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Original Research Article

Consumer involvement in cancer clinical trials: an Australian experience

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ABSTRACT

Background: Healthcare consumer involvement in clinical research is considered best practice, however its relationship to trial success is ambiguous. There is limited Australian evidence. This study seeks to examine whether consumer involvement is associated with trial success in the Australian Cancer Clinical Research Network (CRN) landscape, with a skin cancer focus.
Methods: Drawing on the theories of evidence-based medicine and implementation research, published data was studied to characterize cancer research consumer involvement, in particular skin cancer. Mature data from skin cancer trials with the same Australian sponsor was studied to identify, define and evaluate specific consumer initiatives for an association with trials that completed. Trial success was measured by sufficient recruitment that was adequate to answer the research question. Data were extracted and tabulated (grouped, deidentified). Using descriptive statistics, a multi-disciplinary expert team synthesized and interpreted the data.
Results: All Australian cancer CRNs demonstrated integrated consumer involvement in their organizational governance and trial operations. During 2008-2020, 56 studies were screened; six studies met the criteria. Four consumer initiatives were described (consumer expertise, trial promotion, trial access, patient safety; with examples). The only metric associated with success was the degree of trial access. Only 2/6 selected studies achieved target accrual. There are several study limitations.
Conclusions: Australian CRNs demonstrated integrated consumer involvement that meets the best-practice policies and standards. Trial accrual is challenging including in Australian skin cancer research. Specific consumer initiatives have been identified and described to support trial sponsor governance and trials operations. Future research is warranted.

Keywords: Evidence-based medicine, Implementation research, Oncology, Consumer advocacy, Australia

INTRODUCTION

Healthcare consumer involvement in clinical research is considered best practice, however its relationship to trial success is ambiguous as its assessment is complex.[1-10] Healthcare consumers can be defined of as being patients and potential patients, family members, carers and people who use health care services.[1]

Trial sponsors can and do apply and embed consumer involvement in various ways.[11-15] It is not a single activity and takes many different forms and operates at many different timepoints, levels, strategic and operational functions within trial sponsor organisations. Ensuring trials successfully recruit is essential to advancing patient outcomes. Trials can be defined as successful if they

accrue adequate patients to answer the research question during the projected funding period.

Australia reports the highest incidence of skin cancers worldwide.[16,17] In Australia, two in every three trials is an investigator-initiated trial (IIT) conducted by academic trial sponsors who identify as Clinical Research Networks (CRNs).[18] Various initiatives attract clinical research to Australia, including the tax incentives (reducing costs), swift ethics and regulatory processes (saving time), excellent healthcare (public/private) systems, high-quality infrastructure (providing research integrity and data quality), access to world-class experts and institutions, and an albeit small but uniform, compliant population and language (allowing high health literacy, and protocol compliance).[19-21] The current Australian policies mandate that trial sponsors demonstrate a high degree of consumer engagement, however, there is limited Australian evidence.[22]

A recent systematic review found few studies examining factors influencing academic trial sponsor performance, the studies were mainly generated from sponsors in North America, highlighting a critical evidence gap of knowledge from other regions of the world.[23] The review identified seven common factors influencing sponsor performance, including the role of patients. However, there was no data on the impact of consumers on efficient recruitment and trial success. Further research is justified. The purpose of this study was to identify, define and evaluate strategies used to maximise patient recruitment in the Australian academic trial sponsor setting. There were two primary study aims, including: evaluate and describe the consumer involvement across the Australian cancer CRN landscape, with a focus on skin cancer; and then, identify and characterise completed skin cancer trials that accrued an adequate number of patients to answer each research question within the protocol timeframe. From this, identify, define and evaluate consumer initiatives and their association to trials that can achieve adequate accrual.

METHODS

Applying the theory of evidence-based medicine on the importance placed on completed randomised controlled trials (RCTs) to produce sufficient evidence to improve practice and implementation research using the consolidated framework of implementation research in the clinical trial context websites, published literature and working documents from research funding organisations and the Australian cancer CRNs, was studied and coded to identify, define and evaluate the structural ways academic trial sponsors interact with consumers to improve research quality.[24-41] Using descriptive statistics, an experienced, multidisciplinary team studied the data to address two main research aims, specifically: evaluate and describe the consumer involvement across the Australian cancer CRN landscape, with a focus on skin cancer research; and data from the Australian cancer CRNs websites and company documents[27-41], was studied and consumer involvement relating to the organisational governance and operations, membership services and trial activities were identified. The data were extracted, evaluated, analysed and presented in summary format (Table 1).

