on empowerment (Kennedy et al. 2004; Garcia-Aymerich et al. 2007; Green et al. 2008; Thompson, Nanni, and Schwankovsky 1990; Greenfield, Kaplan, Ware, Yano, and Frank 1988; Greenfield, Kaplan, and Ware 1985; Dobscha et al. 2009). Four of these studies were identified as being at high risk of bias and only Green et al. (2008) was a low risk study. This study involved a complex intervention where one patient group was given access to a web-based clinical pharmacist, and control group patients were advised to



work with their doctors to improve their blood pressure. The lack of significant difference between control and intervention patients could have been attributed to the fact that control patients also had the opportunity to discuss concerns and care plans with a health professional. Hence, any circumstance that encourages positive personal contact with a health professional may be sufficient to increase patient satisfaction.

The complex interventions (Dobscha et al. 2009; Garcia-Aymerich et al. 2007; Green et al. 2008; Kennedy et al. 2004) all focused on empowering and individualized care, and failed to generate any improvements in patient satisfaction. Importantly, Kennedy et al. (2004) did not include a full randomization process in that the delivery of the intervention was dependent on whether the doctor believed that the patient was a suitable candidate. Thus, the intervention was potentially biased by the doctor's beliefs, and perhaps by the existing quality of the doctor-patient relationship. Garcia-Aymerich et al. (2007) used only a small sample that may have reduced power to detect any effects. Furthermore, complex interventions are difficult to control and the bias inherent in these designs may, therefore, obscure positive effects. Thus, the finding that complex interventions were not successful cannot be fully supported.

Although the patient-centred vignettes used in the Saha and Beach (2011) study were slightly longer in duration than the control vignettes and the former led to higher levels of satisfaction, the simple intervention conducted by Maly et al. (1999) demonstrated that higher levels of satisfaction were not necessarily associated with longer duration encounters. In contrast, the simple intervention conducted by Greenfield et al. (1985) revealed no significant difference in either patient satisfaction or consultation time between intervention and control groups. Increases in satisfaction were found when patients were prompted to actively engage in the consultation rather than simply being given information. Thus, it is possible that patient

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satisfaction is inherently linked to active involvement in the healthcare process, even if this engagement occurs as a result of a simple procedural change.

### Perceived Quality of Care

Eleven studies focused on quality of care, using a mixture of generic (i.e. physician satisfaction questionnaire) and specific measures (i.e. Patient Assessment of Chronic Illness Care [PACIC] instrument) (Sullivan, Leigh, and Gaster 2006; Boulton et al. 2008; Boyd et al. 2009; Greenfield, Kaplan, and Ware 1985; Greenfield, Kaplan, Ware, Yano, and Frank 1988; Kinmonth, Woodcock, Griffin, Spiegel, and Campbell 1998; Marsteller et al. 2010; Saha and Beach 2011; Woodcock, Kinmonth, Campbell, Griffin, and Spiegel 1999; Nygardh, Malm, Wikby, and Ahlstrom 2012; Wagner et al. 2012). The studies typically focused on improvements in tangible aspects of care (as rated by either patients or providers) following complex interventions that usually involved training. It was difficult to determine whether or not the training interventions translated into actual care delivery, given that none included a manipulation check (i.e. a measure to see if the independent variable had the intended effect) (Gravetter and Forzano, 2012). Most interventions focused on empowering and respectful care, although three focused only on holistic care (Boulton et al. 2008; Boyd et al. 2009; Marsteller et al. 2010). Although not focused on a complex or simple intervention, Saha and Beach (2011) also found that doctors in the high patient-centred vignettes were rated as being more competent and likely to provide higher quality care than those in the control vignettes. The patient-centred vignettes were specifically designed to convey this approach via partnership and rapport building, with doctors exploring the individual concerns and needs of patients. There was also a focus on verbal and non-verbal communication, i.e. the provision of non-medical jargon and empathy. All the interventions demonstrated significant improvements in quality of care, although four revealed mixed findings as there were

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improvements in some but not all measures (Marsteller et al. 2010; Sullivan, Leigh, and Gaster 2006; Woodcock, Kinmonth, Campbell, Griffin, and Spiegel 1999; Wagner et al. 2012). All but two studies (Kinmonth, Woodcock, Griffin, Spiegel, and Campbell 1998; Woodcock, Kinmonth, Campbell, Griffin, and Spiegel 1999) had a high or moderate risk of bias.

Four studies reported improved quality of care as rated by patients (Kinmonth, Woodcock, Griffin, Spiegel, and Campbell 1998; Boulton et al. 2008; Boyd et al. 2009; Nygardh, Malm, Wikby, and Ahlstrom 2012). Specifically, patients reported improved levels of communication, coordination and decision-making. Woodcock et al. (1999) assessed both patient and provider perceptions of quality and found that intervention patients described the care they received as consisting of more positive qualities and better communication following the training intervention. However, the trained nurses who delivered the intervention reported being less satisfied with the style of care they delivered in the experimental condition. The authors concluded that, following training, the nurses may have doubted their ability to deliver their newly acquired skills and, hence, did not rate their performance highly. It is possible that training raised awareness of new practices and philosophies in a way that encouraged providers to be more critical of their performance until such time as they mastered the new skill.

Two other studies (Marsteller et al. 2010; Sullivan, Leigh, and Gaster 2006) found improvements in some aspects of care quality as rated by providers. Specifically, providers who received training were more likely than control providers to feel competent, capable and knowledgeable, and reported more appropriate use of time, positive relationships with patients and agreement about care. However, other features of care did not significantly improve, such as receptiveness to patients, information provision, satisfaction with the



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management of care, knowledge about patients' circumstances and interactions with specialists.

Three studies used a simple intervention (Greenfield, Kaplan, and Ware 1985; Greenfield, Kaplan, Ware, Yano, and Frank 1988; Wagner et al. 2012). The first two focused on empowering patients by increasing their capacity to engage with providers. Both studies used an objective assessment of care quality, based on external assessment of consultation recordings, and found that the intervention patients were more active, i.e. they asked more questions, and the doctors were less controlling of the interaction, i.e. a reduction in the traditional communication pattern. The two studies also observed patient-reported improvements in the quality of healthcare interactions, even though there was no change in patient satisfaction. The study by Wagner et al. (2012) also focused on empowering patients to utilise their own personal health record, but found only limited improvement in perceived quality of care. Authors for this third study emphasised that the role of health care records in improving the quality of healthcare needs further investigation.

In summary, it appeared that training of providers contributed to increased quality of care as perceived by both providers and patients. Specifically, care appeared to be more coordinated, competent and collegial following training. However, care was also improved by simple changes in the patient's capacity to engage with the provider.

#### Health Outcomes.

Health outcomes were categorized into clinical outcomes, i.e. those based on tangible clinical measurement, functional outcomes, i.e. subjective performance-based outcomes such as activities of daily living and emotional wellbeing, personal outcomes, i.e. self-management skills and patient activation, and system outcomes, i.e. level of service usage and costs of healthcare. Twenty-one studies included health outcome measurements, with six focused on

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clinical outcomes (Garcia-Aymerich et al. 2007; Green et al. 2008; Greenfield, Kaplan, Ware, Yano, and Frank 1988; Kinmonth, Woodcock, Griffin, Spiegel, and Campbell 1998; Woodcock, Kinmonth, Campbell, Griffin, and Spiegel 1999; Wagner et al. 2012), twelve focused on functional/emotional outcomes (Simon, Ludman, Bauer, Unutzer, and Operskalski 2006; Landefeld, Palmer, Kresevic, Fortinsky, and Kowal 1995; Dobscha et al. 2009; Munoz Alamo, Ruiz Moral, and Perula de Torres 2002; Bakitas et al. 2009; Kinmonth, Woodcock, Griffin, Spiegel, and Campbell 1998; Greenfield, Kaplan, and Ware 1985; Greenfield, Kaplan, Ware, Yano, and Frank 1988; Woodcock, Kinmonth, Campbell, Griffin, and Spiegel 1999; Davison and Degner 1997; Nygardh, Malm, Wikby, and Ahlstrom 2012; Nijhof, Bleijenberg, Uiterwaal, Kimpen, and van de Putte 2012), fourteen on personal outcomes (Davison and Degner 1997; Greenfield, Kaplan, and Ware 1985; Greenfield, Kaplan, Ware, Yano, and Frank 1988; Thompson, Nanni, and Schwankovsky 1990; Boyd et al. 2009; Briggs, Kirchhoff, Hammes, Song, and Colvin 2004; Maly, Bourque, and Engelhardt 1999; Garcia-Aymerich et al. 2007; Kinmonth, Woodcock, Griffin, Spiegel, and Campbell 1998; Woodcock, Kinmonth, Campbell, Griffin, and Spiegel 1999; McWilliam et al. 1999; Nygardh, Malm, Wikby, and Ahlstrom 2012; Wagner et al. 2012), and eight on system outcomes (Green et al. 2008; Battersby et al. 2007; Landefeld, Palmer, Kresevic, Fortinsky, and Kowal 1995; Dobscha et al. 2009; Bakitas et al. 2009; Casas et al. 2006; Simon, Ludman, Bauer, Unutzer, and Operskalski 2006; Wagner et al. 2012).

#### Clinical Outcomes.

In terms of clinical measurements, such as blood pressure and diabetic control, all studies involved empowering and respectful care interventions, except Garcia-Aymerich et al. (2007) which involved an empowering and individualized care intervention, and Wagner et al. (2012) which focused on empowerment. Three studies had a low risk of bias (Green et al.

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2008; Kinmonth, Woodcock, Griffin, Spiegel, and Campbell 1998; Woodcock, Kinmonth, Campbell, Griffin, and Spiegel 1999). The only simple intervention, which was designed to encourage patients to ask questions, showed subsequent improvements in HbA1c (Greenfield, Kaplan, Ware, Yano, and Frank 1988). Wagner et al. (2012) allowed intervention patients to contact their physician online, via a nurse, when required, but found no significant change in blood pressure scores compared to the control group. Given that approximately one-third of intervention patients in the study by Wagner et al. (2012) did not utilise their health care records after initial training, it is not surprising that this intervention failed to have any impact.

Two training interventions demonstrated no change, or a deterioration relative to the control group in HbA1c levels, blood cholesterol concentrations, triglycerides and weight/BMI (Kinmonth, Woodcock, Griffin, Spiegel, and Campbell 1998; Woodcock, Kinmonth, Campbell, Griffin, and Spiegel 1999). Two complex interventions revealed mixed findings (Garcia-Aymerich et al. 2007; Green et al. 2008), with improvements in systolic blood pressure, hypertension management and pulmonary function after six months, but not in lung function or BMI. In relation to the negative findings of weight gain in the intervention participants, Kinmonth et al. (1998) noted that intensive diabetic treatment can contribute to weight gain, suggesting that increased adherence to medication routines, i.e. a positive outcome, in their intervention group may have had a negative impact on BMI.

These findings suggest that PCC may have little impact on clinical outcomes. Training of health providers is unlikely to be effective, but simple interventions designed to increase empowerment and active engagement during the medical decision-making process may have a positive impact, presumably by influencing the level of general patient engagement. Complex interventions resulted in mixed findings, with improvements in some clinical indicators and a negative impact on others. These findings highlight the complexity



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of managing chronic conditions and the importance of patient engagement in the process of achieving good clinical outcomes.

