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Financial toxicity in patients with cancer attending a public Australian tertiary hospital – a pilot study



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### Abstract

Keywords: Financial Toxicity, cancer, COST questionnaire, public hospital

### Aim



As therapeutic options for cancer evolve and become more complex the concept of financial toxicity has emerged. The comprehensive score for financial toxicity (COST) and iMTA Productivity Cost questionnaires (iPCQ) represent two tools developed to measure the concept. The aim of this pilot study was to review the impact of financial toxicity in patients with cancer in an Australian public setting where there is a universal health care model.

### Methods



### Results

Of 97 patients approached 66 consented to participate. The median age was 63.5 years. 55% were female. 53 completed COST questionnaires. The median score for financial toxicity was 18 (range 1–42). Higher COST scores indicated greater financial concerns and were associated with poorer quality of life (p=0.004). This was maintained after adjusting for confounders (age, gender, regional postcode.) Univariate analysis demonstrated younger age was associated with higher COST scores (p<0.001), whilst gender (p = 0.243) and geographical location (p=0.243) were not.

# Conclusions

In a cohort of patients receiving systemic cancer therapy in an Australian public setting financial toxicity was associated with poorer quality of life. Despite a universal health-model, the COST questionnaire identified a substantial proportion of patients who experienced financial toxicity.



### Introduction

Therapeutic options available for the management of cancer continue to expand and patients often consult with several specialists including surgeons, radiation oncologists and medical oncologists. Systemic therapy stretches well beyond chemotherapy with immunotherapy and targeted therapies now available for many malignancies. Side effects of these anti-cancer therapies are well recognized and described. However, with this growing complexity in cancer management and its multidisciplinary nature the concept of financial toxicity has evolved. The definition of financial toxicity varies but is generally accepted as encompassing the "objective financial burden and subjective financial distress" experienced by patients directly related to the impact of their diagnosis and its treatment (1).

Current literature highlights this growing toxicity across numerous domains including loss of production (absenteeism from work), out-of-pocket costs (such as medication dispensing fees, hospital parking, transport, accommodation), reduced income and poorer quality of life. Most of the published literature comes from the United States of America where there is a different model of health care to Australia. A recent Australian study highlighted the out-of-pocket medical expenses in a Queensland cohort of 452 patients with cancer. It identified significant median out-of-pocket expenses which were highest for patients with breast (\$4192; IQR, \$1165–7459 AUD) and prostate cancer (\$3175; IQR, \$971–8431 AUD) (2). In addition a systematic review by Gordon et al reported that up to 48% of participants reported financial toxicity in monetary terms and predictors of this toxicity included: being female, younger age, low income at baseline, adjuvant therapies and living further away from a treatment centre (3). Whilst this systematic review was not specific to an Australian context it echoes some recent findings by Durber and colleagues in this setting where those of a younger age (less than 50 years), lower income or were unemployed had greater financial toxicity(4).

The Australian health care system consists of both public and private sectors. Public health is government funded via Medicare the universal health insurance scheme. It provides access to free in-hospital and ambulatory medical care for all Australians. In addition the Pharmaceutical Benefits Scheme (PBS) subsidizes a range of prescription pharmaceuticals (5). The private health sector, whilst regulated by the Government, is privately owned and operated. It allows patient choice of doctor and health facility. Costs for private health care are subsidised by private health insurance which is held by approximately 50% of Australians (6). For the purposes of this pilot study we focused specifically on those patients receiving care in the public setting. Under the National Employment Standards Australian's are also entitled to paid sick leave when ill or injured and paid carers leave when they provide care for a family member. Additionally Centrelink, another Government service, provides assistance to Australians who

face financial hardship with social security payments and support; this can include Disability Support Pensions for patients that have chronic health related conditions preventing them from working of a Caref's Allowance in the form of an income supplement.

