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CANCER FORUM

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The policy of *Cancer Forum* is to provide a forum for debate and the exchange of medical, scientific, political, social and educational comment related to cancer research, treatment, prevention and control. *Cancer Forum* invites submissions of original research articles, reports and letters relating to these themes.

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Reference numbers within the text should be placed after punctuation and superscripted. The maximum number of references is 75. Only papers closely related to the subject under review should be quoted and exhaustive lists should be avoided. Only one publication can be listed for each number. Citation of more than one reference to make a point is not recommended. The Editorial Board prefers a focus on more recent references (in the last 10 years). The list of references at the end of the paper should be numbered consecutively in the order in which they are first mentioned and be consistent with the National Library of Medicine's International Committee of Medical Journal Editors' Uniform Requirements for Manuscripts Submitted to Biomedical Journals. i.e. Halpern SD, Ubel PA, Caplan AL. Solid-organ transplantation in HIV-infected patients. N Engl J Med. 2002 Jul 25;347(4):284-7.

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FORUM: Ethics in cancer

Guest editor: Ian Olver

Reports

Calendar of meetings

ETHICS AND CANCER

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There are ethical issues to consider across the whole spectrum of cancer control. This forum considers topics spanning the issue from prevention to end of life care. Some issues are generic to medicine in general because they encompass principles like the centrality of respect for each patient, which translates to the provision of sufficient information to allow autonomous decision-making, or ensuring equitable distribution of health resources and the attempted elimination of disparities in health care opportunities. Others are more specifically related to cancer, such as ethical issues around public health messaging about cancer risk, or the recognition of over-diagnosis and its consequences when recommending a cancer screening program.

Public health messaging about cancer prevention and screening

Muhlack et al discuss how alcohol consumption is a known modifiable risk factor for cancer and yet an entrenched widespread social practice.[1] It is a good example for studying whether legislation requiring mandatory public health warnings about the health risk of alcohol would be justified. Specifically, health warning labels on alcohol products are being used as the example because this has been proposed as a strategy to reduce alcohol consumption. Such warnings had an impact on tobacco control. Alcohol health warning labels have been defended on the grounds of such warnings providing information only, but the real goal is behavioural change that will result in harm reduction. However, knowledge alone may not change behaviour and society may value the principle of individuals making autonomous choices without government interference. A balance must be struck between the utilitarian nature of public health interventions and liberalism in a society in which interventions are proposed.

Carter explains that there are three established screening programs for each of, cancers of the cervix, breast and bowel in Australia.[2] Evidence of efficacy is judged on a population basis. Does routinely testing a healthy population to attempt to detect cancer earlier than when symptoms develop result in a decreased mortality from that cancer without causing harm? The difficulty is that even if a population may benefit, not every individual will benefit. In some, cancer may be detected but never cause harm, a situation referred to as over-diagnosis, which often leads to invasive further testing, treatment and emotional distress. It can be difficult to judge whether a screening program has a net benefit over harm if different studies yield opposing results. Individuals at least should be fully informed of the potential benefits and risks to them and be able to make their own judgement about whether to participate in a population screening program.

Population data linkage in indigenous health

In a multicultural society, different groups may have different perspectives on data collection to inform health messaging, screening and treatment. For example, 'big data' enables new information to be gleaned from linking large population datasets. Garvey et al highlight some of the complexities of working with and linking such data sets in the context of indigenous health.[3] Firstly, many such datasets may not identify indigenous patients, and being identified as indigenous has not previously had positive outcomes. There can be barriers to accessing state-based data to gain a national perspective in a federated structure, despite the fact that the data collection is often publicly funded, raising an ethical dilemma for data custodians. This dilemma finds expression in Indigenous communities as well, where central ethical approval of a data linkage study would facilitate the research but disempower local communities whose data are included. However, fragmentation of research effort will not be productive either. When formulating public policy in cancer, the cultural differences must be accommodated to achieve the best outcomes across the whole population.

Ethics and the use of genomics in cancer.

Margaret Otlowski examines the challenges that have arisen as we have progressed from single gene testing to whole of genome sequencing, as we move to an era of personalised medicine.[4] The commercial provision of the ability for people to have their whole genome sequenced has progressed beyond the ability to accurately interpret the data generated. Otlowski examines the issues around privacy and consent, but also discusses emerging issues such as the role of the researcher or clinician in recontacting and reporting incidental findings to patients who are being tested for particular mutations when other unanticipated, but possibly significant, mutations are found. She suggests that cancer panel testing may limit the potential problems at the current state of knowledge.