#### Functional Outcomes.

Overall, twelve studies focused on functional outcomes, nine of which identified positive impacts. Of the nine studies, seven showed an improvement in mental/emotional wellbeing (Bakitas et al. 2009; Kinmonth, Woodcock, Griffin, Spiegel, and Campbell 1998; Munoz Alamo, Ruiz Moral, and Perula de Torres 2002; Simon, Ludman, Bauer, Unutzer, and Operskalski 2006; Woodcock, Kinmonth, Campbell, Griffin, and Spiegel 1999; Landefeld, Palmer, Kresevic, Fortinsky, and Kowal 1995; Dobscha et al. 2009) and seven showed improvements in physical symptoms or independence (Greenfield, Kaplan, and Ware 1985; Greenfield, Kaplan, Ware, Yano, and Frank 1988; Landefeld, Palmer, Kresevic, Fortinsky, and Kowal 1995; Munoz Alamo, Ruiz Moral, and Perula de Torres 2002; Simon, Ludman, Bauer, Unutzer, and Operskalski 2006; Bakitas et al. 2009; Nijhof, Bleijenberg, Uiterwaal, Kimpen, and van de Putte 2012). Empowering care featured in all but one of these interventions (Landefeld, Palmer, Kresevic, Fortinsky, and Kowal 1995), which focused on a complex holistic and individualized care intervention.

One study that failed to demonstrate emotional improvements (Davison and Degner 1997) involved a simple intervention, whereas successful interventions mostly involved training for providers or the introduction of trained nurses. There was some evidence that emotional improvements were long lasting in two such studies (Munoz Alamo, Ruiz Moral, and Perula de Torres 2002; Dobscha et al. 2009). Two other studies revealed mixed findings. For example, there were significant improvements in the frequency but not the intensity of depressive symptoms in Bakitas et al's (2009) study of cancer patients. Simon et al's (2006) study of people with bipolar disorder showed significant improvements for mania, but not for

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depression. These study discrepancies were attributed to the difficulty associated with improving outcomes in palliative care populations, such as cancer patients (Bakitas et al. 2009) and the differential effectiveness of pharmaceutical treatments for different disorders (Simon, Ludman, Bauer, Unutzer, and Operskalski 2006).

The five studies that identified some improvement in performance of activities of daily living or physical health focused on patients with peptic ulcers (Greenfield, Kaplan, and Ware 1985), diabetes (Greenfield, Kaplan, Ware, Yano, and Frank 1988), chronic musculoskeletal disorder (Munoz Alamo, Ruiz Moral, and Perula de Torres 2002), chronic fatigue syndrome (Nijhof, Bleijenberg, Uiterwaal, Kimpen, and van de Putte 2012) and elderly patients following discharge from an acute care unit (Landefeld, Palmer, Kresevic, Fortinsky, and Kowal 1995). In these studies, intervention patients reported better overall health status, improved functioning and independence and fewer physical and role limitations, particularly if they were more actively involved in their care. These interventions involved targeted modifications of patients' environments to enhance their access to supports for functional capacity, or to prompt their engagement in medical care, with the exception of Muñoz Alamo et al. (2002), which was a training intervention for doctors..

The positive findings revealed by Muñoz Alamo et al. (2002) only pertained to the number of tender points reported by patients with musculoskeletal pain. Broader functional outcomes, such as mobility, energy and social isolation were not statistically significant. Also, other indicators of functional improvements, including pain intensity and sleep quality remained unimproved. There was also no improvement in self-reported health status for patients with chronic kidney disease in the training intervention by Nygardh et al. (2012). These findings suggest that training and education are insufficient to bring about functional changes. However, a study with low risk of bias (Nijhof, Bleijenberg, Uiterwaal, Kimpen, and van de Putte 2012) demonstrated that online education and support for adolescents with

chronic fatigue syndrome can lead to physical improvements, i.e. fatigue severity and physical functioning. These positive changes were maintained at the 12 month follow up suggesting a sustained impact.

In contrast, the positive changes identified by Landefeld et al. (1995) disappeared after three months, suggesting that it may be unreasonable to expect long-term benefits from a brief intervention without ongoing support. Thus, the conclusions that can be drawn in relation to functional outcomes are that simple targeted PCC interventions that enhance support and encourage patient engagement may have the potential to improve physical independence, but perhaps not in the long-term if they are brief interventions. PCC appears unable to influence physical symptoms, such as sleep quality, pain and intensity of symptoms. Empowering providers, however, appears to have a positive impact on patient emotional wellbeing.

#### Personal Outcomes.

Fourteen studies focused on personal outcomes that involved changes in patients' ways of knowing, thinking or perceiving their circumstances and engaging with their healthcare (Garcia-Aymerich et al. 2007; Greenfield, Kaplan, and Ware 1985; Greenfield, Kaplan, Ware, Yano, and Frank 1988; Kinmonth, Woodcock, Griffin, Spiegel, and Campbell 1998; Thompson, Nanni, and Schwankovsky 1990; Woodcock, Kinmonth, Campbell, Griffin, and Spiegel 1999; McWilliam et al. 1999; Maly, Bourque, and Engelhardt 1999; Briggs, Kirchhoff, Hammes, Song, and Colvin 2004; Boyd et al. 2009; Davison and Degner 1997; Kennedy et al. 2004; Nygardh, Malm, Wikby, and Ahlstrom 2012; Wagner et al. 2012). These studies focused on the level of knowledge and understanding people reported having about their condition, the confidence they felt regarding its management, and their desire to be actively involved in their own treatment or to change the way they took care of their



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disease. In most studies, researchers suggested that these outcomes might be moderators or mediators of other outcomes, indicating the possibility that they could represent the mechanism by which PCC influences more tangible outcomes. However, no studies directly tested this assumption, and thus, these conclusions cannot be drawn.

Eleven of the twelve studies demonstrated improvements in personal outcomes. Specifically, Davidson and Degner (1997) found no difference in the desire to be involved in treatment decision-making, but did find an improvement in the level of active involvement in healthcare following a simple empowering and respectful care intervention. The majority of men with prostate cancer in this study utilised all or some of the information that was provided.

A similar simple patient empowerment intervention conducted by Greenfield et al. (1985) demonstrated an increase in preference for involvement in health care decisions and in the number of questions asked by patients. Although there was no difference in acquired diabetes knowledge between groups, intervention diabetic patients were more active in their care and twice as effective at eliciting the necessary information according to Greenfield et al. (1988). The two studies conducted by Thompson et al. (1990) also found that patients were more likely to ask questions in consultations, and reported higher levels of perceived control. The complex guided care approach of Boyd et al. (2009) that involved training of providers resulted in improved levels of patient activation at 18 month follow-up, and the complex training intervention by Kennedy et al. (2004) also demonstrated higher enablement scores. Furthermore, patients who were treated by intervention staff trained in empowerment in Nygardh et al. (2012) were more likely than those in the control condition to believe it was worthwhile to change the way in which they managed their chronic kidney disease.

Intervention patients reported less decisional conflict in terms of their treatment following a complex intervention that addressed all domains of PCC (Briggs, Kirchhoff,

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Hammes, Song, and Colvin 2004). Intervention patients in Maly et al. (1999) and ‘study 2’ by Thompson et al. (1990) felt less apprehensive about seeing their progress notes and were significantly more likely to seek information compared to the control groups. However, as these researchers did not assess the patient’s actual knowledge of their condition or its management, conclusions could not be drawn as to the impact of this information. In this regard, Garcia-Aymerich et al. (2007) demonstrated an increase in disease-specific knowledge following self-management education, an individually tailored care plan and follow up assessments. However, this study found no improvement in lung functioning to accompany increased knowledge, leading to the conclusion that more tangible benefits may be seen over time as participants gained more control over their condition.

In contrast to these findings, there was no increase in patient activation in Wagner et al. (2012) or in perceived control in Kinmonth et al. (1998) following a PCC training intervention for GPs and practice nurses. These findings were consistent with Woodcock et al. (1999) who focused on different data from the same study; patients had significantly less diabetes knowledge compared to the control group. The authors speculated that the delivery of PCC interventions may allow less time for the delivery of disease specific information because practitioners focus more on patient-driven concerns. However, a significantly reduced desire for information was identified in the intervention group compared to the control group at 22 weeks and one year following a complex empowering intervention conducted by McWilliam et al. (1999). The authors did not anticipate this outcome, but suggested that the patient-centred approach may have actually met the information needs of the intervention participants.

System Outcomes.

Eight studies focused on system outcomes of some kind, although the conclusions were difficult to interpret. Intervention patients who were low users of their online health records had a higher number of hospital inpatient days than those who used their health records (Wagner et al. 2012). However, this study had a moderate risk of bias due to the poor implementation of the intervention. In contrast, a low risk study (Bakitas et al. 2009) found no difference in survival rates following a PCC intervention for cancer patients and no decrease in hospitalisation or emergency department use, although it is not surprising that PCC might not influence the hospitalization of cancer patients. Further, according to Battersby et al. (2007), PCC interventions were generally too short to result in hospital avoidance even for those with chronic conditions. However, these authors did report increased access to and use of community and allied health services among intervention patients that was likely to have been facilitated by vigilant care coordinators who made appropriate referrals (Battersby et al. 2007).

In patients with respiratory conditions, however, Casas et al. (2006) did find a reduction in hospital admission rates and an increase in the duration of admission-free periods among intervention patients, with no commensurate increase in visits to the doctor. . Casas et al. (2006) concluded that their complex integrated care intervention with individualized education programs, access to specialized case managers and a web-based call centre, demonstrated potential for cost-containment, even though no economic evaluation of costs were actually conducted.

Intervention patients in the study conducted by Landefeld et al. (1995) also had shorter mean durations of hospital stay (one day) and did not use more services than the control group during the three months post-discharge. Furthermore, the authors confirmed that fewer acutely ill elderly patients were discharged to long-term institutional care compared to the control group, suggesting that PCC may contribute to more appropriate use



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of community resources as opposed to costly institutional resources. Green et al. (2008) confirmed that PCC resulted in reduced use of specialists and increased use of telephone consultations with community pharmacists, which were associated with improvements in home medication management. However, no change was found in use of primary health care. Interestingly, Dobscha et al. (2009) also found no difference in the use of primary care, suggesting that this resource may be underutilized. Indeed, the study conducted by Simon et al. (2006) found improved medication usage yet no increase in the number of medication management visits for PCC intervention participants who suffered from bipolar, suggesting more positive attitudes towards medication use following complex PCC interventions.

## Discussion

Although health professionals are now expected to adopt patient-centred approaches when caring for patients, there is a dearth of information about how to do so and the benefits of this model of care. This systematic review clarified the benefits that can be expected to accrue from specific components of PCC in relation to consumers with chronic conditions. The findings revealed some consistent patterns of findings across studies but in other cases, results were mixed, difficult to interpret, or based on moderate to high risk study designs. There was also a lack of detail of the interventions design in most of the included studies. These limitations need to be taken into account when considering the findings. Nevertheless, the findings appear to be promising. For example, the results from prior research suggest that simple empowerment interventions resulted in higher levels of patient satisfaction about their care, presumably because it also resulted in higher levels of engagement, need for information and knowledge about their conditions. Training for providers in PCC appeared to contribute to some aspects of care quality, more so from the patient's perspective. This was also demonstrated by the change in patient engagement during patient-centred consultations,

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i.e. more active participation in their care. Similarly, empowerment training for providers resulted in improved emotional outcomes for patients. Although empowering interventions that stimulated patient engagement in health care may contribute to functional outcomes, such as better overall health status and fewer physical and role limitations, PCC as a model of care had little impact on clinical and functional outcomes, other than emotional well-being.