From this, information on the Australian skin cancer CRN was obtained, evaluated and analysed to identify consumer initiatives, including: consumer-specific representation within the network and its trials; demonstrated resource commitment to involve consumers; demonstrated commitment to involve consumers by the board of directors; and demonstrated consumer review mechanisms that are applied across the trial lifecycle (ie. idea generation, study design and development, study implementation and conduct, final analysis and dissemination of results).[36,41-43]

Thematic analysis was used to study and code the data to identify and describe themes relevant to the network's activities.

Then, identify and characterise completed skin cancer trials that accrued an adequate number of patients to answer each research question within the protocol timeframe. From this, identify, define and evaluate consumer initiatives and their association to trials that can achieve adequate accrual.

Published data was studied to identify and characterise completed trials sponsored by the Australian skin cancer CRN.[36,41-43] Only trials that were recorded as having completed prior to the COVID-19 pandemic were selected and evaluated.[44] Trials were defined as completed as those trials that completed their funding term in early 2020. A fully accrued trial was considered to be any study that achieved 95-100% of the target accrual.

We included trials that met the following criteria: sponsored by the Australian skin cancer CRN; from the time of establishment (January 2008) to trials that completed their funding term by early 2020 (January 2020); the protocol's patient population including patients with early to late-stage skin cancers; and studies that were defined as clinical trials: phases I to IV.

The selected data was deidentified and coded (Figure 1).

The data for the completed skin cancer trials with the same trial sponsor was then analysed and tabulated under the following descriptors: phase of trial (classified as: I, II, III, IV, other (specify)); study design (classified as: single arm, randomised controlled trial, other (specify)); type of early to late-stage skin oncology clinical research (classified as: benign, pre-cancerous, malignant); stakeholder engagement in study design (classified as: consumers, multi-disciplinary team (MDT); medical discipline (classified as: dermatology, surgical oncology, radiation oncology, medical oncology, other); treatment interventions (classified as: single or multi-disciplinary specialities); does the trial have access to a cancer MDT

team to identify patients; and did the study meet the study targets? (classified as: <25%, <50%, <75%, 95-100% overall patient recruitment).[45]

A summary of the characteristics (deidentified and coded) of the completed skin cancer trials is presented (Table 2).

The coded data was then studied to identify, define and evaluate specific consumer initiatives (each with measurable metrics) for each of the completed skin cancer trials, and tabulated under the following descriptors.

The consumer expertise for each study was identified and evaluated; the metrics that were identified and evaluated included the involvement of the network's consumer representative(s) in the study (classified as: involved, not involved); whether the consumers had relevant lived experience related to the research question (classified as: relevant experience versus not relevant experience); and duration of consumer engagement across the trial lifecycle (classified as: idea generation, study design and development, study implementation and conduct, final analysis and dissemination of results).[5]

The trial promotion strategies for each study were evaluated to assess whether details of the study were available to the general public (including potential patients, as well as consumers), the metrics that were identified and evaluated included: development and hosting of a dedicated webpage with study-specific information; relevant listing of each study online.[12] The Australian and New Zealand Clinical Trial Registry and Clintrials.gov websites feed into the The Australian Cancer Trials website.[42,43,46] The ClinTrials Refer app is a mobile app and website platform that provides searchable access to current trials available in Australia.[47]

Evaluation of the study-specific research output via a literature search strategy using websites and a medical literature database (by applying title/abstract, key words (author, study name) for each study) to identify: development of consumer education videos for each study; and each study's research output was evaluated regarding consumer engagement and the number of items naming a consumer representative as a co-author contributor / total research output were calculated.[27-41]