The financial hardship experienced by cancer survivors is gaining recognition with patientphysician cost communication being highlighted as essential to high quality health care by the Cost of Care Task Force at ASCO in 2009 (7) and the President's Cancer Panel identifying high cancer drug prices as a national priority in 2018. Several specific patient-reported outcome measures (PROMs) have been developed and validated for use in clinical studies (8). The COST score is a module of the Functional Assessment of Cancer Therapy (FACT) suite of questionnaires. It has been validated in an American cancer setting (9) and more recently in Australian cohorts (4) (10). This 11-item self-reporting tool is the first to directly assess the financial experience of patients with cancer and was designed to cover the personal impact and financial distress of low finances. In the first validation study of a cohort of 233 American patients financial toxicity correlated with poorer quality of life (9). Employment status, race, income and inpatient admissions were all associated with financial toxicity. Health-related decreases in productivity and losses of paid and unpaid work are also potential causes of financial hardship. The iMTA Productivity Cost Questionnaire (iPCQ), developed in the Netherlands, comprises questions on absenteeism, presenteeism and questions related to loss of unpaid work (11). These two questionnaires serve as important tools in evaluating the many facets of financial toxicity and were utilized in our study to provide a more holistic assessment with the COST questionnaire covering the subjective financial distress reported by patients and the iPCO the objective burden.

The aim of this pilot project was to review the impact of financial toxicity on an oncology cohort of patients in the Australian public setting where there is a universal health care model.

# Methods Patients

Adult patients ( $\geq$  18 years of age) with a prior diagnosis of a solid organ malignancy were recruited from a single large inner-city tertiary public hospital cancer centre. Patients were receiving active systemic therapy at the time of questionnaire completion, which consisted of chemotherapy, immunotherapy, targeted therapy or hormonal therapy. This treatment could be in the neoadjuvant, adjuvant or metastatic setting. Eligible patients were prospectively identified by reviewing oncology clinic bookings, patient files and chemotherapy day centre bookings. They were approached and provided consent at their clinic visit. Adequate English literacy was required to complete questionnaires; however, family/friend assistance was

permitted for translation. Professional interpreters were not utilized for non-English speaking patients and such patients were excluded from study.



This was a single centre, exploratory, cross-sectional study. The primary objective was to assess the feasibility of measuring financial toxicity in this cohort of patients utilizing validated self-reporting questionnaires: COST (9) and the iPCQ (11). The COST questionnaire has been used in prior studies in the Australian setting (4) (10) whereas this is the first study to the best of our knowledge using the iPCQ in an Australian cancer population. Secondary objectives included analysis of patient clinical and demographic data to identify potential at risk groups for financial toxicity and possible predictors of the problem including age, sex, income and post code which have been reported to be important risk factors in previous studies (9) (4). Quality of life was measured using the EORTC-QLQ-C30 survey.



### Methods

Patient clinical and demographic data was collected at the time of questionnaire completion. This included whether financial support was being received such as:

- Aged pension: the main Government funded income support payment for Australians who have reached Age Pension age (currently 66 years) and is means tested.
- Disability support pension: Government funded payment for people with permanent physical, psychiatrie or intellectual condition preventing participation in the workforce.
- **Carer's benefit**: Government income supplement to people providing daily care to someone who has severe disability, medical condition or frail age.
- Private insurance (income protection/disability insurance): private income protection designed to pay a benefit if unable to work because of illness/injury.

The COST Questionnaire consisted of 11 questions with a scoring system of zero to four for each question based on a Likert-type scale. The maximum score achievable was 44 and the minimum zero, where higher scores were associated with more financial toxicity. Questions covered financial stress and worry and whether patients felt this was directly attributable to the management of their oncological diagnosis. The iPCQ consisted of 18 questions and incorporated targeted questions on productivity losses such as absenteeism from work (three questions), presenteeism (three questions) and the productivity losses of unpaid work (three questions) as well as collecting some basic demographics (nine questions). The answers to two of the demographics questions (questions four and five) relating to education and employment status were altered for an Australian context. Question four asked for the highest degree of education completed and terminology was adjusted to reflect Australian education levels for example "elementary" was changed to "junior high school" and "vocational education" to "trade

or technical qualification." For question 5 which asked "What do you do?" we abbreviated options to include full or part-time employment, unemployed or retired.

Quality of life was measured by the EORTC-QLQ-C30. This is a high profile validated cancer specific quality of life questionnaire used extensively in the context of clinical trials (12) (13). It is comprised of patient self-reporting questions relating to the effect of the disease and its treatment. A quality of life overall sub score is derived from answers for questions 29 and 30 on this questionnaire.

