**TITLE:** Exploring the integration of environmental impacts in the cost analysis of the pilot MEL-SELF trial of patient-led melanoma surveillance

RUNNING TITLE: Integrating environmental impacts in the cost analysis of the pilot MEL-SELF trial

**TYPE**: Practical application

JOURNAL: Applied health economics and health policy

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## ABSTRACT

## Aims:

Human health is intrinsically linked with planetary health. But planetary resources are currently being degraded and this poses an existential threat to human health and the sustainability of our healthcare system. The aims of this study were to (1) describe an approach to integrate environmental impacts in a cost analysis; and (2) demonstrate this approach by estimating select environmental impacts alongside traditional health system and other costs using the example of the pilot MEL-SELF randomised controlled trial of patient-led melanoma surveillance.

#### Methods:

Economic costs were calculated alongside a randomised trial using standard cost analysis methodology from a societal perspective. Environmental impacts were calculated using a type of carbon footprinting methodology called process-based life cycle analysis. This method considers three scopes of carbon emissions: Scope 1, that occur directly from the intervention; Scope 2, that occur indirectly from the intervention's energy use; and Scope 3, that occur indirectly because of the value chain of the intervention. In this study we only included emissions from patient transport to attend their melanoma clinic over the study period of six months.

### Results

The environmental impact per participant across allocated groups for patient transport to their melanoma clinic was estimated to be 10 kg carbon dioxide equivalent. Economic costs across the allocated groups indicated substantial health system costs, out-of-pocket costs, and productivity losses associated with melanoma surveillance. The largest cost contributor was health system costs, and the most expensive category of health system cost was hospital admission.

#### Conclusion

Calculating environmental impacts is worthwhile and feasible within a cost analysis framework. Further work is needed to address outstanding conceptual and practical issues so that a comprehensive assessment of environmental impacts can be considered alongside economic costs in health technology assessments.

## **KEY POINTS FOR DECISION MAKERS**

- Including environmental impacts is worthwhile and possible within a cost analysis framework.
- Further research is needed to address outstanding conceptual and practical issues before environmental impacts can be considered with economic costs in HTA decision making.
- Engagement with HTA decision makers is critical to ensure adopted methods are fit for purpose.

# STATEMENTS AND DECLARATIONS

## Funding

Jake Williams is supported by a Faculty of Medicine and Health Research Centres Stipend Scholarship (SC4167) at the University of Sydney. Katy Bell is supported by a National Health and Medical Research Council (NHMRC) Project Grant (1163054) and Investigator Grant (1174523). Rachael Morton is supported by an NHMRC Fellowship (1194703) and the Robinson Fellowship at the University of Sydney.

# **Conflicts of Interest**

Jake Williams, Katy Bell, Rachael Morton, and Mbathio Dieng declare that they have no conflict of interest.

### **Ethics Approval**

The study was approved by the Sydney Local Health District Ethics Committee (2019/ETH07531).

## **Consent to Participate**

Informed consent was obtained from all individual participants included in the study.

## **Consent for Publication**

Informed consent for publication of their data was obtained from all individuals included in the study.

## Availability of Data and Material

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

## **Code Availability**

Not applicable.

## **Author's Contributions**

Data analysis was completed by Jake Williams under supervision from Mbathio Dieng. Preparation of the manuscript was completed by all authors.

## **1. INTRODUCTION**

Human health is intrinsically linked with planetary health and "depends on flourishing natural systems and the wise stewardship of those systems to thrive".(1) But planetary resources are currently being degraded and this poses an existential threat to human health and the sustainably of our healthcare systems. Evidence from around the world suggests that health systems are significant contributors to the total greenhouse gas (GHG) emissions of a country, with studies estimating that healthcare is responsible for 7% of GHG emissions in Australia,(2) 4% in England,(3) and 10% in the United States.(4) Some healthcare professionals have responded to this challenge by embracing "sustainable healthcare" practices, to minimise their profession's impact on climate change.(5,6) This includes calls for the preferential use of healthcare with low environmental impact.(5)

