**Title Page**

**Title:**

Using an electronic self-completion tool to identify patients at increased risk of melanoma in Australian primary care

**Short title:**

Melanoma risk in Australian primary care

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This is the author manuscript accepted for publication and has undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi: 10.1111/AJD.13244

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**Acknowledgments:**

Thank you to all the participants in this study and the general practice staff who supported the recruitment.

This research arises from the CanTest Collaborative, which is funded by Cancer Research UK [C8640/A23385]: FMW is Director, JDE is Associate Director, and EH is supported by a CanTest PhD. The researchers gratefully acknowledge the Primary Care Collaborative Cancer Clinical Trials Group (PC4) for their support of this project. The UK MelaTools programme was supported by FMW's Clinician Scientist award from the National Institute for Health Research (RG 68235). The views expressed in this publication are those of the authors and not necessarily those of the NHS, the National Institute for Health Research, or the Department of Health.

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Article type : Original Research

**Title:**

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**Abstract**:

*Background/Objectives*

Australia has the highest incidence of melanoma in the world. Some international guidelines recommend a risk-based approach to screening for melanoma, but few suggest how to account for multiple risk factors or how to implement risk-based screening in practice.

This study investigated the acceptability and feasibility of identifying patients at increased risk of melanoma in Australian general practice using a self-completed risk assessment tool. Stratification of risk was based on the validated Williams melanoma risk prediction model.

*Methods*

Patients and companions aged 18 or older in Australian general practices were approached in the waiting room and invited to enter information about their melanoma risk factors into the tool using an iPad. Acceptability was measured by the proportion of people willing to participate from those invited and feasibility by the number of people able to complete the tool unaided. Risk of developing melanoma was stratified into four risk categories using the Williams model.

*Results*

1535 (90.4%) participants were recruited from two general practices. Only 200 participants (13%) needed assistance to complete the tool. The mean risk score for participants was 15.2 (±SD 9.8). The

Williams model estimated between 5% and 19% of the sample were at increased risk accounting for an estimated 30% to 60% of future incident melanomas.

*Conclusions*

A risk stratified tool using the Williams model was acceptable and feasible for patients to self-complete in general practice clinics. This could be an effective way to identify people in primary care for implementing risk-based targeted melanoma screening and prevention.

**Keywords:** melanoma, primary care, risk assessment, screening

**What this research adds:**

- It is feasible to identify patients in Australian general practice at increased risk of melanoma using an electronic self-completion tool which incorporated a validated risk prediction model.
- Depending on risk thresholds, up to a fifth of patients identified using this tool might require screening and preventive advice.

**Abbreviations:**

ABS – Australian Bureau of Statistics

AUC – Area under the receiver operating curve

PPV – positive predictive value

NPV – negative predictive value

UK – United Kingdom

**Introduction:**

Australia has the highest incidence rates of primary cutaneous melanoma in the world; more than 15,000 new cases of melanoma are projected to be diagnosed in 2019[1]. As the incidence continues to rise, new strategies are important to improve early detection and treatment outcomes[2]. Currently, there is insufficient evidence that population screening for melanoma will reduce morbidity or mortality[3,4]. Some international guidelines recommend a risk-based approach to melanoma screening[4]. Risk stratified screening is likely to be more cost-effective if defined using multiple risk factors instead of age alone[5,6]. In Australia, national guidelines recommended that general practitioners identify people at increased risk of melanoma and provide them with risk-appropriate advice about prevention and early diagnosis[7]. This is currently ad-hoc and unstructured and uses single risk factors to assess risk[8].

Risk factors for melanoma are well established and many different risk prediction models exist to identify populations at increased risk. Two systematic reviews have been recently conducted to compare existing models[9,10]. They both demonstrated that inconsistent definitions of risk factors and risk cut-offs were used by these different models, and the area under the receiver operating curve (AUC) ranged between 0.62-0.86[9,10]. Both reviews established that very few models have been externally validated. None of the identified externally validated models had been developed or validated in Australia, while also being suitable for patient self-completion. The Williams model which was derived from a US population, was one of very few suitable for patients to self-complete[11] and had a reasonable discrimination with an AUC of 0.70 (95% confidence interval 0.64-0.77)[11].