Equitable resource allocation and the challenge of high-cost drugs

The introduction of targeted therapies has resulted in high-cost drugs being approved at regular intervals, which is putting pressure on health budgets. Lipworth et al highlight the dilemma of decision–makers in having to balance the emotive issues of individual patients desperate for access to what they see as potentially life-saving new drugs, and the decision-makers' responsibilities to assess cost-effectiveness and opportunity costs across the whole health consumer population.[5] The latter need to ascertain the value of a treatment and whether the evidence-based outcomes of efficacy justify the cost. This is particularly the case because the price at which the drugs are offered is not so much based on efficacy as what the market in high-income countries will pay. To help navigate conflicting values, Lipworth et al propose the development of a framework based upon accountability for reasonableness, which could then be applied to price negotiations and funding decisions.

Cancer research and consent

In most human research, participants are provided with information so that they can make informed choices about participation. In population-based research, data may have been collected on thousands of patients in cancer registries. Most commonly the results of the analysis of the data in those registries are de-identified. The logistical difficulty of obtaining individual consent may compromise the representativeness of the sample, and therefore the result obtained. Ethics committees have allowed a waiver of consent in this situation, but a more recent option allowed in the *National statement on ethical conduct in human research* of the National Health and Medical Research Council has been opt-out consent.[6] Xafis explores how with opt out consent, information about a study is made publicly available and individuals are then given the opportunity to opt out of having their data included.[7] Although this has been characterised as only presumed consent and it is not clear how many of the population are informed by the public information. The procedure results in high participation rates, which can be important when population data is used, for example to guide cancer policy. The public good is being balanced with any compromise of individual autonomy.

Even when individual consent is obtained for participation in cancer research trials, there is no guarantee that the patient understands what is being presented. Trials measuring the quality of that understanding have confirmed that view.[8] A trial presenting the information by electronic means rather than paper failed to improve recall of the information.[9] However, a randomised study of uniform total disclosure as compared to an individual clinician's discussions, did result in better understanding, though it increased anxiety and decreased willingness to participate in randomised trials.[10] Tattersall reports on a study audiotaping clinicians' discussions with patients of randomised trials that showed great variation in what was presented to the patient.[11] The consensus was that standard treatment options should be discussed before the trial option was introduced.[12] Phase I studies, where the chance of individual patient benefit is small, are more problematic since patients may equate them with care and be more optimistic about the outcome than their treating clinicians. This optimism may be due to poor communication by the clinician, resulting in a lack of understanding by the patients.[12]

End of life issues

End of life issues in cancer have often focused on euthanasia and physician-assisted suicide, both of which are theoretical issues in Australia where these procedures are not legal. Gillam raises issues more pertinent to current Australian practice.[13] If a person is dying, then the freedom of choice should focus on comfort and relief of suffering. What if that relief is obtained from a drug that is illegal, like cannabis, where the evidence of benefit is largely from case studies? Similarly, if the only way to achieve symptom control is terminal sedation, is that a reasonable approach, or can that in any way be equated with euthanasia? Although there is a loss of the characteristics of personhood in someone who is treated this way, the evidence is that it doesn't hasten death, nor was killing the intention of this extreme form of symptom control. If this practice is allowed to control symptoms, where does that leave euthanasia?

Conclusion

A single volume cannot do more than sample the ethical issues that arise in cancer control and the topic covers a spectrum from prevention to palliative care and from individual health to population health. A sampling shows the complexity of competing values and perspectives. However, promoting awareness and discussion moves the debate towards 'reasonable' decisions and policies.

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ETHICAL JUSTIFICATIONS IN ALCOHOL-RELATED HEALTH WARNING DISCOURSES

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Abstract

Cancer is the second most common cause of alcohol-related death in both men and women in Australia. In view of this and other health risks, mandatory health warnings on alcoholic beverages have been proposed in Australia and introduced elsewhere. This paper reviews academic literature and statements from selected advocacy groups to identify the ethical justifications that are used in relation to mandatory health warnings on alcoholic beverages. The paper then analyses how these justifications relate to the ethics of public health interventions in the context of cancer prevention. This involves examining the potential tension between the utilitarian nature of public health interventions and the liberalism characteristic of many of the societies in which those interventions occur.

Public health is the systematic attempt to improve the health and well-being of a population by creating conditions in which good health may flourish. For an intervention to be justified as a public health intervention, there must be good reason to believe that it will in some way contribute to a net positive effect in regards to the health of the population of interest. In this respect, public health is often regarded as utilitarian,* since its main concern is not individual outcomes, but the net effect across a population. By contrast, the prevailing political philosophy of western democracies is liberalism, which encompasses the principle that an individual who is autonomous (that is, capable of making free decisions) ought to be allowed to do as he or she pleases, except where this causes harm to another. The tension between the goals of public health interventions, namely the good of populations, and the political context in which public health interventions often take place, with its emphasis on individual freedom, is addressed in the field of public health ethics. This tension can be observed in discourses around mandatory health warning labels on alcohol beverages, as demonstrated below.