Health technology assessment (HTA) is the process by which the value of healthcare technologies (such as diagnostic tests or medicines) are assessed to ensure that limited healthcare resources are allocated in a way that maximises health benefit. In Australia, HTA relies on clinical effectiveness evidence and health economic analyses that consider patient outcomes relative to economic costs. How environmental impacts of the technology may impact value estimates has not traditionally been considered. Using existing methods environmentally "expensive" interventions may be found to be cost-effective, despite contributing to climate changes that have a detrimental impact on human health. For health systems to minimise their impact on climate change, environmental impact measures need to be included in HTA so that clinically effective, cost-effective, and low environmental impact technologies can be chosen by decision makers.(5,7,8) Australian HTA guidelines have recently recognised this issue by allowing the environmental impacts of a technology to be considered during decision making.(9) However, there have not yet been any applications to the Medical Services Advisory Committee or Pharmaceutical Benefits Advisory Committee that include such impacts, and there are few examples in the available literature.(10–12)

The aim of the current study was to (1) describe an approach to include environmental impacts in a cost analysis; and (2) demonstrate this approach by estimating select environmental impacts alongside traditional health system and other costs using the example of the pilot MEL-SELF randomised controlled trial of patient-led melanoma surveillance.(13)

## 2. METHODS

### 2.1. Overview of an approach to include environmental impacts in a cost analysis

Health economic costing studies aim to estimate the total cost of a healthcare service, intervention, or technology. These studies do not traditionally include environmental impacts but may be expanded to do so. To illustrate how this approach could work in practice, and as the first step of an iterative approach towards including environmental impacts in economic evaluations for HTA, we present a worked example of a costing study that presents financial costs and environmental impacts using data from the MEL-SELF pilot RCT (Australian New Zealand Clinical Trials Registry ACTRN12616001716459). Differences between randomised groups and confidence intervals were not calculated due to the small sample size and missing data.

## 2.2 Measuring environmental impacts

The environmental impact of a healthcare technology can be estimated using the carbon footprint of that technology. A carbon footprint is "the best estimate that we can get of the full climate change impact of something"(14) and usually accounts for the direct and indirect emission of the seven greenhouse gasses (GHG) covered by the Kyoto Protocol.

One approach to carbon footprinting is called process-based life cycle analysis. This is referred to as a "bottom-up" approach because it involves measuring all the greenhouse gasses emitted from all the processes required across the life cycle of a technology, including its development, manufacture, consumption, and disposal.(14,15) The other well-established approach to carbon footprinting is called environmentally extended input-output analysis. This is referred to as a "top-down" approach because it uses monetary flows between industry sectors to estimate the greenhouse gases emitted by a technology.(2,14)

While input-output analysis is useful for comparing different sectors of the economy,(2) it is not appropriate for HTA because it assumes that greenhouse gases increase linearly with price, which is unlikely to be true for healthcare technologies. Prices paid for healthcare goods and services are based on what can be negotiated and paying more for the same item does not mean it has a greater environmental impact. As well as avoiding the use of cost as a surrogate for carbon emissions, life cycle analysis generates the more granular data needed for the comparison of two clinical care alternatives and is the more appropriate method to be used for HTAs.

The first step of a life cycle analysis is to decide what processes to include. Greenhouse gas emissions are categorised as either Scope 1, 2, or 3 by the Greenhouse Gas Protocol. Scope 1 emissions occur directly from the intervention and are controlled by the organisation administering the intervention. This includes on-site energy production and the direct release of greenhouse gasses such as anaesthetic volatile agents, and emissions from cars owned by the organisation. Scope 2 emissions occur indirectly from the energy required for the intervention, such as the electricity used to power hospital buildings and medical equipment. Scope 3 emissions are all other emissions that occur indirectly from the supply chain of the intervention. This accounts for the majority of the healthcare sector's carbon footprint.(16) Patient transport is not considered within the Greenhouse Gas Protocol so does not technically fit within one of the three scopes.

Because of the "bottom-up" nature of life cycle analysis the number of processes that can be included is infinite, so studies must decide on a "boundary" at which point their analysis stops. This may be determined by the amount of available data, the resources available to the study team, or the practicality of the measurement. When processes are excluded from a carbon footprint estimate the result has something called a "truncation error", the size and importance of which depends on the scope of processes that are excluded. The existence of truncation error should not deter researchers from presenting carbon footprint estimates.

After all relevant processes and sources of emissions have been inventoried, they should then be quantified using the most appropriate unit of measurement. The final step of life cycle analysis is to determine the total GHG emitted by each process. This is done using carbon emissions factors. These factors often use carbon dioxide equivalent (CO<sub>2</sub>-e) units, which can account for multiple of the GHG in one figure.