Descriptive statistics were used for baseline characteristics of all recruited patients. To examine the risk factors associated with financial toxicity, linear regression was performed of COST on the pre-specified variables of age, sex, ARIA index, and income category. Next, to examine the effect of financial toxicity on quality of life, linear regression was performed of overall quality of life (as derived from EORTC-QLQ-C30 questions 29 and 30) on COST.

The pilot study protocol and all amendments were approved by the appropriate Human Research and Ethics Committee and all patients provided written informed consent before enrollment. All authors attest that this study was conducted in accordance with the protocol and Good Clinical Practice Standards and vouch for the completeness and accuracy of the data. It is standard practice for patients with significant financial distress to be referred to the hospital social work service for support. No adverse events occurred during the study period.

### Results

Between August and October 2019 97 patients were approached, 66 patients consented to participate and 31 patients declined. The main reason for not participating was being from a non-English speaking background (NESB) (65% or 20/31 patients). In addition, 23% (7/31) of those who declined reported "not being interested". Of the 66 patients who consented to participate, 53 (80%) returned their questionnaires. One patient did not complete the COST questionnaire and was excluded from COST analysis. All 53 patients completed the remaining questionnaires. Basic demographics are shown in Table 1. The median age of participants was 63.5 years and 55% of patients were female. Half were partnered and 92% spoke English as a first language. Thirty four percent had achieved university level education. According to the Accessibility/Remoteness Index of Australia (ARIA)(14) the majority of patients (75%) were from metropolitan areas and the remainder were regional patients. Forty seven percent of patients were receiving a government financial subsidy, 25% were employed and 70% had a total household income of less than \$75,000AUD per annum (below the average Australian income of \$88,452AUD) (15).

In terms of the COST questionnaires, data was analyzed for 52 patients. The median COST score was 18 (95%CI 15–24) with a range from one to 42 (higher scores indicating more financial difficulties). There was strong correlation between the two measures of financial toxicity, the overall COST score and the individual financial question on the EORTC-QLQ-C30 (Pearson r=0.73).

Linear regression demonstrated that with each one-point increase in COST score (more financial toxicity) there was an associated average difference of -0.90 (95%CI -1.51 to -0.30) points in quality of life with strong evidence against the null hypothesis (p = 0.004) (Figure 1). Fifteen percent of the variance in quality of life can be attributed to COST scores or financial toxicity. After adjusting for confounding factors (age, gender, regional location), the effect size was largely the same, at -1.05 (95%CI -1.78 to -0.32, p = 0.006).

Linear regression was also performed for COST scores on the pre-specified risk factors for financial toxicity: age, sex, ARIA Index and income (Table 2). In terms of "age", each additional year of age was associated with an average COST difference of -0.37 (95%CI -0.54 to -0.20) (Figure 2) suggesting more financial toxicity in younger patients (p < -0.001). However there was no association between COST scores and sex (p=0.083), regional location (p= 0.243) or income identified.

The iPCQ responses demonstrated that only 13 (24%) of participating patients were currently employed: nine working full time and four part time (Table 1). Five patients reported working despite feeling unwell and all reported at least one sick day in the four weeks prior. Ten (of 13) patients reported taking a whole week off work in the prior four weeks. Those in the workforce had higher average incomes than those who were unemployed or retired. Eight employed patients reported earning between \$50–75,000 AUD annually and the remainder earnt less than \$50,000 AUD. This compared with 25 unemployed or retired patients who reported annual earnings of less than \$50,000 AUD.

In terms of those not in the workforce, 29 (55%) patients were retired and 10 (19%) unemployed. Across our entire cohort, 14 (26%) patients reported a reduction in unpaid work based on their illness. Education status was also collected with 18 (34%) patients not completing high school and 18 (34%) attaining a tertiary degree.



### Discussion

As we develop a better understanding of the financial impact a diagnosis of cancer has on patients and their families, the concept of "financial toxicity" has emerged (16) (8). The financial distress experienced by patients with cancer has been linked to reduced compliance with treatment (17), poorer quality of life (9) and even reduced survival (18). The development and validation of the COST questionnaire facilitates an understanding of the financial implications a diagnosis of cancer has from the patient's perspective. This tool has been successfully applied in an American setting however there is little information of its use outside that unique health care system.