There was some evidence that the outcomes of PCC interventions might not be sustained over time. Trials of a longer duration to determine if the benefits of PCC are maintained are required. Furthermore, research is needed to determine whether or not the increase in community service use seen in some studies was appropriate or simply added extra cost to the overall system without significant health benefits.

Perhaps the most compelling conclusion in this review is that PCC interventions focused on training health professionals to improve their communication skills whilst directly engaging consumers in the decision making process held the most potential for improving patient engagement and satisfaction. These interventions appeared to influence the perception of the health provider as being competent and trustworthy, resulting in higher levels of agreement and concordance with provider recommendations. There was some evidence to suggest that facilitating a relationship with any provider could bring about similar benefits and the nature of patient-provider relationships requires further investigation to determine the level of communication required to facilitate positive outcomes.

The findings about improved personal outcomes, such as patient engagement, knowledge acquisition, self-management and confidence, were complex and mixed. Although the majority of studies identified positive changes in these areas, they failed to examine the potential role of these factors as mediators or moderators of other outcomes. The findings suggested that providing patients the opportunity to learn more about their health status, by giving information on their condition or their individual progress, or providing the

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opportunity to ask questions, can increase patient desire for knowledge. This may lead to an increase in actual knowledge which, over time, could be translated into more tangible outcomes. However, evidence did not exist that increased knowledge or self-management ability resulted in an improvement in clinical indicators, particularly with short-term interventions. Further research is needed to determine whether or not long-term benefits of PCC might be realized through the early prevention of emotional and functional deterioration.

Patients and providers appeared to perceive quality of care differently, even following the same intervention. In general, patients perceived higher quality care if there was better communication, a trusting relationship and active engagement between the provider and the patient which focused on the patient's needs. However, there were mixed results in relation to provider satisfaction with the care they delivered. Some trained providers reported greater clinical but not personal knowledge of their patients, i.e. more knowledge about the patient clinical characteristics versus personal circumstances, while others reported less satisfaction with the care provided. Consequently, this latter finding raises more questions because it was from a study identified as having a low risk of bias.

Importantly, the provision of PCC did not require longer consultation or appointment times, but required a qualitatively different interaction. The delivery of relatively minimal interventions could potentially increase appropriate service use and minimize costly overuse of treatments that are ultimately likely to result in higher levels of treatment burden for patients and their families. However, this review identified that short-term interventions are unlikely to bring about sustained improvements in clinical indicators. Conversely, it has been recognized in the primary care literature that brief interventions can result in more sustained effects, as identified by Kaner et al. (2007) in their review of brief alcohol interventions. Considering that time emerged as a barrier to the implementation of PCC, there is the need



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for further research into the effectiveness of brief PCC interventions for supporting consumers with chronic illness, particularly in primary care, which is an underutilized resource.

The studies that provided training to health care providers in PCC all assumed that changes in the provider's style of practice followed suit. Several studies demonstrated the flaw in this assumption, suggesting that more PCC did not automatically follow training. Nevertheless, training for health professionals in communication and shared-decision making was generally associated with improvements in satisfaction and perceived quality of care, at least from the patient's perspective. Furthermore, when patients were provided with an opportunity to actively participate in their health care, they appeared to build a trusting relationship with their providers. When negative clinical outcomes were reported, other factors may have contributed to these results, highlighting the complexity of providing health care for consumers with chronic illnesses.

This review represents the first systematic assessment of RCTs supporting the efficacy of interventions involving one or more of the following PCC attributes: holistic, empowering, respectful and individualising care (Morgan and Yoder 2012); specifically for people with chronic illnesses. Although some useful conclusions were drawn from this review, these are limited by variability in the definition of PCC, the outcome measures used and the lack of detail about the actual interventions in the studies. Despite selecting only RCTs, a high risk of bias was identified in most studies, reflecting the complexity of this field of research. Furthermore, the data were insufficient to examine the proposition that different types of PCC might be preferred by some types of patients in different circumstances, which could be a focus for future research.

Notwithstanding these limitations, this review has enabled some important patterns to emerge that should now be tested in more detail. There appear to be definite benefits to be

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derived from patient centred care delivery, particularly empowering interventions or training for providers to support their practice in this area.

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## References

- Amati, F., McDonald, A., Majeed, A., Dubois, E., & Rawaf, S. (2012). Implementation and evaluation of patient centred care in experimental studies from 2000-2010: Systematic review. *International Journal of Person Centered Medicine*, 1, 348-357.
- Bakitas, M., Lyons, K. D., Hegel, M. T., Balan, S., Brokaw, F. C., Seville, J., ... Ahles, T. A. (2009). Effects of a palliative care intervention on clinical outcomes in patients with advanced cancer. *JAMA: The Journal of the American Medical Association*, 302(7), 741-749.
- Battersby, M., Harvey, P., Mills, P. D., Kalucy, E., Pols, R. G., Frith, P. A., ... McGowan, C. (2007). SA HealthPlus: A controlled trial of a statewide application of a generic model of chronic illness care. *Milbank Quarterly*, 85(1), 37-67.
- Bauman, A. E., Fardy, H. J., & Harris, P. G. (2003). Getting it right: Why bother with patient centred care? *Medical Journal of Australia*, 179(5), 253-6.
- Boult, C., Reider, L., Frey, K., Leff, B., Boyd, C. M., Wolff, J. L., ... Scharfstein, D. (2008). Multidimensional geriatric assessment: Back to the future early effects of “guided care” on the quality of health care for multimorbid older persons: A cluster-randomized controlled trial. *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences*, 63(3), 321-327.
- Boyd, C., Reider, L., Frey, K., Scharfstein, D., Leff, B., Wolff, J., ... Boult, C. (2009). The effects of guided care on the perceived quality of health care for multi-morbid older persons: 18-month outcomes from a cluster-randomized controlled trial. *Journal of General Internal Medicine*, 25(3), 235-242.
- Briggs, L. A., Kirchhoff, K. T., Hammes, B. J., Song, M. K., & Colvin, E. R. (2004). Patient-centered advance care planning in special patient populations: A pilot study. *Journal*



McMillan SS, Kendall E, Sav A, King MA, Whitty JA, Kelly F, Wheeler AJ. Patient-centred approaches to health care: a systematic review of randomised controlled trials. The final, definitive version of this paper has been published in *Medical Care Research and Review* 2013; 70(6):567-96. DOI: 10.1177/1077558713496318 by Sage Publications. All rights reserved. © [McMillan SS., et al 2013.]

*of Professional Nursing: Official Journal of the American Association of Colleges of Nursing*, 20(1), 47-58.

Casas, A., Troosters, T., Garcia-Aymerich, J., Roca, J., Hernández, C., Alonso, A., ... del Pozo, F. (2006). Integrated care prevents hospitalisations for exacerbations in COPD patients. *The European Respiratory Journal: Official Journal of the European Society for Clinical Respiratory Physiology*, 28(1), 123-30.

Davison, B., & Degner, L. (1997). Empowerment of men newly diagnosed with prostate cancer. *Cancer Nursing*, 20(3), 187-196.

Department of Health. (2010). *Equity and Excellence: Liberating the NHS*. London: The Stationary Office.

Dobscha, S. K., Corson, K., Perrin, N. A., Hanson, G. C., Leibowitz, R. Q., Doak, M. N., ... Dickinson, K. C. (2009). Collaborative care for chronic pain in primary care: A cluster randomized trial. *JAMA: The Journal of the American Medical Association*, 301(12), 1242-1252.

Egan, M., Kessler, D., Laporte, L., Metcalfe, V., & Carter, M. (2007). A pilot randomized controlled trial of community-based occupational therapy in late stroke rehabilitation. *Topics in Stroke Rehabilitation*, 14(5), 37-45.

Evans, B. J., Kiellerup, F. D., Stanley, R. O., Burrows, G. D., & Sweet, B. (1987). A communication skills programme for increasing patients' satisfaction with general practice consultations. *British Journal of Medical Psychology*, 60, 373-378.

Garcia-Aymerich, J., Hernandez, C., Alonso, A., Casas, A., Rodriguez-Roisin, R., Anto, J. M., & Roca, J. (2007). Effects of an integrated care intervention on risk factors of COPD readmission. *Respiratory Medicine*, 101(7), 1462-9.

Gravetter, F. J., & Forzano, L.A. (2012). *Research Methods for the Behavioral Sciences*. 4th ed. USA: Wadsworth cengage learning.

McMillan SS, Kendall E, Sav A, King MA, Whitty JA, Kelly F, Wheeler AJ. Patient-centred approaches to health care: a systematic review of randomised controlled trials. The final, definitive version of this paper has been published in *Medical Care Research and Review* 2013; 70(6):567-96. DOI: 10.1177/1077558713496318 by Sage Publications. All rights reserved. © [McMillan SS., et al 2013.]

Green, B. B., Cook, A. J., Ralston, J. D., Fishman, P. A., Catz, S. L., Carlson, J., ...

Thompson, R. S. (2008). Effectiveness of home blood pressure monitoring, web communication, and pharmacist care on hypertension control. *The Journal of the American Medical Association*, 299(24), 2857-2867.

Greenfield, S., Kaplan, S., & Ware, J. (1985). Expanding patient involvement in care. *Annals of Internal Medicine*, 102, 520-528.

Greenfield, S., Kaplan, S., Ware, J., Yano, E., & Frank, H. (1988). Patients' participation in medical care: effects of blood sugar control and quality of life in diabetes. *Journal of General Internal Medicine*, 3, 448-457.

Hughes, J., Bamford, C., & May, C. (2008). Types of centredness in health care: themes and concepts. *Medicine, Health Care and Philosophy*, 11(4), 455-463.

Institute of Medicine. (2001). *Crossing the Quality Chasm: A New Health System for the 21st Century*. Vol. 6. Washington, DC: National Academy Press.

Kaner, E. F. S., Dickinson, H. O., Beyer, F. R., Campbell, F., Schlesinger, C., Heather, N., et al. (2007). Effectiveness of brief alcohol interventions in primary care populations. *Cochrane Database of Systematic Reviews*: John Wiley & Sons, Ltd.

Kennedy, A. P., Nelson, E., Reeves, D., Richardson, G., Roberts, C., Robinson, A., ... The North West Regional Gastrointestinal Research Group. (2004). A randomised controlled trial to assess the effectiveness and cost of a patient orientated self management approach to chronic inflammatory bowel disease. *Gut*, 53(11), 1639-45.

Kinmonth, A., Woodcock, A., Griffin, S., Spiegel, N., & Campbell, M. (1998). Randomised controlled trial of patient centred care of diabetes in general practice: Impact on current wellbeing and future disease risk. *BMJ*, 317(7167), 1202-1208.

Landefeld, C. S., Palmer, R. M., Kresevic, D. M., Fortinsky, R. H., & Kowal, J. (1995). A randomized trial of care in a hospital medical unit especially designed to improve the

McMillan SS, Kendall E, Sav A, King MA, Whitty JA, Kelly F, Wheeler AJ. Patient-centred approaches to health care: a systematic review of randomised controlled trials. The final, definitive version of this paper has been published in *Medical Care Research and Review* 2013; 70(6):567-96. DOI: 10.1177/1077558713496318 by Sage Publications. All rights reserved. © [McMillan SS., et al 2013.]

functional outcomes of acutely ill older patients. *New England Journal of Medicine*, 332(20), 1338-1344.

Lepège, A., Gzil, F., Cammelli, M., Lefève, C., Pachoud, B., & Ville, I. (2007). Person-centredness: Conceptual and historical perspectives. *Disability and Rehabilitation*, 29(20-21), 1555-1565.