## 2.3 Environmental impacts measured in our worked example

In this study, 100 patients (NSW, Australia) who were treated for melanoma localised to the skin were randomised to patient-led surveillance (the intervention: patient-performed teledermoscopy with dermatologist feedback), or to clinician-led surveillance (the control: usual care of routinely scheduled clinic visits). The intervention appeared to have a beneficial effect on health outcomes (i.e., early detection of subsequent melanoma) with no detrimental effect on psychological outcomes.(13) The data available from the MEL-SELF pilot RCT included the participant's home post code and the location of and number of visits they made to the participating melanoma clinic. Patients indicated the transport method they used in a healthcare resource diary (health diary). We therefore included emissions caused by patient travel to their clinic. We did not include any other sources of emissions in our estimate and emissions from public transport were assumed to be zero, consistent with previous approaches.(17,18)

We used Google Maps (<u>www.google.com/maps</u>) to estimate the shortest driven distance in kilometres for a return journey between the participant's home post code and the clinic. The volume of petrol consumed during this journey was then calculated using the average fuel consumption of Australian passenger vehicles of 11.1 L per 100 km, as reported in the Survey of Motor Vehicle Use.(19)

We followed the method for calculating transport related fuel emissions provided by the Australian Department of Industry, Science, Energy and Resources in the National Greenhouse Accounts Factors.(20) Emission factors for gasoline in post-2004 vehicles were used to calculate carbon dioxide (CO<sub>2</sub>), methane (CH<sub>4</sub>), and nitrous oxide (N<sub>2</sub>O) emissions in carbon dioxide equivalent units (kg CO<sub>2</sub>-e).

### 2.4. Economic costs measured in our worked example

We estimated economic costs for a subset of participants from the societal perspective over six months in 2021 Australian dollars. Participants were asked to complete paper-based monthly healthcare resource use diaries (health diary), that recorded the number and type of health services used, time off work, time receiving care from family and/or friends, and any out-of-pocket costs. Clinic records for these participants were also available and contained the dates participants visited their melanoma clinic and how many skin excisions were performed. We estimated health system costs, out-of-pocket costs, and productivity changes using these data. Participants with at least four health diaries (of a maximum six) were included in the analysis to ensure an appropriate sample size. Any missing data among this group was assumed to be a zero cost. Costs related to the development and implementation of the intervention were not considered in this pilot costing study.

First, we estimated health system costs. Unit costs were obtained from the Medicare Benefits Schedule(21) for visits to a GP (MBS #23), specialist (MBS #105), nurse (MBS Group M3), allied health professional (MBS Group M3), and for skin excisions (MBS #30071). Hospital related unit costs were obtained from the Independent Hospital Pricing Authority(22) for admission to hospital and emergency department presentations. Unit costs for diagnostic imaging were not identified because the health diary did not contain information about the specific type of test.

Second, we estimated out-of-pocket costs. Patient reported costs from the health diaries were categorised into money spent on sunscreen, hats, clothing, other skin creams, medical care, and parking. Costs incurred from melanoma clinic appointments (i.e., gap payments and private travel costs) were estimated separately using patient medical records. The method for calculating the kilometre distance travelled by patients that drove to clinic is described in Section 2.3. The unit cost of a kilometre driven (\$0.72) was obtained from the Australian Taxation Office (ATO) for the 2020-21 financial year.(23) The cost of private travel by car per participant was calculated by multiplying the distance driven and the unit cost. The number of melanoma clinic visits was obtained from medical records. The unit cost (i.e., gap payment) was estimated by subtracting the MBS benefit amount from the known cost of a follow-up appointment at the melanoma clinic. Reimbursement from

private health insurance companies was not considered. The cost of a melanoma clinic visit per participant was calculated by multiplying the number of visits and the unit cost.