In Australia, cancer is the second most common cause of alcohol-related death in both men (25%) and women (31%).[1] Given that alcohol consumption is a modifiable risk factor for cancer and other health issues, government intervention may be justified. One possible intervention is to mandate health warning labels on alcoholic beverages. This intervention has been proposed in Australia and introduced elsewhere.[2,3] For this reason, it is important to understand the grounds on which the intervention may be justified, together with how it is viewed by stakeholders, including alcohol producers. This understanding can be advanced by answering the following questions: What justificatory language is used in academic and policy circles regarding health warning labels on alcoholic beverages? Are the justifications given appropriate to the public health context? What implications do these justifications have for proposals to mandate labels on alcoholic beverages specific to cancer risks? This paper answers these questions, principally by reviewing the justifications used in the academic literature and in some advocacy statements made by public health and industry stakeholders.

Criteria for search

We searched the Scopus database with a search string designed to identify academic literature on warning or communicating risk by means of labels on alcoholic beverages:

TITLE-ABS-KEY (alcohol AND ((warning OR (risk w/2 communicat*)) AND label*)

The initial return of 172 documents was culled for relevance by title and abstract where possible, giving a remainder of 93 documents. At this stage, two criteria were used to determine relevance: (1) was the document a publication, in English, in a peer-reviewed journal in a relevant academic area; and (2) did the document feature discussion of

alcohol warning labelling. To be included in the review, a document did not need to focus solely on alcohol or labelling interventions. The 93 documents were then further culled for relevance using a third criterion: (3) does the document feature justificatory language referring to mandatory warning labels, where the justification may be explicit or implicit. This gave a remainder of 65 documents. The same three criteria were applied to a separate collection of documents assembled for a forthcoming systematic review relating to alcohol warning labels. This resulted in the inclusion of 41 new documents, giving a total of 106 scholarly publications (see appendix 1).

To review some advocacy literature, we selected statements from four groups who have made public statements on the topic of alcohol warning labels. The Foundation for Alcohol Research and Education (FARE) was selected as representing a public health position on alcohol.[4] Cancer Council Australia was selected because it specialises in cancer research and prevention.[5] DrinkWise Australia was selected as a prominent example of an Australian alcohol industry health initiative.[6] Finally, the combined response from the Australian alcoholic beverage industry to the Blewett Labelling Review was selected as representative of the views of alcohol producers in Australia.[7]

After selecting these advocacy statements and identifying the 106 scholarly publications, an initial reading of each text was carried out to identify patterns in the ethical justifications being used, whether these justifications were explicit or implicit. When patterns became apparent, texts were re-read in greater detail to clarify the nature of the identified patterns and any relationships between them.

Current policies and viewpoints

The academic literature featured three main justifications for including health warning labels on alcoholic beverages. The labels: (1) inform consumers; (2) reduce harm to consumers by generating behavioural change; and (3) reduce the wider social and economic burdens of alcohol. These justifications generally built upon one another, producing arguments of increasing complexity— the improved decision making of informed consumers generates behavioural change (in the form of reduced alcohol consumption), and this behavioural change then reduces the wider social and economic burdens of alcohol. The academic literature rarely used explicitly ethical language, instead only implying ethical justifications, generally as background information to a particular research project. Only 11 of the 106 papers used explicitly ethical language in discussion of warning labels, and of those 11 papers, four were direct responses to an ethics paper on the topic.[2,3,8-16]

Over half of the articles either quoted or referred to the warning label made mandatory in the United States, especially its stated purpose: "The purpose of the alcohol labelling regulation, according to the federal government, was to inform the American public of health risks, including birth defects, associated with the consumption and abuse of alcohol, and to serve as a reminder of health hazards".[17] Most of the academic literature featured the strong assumption that informing the public generates behavioural change, and this was evident in the language used. For example, one study of warning label awareness justified their interest in "federally mandated warning messages on alcoholic beverages ... because the consumption of alcohol and cigarettes leads to a high prevalence of health problems among Hispanics in the United States".[18] A study of adolescent exposure to and awareness of warning labels in the United States chose this population of interest because "it is during adolescence that health behaviors are being established and experimentation with alcohol and other drugs first occurs".[19] Laughery et al argued that "the user has both a need and a right to understand the potential hazards associated with a product,"[16] specifically to facilitate decision making. This 'right' makes explicit that justifications for warning labels are not simply a practical concern, but also an ethical one. Martin-Moreno et al also raised the question of what consumers have a right to know, making explicit an ethical element to labelling.[3]

Whether or not warning labels are actually effective at generating behavioural change is debated in the academic literature, with warning label composition and placement being raised as issues to be addressed in implementation.[20,21] In the reviewed academic literature, comparisons were made to tobacco, where warning labels have been shown to be effective,[22-25] with the caveat that tobacco presents greater health risks than alcohol, so one cannot assume that alcohol warning labels will have a substantially similar effect.[15,20,21]