Usher-Smith and colleagues evaluated the Williams model, using an electronic self-completed survey, MelatoolsQ, to assess the feasibility of using this approach among the United Kingdom (UK) primary care population, and the prevalence of the at-risk population. Their study found that it was acceptable and feasible to use for self-completion in the waiting rooms of UK general practice[12].
Within the context of the Medical Research Council framework for the development and evaluation of complex interventions[13], this study was designed to determine the feasibility of using the MelatoolsQ for Australian recruitment and to estimate prevalence of the at-risk population to inform a large potential future trial. Using a version of the MelatoolsQ modified for the Australian context, this study assessed the acceptability and feasibility of identifying patients at increased risk of melanoma in Australian primary care and estimated the prevalence of the at-risk population.

**Methods:**

*Study population and data collection*

Ethical approval for this study was gained from the University of Melbourne Human Research Ethics Committee (1545602.2). Participants were recruited from two large general practices in outer metropolitan Melbourne between February 2016 and August 2017. Participants and companions aged ≥18 years were approached in general practice waiting rooms by trained researchers at different times of the day and different days of the week. Posters were also placed in the waiting room to advertise the study. Those willing to take part were invited to complete an electronic assessment tool using iPads. Researchers recorded if participants required assistance to complete the survey. Reasons for not wishing to participate were recorded.

*Australian MelatoolsQ tool*

The iPad administered the melanoma risk assessment tool (MelatoolsQ). MelatoolsQ consisted of two sections to collect the risk variables as defined by the Williams risk prediction model, and additional demographic variables. The demographic section included questions on ethnic background, education level, employment status, and living status. The questions in the tool were phrased as originally reported in the Williams model and included: sex, age, natural hair colour at the age of 15 years, number of raised moles on both arms, density of freckles on both arms before the age of 20 years, number of severe sunburns up to the age of 18 years and prior non-melanoma skin cancer (basal cell carcinoma and squamous cell carcinoma)[11]. Participants were also asked whether they had had a melanoma. Photographic images were included of raised moles and freckles alongside those questions to assist completion by each participant independently.

*Statistical methods*

The risk score for each participant was calculated using the points scoring system developed by Williams et al and patients were categorised using four risk score cut offs based on their risk[11]. The scoring system ranged between 0 and 67, the higher the risk score the greater the risk (table 1). We calculated the proportion of participants who would be identified as at increased risk using each of the four risk score cut-offs used by Williams et al.[11]: 25, 28, 30, 34. We repeated this, weighted to the age and sex distribution of the Australian population using the Australian Bureau of Statistics (ABS) 2016 Census data[14], to obtain estimates of the proportion of the Australian population who would be classified as at increased risk. To estimate the positive predictive value (PPV) and negative predictive value (NPV) for each cut-off we assumed that the Williams model[11] would perform equally in the Australian population as in the published validation study. We used the sensitivity and specificity reported by Williams et al. for each of the four risk score cut-offs[11] and the published national data for the 2015 age standardised melanoma incidence[15] to estimate 5-year PPVs and NPVs. We computed the mean risk score and standard deviation for the entire sample and compared the mean risk to the UK data from Usher-Smith et al.[12] using a two-sample t test with equal variances. Using the Socio-economic indexes for areas (SEIFA) from the ABS 2011 Census[16], participants' postcodes were stratified into low, moderate and high socio-economic status. All analyses were performed using Stata version 13[17].

**Results:**

*Participant recruitment* (Figure 1)

1,960 people were consecutively approached and invited into the study. 132 were ineligible (6.7%) either due to poor English (n=86) or being too unwell (n=46) and 152 people (7.8%) declined to participate. 1,651 participants were recruited (90.4%) and 1,535 participants completed the risk assessment tool (91.7%%). 139 people agreed to take part but were called into their appointment before completing the tool (figure 1). We excluded 41 (2.1%) participants who had a history of melanoma as they are already defined as high risk for melanoma, leaving 1,493 participants in the final analyses.

*Participants* (table 2)

Our study participants were slightly younger (65% under age 44 compared to 51%) and contained proportionately fewer males (40.7% male compared to 49.2%) when compared with the Australian population[14]. the latter reflecting the primary care consulting population. This study had a broad range of ethnicities, however the majority reported to be Anglo-Australian (32%).

*Acceptability and feasibility*

Only 200 participants (13%) required assistance to complete the survey. Of these, 104 (52%) required assistance counting their moles on their arms, 76 (38%) were not confident using the iPad and 20 (10%) could not read the survey as they did not have their reading glasses with them.