Third, we estimated productivity changes using the human capital approach, as opposed to the friction cost approach, which measures lost productivity as the amount of time by which working life is reduced due to melanoma. The amount of time participants took off work to attend skin check appointments, and the amount of time of unpaid care they received from family and friends was recorded in the health diary in hours. The unit cost of time-off-work was taken from the Australian Bureau of Statistics (ABS) reported median Australian hourly earnings.(24) The opportunity cost of time off work was calculated by multiplying the amount of time and the unit cost. The unit cost of unpaid care was estimated by methods reported elsewhere.(25) The average Australian hourly ordinary earnings of personal carers and assistants (\$30.70)(24) was adjusted for wage growth to the Jun-21 financial quarter (5.7%) consistent with the Wage Price Index of Australia(26) and loadings for on-costs (0.23%), capital (5.25%), and supervision and administration (2.35%) were applied. The estimated unit cost was \$34.85. The replacement cost of unpaid care was calculated by multiplying the amount of time and care was calculated by multiplying the amount of unpaid care was calculated by multiplying the amount of unpaid care was calculated by multiplying the amount of time of Australia(26) and loadings for on-costs (0.23%), capital (5.25%), and supervision and administration (2.35%) were applied. The estimated unit cost was \$34.85. The replacement cost of unpaid care was calculated by multiplying the amount of time and care was calculated by multiplying the amount of time of unpaid care was calculated by multiplying the amount of time and care was calculated by multiplying the amount of time and the unit cost.

Discounting of economic costs was not required as all costs were accrued within 12 months. All costs were inflation adjusted to the financial quarter Jun-21 (2021) in Australian dollars, consistent with the Consumer Price Index of Australia.

## 3. RESULTS

#### 3.1 Environmental impacts

Measured environmental impacts were limited to those caused by patient travel by car to attend their melanoma clinic. Complete data was available for all 100 participants. The average (SD) distance driven by participants to attend their treating clinic over six months was 41 (126) km (intervention: 64 km, control: 18 km), the average volume of petrol consumed was 4.5 (14) L (intervention: 7.1 L, control: 2.0 L), and the average carbon footprint was 10 (32) kg CO<sub>2</sub>-e (intervention: 16 kg CO<sub>2</sub>-e, control: 4.7 kg CO<sub>2</sub>-e). 10 kg CO<sub>2</sub>-e per participant is equal to 1000 kg CO<sub>2</sub>-e across the study population, equivalent to an economy flight between Sydney and Perth. Full details of these results are presented in Table 1.

#### 3.2 Economic costs

Of the 100 participants randomised, 41 (41%) completed at least four health diaries and were included in the economic cost calculations. Table 2 summarises participant use of health services. Visits to general practitioners and specialists were the most frequently used services (participating melanoma clinic and other clinics recorded in the health diary). Table 3 summarises the cost of these health services to the health system. The average (SD) cost per participant was \$759 (\$2584) during the study period of six months (intervention: \$1321, control: \$168) and the most expensive contributor was hospital admission. Table 4 summarises productivity losses. The average productivity loss per participant was \$88 (\$129) (intervention: \$93, control: \$82). Table 5 summarises out-of-pocket costs. The average (SD) out-of-pocket cost per participant was \$183 (\$236) over six months (intervention: \$206, control: \$159) and the most expensive contributor was gap payments for visiting a melanoma clinic.

#### 4. DISCUSSION

The aim of this study was to describe and demonstrate an approach to include environmental impacts in a cost analysis. Using data from the MEL-SELF pilot RCT we have demonstrated a method for simultaneously estimating economic costs and environmental impacts to better indicate the true cost of the health gains from an intervention. The health outcomes of the intervention have been reported in detail previously.(13)

Our results indicate that the largest cost contributor was health system costs, and the most expensive category of health system cost was hospital admission, which was infrequently used but a high-cost healthcare service. While patient travel to their melanoma clinic is a particularly relevant environmental consideration for a telehealth intervention such as in the MEL-SELF pilot RCT, it is only a small proportion of the total GHG emissions caused by melanoma surveillance and as a result our carbon footprint has a high truncation error. Previous research suggests telehealth may be associated with a reduction in the carbon footprint of healthcare, primarily due to a reduction in transport-based activity.(27) However, our results suggest this saving in GHG emissions may be offset by downstream face-to-face clinic visits and other healthcare use prompted by the telehealth intervention. In this MEL-SELF pilot RCT example the telehealth intervention directly prompted some patients to arrange for a face-to-face appointment. This is consistent with research suggesting that increased telehealth use for primary care is associated with an increase in downstream healthcare use.(28)