From this, the final analysis publication for each of the selected trials was then identified and studied to identify: whether the author string named a consumer as a co-author (in line with the authorship guideline recommendations), and whether any consumer representative (individual or group) contribution was described in the publication, including in the 'Acknowledgement' section.[48]

The trial access for each study was evaluated to assess whether patients have access to participating sites), the metrics that were identified and evaluated included: site selection strategy that was applied (classified as: single site versus multi-site); site number (classified as: <5 sites, 6 to 20 sites, 21+ sites); site distribution (classified as: whether the sites were in metropolitan and or regional areas in Australia and or recruiting internationally); site expertise level (classified as: whether sites were considered academic centres of excellence, and or included community hospitals); and evidence of protocol amendments to adjust the protocol eligibility inclusion and exclusion criteria.

The patient safety reporting mechanisms for each study was evaluated to assess the involvement of consumers in the independent reporting mechanisms employed via the (protocol-specific) Human Research Ethics Committees (HREC; equivalent to the Institution Review Board) who approved and monitored each study, metrics that were identified and evaluated included: evaluation of the relevant study-specific HREC with consideration to each committee's formation, membership and/or consumer representation.

A summary of the consumer involvement initiatives and measurable metrics for the completed skin cancer trials is presented (Table 3).

This team includes experienced cancer doctors and trialists who are active contributors to cancer research and engaged in various cancer research activities worldwide. Using a consensus from these subject matter experts, we decided to focus only on trials that: completed prior to the COVID-19 pandemic to reduce the interference; classified as completed (defined as any trial that achieved 95-100% of the target accrual); and only include trials which identified the Australian skin cancer CRN as the trial sponsor.[44] From this, the subject matter experts on this team, studied and coded the data to identify, discuss and distil the data into consumer initiatives with measurable metrics.

RESULTS

Data from the Australian CRNs websites was studied and consumer involvement functions related to the governance of the network operations, membership services and clinical trial activities was identified.

All 14 Australian cancer CRNs have created and support dedicated consumer representation in their overall organisational governance structure. These roles are responsible for providing independent consumer-specific input into the activities of each network. 11/14 of the groups are incorporated business entities and have dedicated consumer representatives who hold directorship roles, the remaining three are unincorporated groups and offer dedicated consumer representation via their management committees. The general activities of the dedicated consumer groups include (but are not limited to): consumer oversight of trial idea development, protocol development, trial activity and dissemination of research results. Additionally, all Australian CRNs have consumers who are appointed to various roles across the network, for example: there are consumer appointments to office bearer roles, scientific committees, trial management committees, trial steering committees and management boards. The governance activities of the skin cancer CRN conform

with the best practice standards maintained by all Australian cancer CRNs (Table 1).

The consumer representation, frequency and mechanisms relating to consumer involvement of the skin cancer CRN were then studied. Three consumer-specific themes which supported high-quality consumer interaction were identified, defined and described including the following.

Dedicated consumer representation at an operations level

Appointment of a board director who self-identifies as being a consumer; appointment of dedicated consumer representatives to consumer advocacy groups within the network; and the company documents provide a statement of commitment to ensure appropriate consumer engagement.

Dedicated consumer representation at a trials level

Appointment of consumer experts on individual study teams; and appropriate consumer review mechanisms are in place to support the network's members and the trials that they develop, three separate initiatives were identified including: independent consumer review processes throughout trial lifecycle, consumer contributions to protocol and study document development; and inclusion of consumers (and processes) in the main competitive grant schemes in Australia.[49-51]

Overall resource commitment to support consumer engagement

Creation of dedicated consumer roles, and associated resourcing, to involve consumers in the network operations including its trials; evidence of the development of consumer activities and resources; and evidence of collaboration with external consumer advocacy representatives (individual and/or groups).

Then, identify and characterise completed skin cancer trials that accrued an adequate number of patients to answer each research question within the protocol timeframe. From this, identify, define and evaluate consumer initiatives and their association to trials that can achieve adequate accrual.

During 2008-2020, 56 skin cancer studies were screened; 50 trials did not complete as they were actively recruiting or in development. Only six studies met the criteria as having completed their funding term by early 2020. Of these six studies, two studies completed and accrued sufficient patients (95-100% target accrual) and four studies completed however did not accrue sufficient patients (≤50% target accrual).