Lewin, S., Skea, Z., Entwistle, V. A., Zwarenstein, M., & Dick, J. (2001). Interventions for providers to promote a patient centred approach in clinical consultations. *Cochrane Database of Systematic Reviews*.

Liberati, A., Altman, D., Tetzlaff, J., Mulrow, C., Gotzsche, P., Ioannidis, J., ... Moher, D. (2009). The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate healthcare interventions: Explanation and elaboration. *British Medical Journal*, 339, b2700.

Little, P., Everitt, H., Williamson, I., Warner, G., Moore, M., Gould, C., ... Payne, S. (2001). Observational study of effect of patient centredness and positive approach on outcomes of general practice consultations. *British Medical Journal*, 323(7318), 908-911.

Luxford, K., Piper, D., Dunbar, N., & Poole, N. (2010). *Patient centred care: Improving quality and safety by focusing care on patients and consumers — discussion paper*. Canberra: Australian Commission on Safety and Quality on Health Care.

Maly, R. C., Bourque, L. B., & Engelhardt, R. F. (1999). A randomized controlled trial of facilitating information giving to patients with chronic medical conditions: Effects on outcomes of care. *The Journal of Family Practice*, 48(5), 356-63.

Marsteller, J. A., Hsu, Y. J., Reider, L., Frey, K., Wolff, J., Boyd, C., ... Boulton, C. (2010). Physician satisfaction with chronic care processes: a cluster-randomized trial of guided care. *Annals of Family Medicine*, 8(4), 308-15.



McMillan SS, Kendall E, Sav A, King MA, Whitty JA, Kelly F, Wheeler AJ. Patient-centred approaches to health care: a systematic review of randomised controlled trials. The final, definitive version of this paper has been published in *Medical Care Research and Review* 2013; 70(6):567-96. DOI: 10.1177/1077558713496318 by Sage Publications. All rights reserved. © [McMillan SS., et al 2013.]

McCormack, B., & McCance, T. (2006). Development of a framework for person-centred nursing. *Journal of Advanced Nursing*, 56(5), 472-479.

McWilliam, C. L., Stewart, M., Brown, J. B., McNair, S., Donner, A., Desai, K., ... Galajda, J. (1999). Home-based health promotion for chronically ill older persons: results of a randomized controlled trial of a critical reflection approach. *Health Promotion International*, 14(1), 27-41.

Mead, N., & Bower, P. (2000). Patient centredness: a conceptual framework and review of the empirical literature. *Social Science and Medicine*, 51(7), 1087-1110.

Mead, N., & Bower, P. (2002). Patient centred consultations and outcomes in primary care: A review of the literature. *Patient Education and Counseling*, 48(1), 51-61.

Moher, D., Liberati, A., Tetzlaff, J., & Altman, D. G. (2009). Preferred reporting items for systematic reviews and meta-analyses: The PRISMA statement. *PLoS Medicine*, 6, e1000097.

Morgan, S., & Yoder, L. H. (2012). A concept analysis of person-centered care. *Journal of Holistic Nursing*, 30(1), 6-15.

Muñoz Alamo, M., Ruiz Moral, R., & Pérula de Torres, L. A. (2002). Evaluation of a patient centred approach in generalized musculoskeletal chronic pain/fibromyalgia patients in primary care. *Patient Education and Counseling*, 48(1), 23-31.

Nijhof, S. L., Bleijenberg, G., Uiterwaal, C. S., Kimpfen, J. L., & van de Putte, E. M. (2012). Effectiveness of internet-based cognitive behavioural treatment for adolescents with chronic fatigue syndrome (FITNET): A randomised controlled trial. *Lancet*, 379(9824), 1412-1418.

Nygardh, A., Malm, D., Wikby, K., & Ahlstrom, G. (2012). Empowerment intervention in outpatient care of persons with chronic kidney disease pre-dialysis. *Nephrology Nursing Journal*, 39(4), 285-93.

McMillan SS, Kendall E, Sav A, King MA, Whitty JA, Kelly F, Wheeler AJ. Patient-centred approaches to health care: a systematic review of randomised controlled trials. The final, definitive version of this paper has been published in *Medical Care Research and Review* 2013; 70(6):567-96. DOI: 10.1177/1077558713496318 by Sage Publications. All rights reserved. © [McMillan SS., et al 2013.]

Rathert, C., Wyrwich, M. D., & Boren, S. A. (2012). Patient-centered care and outcomes: A systematic review of the literature. *Medical Care Research and Review*.  
doi: 10.1177/1077558712465774

Saha, S., & Beach, M. C. (2011). The impact of patient-centered communication on patients' decision making and evaluations of physicians: A randomized study using video vignettes. *Patient Education and Counseling*, 84(3), 386-392.

Sibbald, B., & Roland, M. (1998). Understanding controlled trials: Why are randomised controlled trials important? *BMJ*, 316 (7126):201.

Simon, G. E., Ludman, E. J., Bauer, M. S., Unutzer, J., & Operskalski, B. (2006). Long-term effectiveness and cost of a systematic care program for bipolar disorder. *Archives of General Psychiatry*, 63(5), 500-508.

Stewart, M. (2001). Towards a global definition of patient centred care. *British Medical Journal*, 322(7284), 444-445.

Sullivan, M. D., Leigh, J., & Gaster, B. (2006). Brief report: Training internists in shared decision making about chronic opioid treatment for noncancer pain. *Journal of General Internal Medicine*, 21(4), 360-2.

Thompson, S., Nanni, C., & Schwankovsky, L. (1990). Patient-oriented interventions to improve communication in a medical office visit. *Health Psychology*, 9(4), 390-404.

Wagner, P. J., Dias, J., Howard, S., Kintziger, K. W., Hudson, M. F., Seol, Y. H., et al. (2012). Personal health records and hypertension control: a randomized trial. *Journal of the American Medical Informatics Association*, 19(4), 626-34.

Woodcock, A. J., Kinmonth, A.-L., Campbell, M. J., Griffin, S. J., & Spiegel, N. M. (1999). Diabetes care from diagnosis: Effects of training in patient centred care on beliefs, attitudes and behaviour of primary care professionals. *Patient Education and Counseling*, 37(1), 65-79.

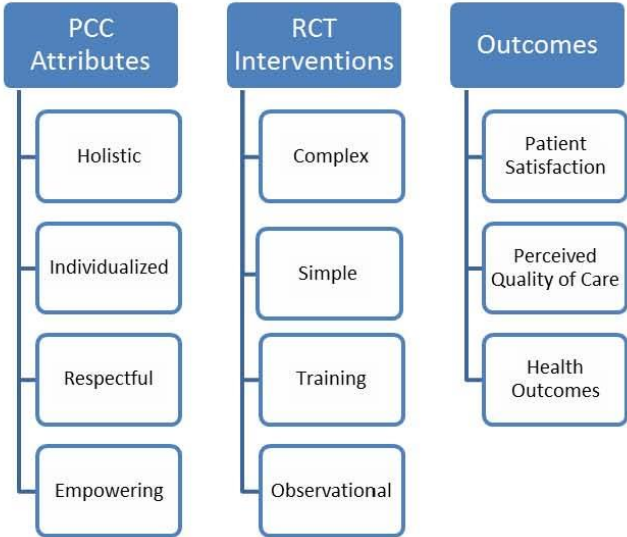


Figure 1. Conceptual model for systematic review



Table 1: Summary of RCTs

Author (Year)	Study Size N =(Intervention/ Control)	Intervention	Attributes	Bias	Outcome Measures and Findings
Bakitas et al. (2009)	161/ 161 Advanced cancer patients	Complex intervention  Advanced practice nurse conducted four educational and problem-solving sessions, monthly telephone follow-ups and group shared appointments.	Empowerment, Holistic	Low	Edmonton Symptom Assessment Score: trend towards lower symptom intensity. Centre for Epidemiological Studies Depression Scale (CES-D): lower depressed mood. Service use: No group differences in survival, days in hospital and ICU or emergency department visits.
Battersby et al. (2007)	295 GPs, 4603 patients, 100 service coordinators 4 regional sub-trials: Central: 271/138 Southern: 887/427 Eyre: 1353/513 Western: 604/410 Chronic illness patients	Complex intervention  Service coordinator used a problem and goals approach to develop a care plan and to assist with service access.	Empowerment, Holistic, Individualized, Respectful	High	Increased utilisation of community allied health services.
Boult et al.	7/7 teams from 8	Complex intervention &	Holistic	High	Patient Assessment of Chronic Illness Care

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(2008)	practices 49 physicians 7 nurse care managers 485/419 multi morbid older adults	training  Nurse care managers completed an educational program on: comprehensive assessment, motivational interviewing, evidence based guidelines for chronic conditions, self-management, cultural competence, community resources, educating and supporting caregivers and using the guided care electronic health record. They then provided 8 clinical services: home assessment, care plan, action (self-care) plan, monitoring, self-management coaching, care coordination, hospital- community transitions, caregiver education and support, facilitating community resources.			(PACIC): twice as likely to rate overall quality of care as high at 6 months for goal setting, coordination and decision support. Primary Care Provider Survey and Primary Care Assessment Tool: increased physician satisfaction for patient and carer communication and education, motivating patients and referrals to community resources. Increased knowledge of medication profile. Nurses' job satisfaction instrument: moderate- high satisfaction with model of care.
Boyd et al. (2009)	Same study as Boult <i>et al.</i> , (2008) – 18 month outcomes	Complex intervention & training	Holistic	High	PACIC: higher mean quality of care scores, with improvements in care coordination and decision support. Twice greater odds of rating their chronic care highly.

					Significant improvements in goal setting, coordination of care, problem solving, and patient activation.
Briggs et al. (2004)	13/14 patient-surrogate pairs  Advanced care patients	Complex intervention  1 hour interview: assess patient understanding of current medical condition and prognosis; explore misconceptions and rationale for advanced care planning, statement of treatment preferences survey and summary.	Empowerment, Respectful, Individualized	High	Higher congruence between patient and surrogate. Decreased patient decisional conflict regarding future medical treatment No group difference in patient and surrogates' knowledge of Advanced Care Planning. Higher quality of communication about end-of-life care.
Casas et al. (2006)	65/90 patients  2 tertiary hospitals (1 Belgium, 1 Spain)  Patients with COPD	Complex intervention  Individually tailored intervention (including 2 hour self-management education program and follow up phone calls). Specialised nurse case manager through a web-based call centre to arrange non-scheduled visits.	Individualized, Empowerment	Moderate	Fewer hospital re-admissions and higher rates of admission-free times. No group difference in the number of doctor visits
Davison and Degner	30/30 men with prostate cancer	Simple intervention  Patients were asked to think	Empowerment, Respectful	High	Higher proportion of men assumed a more active role in treatment decision making in intervention group.



(1997)		about the type of information they needed to assist them in deciding treatment. Encouraged to participate in treatment decisions (with a question list) and to bring family to consult. Provided with audiotape.			Speilberger state anxiety inventory: higher state anxiety at pre-test and lower at 6 weeks. No group difference. Centre for Epidemiologic Studies Depression Scale: no. significant group difference.
Dobscha et al. (2009)	22/24 clinicians 187/214 chronic pain patients	Complex intervention & training  Patient follow ups and information workshops with written information and a case manager assessment visit (identification of fear-avoidance beliefs, exploring treatment barriers, screening for comorbid psychiatric disorders, development of Individualized goals).	Empowerment, Holistic, Individualized	Moderate	Global VA Health Satisfaction: no group difference in ratings over 12 months. No differences for mental health or pain consultation service appointments or primary care visits. Improvements in pain-related disability and intensity. Patient Health Questionnaire: Greater improvements in intervention patients with depression.
Egan et al. (2007)	6/8 stroke patients	Complex intervention  Up to 8 visits by occupational therapist to identify meaningful activities and goals.	Empowerment, Holistic, Individualized, Respectful	High	Canadian Occupational Performance Measure: increased satisfaction with performance.