Research into different methods of including environmental impacts in healthcare decision making is still in its infancy and several conceptual and practical issues arise when trying to apply these methods.(29) The primary issue is that there is no agreed method for reporting environmental impacts alongside economic costs. Hensher argues that environmental impacts are a negative externality that should be internalised within the cost side of an economic evaluation, and that the most effective way to do this is by using shadow prices and the "social costs of carbon".(30) Alternatively, Marsh et al suggest that cost-benefit analysis and multi-criteria decision analysis could be used to capture environmental impacts within HTA decision making but separate to the costs of an economic evaluation.(31) Decision-maker preferences for these methods is unknown, however they all require an estimate of the environmental impact of the technology being assessed. We suggest that carbon footprints can be included alongside costs in an economic costing study now, while further work is done to determine the best method for evaluating a technology based on this information.

### 4.1. Limitations of our approach to include environmental impacts in a costing study

There were several limitations in our cost analysis of the MEL-SELF pilot RCT example. These include a small sample size and the large amount of missing data, largely caused by poor adherence to the paper-based health diary. This prevented any meaningful comparison between randomised groups and any notional difference in costs or impacts should not be interpreted as a true difference between the study groups. We have improved data collection processes in a larger RCT of the same MEL-SELF intervention that is underway, including use of a digital diary to measure health resource use.(32) Second, the current study is limited in scope, particularly for the environmental impact estimates, which were limited to patient transport to treating melanoma clinic appointments only and did not include travel for other clinics or healthcare use, nor emissions related to the manufacture and use of the mobile dermatoscope, or the delivery of healthcare services. The larger ongoing trial also aims to provide a much more comprehensive measurement of these environmental impacts. Furthermore, although economic cost estimates were broadly inclusive, we did not have resource use and cost data to include medications or complementary and alternative medicines.

There are some practical barriers that need to be addressed before environmental impacts can be routinely included in costing studies. Our study suggests that calculating a carbon footprint requires specific consideration during the design phase of a RCT (or other study) to ensure that the scope of GHG emissions allows for a meaningful estimate (with low truncation error) to be made. Health diaries designed to collect information about environmental impact may be a useful method of doing this but rely on high completion rates. A detailed process-based life cycle assessment requires specialist expertise from environmental scientists, but there is currently a workforce shortage of people with these skills. HTA is also a highly prescriptive process(9,33) and while academic economic evaluations may freely consider environmental impacts in their analyses, these won't necessarily be suitable for HTA applications to decision makers for technology reimbursement. For example, costbenefit analyses should not be presented in the base-case analysis for submissions to the Australian Medical Services Advisory Committee. Engagement with HTA decision makers is critical to ensure proposed adopted methods are fit for purpose.

## 4.2. Conclusions

Including environmental impacts is worthwhile and possible within a cost analysis framework but requires careful planning from the study design stage, and the input of specialist environmental scientists. Further research is needed to address outstanding conceptual and practical issues before environmental impacts can be considered with economic costs in economic evaluations for HTA decision making.

## 6. TABLES

Environmental impact <sup>b</sup>	Intervention	Control	Total
	(n=49)	(n=51)	(n=100)
Distance driven (km)	64 (167)	18 (57)	41 (126)
Petrol consumed (L)	7.1 (19)	2.0 (6.4)	4.5 (14)
Total carbon footprint (kg CO <sub>2</sub> -e) <sup>c</sup>	16 (43)	4.7 (15)	10 (32)

Table 1: Average environmental impact (greenhouse gas emissions in kg CO<sub>2</sub>-e) per participant<sup>a</sup>

Abbreviations: CO<sub>2</sub>-e, carbon dioxide equivalent

- a. All values are reported as the mean (SD) per participant over six months to two significant figures unless otherwise stated.
- Environmental impact estimates are limited to participant transport to and from their treating melanoma clinic. The mean number of treating melanoma clinic visits per participant was 0.78 (0.45 in the control group and 1.1 in the intervention group).
- c. Carbon dioxide (CO<sub>2</sub>), methane (CH<sub>4</sub>), and nitrous oxide (N<sub>2</sub>O) included in carbon dioxide equivalent estimate.