Of the two studies that achieved 95-100% target accrual, one of these was a feasibility study, this means that only 1/6 selected studies generated sufficient evidence to change practice and informed the treatment guidelines worldwide (Figure 1).

The six selected trials were designed for patients diagnosed with early to late stage skin cancer, were developed by both MDTs and consumer stakeholders, and lead by experts in dermatology, surgical oncology and radiation oncology. All six studies had access to cancer MDT meetings which were used to identify potential patients. Five studies were two-arm, phase III, randomised controlled trials (RCTs); the remaining study was a single-arm phase 1b/II study. Three studies allocated treatments within the same speciality (i.e. patients would be treated by the same specialist no matter the randomisation), the remaining three studies involved multi-disciplinary speciality (i.e. patients would be allocated to difference specialities depending on randomisation). A comparison table of the characteristics of the selected completed skin cancer studies is presented in Table 2.

By studying the data, four consumer-themed initiatives were identified, defined and evaluated. These initiatives include: consumer expertise, trial promotion; trial access and patient safety. Measurable metrics were defined for each initiative and the results for the selected studies are summarised in Table 3.

The four consumer involvement initiatives are described as follows.

Consumer expertise

The consumer expertise for each study was evaluated: 6/6 studies involved consumer representatives; 5/6 studies involved consumers who had relevant lived experience related to the research question; and 6/6 studies demonstrated the duration of consumer engagement across the trial lifecycle including idea generation, study design and development, study implementation and conduct.[5] There was no evidence for consumer involvement in the final analysis and dissemination of results for any study.

Trial promotion

The trial promotion for each study was evaluated to assess whether the study and details of the study were available to the general public including potential patients and consumers, the metrics that were identified and evaluated included: 6/6 studies were described on a dedicated website with study-specific information; 6/6 studies were listed on public registries (e.g. ANZCTR, USA clintrials registry, Australian Cancer Trials registry website and the ClinTrials Refer app); and evaluation of the research output for each study identified - 3/6 studies produced a study-specific consumer education video to explain each study in lay language, no study named a consumer as a co-author in any research output for any study, including the final publication of the study results, and only 1/6 of the final publications acknowledged patients and consumers for their participation and contribution.

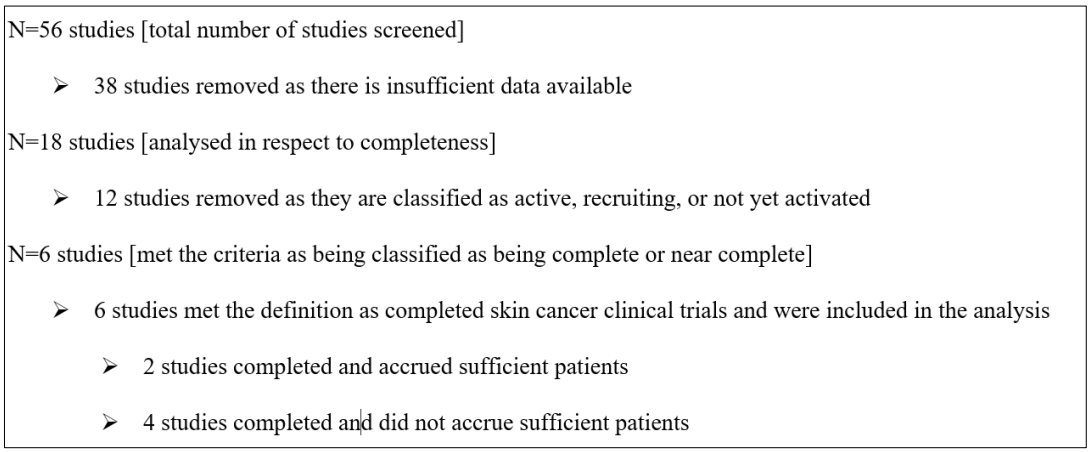

Figure 1: Study schema - identification of the completed skin cancer trials.

Table 1: Australian cancer CRNs organisational arrangements involving consumers.