*Distribution of melanoma risk factors and scores*

The prevalence of the melanoma risk factors for the sample is presented in Table 3. As expected, due to the large proportion of people born in South East Asia and the Mediterranean countries, a low proportion of our study sample had red hair at the age of 15 (2.8%) or had had a prior non-melanoma skin cancer (5.7%).

After weighting to the Australian age and gender distributions, using the four different potential cut-offs from the Williams model, we estimated the proportion of the sample who would be at increased risk of melanoma and the associated proportion of incidence melanoma cases for each estimated threshold. 19.8% of the sample were classified at increased risk if the threshold was 25, accounting for 60% of future incident melanomas. 13.5% were classified as at increased risk if the threshold was 28, accounting for 50% of future incident melanomas. 9.8% would be classified as at increased risk if the risk threshold was 30, accounting for 42% of future incident melanomas. Lastly, 5.3% were classified at increased risk if the risk threshold was 34, accounting for 30% of incident melanomas (figure 2).

*Comparison to the UK study*

The mean risk score for all 1,493 participants was 15.2 (±SD 9.8); this was significantly lower than the UK score (17.1, ±SD 8.5) [difference in mean scores between UK and Melbourne 1.9 (95% Confidence interval (CI) 1.4-2.4), p<0.001]. Comparing the risk score cut-offs with the UK study data, the values were generally similar (Figure 2), however a slightly greater proportion of the population would be classified as increased risk at all thresholds in Australia after adjusting for age and sex (table 4). Estimated PPVs and NPVs are also given for each risk score cut-off for this study population and the UK population, based on the relative risk, sensitivity and specificity reported by Williams et al.[11] The PPVs for this study population is higher than the UK due to the higher prevalence of melanoma in the Australian population.

**Discussion:**

*Summary of main findings*

Using an electronic tool which implements the Williams melanoma risk model[11] to identify patients at increased risk in Australian primary care waiting rooms is acceptable and feasible. This was evidenced by the high response rate and low number of patients needing assistance to complete the survey. These findings support the implementation of a real-time risk stratification tools for use by patients in primary care to allow tailored screening and prevention of melanoma.

*Strengths and limitations*

A strength of this study is the simple survey design and data collection method. The MelatoolsQ software used in this study had a user-friendly design and provided enough information for most participants to complete the questions unaided. We included photos as examples to assist participants with counting their moles and determining their freckle density on their arms. These photos, along with the detailed explanation for each question, enabled participants to easily self-complete the survey. A minor limitation of this study was not assessing participants ease of completion while using the tool. This would have strengthened our feasibility data. However, this may not be completely indicative of acceptability. In a previous study by Harty and colleagues 84% of participants claimed a colorectal cancer risk prediction tool easy to use but 41% of participants required assistance to complete the questions[18]. With almost 90% of the participants not needing assistance and the high recruitment rate in our study, this provides essential feasibility data for future trials aiming to recruit patients in primary care who are at increased risk of melanoma.

The sample demographics differed from the Australian population by gender and age, the demographics were applicable to the general practice population that we were testing the tool for. Our study population was relatively ethnically diverse, and this in turn potentially would lower the mean risk scores compared to the UK findings, where the population was predominately white/British (91%)[12]. However, the ethnic diversity we recorded is representative of the current Australia population as reported by the Australian Bureau of Statistics[14]. Our ethnically diverse sample had over 50% with dark hair and a lower proportion with fair skin compared to the UK study[19].

Despite the large sample size and high recruitment rate, a limitation of this study is only sampling patients from two general practices in Melbourne. Compared to the Usher-Smith et al. study[12] which recruited from more than 20 general practices in three different regions throughout the UK (England, Scotland and Wales), our study sample size is relatively small. We accounted for this by adjusting for age and sex of the Australian population but are limited by the uncertainty of the estimates of prevalence for the other risk factors in the tool.

*Context with other literature*

Past research on risk models for melanoma demonstrated a large variety of risk factors, measured in a multitude of ways[9,10]. Family history has been shown to be a strong indicator of risk, however it was not selected for inclusion in the Williams model[11]. Including family history could potentially increase the AUC, however this would make it more challenging and potentially unreliable to self-complete on an iPad without assistance. A new risk model developed by Vuong et al.[20] with a similar AUC to the Williams model has been developed since the data collection of this study. It includes family history and has been validated in an Australian population. We expect our findings would be generalisable, in terms of feasibility and acceptability, if a tool implemented this model and is likely to perform better in an Australian population than the Williams model.