The least common (and most complex) of the arguments put forth was that the reduction of harm resulting from behavioural change would reduce the wider social and economic burdens of alcohol. This argument was presented both explicitly and implicitly.[3,26-30] Pettigrew et al described the financial burden of alcohol-related harms and explicitly stated that "calls for warning labels also reflect a growing evidence base relating to the relationship between alcohol consumption and a range of health problems, including cancer, diabetes, cardiovascular disease, overweight and obesity, liver disease, fetal abnormalities, cognitive impairment, mental health problems, and accidental injury".[30] Four years after the introduction of warning labels in the United States, Malouff et al described the "100,000 deaths a year in the United States, as well as untold illness, lost productivity and misery for both drinkers and others," and described warning labels as an effort to reduce alcohol abuse.[29] Martin-Moreno et al described an array of "harmful consequences for both individuals and communities", and described the labelling of alcoholic beverages as an opportunity to address the information gap between what consumers know and what is required to make informed decisions about alcohol consumption. Other

authors touched upon the heavy social and economic burdens of alcohol consumption, but did not explicitly link these to warning labels.[26-28]

FARE and Cancer Council Australia put forward justifications similar to those of the academic literature, but in greater detail. Both FARE and Cancer Council Australia used language about informing consumers and reducing harm. Cancer Council's statement supported mandatory warning labels to inform, asserting that people ought to be informed "that the product they are purchasing and/or consuming can have a serious impact on their health and wellbeing", and that "access to information on how to use alcohol … should accompany the sale and supply of all alcohol products as a public health promotion message and disease prevention measure."[5] FARE recommended that warning labels should "alert the consumer to particular harms associated with alcohol consumption" and that they "can contribute greatly to improving health by increasing awareness of harms."[4]

Position statements from both FARE and Cancer Council make explicit that labels alone are insufficient to change behaviour and should be implemented as part of a wider scheme of interventions. In this way, they introduce nuance into the justification that informing consumers about health risks changes health-related behaviour. Rather than draw a direct causal link between informing consumers and changing behaviour, they argue that numerous determinants of behaviour can and should be targets of intervention. Cancer Council recommends that labels be "part of a wider alcohol control strategy",[5] and FARE recommends changes to "industry practices that impact on the access and availability of alcohol", particularly practices that appeal to young drinkers.[4] Both organisations single out drinking while pregnant for inclusion on warning labels, with Cancer Council also recommending warnings about other risks associated with alcohol such as medical side-effects, drinking and driving/operating machinery, physical violence and social/health/injury problems.[5]

DrinkWise, the Australian alcohol industry's voluntary program of alcohol warning labels, does not directly refer to harm that labels might reduce and describes their labels as intended to "inform and educate". In this way, they evoke the argument that a label's purpose is to inform consumers. The only harm-related language can be found in a statement of the intention of DrinkWise labels: to "help consumers enjoy alcohol with more responsibility and care".[6] In contrast to the nuanced statements from FARE and Cancer Council, this implicitly draws a direct causal link between informing consumers and improving health behaviour. The Australian alcohol beverage industries' submission to government regarding mandatory labelling emphatically rejects calls for warning labels, also appealing to harm reduction (or a lack thereof) by arguing that "the overwhelming evidence clearly shows that warning labels have no impact on drinking behaviour, especially among at-risk groups."[7]

Available options

Public health interventions use population-level tools to achieve population-level gains. However, these interventions have often been implemented in a society that supports the right of the individual to act as they please, unless this puts others at risk. For example, the British Public Health Act of 1848 brought water and sewerage under government control. While such arrangements are now commonly accepted, it was said in a newspaper at the time that "a little dirt and freedom" was "more desirable than no dirt at all and slavery."[31] This extreme attitude is no longer common, with government interference being seen as normal and even expected in such areas. Public utilities, road rules, food safety standards, product safety standards and occupational health and safety standards are an everyday part of life in Australia and elsewhere. So even in liberal societies, restrictions on liberty are often accepted and seen as justified, especially when they are needed to protect others.

Historically, public health interventions have tended to proceed on the basis that the liberties of some can justifiably be curtailed for the benefit of many, especially when benefits are substantial and the liberties curtailed are comparatively minor. Requiring alcohol producers to place warning labels on their product in order to reduce alcohol-related harm seems to align with this tradition – one group (the producers) have a limit placed on their liberty (their choice in labelling) in order to protect many (the consumers) from harm. While this is true, the assumption inherent in this case is that an individual will make the 'right' (healthy) choice when given the relevant information. This is not necessarily the case, and as noted, the question of the effectiveness of labelling in generating behavioural change is debated in the literature. In this way, the justification centred on generating behavioural change through informing is strongly aligned with the liberal notion of the autonomous individual – informing consumers gives them the information necessary to make an autonomous (free and informed) decision.