The objective of this study was to assess the degree of financial toxicity experienced by an Australian cohort of patients with cancer and its association with quality of life. Our study was unique in that it applied the COST questionnaire to an Australian cohort in every day clinical practice. Our eligibility were broad to include all patients receiving treatment for both early and advanced stage cancer at a tertiary referral cancer centre. Our findings were in keeping with previous studies (9) (19) in that higher COST scores were associated with poorer quality of life. Previous studies have also identified younger age (20), being female (3) and lower incomes (21) to be associated with higher financial toxicity. Similarly this association with age but no relationship to gender or income was established in our small sample size. Our study also aligns with current literature (22) (23) (24) demonstrating that working-age patients with cancer are more likely to experience all domains of financial hardship. The demographic of our cohort had numerous additional features associated with disadvantage including regional status (26%), below average income (70%) and low educational status (34% not completing high school) which needs to be considered when evaluating our population. These risk factors are supported by a study in colorectal patients receiving chemotherapy where those with lower household incomes were identified to be at greater financial risk (20) along with other studies confirming broader demographic risk factors such as low education status and distance from major cancer centre as additional contributors to financial toxicity (3). In Australia, breast cancer has been the focus of research in this field. The Breast Cancer Network of Australia reported \$5,000AUD in out-of-pocket costs for women in the first 5 years from breast cancer diagnosis and a drop by 50% in the total number of household hours worked in the first year (25). Women living outside of metropolitan areas also had additional travel and accommodation costs. A recent study looking at financial resilience demonstrated approximately 65% of Australians were facing some level of financial hardship. Half were identified to have limited financial reserve (defined as less than two months of usual wage) with 10% reporting no savings (26). This degree of baseline financial vulnerability highlights how significant the financial impacts of a cancer diagnosis can be [25].

Whilst our study demonstrated financial toxicity among cancer patients, a potential limitation may have been the reluctance of patients to disclose sensitive information related to their finances. Additionally, we did not select patients based on the duration of their systemic therapy

whilst other studies have shown that financial hardship accumulated over time on treatment. Both of these factors may have underestimated the impact of financial toxicity in our cohort. Twenty patients approached for the study were unable to participate due to being from a NESB. This too may have affected our results as these patients represent a very important treatment group and thus our findings may not be entirely representative of all patients being treating in the public setting in Australia. In our public health service the only funding source for systemic therapy is via the government PBS subsidy. There is no mechanism for self-funding of medications. A detailed description of the sources of financial hardship was not possible based on the quantitative measures used however this aspect will be explored further using qualitative semi-structured interviews in those patients from this cohort with COST scores indicating significant financial toxicity.

Loss of income due to absenteeism from work for both patients and their carers is another trigger for financial hardship (27) (28) (29). Yabroff et al (30) found that cancer survivors were more often unable to work or were more limited in their work due to their illness. This continued more than 11 years post diagnosis and put patients at increased risk of long-term job loss. This pattern has been clearly established in both the short and long term for patients receiving chemotherapy (31) (32) but remains less clear for other systemic therapies (i.e endocrine therapy, immunotherapy) (33). For our cohort 13 (24%) patients were employed with five patients working despite feeling unwell and all patients having had sick leave in the prior four weeks - highlighting this impact.

The definition of financial toxicity, whilst debated, is thought to encompass both the "objective financial burden and subjective financial distress" experienced by patients directly related to the impact of their diagnosis and its treatment (1). In this study we attempted to explore these two aspects: 1) subjective distress as measured by the COST questionnaire 2) objective distress as measured by the iPCQ. Unfortunately there is significant variability in reporting subjective financial distress, making it difficult to compare current literature, and a lack of standardization of assessment methods making it difficult to implement measurement tools in practice (34) (35). Objective financial burdens are perhaps better defined due to their use in health economic analysis (34) where a large focus has been on out-of-pocket costs (36). Having better standardized tools to measure financial toxicity will help further this field. A comprehensive assessment should include financial spending, use of passive financial resources (such as using savings or selling property), psychosocial responses, support seeking, coping with care and coping with one's lifestyle as per Witte et al (34). These measures then also need to be adapted to different contexts and health care systems. The COST measure, whilst addressing some of these domains (one question on spending, two on financial resources and eight on psychosocial response), was established in an American setting and its application to an Australian cohort where there is universal health coverage and thus fewer out-of-pocket expenses must be challenged. Furthermore compensation benefits such as paid sick leave exists in Australia whereas such a process is generally not mandate in the United States (37). These factors served