Australian cancer clinical research networks [acronym]	Governance: is there a dedicated consumer role?
Australasian Gastro-Intestinal Trials Group [AGITG]	Yes, Director appointment
Australasian Leukaemia and Lymphoma Group [ALLG]	Yes, Director appointment
Australia and New Zealand Sarcoma Association, formerly called the Australasian Sarcoma Study Group and the Australian Sarcoma Group [ANZSA]	Yes, Director appointment
Australian and New Zealand Children's Haematology and Oncology Group [ANZCHOG]	Yes, Director appointment
Australian and New Zealand Urogenital and Prostate Cancer Trials Group [ANZUP]	Yes, Director appointment
Australia New Zealand Gynaecological Oncology Group [ANZGOG]	Yes, Director appointment
Breast Cancer Trials, formerly called the Australian and New Zealand Breast Cancer Trials Group [BCT]	Yes, Director appointment
Cancer symptom trials [CST]	Yes, via the management committee ^
Cooperative Trials Group for Neuro-Oncology [COGNO]	Yes, via the management committee ^
Primary Care Collaborative Cancer Clinical Trials Group [PC4]	Yes, Director appointment
Psycho-oncology Cooperative Research Group [PoCOG]	Yes, via the management committee ^
Thoracic Oncology Group Australasia, formerly called the Australasian Lung Cancer Trials Group [TOGA]	Yes, Director appointment
Trans-Tasman Radiation Oncology Group [TROG]	Yes, Director appointment
Melanoma and Skin Cancer Trials, formerly called the Australian and New Zealand Melanoma Trials Group [MASC Trials]	Yes, Director appointment

^ These networks are unincorporated legal entities and support a volunteer membership-based research network in collaboration with a university. These networks provide dedicated consumer representation roles via their management committee structures.

Trial access

The trial access for each study was evaluated to assess whether patients have access to participating sites), the metrics that were identified and evaluated included: 6/6 studies were available at multiple participating sites; the two studies that achieved 95-100% patient recruitment engaged 21+ participating sites for each study, the remaining studies that achieved 50% or less engaged less sites overall; three sites engaged 10 to 20 sites per study, and one study had ≤5 sites; 5/6 studies (including both studies that achieved 95-100% patient recruitment) were open and recruiting at participating sites across Australia (in the metropolitan and regional centres) and internationally; the one phase Ib/II study was open and recruiting at participating sites across Australia (in the metropolitan and regional centres) but not internationally; 6/6 studies were open and recruiting at sites considered academic centres of excellence as well as community hospitals; and 6/6 studies adjusted protocol eligibility criteria.

Patient safety

The patient safety reporting mechanisms for each study were evaluated and the findings include: the six HREC-

relevant to each of the completed skin cancer studies demonstrated that each ethics committee has embedded consumer roles (also identified as 'lay' people) into their trial specific committee formation and membership. These arrangements complied with the local policies and the highest quality medical research standards promoted by the regulators and in line with ICH-GCP recommendations.[1-4]

A summary of the consumer involvement initiatives and measurable metrics for the completed skin cancer trials is presented (Table 3).

Table 2: Characteristics of the selected completed skin cancer trials with the same sponsor.

Deidentified protocol	Protocol A	Protocol B	Protocol C	Protocol D	Protocol E	Protocol F
Phase of trial *	III	III	III	III	Ib/II	III
Study design +	RCT	RCT	RCT	RCT	Single	RCT
Type of skin oncology clinical research #	Malig	Malig	Malig	Pre-Can	Malig	Malig
Engagement of stakeholders ^	Cons, MDT	Cons, MDT	Cons, MDT	Cons, MDT	Cons, MDT	Cons, MDT
Category of medical discipline of the trial†	Rad Onc	Surg	Rad Onc	Derm	Rad Onc	Surg
Treatment interventions ¤	Multi	Single	Multi	Multi	Single	Single
Was there access to a cancer MDT meeting to screen patients?	Yes	Yes	Yes	Yes	Yes	Yes
Did the study meet the study targets? (% accrual target achieved)	Yes (95-100%)	Yes (95-100%)	No (50%)	No (<50%)	No (<50%)	No (<25%)

Continued.