This idea of the drinker as an enlightened individual who will make the 'right' decision when given the relevant information is problematic because we know that there are many factors that impact drinking behaviour, with the most influential being pricing.[32] Additionally, in many Anglo-centric cultures, alcohol is deeply embedded in the social fabric to the point where choosing not to drink sometimes requires subterfuge or the provision of a socially acceptable excuse.[33] The drinker is not tabula rasa, but instead makes their decision within a pre-existing framework of normalised and acceptable drinking practices. To drink in spite of the health risks may also be perfectly consistent with an individual's priorities or view of the good life.

A recent paper discusses some of these issues, with a specific focus on cancer warning labels.[2] Its authors argue that autonomy (the capacity for self-government) can be

compromised by factors such as one's culture or lack of knowledge, and so mandated warning labels might be a justifiable means of achieving harm reduction, namely by improving consumers' ability to make autonomous choices and by changing the cultural environment in preparation for other interventions. The authors argue that warning labels ought not to be considered a standalone intervention but rather part of a suite of wider alcohol controls, and that although labels by themselves may not have a measurable impact on health behaviours (e.g. a reduction of alcohol consumption), they pave the way for future interventions. This means that labels could instead be considered part of a suite of interventions that, when considered as a whole, produce behavioural changes and thereby avert harms.

Conclusion

The academic literature and policy statements reviewed proposed three hierarchically structured justifications for the use of alcohol warning labels: (1) to inform consumers, so they might (2) improve their health outcomes through behavioural change, thereby (3) reducing wider social and economic burdens. We argue that the first two justifications amount to an argument which understates the importance of social, economic and cultural factors in influencing alcohol consumption. While it is laudable to try to ensure that people know the risks that they run in consuming alcohol, a public health intervention can only be justified if there is good reason to believe that it will contribute to improving health in some way, and we cannot assume that knowledge of risks alone is enough to change health-related behaviours and thereby improve health across the population.

Despite this, many accounts in the academic literature and industry statements use precisely this argument for warning labels on alcohol. This fits with the prevailing political climate of liberalism, which assumes that knowledge usually leads to right action and places both the right to choose and the responsibility for any consequences squarely with the individual. The pro-label advocacy literature presents a more nuanced justification for warning labels. It acknowledges that a range of modifiable factors impact on one one's drinking choices and behaviour, and that labels must be considered as part of a suite of interventions collectively aimed at effecting change at a population-level.

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*Utilitarianism is the ethical theory according to which population-wide utility (which may be understood as welfare) is the measure by which an action is right or wrong.

Appendix 1: Reviewed works, alphabetical by author

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ETHICAL ASPECTS OF CANCER SCREENING

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Abstract

Screening for cancer or cancer risk is well-established in high-income countries. This article considers ethical aspects of cancer screening. Ethical evaluation of screening depends on a contested evidence base, interacts with people's fear of cancer, and their enthusiasm for technology in general and screening in particular. Cancer screening is both a clinical and a public health activity, and so the often-conflicting frameworks from both clinical ethics and public health ethics are relevant to its evaluation. Cancer screening is an intrusion by health services into the lives of well individuals and so requires strong justification. Cancer screening can and should prevent harms to physical health, but its ability to do so is contingent on many factors and finely balanced; screening can also affect psychological wellbeing. When communicating about screening programs, care must be taken to support rather than undermine the autonomy of people considering participation. The benefit offered by cancer screening programs should be large enough to justify the opportunity costs of screening and the consequent cascade of intervention. Treatment should be offered in a way that avoids creating financial strain for individuals. Other relevant ethical issues include equity of opportunity and outcome in screening and accountability to communities. It is not clear how population-level and individual-level outcomes and interests in cancer screening should be balanced; future work should focus on resolving these difficult issues.

Screening for cancer or cancer risk is well-established in high-income countries. In Australia this includes organised population-based screening programs for breast cancer, cervical cancer risk and colorectal cancer risk. In addition, prostate specific antigen (PSA) testing to detect prostate cancer risk in asymptomatic men is done so frequently that it has become a de-facto screening program. This article considers ethical aspects of cancer screening.

Screening is the application of a test (which for practical reasons must generally be affordable and easy to use) to large, normal-risk populations of asymptomatic people – people who appear to be well. This testing is generally initiated by health authorities rather than individuals. Screening aims to separate people at higher risk from those at low risk. Higher risk people then receive diagnostic testing, and treatment if disease is present.[1,2]

Ethics addresses the question of what, in any given situation, is the right or good thing to do, and why those actions are more justifiable than alternatives. An ethical evaluation of cancer screening is an analysis of whether screening for a particular cancer in a certain way is the right thing to do, and if so, why.