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Evans et al. (1987)	20/20 GPs 200/200 GP patients	Training  GPs attended 2 three-hour communication seminars (focused on awareness and knowledge of potential communication problems in consultations).	Respectful	High	Doctor-patient communication survey: higher overall levels of satisfaction.
Garcia-Aymerich et al. (2007)	44/69 COPD patients Spanish Centre sub-study of Casas <i>et al.</i> (2006)	Complex intervention  Comprehensive assessment, self-management education session, individually tailored care plan, follow ups, one home visit by care team, and access to call-centre.	Empowerment, Individualized	High	BMI: increased BMI. Pulmonary function tests: PaO2 levels improved after 6 months but worsened for control patients. Dyspnoea worsened slightly in both groups but no change in lung function. Satisfaction with health services: no group difference. Improved disease self-management (identification and treatment of exacerbation, correct inhaler technique).
Green et al. (2008)	258 usual care; 259 home BP monitoring and web training; 261 home BP monitoring, web training and web-based pharmacist care	Complex intervention  Intervention groups received training in web-site use, home BP monitoring, educational material and encouragement to work with GP. Pharmacist care - an action plan for at least one patient selected goal. Patients	Empowerment, Individualized, Respectful	Low	BP: no group difference between BP monitoring/web training and usual care but improvement in systolic measurements. Pharmacist care group had significantly better BP control, systolic BP and diastolic BP than usual care. BMI: No difference Consumer assessment of healthcare providers and systems instrument: no difference for satisfaction. Service use: significant decrease in percentage of specialist visits for pharmacy care group. No

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		encouraged to provide regular feedback until BP controlled with home monitor.			differences in primary care visits.
Greenfield et al. (1985)	23/22 patients with peptic ulcer disease	Simple intervention  Reviewed patient's medical record and treatment algorithm for chronic ulcer disease. Discussed behavioural change to encourage increased patient involvement. Patients given a copy of medical record and treatment algorithm. Both groups had 20 min consultation with clinic assistant (control group provided with disease information but not medical record or coaching).	Empowerment, Respectful	Moderate	Consultation times: no group difference. Audio recordings of consults: reduction in "traditional communication pattern" (i.e. doctor directs interaction and patient provides factual information). Increase in inter-personal involvement. Health Status (questionnaire): fewer physical and role limitations (i.e. work). Preference for active involvement (Questionnaire): increase in preference for involvement. Fewer role and physical limitations for patients who were more active. Patient satisfaction (Questionnaire): no group difference.
Greenfield et al. (1988)	39/34 patients with diabetes	Simple intervention  Provided patient's medical record and encouraged patient's to use the information to ask questions. Rehearsed negotiating skills.	Empowerment, Respectful	High	Consultation times: no group difference. HbA1c: decrease HbA1c. Functional limitations index: improvements in mobility, role, and physical limitations. Audio recordings of consults: twice as effective in eliciting information from the doctor as the control group and more active during the visit.



		Both groups had two, 20min sessions with clinic assistant (control group provided with educational material but not medical record or coaching).			Patient satisfaction (Questionnaire): no group difference.
Kennedy et al. (2004)	9/10 hospital sites 279/403 patients with Inflammatory Bowel Disease (IBD)	Complex intervention and training  Negotiation of self-management plan with patient, direct access to services, provision of an information guidebook and a PCC approach to care by a trained clinician.	Empowerment, Individualized, Respectful	High	Consultation Satisfaction (Questionnaire): no group difference. Increased enablement score.
Kinmonth et al. (1998)	21/20 practices 23 Drs and 32 nurses/20 Drs and 32 nurses 142/108 patients with type 2 diabetes	Training  Doctors and nurses received 0.5 day training (active listening and negotiation of behavioural change). Nurses also received a full day to practice skills. (Nurses in control group were offered similar support sessions on use of guidelines and materials).	Empowerment, Respectful	Low	More likely to report excellent communication with doctors and greater satisfaction with treatment. No group difference in agreement between patients and doctors on main concerns, perceived personal control. Wellbeing (Questionnaire): higher scores. HbA1c and total blood cholesterol concentration: no group difference. BMI and triglycerides: better scores for knowledge, BMI and Triglycerides in control group.
Landefeld	327/324 acutely	Complex intervention	Holistic,	Moderate	Interviews (Functional Status): at discharge,

et al. (1995)	ill older patients	Specially prepared environment, PCC (daily assessment by nurse of cognitive, physical, psychosocial functioning, protocols to improve self-care, functioning, based on assessment. Daily rounds by multidisciplinary team), discharge planning, review of medical care.	Individualized		<p>improved ability to perform basic activities (i.e. bathing, dressing), higher (mean) number of activities performed.</p> <p>More intervention patients improved, and fewer became worse, in the ability to bathe and dress during the admission to discharge period. Higher level of functioning at discharge compared to 2 weeks prior.</p> <p>Fewer intervention patients were discharged to long term institutions vs. control group (<math>p=0.01</math>). No group difference in admission to long term institutions after discharge.</p> <p>Mini Mental State Examination and Geriatric depression scale: improved health status but no difference in mental status or depression score when controlled for depression scores on admission. No group difference or change over time in functional status.</p> <p>No group differences in mean number of activities of daily living performed or overall health status 3 months post-discharge. No group difference in number of paid health care services.</p>
Maly et al. (1999)	134/131 health consumers with chronic illness	<p>Simple intervention</p> <p>Recorded two questions for the doctor to review and supplied with medical progress notes. (Control group provided with health information only).</p>	Empowerment, Individualized	High	<p>Satisfaction: improved satisfaction with medical care.</p> <p>Duration of Patient-Physician encounter: no group difference.</p> <p>Visit length: no group difference.</p> <p>Increased interest in seeing medical records and higher propensity for health-information seeking.</p>

Marsteller et al. (2010)	25/24 physicians Same study as Boulton <i>et al.</i> (2008) and Boyd <i>et al.</i> (2009) – focuses on physician satisfaction	Complex intervention and training Guided care model	Holistic	High	Primary Care Assessment Tool and Physician Questionnaire: more satisfied than control physicians with communicating with their older chronically ill patients and families, and better knowledge of their patients' clinical characteristics after one year. No group differences at one year follow up for other variables (i.e. satisfaction with management of chronic care, knowledge of patient's personal circumstances, ratings of the practice's care coordination activities, time spent managing patients, knowing about specialist visits, sending information to specialists and receiving useful information from specialists).
McWilliam et al. (1999)	12-16 home visits (1 hour) with community nurse duration.	Complex intervention	Empowerment	Moderate	More independent, greater perceived ability to manage own health. No group difference for overall mindset (post-intervention and at 1 year). Reduced desire for more information compared to control group increase in desire at 22 weeks. Both groups experienced decreased hospital stays but no group differences in health resource utilisation. More independent and less in need of information at 1 year. Cost of the intervention was offset by the overall savings in the usual health services resource utilisation
Muñoz Alamo	10/10 Drs 63/47 patients	Training	Empowerment, Holistic,	High	Visual Analogue Scale: no group difference for pain intensity.

et al. (2002)	with benign chronic musculoskeletal pain (CMP) and fibromyalgia (F).  13 health centres	Doctors undertook communication skills training (appropriate communication, mutual discussion and partnership, provision of clear information, looking for common ground and avoiding saying there is anything wrong.).	Individualized, Respectful		Goldberg Scale of Anxiety and Depression: improvement after 1 year in psychological distress. Nottingham Health Profile (NHP Questionnaire): reduced number of tender points. Except for sleep, all other NHP-variables (i.e. physical mobility, energy, social isolation) showed improvement (but not significant). More pronounced improvements for patients with CMP than those with F.
Nijhof et al. (2012)	68/67 adolescents with chronic fatigue syndrome	Complex intervention  Intervention group received support from cognitive behavioural psychotherapist via email and online, interactive modules. Parents followed a parallel program.	Empowerment, Individualized	Low	Checklist individual strength (CIS-20): less fatigued. Child health questionnaire (CHQ-CF87): increased levels of physical functioning. Sustainable treatment effects at 12 months for intervention patients who had recovered at 6 months.
Nygardh et al. (2012)	25/21 patients with chronic kidney disease	Training  Staff members completed a six step educational training program including: learning seminars, workshops to give high-quality care, quality improvement training, empowerment workshops, person-controlled education and reflection meetings.	Empowerment	High	Individualized Care Scale (ICS): more intervention patients were asked about their personal situation by staff. Ways of Coping Questionnaire-Swedish Version: higher levels of escape avoidance coping. Self-reported health status (EQ-5D): better scores at follow up for the control group



Saha and Beach (2011)	134/114 patients with or risk factors for Coronary Artery Disease 16 high and 16 low PCC vignettes	Observational  Intervention patients viewed a vignette depicting a physician with high PCC behaviour (control patients viewed a low PCC vignette). Videos were standardised for: doctor's rationale for recommendation, evidence of risks and benefits and strength of recommendation.	Empowerment, Holistic, Individualized, Respectful	Moderate	Post-vignette Questionnaire: intervention patients rated the doctor as more competent and trustworthy and the necessity of surgery higher than control patients.  More likely to undergo the recommended surgery and felt they would be more comfortable with the doctor.  Global ratings of high-PCC doctor were 22% higher.  Level of PCC was not associated with patients wanting a 2 <sup>nd</sup> opinion but high PCC vignettes were longer in duration (average 5mins 20sec) than the low-PCC vignettes (average 4mins).
Simon et al. (2006)	212/229 patients with bipolar disorder	Complex intervention and training  Assessment and care planning with the nurse (collaborative process),	Empowerment, Holistic, Individualized, Respectful	Moderate	Psychiatric Status Rating: lower mania scores at 24 month follow up. Lower duration of mania symptoms.  No group difference for depression (frequency or severity) at follow up. No group difference for medication management visits.

		monthly follow up calls, structured feedback to mental health provider, structured group psycho-educational program, as needed support			
Sullivan et al. (2006)	26/23 GPs	<p>Training</p> <p>Two hour education session involving video presentations on the shared-decision making model and discussions. Both groups received an education pack (resources and treatment recommendations for chronic pain).</p>	Empowerment, Individualized, Respectful	High	<p>Physician Satisfaction Questionnaire: increased satisfaction, relationship quality, appropriate use of time and patient-care agreements.</p> <p>Physician patient centredness measure: no group differences for overall patient centred score, doctor receptiveness, patient involvement and affective content of the relationship. More likely to provide information to patients and to complete patient-care agreements.</p> <p>Majority of intervention participants felt more competent to care for patients with chronic pain.</p>
Thompson et al. (1990)	Study 1: 29/24 Obstetric and Gynaecological patients	<p>Simple intervention</p> <p>Patients given a list of health concerns (i.e. breast exam) and asked to write down min. 3 questions for the doctor.</p>	Empowerment	High	<p>Family Practice Patient Questionnaire: no group difference in patient doctor satisfaction or length of visit.</p> <p>No group difference in number of questions asked. More likely than control group to ask all the questions they wished to ask.</p> <p>Family Practice Patient Questionnaire: higher visit satisfaction, higher perceptions of control.</p>
	Study 2: N=18 (messages) N=13(list questions)	Two interventions: one group were provided with a message that the doctor encouraged them to ask	Empowerment	High	<p>No differences between the two intervention groups.</p> <p>Patients were more satisfied with visit when they</p>

	N=18 (control)	questions and a waiting room questionnaire. Second group were given a checklist of information (i.e., cause of problem) to be obtained during the visit instead of a general list of health topics			were less anxious, more confident, and when they had seen the doctor multiple times. Satisfaction was not significantly related to the number of questions patients wanted to or did ask.
Wagner et al. (2012)	194/252 Patients with hypertension	Simple intervention  Intervention patients were provided with training and access to a personalised health care record (PHR). Patients could access educational material, health data, make goals, and securely message their physician (these were triaged by a nurse)	Empowerment	Moderate	No improvement in blood pressure, patient activation (Patient Activation Measure; PAMS), or satisfaction with care (Consumer Assessment of HealthCare Providers and Systems Clinician and Group Survey; CAHPS and PACIC). Higher provider communication and helpfulness scores, and a trend towards better diastolic blood pressure were associated with greater PHR use.
Woodcock et al. (1999)	22/21 practices 64 practice nurses and 43 GPs Same study as	Training	Empowerment, Individualized, Respectful	Low	Attitudes: time major constraint to using patient centred approach for both nurses and GPs. Control group nurses were significantly more likely to believe they should decide on the best course of action. Intervention group rated care more positively than control group. Behaviour: intervention nurses were significantly less satisfied than control nurses with their style

of care but their patients were more satisfied. Patients reported that all aspects of care had been delivered more in intervention than control practices. They reported better communication with GP, greater satisfaction with treatment and greater well-being. However, they had higher triglyceride levels, were heavier 1 year after diagnosis and had significantly less knowledge about diabetes.