Classified as: Ben: benign, Pre-can: pre-cancerous, Malig: malignant; ^ classified as: Cons: consumers, MDT: MDT team; † classified as: Derm: dermatology, Surg: surgical oncology, Rad Onc: radiation oncology, Med Onc: medical oncology, other, specify; * classified as: phase: I, II, III, IV, other, specify; + classified as: single: single arm, RCT: randomised controlled trial, other, specify; ¤ classified as: single: single speciality, multi: multi-disciplinary specialities

Table 3: Key consumer initiatives (with metrics).

Anonymised protocol	Protocol A	Protocol B	Protocol C	Protocol D	Protocol E	Protocol F
Did the study meet its recruitment goals?	Yes (95-100%)	Yes (95-100%)	No (50%)	No (<50%)	No (<50%)	No (<25%)
Evaluation of the consumer expertise						
Describe the consumer involvement[ß]	Inv	Inv	Inv	Inv	Inv	Inv
Whether the consumers had relevant lived experience of the disease under study[«]	Lived exp	Lived exp	Lived exp	Not lived exp	Lived exp	Lived exp
Duration of consumer engagement across the trial lifecycle[§]	Idea, design, conduct	Idea, design, conduct	Idea, design, conduct	Idea, design, conduct	Idea, design, conduct	Idea, design, conduct
Evaluation of the trial promotion						
Was there a dedicated webpage with study-specific information?	Yes	Yes	Yes	Yes	Yes	Yes
Was the study listed on Australian Cancer Trials portal?	Yes	Yes	Yes	Yes	Yes	Yes
Was this study listed on a clinical trial registry?	Yes (ANZ, USA)	Yes (ANZ, USA)	Yes (ANZ, USA)	Yes (ANZ, USA)	Yes (ANZ, USA)	Yes (ANZ, USA)
Was this study listed on the ClinTrialsRefer app[#]?	Yes	Yes	Yes	Yes	Yes	Yes
Evaluation of the research output						
Were other consumer education resources developed?	Yes, video	No	No	Yes, video	No	Yes, video

Continued.

Anonymised protocol	Protocol A	Protocol B	Protocol C	Protocol D	Protocol E	Protocol F
Was a consumer co-author/research output	1/103	0/29	0/45	0/33	0/12	0/17
Details of the final analysis and study report manuscript published						
Named consumer co-authors?	No	No	No	No	No	No
Acknowledgement of patients and or consumers^	Ackn	Not ackn	Not avail	Not avail	Not ackn	Not avail
Evaluation of the trial access						
Site selection strategy*	Multi	Multi	Multi	Multi	Multi	Multi
Number of sites@	21+	21+	6-20	6-20	≤5	6-20
Site distribution +	Metro, rural, global	Metro, rural, global	Metro, rural, global	Metro, rural, global	Metro	Metro, rural, global
Site expertise level >	Centres, Hosps	Centres, Hosps	Centres, Hosps	Centres, Hosps	Centres, Hosps	Centres, Hosps
Evidence of protocol amendments	Yes	Yes	Yes	Yes	Yes	Yes
Evaluation of the patient safety reporting mechanisms						
Did the relevant HREC committee include consumer representatives	Yes	Yes	Yes	Yes	Yes	Yes

 Classified as: Inv=involved, not inv=not involved; « classified as: lived exp: relevant lived experience of the disease, not lived exp: no lived experience of the disease; § classified as: idea=idea generation, design=study design and development, conduct=study implementation and conduct, results=final analysis and dissemination of results; ‡ classified as: ANZ=ANZCTR; USA=CT.gov; oth=other, specify; # please note: the Clin Trials Refer app was only available from 2017; ^ classified as: ackn=yes, consumer participation and contribution was acknowledged in the study, not ackn=no acknowledgment; not avail=not available; * classified as: single=single site; multi=multi-site; @ classified as: ≤5 sites; 6 to 20 sites; 21+ sites; + classified as: metro=AU: metropolitan; rural=AU: regional; global=international; > classified as: centres=academic centres of excellence; hosps=community hospitals

DISCUSSION

What this paper adds

All 14 Australian cancer CRNs demonstrate high-quality consumer involvement, including across their organisations' governance and trial operations. This study identified and described three consumer-specific organisational initiatives (dedicated consumer representation at an operations level and at a trials level, as well as overall resource commitment) to optimise the governance arrangements and consumer mechanisms to support high-quality consumer interactions and experiences. This study identified and described four consumer initiatives (consumer expertise, trial promotion; trial access and patient safety; each with measurable metrics) that academic trial sponsors can consider when planning and supporting day-to-day trial conduct.