Using the Williams model[11] we demonstrated that with a low risk score cut-off of 25, 20% of the population would be categorised as increased risk which would capture nearly 60% of melanomas. This could underpin a program of targeted prevention and surveillance delivered principally in primary care. The Williams model could be used to further stratify this at risk population to tailor frequency of clinical skin examination or use of novel technologies to support self-skin monitoring[21] and primary preventive behaviours.

Moloney and colleagues[22] demonstrated the effectiveness of risk stratifying the population and focusing on a high-risk population to facilitate early diagnosis. Along with the two cost effectiveness studies (Watts et al. 2017[5] and Wilson et al. 2018[6]) which demonstrated the possibility of saving costs by stratifying risk. These studies show the need for further country-specific health-economic modelling of different risk stratified melanoma screening programs.

*Implications and conclusions*

This study provides useful information for planning research into future screening and educational programs for melanoma detection in Australia. A recent cost-effectiveness study modelling a risk-stratified population screening in a UK population using the Williams model showed that such an approach would be effective and enrolling only high-risk participants would be most cost-effective[5]. In Australia, there are high rates of skin cancer screening occurring with little consideration to a person' melanoma risk. Further country specific-modelling as well as clinical implementation research is required to determine the feasibility of implementing a risk-stratified approach to targeted surveillance.

This study reported the use of a self-completed, electronic survey to identify patients in Australian general practice at increased risk of melanoma. This study shows it would be potentially feasible to implement this in an Australian general practice setting to support real-time risk stratification and better target melanoma screening and prevention.

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**Tables:**

**Table 1.** Risk factors and risk score calculation from the Williams melanoma risk model (range 0-67)[11]

| **Risk Factor** | **Point score** |
|---|---|
| | N (%) |
| Gender | |
| Male | 7 |
| Female | 0 |
| Age (Years) | |
| < 44 | 0 |
| 45-54 | 5 |
| 55-64 | 8 |
| ≥ 65 | 11 |
| Natural hair colour at the age 15 years | |
| Dark brown/black | 0 |
| Light Brown | 4 |
| Blonde | 5 |
| Red | 8 |
| Number of severe sunburns aged 2-18 years | |
| None | 0 |
| 1-4 | 1 |
| 5-9 | 4 |
| 10 or more | 7 |
| Prior non-melanoma skin cancer | |
| No | 0 |

| | |
|---|---|
| Yes | 13 |
| Number of raised moles | |
| None | 0 |
| 1 | 3 |
| 2 | 5 |
| 3 or more | 11 |
| Density of freckles on arms before age 20 years | |
| None | 0 |
| A few | 4 |
| Several | 6 |
| A lot | 10 |
| **Total score:** | **67** |

**Table 2.** Sociodemographic characteristics of participants

| Characteristic | Participants n (%) n=1,535 |
|---|---|
| Gender | |
| Male | 625 (40.7) |
| Female | 910 (59.3) |
| Age (Years) | |
| 18-34 | 677 (44.1) |
| 35-44 | 320 (20.9) |
| 45-54 | 249 (16.2) |
| 55-64 | 178 (11.6) |
| 65-74 | 75 (4.9) |
| >75 | 36 (2.3) |
| Ethnic background | |
| Australian | 182 (11.9) |
| British | 308 (20.1) |
| Western European | 242 (15.8) |
| Eastern European | 144 (9.4) |
| African | 34 (2.2) |

| | |
|---|---|
| Asian | 170 (11.1) |
| South East Asian | 52 (3.4) |
| Middle Eastern | 71 (4.6) |
| Maori | 25 (1.6) |
| ASSI/ATSI* | 13 (0.8) |
| Mixed Ethnicity | 258 (16.8) |
| Other | 36 (2.3) |
| Education | |
| Year 10 | 196 (12.8) |
| Year 11 | 141 (9.2) |
| Year 12 | 420 (27.3) |
| Trade | 216 (14.1) |
| Bachelor degree | 324 (21.1) |
| Post-graduate qualification | 238 (15.5) |
| Employment status | |
| Retired | 132 (8.6) |
| Unemployed, seeking | 49 (3.2) |
| Unemployed, unable | 20 (1.3) |
| Student | 76 (5.0) |
| Working part-time | 180 (11.7) |
| Working full-time | 613 (39.9) |
| Home-carer/maker | 409 (26.6) |
| Permanently sick/disabled | 56 (3.7) |
| Living alone | |
| No | 1386 (90.3) |
| Yes | 149 (9.7) |
| SEIFA status (VIC tertiles)** | |
| Lowest SES (0-40%) | 325 (21.2) |
| Mid-range SES (41-80%) | 745 (48.5) |
| Higher SES (81-100%) | 465 (30.3) |
| Past history melanoma | |
| No | 1493 (97.3) |