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### Appendix 3.3 – Treatment Burden for Chronic Disease

This is the post-print (final draft post-refereeing) version of the following manuscript:

Sav A, McMillan SS, Kelly F, Kendall E, Whitty JA, King MA, Wheeler AJ. Treatment burden among people with chronic illness: what are consumer health organizations saying? The final, definitive version of this paper has been published in *Chronic Illness* 2013; 9(3):220-232. DOI: 10.1177/1742395312463411 by Sage Publications. All rights reserved. © [Sav A., et al 2012.]

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## **Treatment burden among people with chronic illness: What are consumer health organisations saying?**

### **Introduction**

Chronic illnesses such as cardiovascular and respiratory diseases, cancer and diabetes are leading causes of morbidity and death<sup>1</sup> across the world. The high and increasing prevalence of these conditions contributes to their substantial burden and impact on quality of life, particularly in the ageing population<sup>2</sup>. Although the burden associated with chronic illness is well documented, the extent to which it is associated with the treatment and management of these diseases has been poorly defined. Furthermore, while the burden of treatment from a societal and economical perspective has received large attention<sup>3,4</sup>, the personal experiences of treatment burden among people with a chronic illness is less emphasised. Research shows that treatment burden among people living with a chronic illness is different from the burden of illness<sup>5</sup>. The burden of illness is directly attributable to the burden that a chronic illness imposes on a person, their family members and the health system. In contrast, treatment burden is the burden experienced by the person with chronic illness and their family members, as a result of treatment (i.e. medical intervention) and excludes the burden on the health system (e.g., cost of hospitalisation to the government). Research indicates that treatment burden results in a number of negative outcomes on people and their family members, including treatment non-adherence<sup>6-8</sup>, side effects<sup>9</sup>, specific symptoms<sup>10</sup>, recurrence of disease<sup>11</sup>, decline in health<sup>10</sup> and quality of life<sup>12,13</sup>, reduced survival<sup>11</sup>, decreased treatment satisfaction<sup>14</sup>, and ineffective use of health resources<sup>9,15</sup>.

There is further evidence that poor coordination between healthcare providers, unnecessary treatment and reliance on intensive treatment options rather than less invasive management can lead to additional burden associated with the work of managing condition(s)<sup>5</sup>. Patients and practitioners often have different perspectives about treatment burden and practitioners may lack the strategies to detect patients who are overwhelmed by such burden<sup>5</sup>. This situation inadvertently places greater burden on patients, thus exacerbating the problems associated with treatment burden.

Beyond the mainstream health services, Consumer Health Organisations (CHOs) can provide important assistance and advocacy for some people living with a chronic illness. CHOs are broadly defined as organisations that promote and represent the interests of healthcare users and carers with a chronic illness<sup>16</sup>. In Australia, as in many countries, there is a large number of national CHOs that are concerned with the treatment and prevention of these conditions (e.g., Heart Foundation, Leukaemia Foundation, and Schizophrenia Fellowship). CHOs can provide practical, psychological and informational support to consumers and carers<sup>17</sup> and most also lobby for better standards of care to reduce the burden of treatment and illness for the consumers they represent.

Core functions of CHOs include the provision of educational resources, skills training, self-management, and psychological support; services that may not be readily available through the formal health system<sup>18</sup>. Many of these organisations work in partnership with health professionals and educators, researchers and healthcare providers, conducting training workshops, education classes and forums to assist people to manage their illnesses. Some members of CHO can also participate in programs from their own homes (e.g., telephone-based or online support), which may help alleviate some of the stress on the health system and overcome issues of healthcare access. Depending on the individual's ability to self-manage and also the status and manageability of his/her chronic illness, he/she can sometimes have more contact with a CHO than with the treating health professional. This can particularly be the case if the individual participates in programs that may not be offered by the treating health professional. Despite this central role in assisting people with their illnesses, limited research has explored how such organisations perceive the treatment burden consumers experience. The capacity of CHOs to adequately represent consumer needs relies on the extent to which they can articulate and appreciate complex concepts such as treatment burden. Given the likelihood of discrepancies between consumer and provider perspectives, it is possible that consumer experiences are not being adequately advocated. Thus, knowledge about CHO perspectives on treatment burden and its impact could add to our understanding about how to best support consumers and their families.

The aim of this study is to (a) explore the perspectives of CHO representatives on consumers' experiences of treatment burden and (b) establish the capacity of CHO representatives to articulate consumer needs and hence, underline their role as advocates for people and argue for their greater role in the health system. To our knowledge, no prior study has examined treatment burden from this perspective. This study is part of a broader research project that will explore the perspectives of health consumers and health professionals concerning the burden of multiple treatments, person-centred care, and the role of community pharmacy in supporting people to manage their chronic illnesses.

## Methods

The study was guided by the interpretive paradigm and used qualitative research methods as demanded by the exploratory nature of this study. Semi-structured in-depth interviews were undertaken with senior representatives ( $n = 15$ ) of 12 Australian CHOs to explore their organisational perspectives of the nature and experience of treatment burden associated with chronic illness. In-depth interviews can take many forms, but most qualitative research is based on the semi-structured approach<sup>19</sup>. This method enabled us to broadly define the topic of the interview, but simultaneously allowed us to explore the unique perspective of each individual. Ethical approval for the study was obtained from the Human Research Ethics Committee of an Academic University (PHM/10/11/HREC).

## Participants

Participants were purposively sampled to reflect the range of relevant CHOs in Australia, with guidance from our research advisory board and other key stakeholders. Additional participants were also identified during the course of the interviews. Our aim was to focus on the CHOs that represented people with the following chronic illnesses: diabetes, musculoskeletal disorders, cardiovascular illness, mental illness, asthma, and cancer. These conditions contribute a significant burden in terms of mortality, morbidity, or both<sup>1</sup>, and have been identified as high priority areas by the Australian Government<sup>20</sup>. Consequently, these priority illnesses were the key factor underpinning the sampling framework. Nine of the twelve CHOs were state-based (i.e., Queensland only) while the other three operated across Australia. Although their primary activities were diverse, the core activities of most of these



organisations involved providing practical and psychosocial support to consumers, advice and information, promoting community awareness, supporting research, and advocating for legislation, policy and funding. To control for the fact that perspectives may differ within the selected organisations depending on whether employees were engaged in policy development or program implementation or both, at least two participants (e.g., board member, program coordinator or director) were interviewed from five organisations.

#### Procedure

An interview guide was developed, piloted with a senior member of a CHO and refined prior to the commencement of the interviews. The interview guide was further refined and adapted as specific information came to light after completion of initial interviews, which enabled the interviewers to explore new topics. Topics discussed in the interview included: background of the CHO and its members, level of interaction with members, perspectives on the burden of chronic illness and the burden of treatment for members, and perspectives on alleviating treatment burden.

Upon confirmation of the individual and organisational verbal agreement to participate, the study information sheet and interview guide were emailed to the participants. Participants were re-assured of their confidentiality; informed consent was obtained from all participants prior to the interview. Interviews were conducted face-to-face or via telephone by experienced researchers. Interviews took place at a range of times that were convenient for participants during January and March 2012. The average interview duration was 64 minutes and all interviews were recorded and transcribed verbatim.

#### Data analysis

Analysis of the semi-structured in-depth interviews was completed using an iterative thematic approach, which is a commonly adopted approach to analysing qualitative data in healthcare research<sup>21</sup>. Three researchers read and re-read the transcripts to familiarise themselves with the data for thematic analysis. The researchers used the electronic qualitative data analysis package QSR NVIVO 9 to code the data into themes and sub-themes in accordance with thematic analysis. Memoing was also used to record how the themes were derived and what

they represented. Data saturation was established when the participants' perspectives became recurring and adhered to previously collected data. All themes were numbered in order to ensure the auditability of the analysis. Trustworthiness of the study was established by ongoing peer debriefing sessions and returning the written transcripts to some participants to determine if a true picture of their perspectives was presented (member checking).

## Results

The thematic analysis of the interviews revealed a number of inter-related themes. In explaining and discussing these themes, supporting evidence is provided in the form of quotes from participants generated through the semi-structured in-depth participant interviews. The following components of treatment burden were identified:

- Medication burden
- Carer burden
- Time and travel burden
- Financial burden
- Health service use burden

### Medication burden

Medication burden included aspects related to the burden associated with taking multiple medications (polypharmacy), side effects of medication, stigma, and adverse events resulting from medication use. The thematic analysis suggested that the burden associated with medication use is substantial and highly prevalent. Most of the interviewees described frequent occurrence of medication burden among the consumers they represented. For example, one participant said:

*People with diabetes that are on insulin ... they really need to know how the insulin works (Interview\_H)*

The lack of understanding and confusion about the use of medications was described as being extremely burdensome. Although dose administration aids, such as Webster-pak® (blister

packs to personalize and organise medication regimens) assisted consumers in following and understanding their medication regimens more accurately, they also incurred a cost, leading to financial burden among consumers:

*I'm not against Webster-pack... some people find they have to have it but I think...  
[consumers] find the cost quite difficult at times (Interview\_F)*

The interviewees also described instances where consumers had mismanaged their medications, leading to inappropriate or dangerous consequences. For example:

*... one person I knew had been using the same syringe for three years. It was that old  
and blunt (Interview\_H)*

*I did a medicine survey with 5000... [chronic illness] members to look at usage and it  
was just appalling to see the mismanagement of medicines (Interview\_F)*

Burden of medication use was further complicated by the confusion surrounding generic medicines (i.e., a less expensive but comparable brand). Several interviewees discussed how generic medicines led to confusion among consumers, particularly among those with low levels of health literacy. Misunderstandings generally resulted from the physical similarities between the generic and branded medications. For instance, one interviewee stated:

*...the generic medicines are still causing a huge amount of confusion, people are  
taking both the brand medicine and generic medicine because they don't realise  
they're the same thing (Interview\_F)*

Side effects, which arose from medications or interactions between medications, were also identified as a source of burden for consumers. For example, weight gain, dizziness, nausea, nightmares, and dry throat were all identified as potential common side effects. The following concern was mentioned by an interviewee when she was discussing the side effects of medication for consumers with diabetes:

*Also some diabetes medications - certainly they're starting to replace them now, but some of the stronger medications actually tend to make you put on weight (Interview\_D)*

The interviewees also discussed the psychological burden associated with taking medication, although this type of burden was often intermingled with the broader stigma associated with having an ongoing chronic condition. Medication use was merely the trigger that alerted the community to the presence of a chronic condition. However, the public nature of some medication regimens meant that users were more likely to become the subject of public scrutiny:

*People with... [chronic illness] tend to be stigmatised because the community's message is you're fat and lazy so it's your fault you've got diabetes (Interview\_D)*

Finally, many participants described the cyclical nature of treatment burden, indicating for example, that increased medication burden may result in non-adherence to medication, which may then result in further burden.