Table 2: Average healthcare resource use per participant (volume)<sup>a</sup>

Healthcare resource use <sup>b</sup>	Intervention	Control	Total
	(n=21)	(n=20)	(n=41)
Number of healthcare visits			
General practitioner <sup>c</sup>	1.3 (1.7)	1.1 (1.4)	1.2 (1.5)
Medical specialist <sup>c</sup>	1.3 (2.5)	0.55 (0.89)	1.0 (1.9)
Nurse	0 (0)	0.10 (0.31)	0.049 (0.22)
Allied health professional	0.76 (1.3)	0.85 (1.5)	0.80 (1.4)
Number of hospital visits			
Emergency department presentation	0.048 (0.22)	0.050 (0.22)	0.049 (0.22)
Hospital admission (nights)	0.19 (0.60)	0 (0)	0.10 (0.44)
Number of investigative tests and procedures			
Diagnostic imaging test	0.43 (0.75)	0.25 (0.55)	0.34 (0.66)
Skin lesions excised	0.86 (1.2)	0.20 (0.52)	0.54 (1.0)

- a. All values are reported as the mean (SD) per participant over six months to two significant figures unless otherwise stated.
- b. All units are number of visits/tests unless otherwise stated.
- c. This includes the number of visits at the recruiting melanoma clinic; the mean number of these clinic visits per participant was 0.78 (0.45 in the control group and 1.1 in the intervention group).

Table 3: Average cost to the health system per participant<sup>a</sup>

Health system cost (AU\$)	Intervention	Control	Total
	(n=21)	(n=20)	(n=41)
General practitioner	52 (65)	41 (53)	47 (59)
Medical specialist	61 (112)	25 (40)	43 (86)
Nurse	0 (0)	6 (20)	3 (14)
Allied health professional	49 (87)	55 (99)	52 (92)
Emergency department presentation	47 (214)	30 (133)	38 (177)
Hospital admission	1066 (3367)	0 (0)	546 (2441)
Skin excisions	47 (65)	11 (28)	29 (53)
Total	1321 (3552)	168 (234)	759 (2584)

Abbreviations: AU\$, 2021 Australian Dollars

a. All values are reported as the mean (SD) per participant over six months to zero decimal places unless otherwise stated.

Table 4: Average productivity loss per participant<sup>a</sup>

Productivity loss	Intervention	Control	Total
	(n=21)	(n=20)	(n=41)
Time-off-work (hours)	0.93 (3.1)	1.7 (2.7)	1.3 (2.9)
Time-off-work (AU\$)	33 (111)	59 (96)	46 (103)
Unpaid care (hours)	1.7 (2.4)	0.66 (1.8)	1.2 (2.2)
Unpaid care (AU\$)	60 (83)	23 (62)	42 (75)
Total (AU\$)	93 (132)	82 (129)	88 (129)

Abbreviation: AU\$, 2021 Australian Dollars

a. All values are reported as the mean (SD) losses per participant over six months to two significant figures unless otherwise stated.

Table 5: Average out-of-pocket cost per participant<sup>a</sup>

Out-of-pocket costs (AU\$)	Intervention	Control	Total
	(n=21)	(n=20)	(n=41)
Sunscreen <sup>b</sup>	18 (32)	29 (59)	23 (47)
Hat <sup>b</sup>	6 (14)	4 (14)	5 (13)
Clothing <sup>b</sup>	16 (57)	9 (21)	13 (43)
Other creams <sup>b</sup>	1 (4)	10 (22)	6 (16)
Medical <sup>b</sup>	0.3 <sup>e</sup> (2)	9 (30)	5 (21)
Parking <sup>b</sup>	7 (18)	2 (6)	5 (14)
Private travel by car <sup>c,d</sup>	36 (65)	8 (17)	22 (49)
Gap payment <sup>c,d,f</sup>	122 (147)	48 (93)	86 (127)
Other <sup>b</sup>	0 (0)	39 (175)	19 (122)
Total	206 (180)	159 (286)	183 (236)

Abbreviations: AU\$, 2021 Australian Dollars

- a. All values are reported as the mean (SD) per participant over six months to zero decimal places unless otherwise stated.
- b. Costs self-reported by patients in monthly healthcare resource use diary.
- c. Costs estimated using medical records and other sources.
- d. Estimate only includes costs attributable to an appointment at a treating melanoma clinic and no other categories of healthcare use, including other GP and specialist clinic visits.
- e. Calculated to one significant figure.
- f. Difference between provider charge and Medicare benefit paid.

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