| | |
|---|---|
| Yes | 42 (2.7) |

*ASSI/ATSI: Australian South Sea Islanders/ Aboriginal and Torres Strait Islander

** SEIFA: Socio-Economic Indexes for Areas, Victorian tertiles

**Table 3.** Risk factor profile of participants, comparing Australian and UK data[12]

| **Risk Factor** | **Australian Data** N (%) | **UK Data** N (%) |
|---|---|---|
| Gender | | |
| Male | 625 (40.7) | 2691 (35.6) |
| Female | 910 (59.3) | 4875 (64.4) |
| Age (Years) | | |
| < 44 | 997 (65.0) | 3026 (40.0) |
| 45-54 | 249 (16.2) | 1260 (16.7) |
| 55-64 | 178 (11.6) | 1200 (15.9) |
| ≥ 65 | 111 (7.2) | 2080 (27.5) |
| Natural hair colour at the age 15 years | | |
| Dark brown/black | 854 (55.6) | 2908 (38.4) |
| Light Brown | 460 (30.0) | 3038 (40.2) |
| Blonde | 178 (11.6) | 1254 (16.6) |
| Red | 43 (2.8) | 366 (4.8) |
| Number of severe sunburns aged 2-18 years | | |
| None | 543 (35.4) | 3701 (48.9) |
| 1-4 | 702 (45.9) | 3196 (42.2) |
| 5-9 | 156 (10.1) | 412 (5.4) |
| 10 or more | 132 (8.6) | 257 (3.4) |
| Prior non-melanoma skin cancer | | |
| No | 1448 (94.3) | 7383 (97.6) |
| Yes | 87 (5.7) | 183 (2.4) |
| Number of raised moles | | |
| None | 951 (61.9) | 4972 (65.7) |
| 1 | 231 (15.1) | 1060 (14.0) |
| 2 | 137 (8.9) | 637 (8.4) |
| 3 or more | 216 (14.1) | 897 (11.9) |
| Density of freckles on arms before age 20 years | | |

| | | |
|---|---|---|
| None | 561 (36.6) | 3091 (40.9) |
| A few | 593 (38.6) | 2582 (34.1) |
| Several | 195 (12.7) | 938 (12.4) |
| A lot | 186 (12.1) | 955 (12.6) |
| **Mean score (±SD)** | **15.2 (9.8)** | **17.1 (8.5)** |

**Table 4.** The population above various risk score cut offs of the Williams model melanoma risk score[11] along with estimated positive predictive values (PPVs) and negative predictive values (NPVs)

| Region | Risk score cut-off | Sample above cut-off (%) | Practice/ General Population above cut-off* | Sensitivity (%) | Specificity (%) | 5-Year PPV (%) ** | 5-Year NPV (%) *** |
|---|---|---|---|---|---|---|---|
| Australia | 25 | 16.9 | 19.8 | 61 | 80 | 7.9 | 99.9 |
| | 28 | 11.4 | 13.5 | 50 | 85 | 8.5 | 99.9 |
| | 30 | 8.0 | 9.8 | 42 | 90 | 10.8 | 99.9 |
| | 34 | 4.2 | 5.3 | 29 | 95 | 14.8 | 99.9 |
| UK | 25 | 17.9 | 19.4 | 61 | 80 | 4.0 | 99.9 |
| | 28 | 11.0 | 11.8 | 50 | 85 | 4.3 | 99.9 |
| | 30 | 8.0 | 8.6 | 42 | 90 | 5.5 | 99.9 |
| | 34 | 3.3 | 3.9 | 29 | 95 | 7.5 | 99.9 |

* For Australian data, weighted for the Australian population age and sex and for the UK data weighted for the practice registered population