#### Carer burden

As expected, the burden placed on family members who were supporting a consumer with a chronic illness was widely discussed during the interviews. Caring for a family member required the carer's commitment, time and energy. Many of the stakeholders discussed instances where carers became distressed and frustrated as a result of the burden associated with treatment, particularly parents of young children. On many occasions, the carer's life was put on hold and their own needs, including their health and wellbeing, were neglected:

*We see this time and time again, where the carer may become socially isolated, doesn't leave the home, doesn't have any energy to communicate with others. Their own needs become neglected - their self-care becomes neglected. Their health deteriorates (Interview\_E)*



*Often the burden is felt more strongly by a family member than it is by the person with... [chronic illness]. Sometimes that can be the case (Interview\_G)*

*So in terms of a parent managing a child's... [condition], I mean it's extremely frightening in terms of watching your child having difficulty breathing (Interview\_B)*

As the above quotes illustrate, the interviewees felt that the carers often placed their own needs secondary to the person they were caring for and the burden was at times reported to be experienced more strongly by the carer than the person with the chronic illness. This was problematic because some carers were battling chronic conditions themselves. The burden of caring for someone was further complicated by an unsupportive healthcare environment. Many participants suggested that the carers felt unsupported by the healthcare system and often felt marginalized by health professionals during the treatment process. One interviewee who cared for her dying mother described this feeling:

*As a hidden carer myself, did I have the same issues? Yes. I thought that I was marginalized. I thought - despite my four university degrees - I was treated like a complete and utter idiot by the medical profession... (Interview\_I)*

Feelings of lack of support and marginalisation were reported to lead to a sense of hopelessness, mistrust in the healthcare system, and heightened feelings of distress among carers.

#### Time and travel burden

The time taken to administer and monitor treatments and the travel associated with obtaining treatment were significant causes of treatment burden. Participants believed that treatment required the devotion of significant periods of time for many consumers, particularly when they were required to monitor their daily treatment, learn about its consequences and develop an understanding of the various treatments available. Furthermore, many consumers needed to make permanent lifestyle changes such as exercising, monitoring nutrition and weight,

testing blood sugar levels, which all contributed to time burden. In describing the daily burden of consumers living with ongoing chronic health conditions, the interviewees pointed out:

*If you're managing your diabetes...you need to be testing your blood sugars very regularly, often four, five, six times a day, adjusting the dose of your medication based on what your blood sugar levels are telling you and what you're eating or how much you're exercising, how much stress you're under. It's a very complex condition to manage (Interview\_D)*

*Well they need to monitor every day their weight, they need to monitor their salt and alcohol intake, fluid intake as well...The drug burden is massive [people with heart failure] (Interview\_J)*

According to participants, accessing treatment was also burdensome for some consumers. For instance, several interviewees discussed how attending health clinics could be difficult and costly, particularly for consumers without reliable private transport:

*Even just getting to the doctors can be quite a physical problem... (Interview\_F)*

Another added:

*... the travel and distance is another thing that is another big cost, too (Interview\_H)*

Accessing treatment was particularly burdensome for consumers who resided in outer regional areas of Australia, as these consumers needed to make substantial travel efforts to access healthcare.

Financial burden

One of the most widely discussed types of burden associated with treatment of chronic illness related to financial stress. All of the interviewees agreed that living with an ongoing chronic illness was expensive and negatively impacted on a person's finances:

*... there's a huge financial burden to living with [chronic illness] for the consumer, they've got to pay for the pain relief, you know there are medications that are quite expensive, there are many visits to health professionals (Interview\_A)*

Not surprisingly, the cost of treatment was perceived to be particularly burdensome for low income earners such as pensioners and the unemployed. Participants believed that consumers had to prioritize their medications according to cost and only adhered to medications they perceived to be effective in the management of their chronic illness:

*So there's a huge financial burden to living with... [illness] for the consumer, they've got to pay for the pain relief, you know there are medications ... that are quite expensive (Interview\_A)*

*... there's the pensioner who again is trying to manage the chronic pain of arthritis who most probably may not be able to afford their pain medicine on top of their other medicines for their other chronic conditions (Interview\_F)*

Financial burden also originated from the need for regular medical appointments and specialist care. One participant commented:

*There's the cost of the medications, there's the regular visits with the GP (Interview\_C)*

The burden of treatment impacted negatively on the ability of consumers and carers to participate in paid employment. For example, participants observed that many carers took time off work in order to care for their loved ones. When consumers were receiving intensive treatments, such as chemotherapy, participants described losses of productivity and high

absenteeism from paid employment. Hence, financial costs were not only associated with out-of-pocket expenses, but also with the loss of income from their employment. In discussing this matter, one participant said:

*... the other burden...[carer] they bear during the workforce, is you know, their .... loss of productivity, high absenteeism, sometimes they're ... using a lot of sick days to manage their illness (Interview\_A)*

#### Health service use burden

An important aspect of treatment burden was associated with health service use. On many occasions, participants referred to the disjointed nature of care delivered within the Australian healthcare system. This lack of coherence created a sense of confusion among consumers, leading to treatment burden. One participant noted:

*... health professionals can send mixed messages, that a person with diabetes might see one doctor who says 'a', and then sees a pharmacist or a nurse or a dietician who says something different about their diabetes, so they get mixed messages... (Interview\_G)*

As the above quote indicates, the lack of continuity of care could result in various health professionals offering mixed information which resulted in confusion and frustration for the consumer, leading to potential treatment burden. Confusion was also exacerbated for those who were required to transition from one aspect of the health care system to another:

*A big problem for those people [with chronic illness] is that the transition from paediatric services to adult services is a huge hole. There's a lot of people that get lost to treatment, come back in when they've got very sick (Interview\_D)*

Many participants also gave detailed accounts of how other aspects of healthcare, such as poor doctor-patient relationships and waiting and consultation times, led to treatment burden among consumers. For example, poor therapeutic relationships resulted in inadequate



information about health conditions and their potential treatment being provided to the consumer. This issue was further complicated by the limited consultation time allowed for interactions between the health practitioner and the patient. Discussing this issue, one participant said:

*If you think about seven minute appointments...you can't get four co-morbidities dealt with in seven minutes at the GP (Interview\_F)*

Not surprisingly, the lack of continuity of care was associated with medication regimen changes, leading to increased medication burden. Finally, some participants discussed how the stigma associated with chronic illness and old age further complicated the doctor-patient relationship, adding to the burden experienced by consumers. As people aged, it almost seemed expected from them to accept some of the burden as part of the aging process. One participant argued:

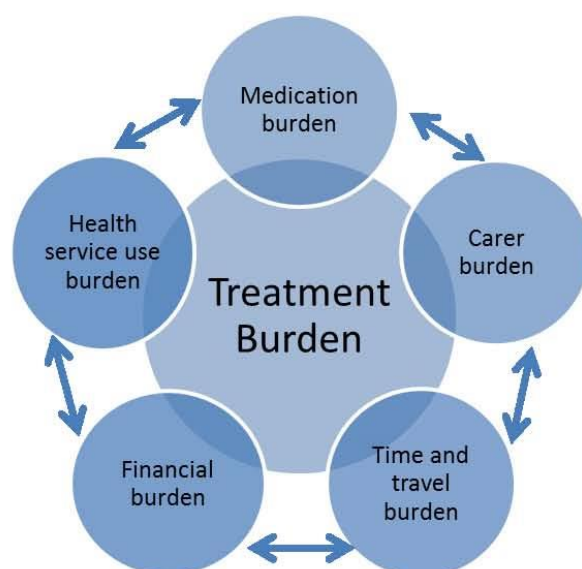
*I think it's very much associated...I don't know stigma, or something that is, that is attached to GP's saying to older people, well, well you're old you know, surely you don't expect to still be running around like an 18 year old...I think that's their philosophy you know (Interview\_A)*

## **Discussion**

### **Summary of main findings**

This research has offered an understanding of the perspective of CHOs when articulating the treatment burden of consumers with chronic conditions. Although research has been conducted on how people with a chronic illness experience treatment burden<sup>8,12,22,23</sup> and the importance of multidisciplinary and coordinated care in alleviating this experience, CHOs offer an inexpensive and largely untapped resource. The current study suggests that CHOs have a thorough understanding of the multidimensionality and cyclical nature of treatment burden and are able to articulate the complex needs of their consumers clearly. They recognised the interacting impact of medication burden, carer burden, time and travel burden,

financial burden, and health service use burden, contributing to the overall treatment burden felt by consumers (Figure 1).



**Figure1:** Treatment burden for chronic illness

#### Existing literature

The views expressed by CHOs mirrored that found in existing research on the personal experiences of consumers. For example, literature indicates that burden associated with medication, particularly the side effects of medication<sup>9,15,22</sup>, are one of the most common forms of treatment burden. Of concern, is that the prevalence of side effects from medication is likely to increase over the next decade in Australia. Reports indicate that Australians between the ages of 65 and 75, who were taking an average of four medications in 2009, will be taking, on average, six medications by 2019<sup>24</sup>. In addition, there is evidence that carer burden<sup>25,26,27</sup>, the time taken for daily tasks that must be performed by people in order to monitor their illness<sup>8</sup>, financial burden<sup>10,23,28</sup>, and the burden associated with accessing and using healthcare services<sup>10</sup>, are all common forms of burden. Furthermore, research points to the multidimensional and cyclical nature of treatment burden, suggesting that the presence of medication burden can be a result of health service use burden (e.g., lack of continuity of

healthcare)<sup>8</sup>. A study by Moss and Crane<sup>10</sup> for example, indicates that poor communication between patients and healthcare providers about medication compliance may result in polypharmacy, which increases the risk of treatment burden.

We believe that the ability of CHOs to clearly articulate the complex needs of their consumers and their depth of understanding regarding the multidimensionality of treatment burden reflects more active engagement with consumers than sometimes acknowledged within the healthcare system. These organisations operate largely outside the mainstream health system to act as ‘independent’ healthcare advocates, and assist consumers to manage their illness through a variety of programs. Their wealth of knowledge is hardly surprising given their proactive level of engagement with consumers across multiple aspects of chronic illness management. Furthermore, they are generally led by members who themselves have first-hand experiences of chronic illness<sup>18</sup>. Through these insights, CHOs have been able to identify challenges introduced by an unsupportive or uncoordinated healthcare system and then work informally in parallel to this system to mitigate resultant treatment burden. These findings reveal CHOs to be a valuable resource for both consumers and healthcare professionals in the ongoing management of chronic illness.