Ethically-relevant contextual issues

An analysis of the ethics of cancer screening occurs in a context: it depends both on the evidence about screening and on the culture in which screening occurs.

Screening is usually not initiated by the person being screened

In ordinary clinical medicine, a patient approaches a health professional seeking resolution of a symptom or problem. In contrast, in screening, health authorities encourage apparently well people to be tested, an act that may turn them into a sick patient.[2] This intrusiveness suggests the need for a strong justification for screening programs - perhaps stronger than for treatments for symptomatic disease.

Ethics depends on evidence, but evidence is contested

Ethical evaluation depends on good evidence, in this case, epidemiological evidence about the benefits and harms that screening offers. Unfortunately, the evidence-base for even for the best-established programs is contested.[3-5] It has developed in disparate contexts, and its coherence and generalisability is often unclear. Experts disagree on the quality of studies and potential screening harms are often not studied. These uncertainties hamper ethical evaluation of screening programs.[4]

Public perceptions and cultural meanings interact with moral judgements

Perceptions about cancer can affect people's moral judgements about screening. Cancer is an especially-feared disease, strongly associated with death.[6,7] Screening offers a solution to the problem of cancer led by technological development, which may increase its appeal.[8,9] There is general enthusiasm for cancer screening. A US study found that 87% of respondents believed screening was almost always a good idea and 32-41% believed that an 80 year-old who did not participate in screening was irresponsible.[10] (Note that an 80 year-old would not ordinarily be screened for cancer: the investigators asked this question to test how strong

respondents' commitment to screening was, even in the absence of the possibility of benefit.) In an Australian study, 80% of participants believed early detection saved lives most or all or the time, and 70% wanted to be tested even for a cancer that could not be effectively treated.[11] This combination (frightening cancer, high-tech solution, enthusiasm for screening) may make people generally vulnerable to misperceiving cancer risk, or to taking up offers of unproven screening tests, and suggests a heightened responsibility for those who offer screening to healthy populations.[3]

Ethical issues in screening activities

Both clinical ethics and public health ethics are relevant to screening

Cancer screening is both a public health and a clinical activity.[2] It is 'public' in that it is used as a tool to improve the health of the general population, supported by public funds, organised into national programs that include public communication campaigns, and is standardised (e.g. the target group, the test used, the quality of pathology or radiology services). Although organisation varies enormously between jurisdictions,[12] the resulting standardisation and improvements in service quality are important potential shared benefits of organising screening. This 'public' character of screening programs suggests that frameworks for public health ethics are likely to be relevant.[13] Public health ethics frameworks emphasise values and principles such as: reasoning at the level of the population, working for common good, maximising utility through effective interventions, distributing opportunities or outcomes fairly, acting in ways that promote trust in the health system (e.g. communicating honestly, facilitating public participation), ensuring that interventions are necessary and proportional to the problem, and avoiding coercion or restrictions on important liberties.[14-18]

Conversely, screening is frequently implemented in clinic-like situations, either by a person's usual primary care physician as exemplified by PSA testing and cervical screening, or by a specialist technician in the case of mammography. The choice to participate in or refuse cancer screening is largely a matter for individuals. Unlike vaccination, where high participation is needed to sustain herd immunity, there is little common good arising from an individual's participation in cancer screening. Thus the concerns of clinical ethics, such as avoiding harm to individuals and respecting the decision of individuals about whether screening is in their best interests for example, are also relevant.[19-21]

This ethical tension is not yet resolved. It seems likely that the public aspects of screening programs should be assessed according to public health ethics criteria and the clinical aspects according to clinical ethics criteria. How we should adjudicate if these come into conflict - for example, if seeking informed consent to participate decreases population-level mortality benefit or program cost effectiveness - is not clear.

Cancer screening should protect physical health and avoid physical harm

Preventing harms to physical health is the stated goal of most screening programs. Each Australian cancer screening program, for example, takes as its aim: "to reduce illness and death from [the relevant] cancer."[22]

However, screening alone cannot prevent harms to physical health (that is, prevent morbidity and mortality from cancer). This relies on the cascade of diagnostic testing and treatment that follows screening.[23,24] This cascade can prevent harms that would have been caused by cancer. But it can also cause physical harm, such as pain, disfigurement or functional deficits (for example, impotence and/or incontinence after prostate biopsy and treatment). If cancer could be reliably detected, and if all cancers inevitably and linearly progressed to death, and if early treatment was always more effective than later treatment, the harms of the screening cascade would readily outweigh the harms of cancer.[25] Unfortunately, benefits and harms in the cascade are often delicately balanced.