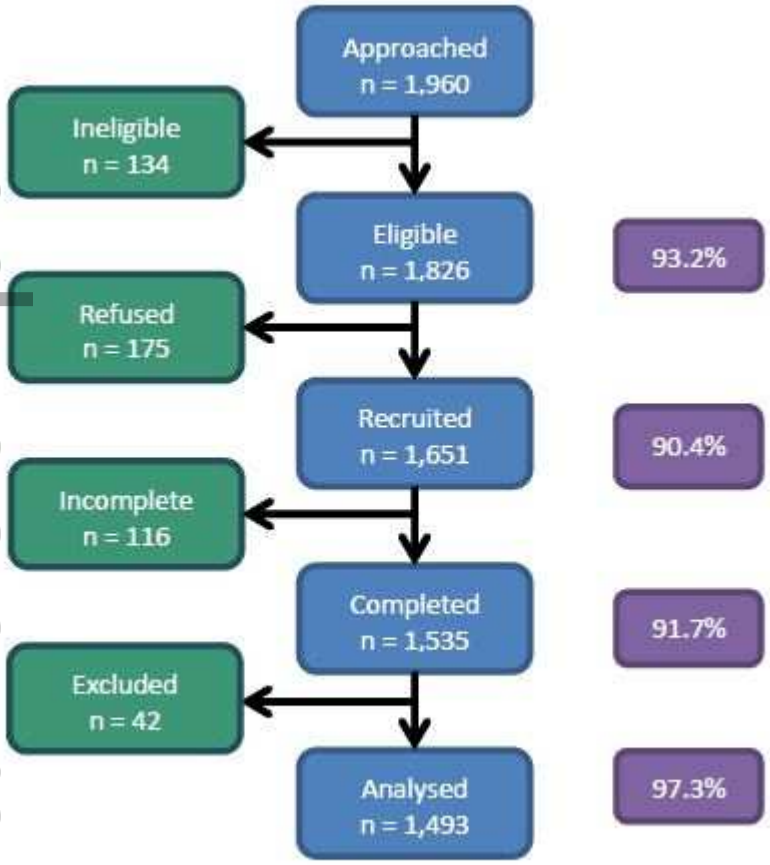
** Estimated 5-year PPV the estimated proportion of the population considered higher risk who would be diagnosed with melanoma in the next 5 years, assuming the same performance of the Williams model as reported in Williams et al 2011[11] and a prevalence of newly diagnosed cases of 259 per 100,000 for Australia (the 2016 age–standardised incidence rate for melanoma in Australia from data from the AIHW Australian Cancer Database 2016 multiplied by 5), 130.5 per 100,000 for UK (the 2016 age–standardised incidence rate for melanoma from the Office for National Statistics UK 2017 multiplied by 5).

*** Estimated 5-year PPV the estimated proportion of the population considered higher risk who would be diagnosed with melanoma in the next 5 years, assuming the same performance of the Williams model as reported in Williams et al 2011[11] and the same prevalence as the PPV above for both Australia and the UK.

**Figures legends:**

**Figure 1.** Recruitment flow chart

**Figure 2.** Distribution of risk scores for the Australian population and the UK population from Usher-Smith et al.[12]. Vertical lines represent the four different risk score cut-offs (25, 28, 30 and 34) of the Williams model[11] with the percentage of the population above the cut-off.

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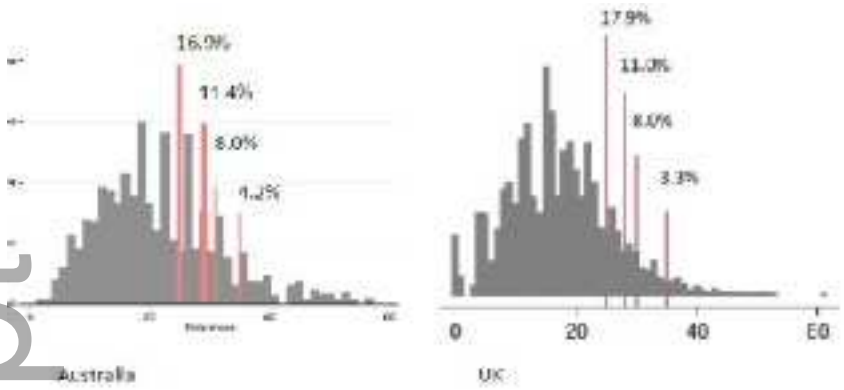


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