Our findings underscore the importance of the role of CHOs within the Australian healthcare system. The inherent complexity of human health and the nature of treatment burden require the active involvement of CHOs, who have in-depth knowledge of their consumers’ needs. Given their depth and breadth of knowledge regarding their consumers, there are clear opportunities for such organisations to collaborate with healthcare professionals and other organisations. Collaboration is also needed in order to address the disjointed health system, which is in itself a significant source of burden according to study participants. The fact that the healthcare system contributes significantly to treatment burden is particularly ironic as one of its purported aims is to ease burden. Hence, there is a need for strategies that promote collaborative efforts to alleviate treatment burden and optimise treatment outcomes by capitalizing on the expertise and grounded understanding of consumers that can be found in CHOs. While enhanced referral to CHOs may result in a fragmented system of care for some patients, the benefits gained by enhanced referral and collaboration can outweigh the risks,



underscoring the importance of integrating these organisations into the formal health system. There is clear opportunity to more formally integrate these two systems of healthcare provision and capitalise on the synergies and subsequent health benefits for consumers that will conceivably result from effective collaboration.

The discussions generated in the interviews have clear implications for healthcare professionals both individually and collectively about their role in alleviating the burden of treatment for patients and their families. Many participants from the CHOs highlighted incidents where their members experienced burden as a result of poor personal interactions with their healthcare practitioners. Poor health practitioner-patient relationships and a lack of adequate information regarding treatment were associated with high levels of treatment burden. Furthermore, poor communication between patients and healthcare providers about treatment may lead to confusion about treatment options and the delivery of unnecessary treatment<sup>7,10</sup>. There is a clear need for healthcare practitioners to maintain a relationship that is sensitive to patients and their carers' preferences, but also offer explanations of treatment options and information about their potential side effects. Hence, a healthcare model where people feel that they are valued and a respected member in their healthcare are needed. This will enable patients to become more actively involved in decision making and integrate treatment into their daily lives, ultimately improving adherence and treatment outcomes.

Research indicates that CHOs are underutilised and only a minority of people appear to access them<sup>17,29</sup>. Although the reasons for underutilisation are complex, one important barrier is the lack of referrals pathways between GPs and such organisations. There is evidence to suggest that some GPs may have insufficient knowledge of CHOs or the services they provide and may believe these organisations have no significant benefits for patients, signalling the importance of better integration of these organisations into the formal health system<sup>17,29</sup>. Health practitioners are viewed as being highly trustworthy and their advice increases the likelihood of patients acting on health information<sup>30</sup>. By endorsing the value and role of CHOs, health practitioners can create pathways for their patients into longer-term supportive communities. Through this mechanism, the constraints faced by the health practitioners (e.g., short consultation time) in providing sufficient information and



knowledge, support and skill management can be complemented by a relevant CHO. More active involvement of people with chronic illness and their carers in CHOs could provide them with important experiential learning and a sense of belonging, as well as opportunities for social engagement and psychosocial resources that may be difficult to obtain within the formal healthcare system. The current study has suggested that CHOs clearly have capacity to understand and articulate the complex needs of their consumer groups, highlighting the value of their role in the overall health delivery continuum.

#### Strengths and limitations of this study

This study provides first-hand insight into the perspectives of key stakeholders from CHOs about the nature of treatment burden as experienced by their consumers. Many of the issues discussed by key stakeholders from such CHOs corroborated existing research, highlighting the positive role that these organisations can have in mitigating treatment burden for people with chronic illness. Because the study relied on an exploratory qualitative investigation of these perspectives at one point in time, the complex relationships among themes could not be established. In addition, the study used self-reported data which can be influenced by interviewer bias. However, the potential for interviewer bias arising from two different interviewers was minimised with the use of a standardised interview guide and the study's trustworthiness was increased by using member checking strategies. Furthermore, it was necessary to develop an initial understanding of CHOs perspectives, and self-reported data was the most appropriate way of doing so. In addition, while a non-random purposive sampling strategy was used to locate key stakeholders, this was the most appropriate method of ensuring that their perspectives were included<sup>31</sup>. A non-random purposive sampling method enabled us to obtain rich information from key informants, which may not have been obtained by using a random sampling method.

#### Implications for future research

The depth of knowledge CHOs have about the nature of treatment burden experienced by their members highlights the importance of future research in this area. Although this study has given invaluable insight into the perspectives of such organisations concerning treatment burden as it relates to the consumers they represent, their recommendations for assisting

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people with a chronic illness were not fully explored. Their depth of knowledge about such topics establishes CHOs as an important source of data for future research and policy recommendations and emphasizes the importance of their role in the healthcare system as both providers and advocates.

In conclusion, this study has provided important insights into how CHOs understand treatment burden among the consumers they represent. The depth and breadth of expertise, and experiential knowledge that such organisations have in this area underscores the importance of CHOs. This study has suggested that CHOs need a more proactive and integrated role within the health system to better assist people with chronic illness and to minimize the extent to which the system contributes to treatment burden.

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## References

1. World Health Organization. *Noncommunicable diseases country profiles 2011*. Geneva: Switzerland, 2011.
2. Australian Bureau of Statistics, . National Health Survey: Summary of Results, 2007-2008 (Reissue). 2010.  
[http://www.abs.gov.au/ausstats/abs@.nsf/Latestproducts/4364.0Main%20Features22007-2008%20%28Reissue%29?opendocument&tabname=Summary&prodno=4364.0&issue=2007-2008%20%28Reissue%29&num=&view=, 2 May, 2011.\)](http://www.abs.gov.au/ausstats/abs@.nsf/Latestproducts/4364.0Main%20Features22007-2008%20%28Reissue%29?opendocument&tabname=Summary&prodno=4364.0&issue=2007-2008%20%28Reissue%29&num=&view=, 2 May, 2011.))
3. Donohue JM, Pincus AH. Reducing the societal burden of depression: a review of economic costs, quality of care and effects of treatment. *Pharmacoeconomics*, 2007; **25**: 7-24.
4. Kutikova L, Bowman L, Chang S *et al*. The economic burden of lung cancer and the associated costs of treatment failure in the United States. *Lung Cancer*, 2005; **50**: 143-154.
5. May C, Montori VM, Mair FS. We need minimally disruptive medicine. *British Medical Journal*, 2009; **339**: 485-487.
6. Olinder AL, Kernell A, Smide B. Missed bolus doses: devastating for metabolic control in CSII-treated adolescents with type 1 diabetes. *Pediatric Diabetes*, 2009; **10**: 142-148.
7. Vijan S, Hayward RA, Ronis DL *et al*. Brief report: the burden of diabetes therapy: implications for the design of effective patient-centered treatment regimens. *Journal of General Internal Medicine*, 2005; **20**: 479-482.
8. Gallacher K, May CR, Montori VM *et al*. Understanding patients' experiences of treatment burden in chronic heart failure using normalization process theory. *Annals of Family Medicine*, 2011; **9**: 235-243.
9. Graves MM, Adams CD, Bender JA *et al*. Volitional nonadherence in pediatric asthma: parental report of motivating factors. *Current Allergy and Asthma Reports*, 2007; **7**: 427-432.
10. Moss L, Crane PB. Exploring polypharmacy in elderly women after myocardial infarction. *Journal of Women and Aging*, 2010; **22**: 22-33.
11. de Kraker J, Graf N, Van Tinteren H *et al*. Reduction of postoperative chemotherapy in children with stage I intermediate-risk and anaplastic Wilms' tumour (SIOP 93-01 trial): a randomised controlled trial. *Lancet*, 2004; **364**: 1229-1235.
12. Henry DH, Viswanathan HN, Elkin EP *et al*. Symptoms and treatment burden associated with cancer treatment: results from a cross-sectional national survey in the U.S. *Supportive Care in Cancer*, 2008; **16**: 791-801.
13. Fiese BH, Wamboldt FS, Anbar RD. Family asthma management routines: connections to medical adherence and quality of life. *Journal of Pediatrics*, 2005; **146**: 171-176.
14. Brod M, Christensen T, Bushnell D. Maximizing the value of validation findings to better understand treatment satisfaction issues for diabetes. *Quality of Life Research*, 2007; **16**: 1053-1063.
15. Thomas P. The stable patient with schizophrenia - from antipsychotic effectiveness to adherence. *European Neuropsychopharmacology*, 2007; **17**: 115-122.
16. Allsop J, Jones K, Baggott R. Health consumer groups in the UK: a new social movement? *Sociology of Health and Illness*, 2004; **26**: 737-756.
17. Young CE, Mutch AJ, Boyle FM *et al*. Investigating referral pathways from primary care to consumer health organisations. *Australian Journal of Primary Health*, 2010; **16**: 260-267.
18. Coppa K, M Boyle F. The role of self-help groups in chronic illness management: A qualitative study. *Australian Journal of Primary Health*, 2003; **9**: 68-74.
19. Neuman WL. Social research methods: Qualitative and quantitative approaches. Boston: Allyn and Bacon, 2006.
20. Australian Institute of Health and Welfare. *Australia's health, 2010. Australia's health series no. 12. Cat. no. AUS 122*. In: Australian Institute of Health and Welfare, ed. Canberra: Commonwealth of Australia; 2010.

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21. Pope C, Zieblan S, Mays N. Analysing qualitative data. In: Pope C, Mays N, eds. *Qualitative research in health care*. 3rd ed. Oxford: Blackwell Publishing Ltd; 2006:63 - 81.
22. Bernhard J, Maibach R, Thurlimann B *et al*. Patients' estimation of overall treatment burden: why not ask the obvious? *Journal of Clinical Oncology*, 2002; **20**: 65-72.
23. Ow R. Burden of care and childhood cancer: experiences of parents in an Asian context. *Health and Social Work*, 2003; **28**: 232-240.
24. Australian Department of Health and Ageing. Evaluation of the DAA/PMP Programs. 2010. Available at: [http://www.health.gov.au/internet/main/publishing.nsf/Content/5B1B138DA00BB9C7CA2578150083984E/\\$File/DAA%20PMP%20Report.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/5B1B138DA00BB9C7CA2578150083984E/$File/DAA%20PMP%20Report.pdf), accessed 11 May 2012,
25. Son J, Erno A, Shea DG *et al*. The Caregiver Stress Process and Health Outcomes. *Journal of Aging and Health*, 2007; **19**: 871-887.
26. Sharpe L, Butow P, Smith C *et al*. The relationship between available support, unmet needs and caregiver burden in patients with advanced cancer and their carers. *Psycho-Oncology*, 2005; **14**: 102-114.
27. Tooth L, McKenna K, Barnett A *et al*. Caregiver burden, time spent caring and health status in the first 12 months following stroke. *Brain Injury*, 2005; **19**: 963-974.
28. Gutierrez-Maldonado J, Caqueo-Uriazar A. Effectiveness of a psycho-educational intervention for reducing burden in Latin American families of patients with schizophrenia. *Quality of Life Research: An International Journal of Quality of Life Aspects of Treatment, Care & Rehabilitation*, 2007; **16**: 739-747.
29. Boyle FM, Mutch AJ, Dean HJ *et al*. Consumer health organisations for people with diabetes and arthritis: who contacts them and why? *Health and Social Care in the Community*, 2009; **17**: 628-635.
30. Kreuter MW, Chheda SG, Bull FC. How does physician advice influence patient behavior? Evidence for a priming effect. *Archives of family medicine*, 2000; **9**: 426-433.
31. National Chronic Disease Strategy. 2006. [http://www.health.gov.au/internet/main/publishing.nsf/content/7E7E9140A3D3A3BCCA257140007AB32B/\\$File/stratal3.pdf](http://www.health.gov.au/internet/main/publishing.nsf/content/7E7E9140A3D3A3BCCA257140007AB32B/$File/stratal3.pdf), 2011 April 28,