Screening and the resulting cascade will be more likely to do net harm under the following conditions:

1. When test characteristics are poor, so that large numbers of low risk people are directed to diagnostic testing and/or treatment.[4,26]

2. When treatment for later, symptomatic disease is very effective, so screening is less necessary.

3. When the disease diagnosed is not destined to cause harm i.e. when a disease is present, but not destined to cause symptoms, such that diagnosing and treating it will cause net harm (the problem known as overdiagnosis).[27-29]

4. When the population-level risk of the disease is low, such that more people will need to be screened to save one life and more net harm is likely.[4,25]

What should count as a benefit or a harm of screening is also not clear. Policymakers, clinicians and citizens have different views on what is important.[30,25,31] For example, some may wish to avoid every cancer death at any cost, while others may prioritise avoiding unnecessary treatment. Determining whether screening prevents harm requires deciding which harms matter, finding data about them, and deciding how they should be weighted in analysis.

Cancer screening and psychological wellbeing

Social marketing about screening commonly suggests that screening can provide reassurance that disease is absent.[32,33] If this correct, a negative screening result may

serve the goal of improving psychological wellbeing.[2] However, in population screening, how or when such reassurance should count as a benefit is not clear.

As noted, fear of cancer is common in populations. Cancer was historically difficult to treat, and so was associated with suffering and death. Even after significant improvements in treatment, cancers are leading causes of death in middle age in Australia and directly experienced by many, so some fear of cancer is not unreasonable.[34,35] However, fear or anxiety may also arise from public health communication campaigns designed to encourage people toward screening or other health behaviour change.[36,37] That is, at least some anxiety about cancer may effectively be iatrogenic. If this is the case, it seems dubious to count the relief of this anxiety as a benefit of a screening program. In addition, screening itself produces some psychological harms. False positives in particular, which cumulate across a lifetime of participation,[38] have been shown to have lasting detrimental effects on psychological wellbeing of a similar magnitude to a cancer diagnosis.[39]

Supporting autonomy in screening

Screening can, in itself, promote or support autonomy by providing information.[2] On the surface, this seems relatively straightforward. A person enters screening knowing little about their cancer risk, and exits knowing a great deal more. There are certainly situations in which this will allow people to make better decisions about their health care, consistent with their own values.

However, communication within screening programs also has the potential to undermine autonomy.[40] Screening communication and social marketing sometimes seems designed to secure high participation rates - even to coerce participation - rather than support autonomy.[33,41] Information is often incomplete because harms are rarely described and relative instead of absolute risks are often used.[26,33,36,42-44] Relative risks are known to discount harms and inflate benefits in people's perceptions, and such systematic biasing of people's perceptions has been criticised as a form of unethical manipulation.[45] System incentives for high screening rates including performance payments and key performance indicators may encourage this bias.[25,33,46] Concern has also been expressed that screening communications that emphasise a responsibility to screen may make people who decide to refuse screening feel guilty.[37]

A more ethically justifiable screening program might focus on improving people's understanding of why they might choose to screen, preserving voluntariness, rather than pushing people towards participation.[19,25,47] Empirical work shows that people choose differently when they are better informed;[48] informed choosing may also improve psychological wellbeing by increasing people's sense of mastery and self-authorisation.[49] The benefit-harm trade-offs of screening are complex. Supporting people to understand them is no small task and understanding should not be assumed.[43,50] Sustaining valid consent to screen may require re-contacting people at intervals, offering opportunities to reconsider prior decisions and be informed about changes to screening practices and evidence.[50] While some have argued against providing citizens with quantitative information about screening on the grounds that they cannot understand it,[51] this is difficult to justify, and is inconsistent with what informed citizens consider reasonable.[52] Particular care needs to be taken however, when working with people who are educationally or socioeconomically disadvantaged,[49] and work is ongoing regarding the provision of appropriate decision assistance to people with limited literacy and numeracy.[53,54]

Other relevant ethical considerations

Screening programs carry large opportunity costs because they are expensive to run well, so it is important to periodically assess whether they are providing adequate health benefit and/or improvements in health equity to justify that cost.[23,26,29,55] Concern has been expressed that screening may divert funding away from forms of primary prevention that would have a larger effect on all-cause mortality and morbidity,[56] or away from providing necessary care to those who are acutely ill.[57-59]

Financial strain is a particular problem in user-pays health systems, where cancer can readily cause bankruptcy. In some user-pays health systems, people may receive a positive screening result from a free screening service, and then not be able to access affordable treatment.[60,61] Conversely, unregulated private fee-for-service screening can generate large cost burdens for public or insurance-funded follow-up services.[29] Knowing that one is at high risk of developing cancer may, in some contexts, make one less employable or insurable.[62] This is just one reason why confidentiality and privacy are important ethical issues for screening programs.[47]

Screening tends to have differential uptake among people of higher and lower socioeconomic status and people from different cultural backgrounds.[49] An ethical judgement about this depends on whether or not it is considered to be in people's best interests to participate in a particular kind of screening. It also depends on how justice is conceived. For example, if screening programs aim to provide the greatest possible health improvement for the least well off, they will be designed very differently than if they are intended to achieve the largest and most efficient improvement in aggregated population health.[49]

As with any health service, there are important issues to consider regarding how best to involve, and be accountable to, communities,[34] and how to ensure that screening is provided in a way that is respectful and culturally appropriate.[63]

Does cancer screening serve individual or common interests?