What is already known on this subject

The theory of evidence-based medicine recognised the importance of consumers to high-quality science; consumers are valued and essential to high-quality clinical research worldwide.[24,25]

Many research organisations and policy makers worldwide now recognise and mandate consumer involvement as part of organisation and trial-specific operations.[1-4]

Many research grant funding opportunities now recognise and mandate specific consumer involvement as an eligibility criterion to apply for research funds.[49-51]

We believe this is the first-time an analysis has been undertaken to describe the consumer landscape across Australian cancer CRNs, to identify, define and evaluate consumer initiatives and define measurable metrics that trial sponsors can apply to engage consumers. The results of this study show that the Australian cancer CRNs, including in skin cancer, have embraced consumer initiatives at both a governance and trial level; this reflects current policy and how it is valued.

The results of this study have identified, defined and evaluated three consumer-specific initiatives with discrete metrics that support high-quality consumer interaction (dedicated consumer representation at an operations level and at a trials level; as well as overall resource commitment). Fledging membership-based networks can now consider these themes when developing and establishing their own consumer engagement mechanisms. The study also identified and described four key consumer initiatives (consumer expertise, trial promotion, trial access, patient safety; with examples) that sponsors can consider when planning and supporting recruiting trials to optimise when and how consumers can be involved to support the day-to-day trial operations.

Financial modelling has suggested consumer involvement to be a good investment saving the sponsor's time and

money, as well as enabling the swifter generation of results.[52] Early consumer engagement in the protocol development activities and throughout the trial lifecycle may optimise trial activity, however, resourcing varies, findings vary and the evidence for its application remains unclear.[53-55] There is Australian evidence but it is limited. Clinical research resources (including frameworks, website and tools) have been recently launched promoting consumer initiatives in the Australian context.[22,56,57] The findings of an Australian report found that whilst consumer involvement is valued, it is not yet standard practice and there is broad variation in its measurement and impact.[10] Fogarty et al called for more effective consumer involvement to improve Australian skin cancer outcomes.[58] More resources and research in this area could raise standards.[9,10,15]

The results of this study indicate that consumer involvement is multifaceted; consumer involvement alone did not ensure that sufficient patients were able to be recruited. By comparing the results for the two completed studies that recruited 95-100% of their target accrual, and the remaining four completed studies that recruited ≤50%, the only metric that was associated with study success is related to the degree of trial access (i.e. the number of sites) (Table 4). For both studies (protocols A and B) that achieved 95-100% patient recruitment, there were 21+ sites participating in each study world-wide. Whilst all six studies were open at multiple participating sites; protocols A and B engaged 21+ sites worldwide. These protocols established larger study-specific communities and in doing so, the participating clinicians and sites may have shared a strong overall sense of purpose and perhaps the level of interest to engage may have reflected the overall importance of the research question of each protocol; maybe these things contributed to trial culture? Protocols A and B had similar results across every initiative and its associated metrics accept in regard to trial promotion. Protocol A developed a consumer education video and the final publication acknowledged patients and consumers.

Different trial sponsors may engage consumers in different activities at different times. Given the academic nature of the selected studies, consumer involvement earlier in the trial lifecycle may be more relevant to academic sponsors as it is closely linked to funding opportunities and is commonly mandated by funding agencies.[49-51] In our study, all six studies demonstrated consumer engagement earlier in the trial lifecycle (i.e. idea generation, study design and development, study implementation and conduct phases) however, there was no evidence for consumer involvement in the dissemination of results and translating findings into practice. This situation may be different for commercial sponsors, when the involvement of consumers is closely linked to their post-approval marketing and commercialisation strategy? Previous studies that have analysed commercial sponsor activities relating to consumers are few but some describe that need to more clearly demonstrate the return on investment for patient-centric activities as there is scepticism of the value proposition of consumer involvement in research (i.e. earlier in the trial lifecycle), as well as the need for more research to better evaluate newly developed tools to optimise consumer involvement.[6,8,13] In contrast to previous research, the results of this study did not support that early consumer engagement optimised study success.[54] Regardless, successfully demonstrating consumer involvement is likely to have been critical to each of the eligible studies being successful in initially securing adequate competitive-grant funding given the academic sponsorship of these studies.