as important rationales for our study and highlight the difficulties in standardizing tools to measure financial toxicity in the global setting.

Financial toxicity is becoming increasingly important but its measurement has been difficult due to a lack of agreed definitions and standard measures. We have identified that the COST self-reporting questionnaire could be used to identify a proportion of patients experiencing meaningful financial toxicity in an Australian malignant cohort; however, results need to be confirmed in larger studies. These results are both important for highlighting the existence of financial toxicity within a universal health care model and its impact on quality of life. There is increasing endorsement of financial consent in the private health sector in Australia with cost communication in patient interactions having been proven to be associated with improved patient satisfaction(29). This is thought to be less relevant in the public health system where universal health care is provided, however this study suggests there are additional out-of-pocket costs even in this setting impacting quality of life.

This pilot study supports that financial hardship occurs even in a universal health care system and impacts quality of life. Further study confirming these findings in larger groups and a more in depth inquiry into the source of financial hardship in this context is warranted so that initial screening can be implemented and interventions developed to help attenuate this form of toxicity.



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Figure 1 Linear regression of EORTC Overall Quality of Life score on COST.  $R^2 = 0.15$ 

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Figure 2: Scatter plot and linear regression of COST versus age, with line of best fit superimposed.

Author

Parameter	<i>n</i> = 53
Median age (range)	63.5 years (32 - 89)
Gender, <i>n</i> (%)	
Male	24 (45%)
Female	29 (55%)
Remoteness Classification, n (%)	
Metropolitan	39 (74%)
Regional CO	13 (25%)
Missing	1 (2%)
Language, n (%)	
English first language	49 (92%)
English second language	4 (8%)
Marital Status, n (%)	
Partnered	27 (51%)
Separated	10 (19%)
Widowed	4 (8%)
Single	9 (17%)
Not reported	3 (6%)
Financial Support, n (%)	
Aged pension	15 (28%)
Disability support pension	8 (15%)
Carers benefit	2 (4%)
Private insurance	5 (9%)
Nil	21 (40%)
Not reported	2 (4%)

**Table 1:** Demographic characteristics of study patients (n = 53)

Education, n (%)	
Years 7 – 9	7 (13%)
Years 10 - 11	11 (21%)
Year 12	9 (17%)
Apprenticeship	7 (13%)
University	18 (34%)
Missing	1 (2%)
Employment status n (%)	
Full time	9 (17%)
Part time	4 (8%)
Unemployed	10 (19%)
Retired	29 (55%)
Missing	1 (2%)
Annual Total Household Income (\$AUD), n (%)	
< 50,000	29 (55%)
50-75,000	8 (15%)
75-100,000	3 (6%)
>100,000	9 (17%)
Missing	4 (8%)

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### Table 2: Risk factors for financial toxicity

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	Coefficient	Standard error	P value	95% confidence interval	
Age (per year)	-0.37	0.08	< 0.001	-0.54	-0.20
Sex	4.64	2.62	0.083	-0.63	9.91
Female					
ARIA* Index	-3.63	3.07	0.243	-9.80	2.54
Regional area					
Income					
50k to 75k	1.43	3.96	0.719	-6.54	9.41
75k to 100k	0.43	6.01	0.943	-11.68	12.55
> 100k	2.54	3.78	0.505	- 5.08	10.17

\*Accessibility/Remoteness Index of Australia (ARIA)



### **Graphical Abstract Text**



This pilot study aimed to measure the impact of financial toxicity in patients with cancer in an Australian public setting where there is a universal health care model. The COST questionnaire identified a cohort of patients who experienced financial toxicity which was associated with reduced quality of life.

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