Many academic trial sponsors including the Australian cancer CRNs operate in modestly funded environments. Consumer representatives participate voluntarily and adequately maintaining any relationships can be resource intense. The research community has an obligation to intentionally build research teams who can succeed whilst ensuring consumer resources are used wisely. We caution trial sponsors to exercise caution to ensure adequate resourcing, recognition and compensation to sustain consumer initiatives properly and to avoid tokenism.[59] We advocate for the appropriate recognition of consumers and for the provision of adequate resourcing to support trial sponsors to ensure appropriate consumer involvement. Inadequate or ineffective deployment of modest resourcing may damage relationships with consumers, compromising research results and delaying (or preventing) opportunities to improve patient outcomes. Despite the recent development of budgeting tools now being made available, the uptake of these tools is unknown, and the competitive nature of grant funding remains.[60] These are challenges that academic trial sponsors continue to manage, and the results of this study reinforce the need for more research in this area.

Limitations

The complexity of evaluating consumer involvement has already been extensively reported, and is reflected in these results. Staley et al suggested that data saturation on these themes may have already been reached, however given the bulk of the current literature stems from researchers in the USA and UK, the authors of this study were mindful of this opportunity to shed light on consumer involvement in the Australian context.[6]

The intention of this study was as a descriptive analysis using already completed clinical trial data to evaluate what worked and what did not, drawing on the Theory of Implementation Research in the clinical trial context, coupled with thematic analysis.[26] However, the results of this study demonstrated that the methods used and definitions did not differentiate outcomes. This indicates that there is nuance in measurement and evaluation that this study has been missed. It is also possible that our definition of study success was not correct in this context.

In addition, as a descriptive analysis (drawing on a small number of completed studies), this study carries a risk of bias. The thematic analysis undertaken by the subject matter experts on this team to develop metrics and results

of the study may not represent the true situation. Consequently, the conclusions may be potentially biased and despite our best efforts, the findings may have potentially little value for translation in other settings.

We acknowledge that the project team engaged with consumers on aspects of this study, but that this study did not fully address or include consumer perspectives on their own experiences in this setting. This study intentionally involved a sponsor-perspective to consider the role and responsibility of CRNs as trial sponsors conducting research and how they engage with and facilitate consumers – rather than specific consultation with only consumers and their experiences. We acknowledge this design, reinforces Staniszewska et al suggestion that quantitative measurement of consumer involvement fails to capture the qualitative experience of consumer involvement.[7] Nor did this study address any of the clinical trial reforms (improving the way in which clinical trials can be conducted) established since the COVID-19 pandemic.[44] Future study on these themes may enrich the literature and may be a potential area for future research.

CONCLUSION

The Australian cancer CRNs have demonstrated integrated consumer involvement that meets the best-practice policies and standards. This study has identified, defined and evaluated specific consumer-specific initiatives that academic trial sponsors can consider when planning when and how to engage consumers. The three organisational initiatives include: dedicated consumer representation at an operations level and at a trials level, as well as overall resource commitment. The four key consumer initiatives for trial activities include: consumer expertise, trial promotion, trial access and patient safety; each with specific and measurable metrics). Whilst it was expected that consumer involvement would have accelerated the study outcomes improving the research efficiency overall, consumer involvement evaluated by the methods we used was not associated with trial success; the one exception being the number of sites in each study (defined as trial access).

These findings can be used by academic trial sponsors and research networks to strengthen consumer engagement and improve trial success. The results may also be used to optimise organisational governance structures, consumer mechanisms, as well as day-to-day trial operations, thereby enhancing the quality of and experience with consumers. Further research is warranted.

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