Decisions about whether screening serves the interests of a population are distinct from decisions about whether screening serves the interests of a particular individual.[5,25,64] It is not yet clear how to balance these distinct population and individual-level dimensions of screening activities.[2,41,65] There are advantages to a public approach to screening, particularly in ensuring standardisation and quality in service provision. However, from a more individual perspective, to coerce or manipulate citizens to subject themselves to invasive procedures for the sake of achieving a participation target, or changing a population-level mortality statistic, seems questionable. Different individuals have different goals and values, and so will - if they understand an offer of screening - make different choices. Even expert policymakers disagree on what the goals of screening should be, and so what values should be prioritised in decision making.[66] Anya Plutynski summed up the tension this way:

"Although a narrow utilitarian or expected utility perspective might simply attach values to lives saved, and so use any strategy (including representing risk deceptively, or discounting or hiding cost to patients due to unnecessary biopsies or overdiagnosis), there are broader issues at stake. Questions of risk and benefit need to be supplemented by some discussion of the reasonable variability in values patients attach to different risks, the norms of clinician-patient relationships, and what respect for autonomy and informed consent requires. Questions about risk and benefit can be better answered once we know how sensitive or specific are our screening tools, how prevalent the disease, and thus what the risks are of false positives. However, we also need to assess the values behind general versus individually tailored recommendations, and arguments for and against individual consultation with clinicians, versus general recommendations that may benefit some, but not most patients."[25]

The literature regarding the ethics of cancer screening is relatively new, and still in development. This review suggests that there are at least two central questions that need resolution if the field is to advance. The first is to determine how the competing potential goals of screening should be prioritised and balanced against one another. The second related question is the extent to which cancer screening is an individual clinical service, to which the principles of clinical ethics apply, and/or a public health service, to which the principles of public health ethics apply. These questions provide important challenges to future research on the ethics of cancer screening.

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BIG DATA IN AN INDIGENOUS HEALTH CONTEXT: OPPORTUNITIES AND OBSTACLES

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Abstract

The ability of health researchers to unearth previously unsuspected health risks, trends and commonalities at a population level through matching information across different datasets is well attested. However, as more of this type of research is conducted, the spotlight is being shone on the barriers to accessing these data. Less well known are the complexities experienced by researchers working with datasets in an Aboriginal and Torres Strait Islander health context. We present the insights of a number of researchers, clinicians and public sector representatives who have extensive experience of data linkage in the Aboriginal and Torres Strait Islander health sector, on key issues and practical and ethical implications of utilising big datasets. Obstacles are further highlighted in the experiences of a national multicentre cancer cervical screening study. While researchers must at all times respect the individuals whose information is contained within these datasets, and abide by the legislative structures governing their use, measures to streamline data linkage processes are required. Realising the potential of existing health data that previously has not been available may underpin significant improvements in indigenous health and ultimately life expectancy.

Big data is a term for data sets that are so large or complex that traditional data processing applications are inadequate. Challenges include analysis, capture, data curation, search, sharing, storage, transfer, visualization, querying and information privacy. (wikipedia.org/wiki/Big_data: accessed 14th April 2016)

The growing ability of health researchers to unearth previously unsuspected health risks, trends and commonalities at a population level through matching information across different datasets is well attested.[1,2] However, as more of this type of research is conducted, the spotlight is increasingly being shone on the barriers to accessing and using these data.[3] Less well known are the complexities experienced by researchers working with data sets in an Aboriginal and Torres Strait Islander health context.

The complexity of conducting research across multiple centres in Australia is discussed widely by the research community. A number of publications have highlighted these difficulties, including the length and complexity of the ethics approval process, but the situation remains a time-consuming and challenging component of any project of this type.[3,4] While it is imperative that a rigorous and thorough ethical review process is maintained, the current system is exhaustive and costly in terms of the resources that are taken up to ensure compliance, and the delays in obtaining multiple approvals to proceed. As most research in Australia is publicly funded, all taxpayers should be comfortable that their tax dollars are being judiciously utilised.

The opportunities and obstacles that present when using large data sets and data linkage in indigenous health research, and how this approach is contributing to indigenous health research in Australia, has also been the topic of discussion, including at a roundtable conducted by Australia's National Institute for Aboriginal and Torres Strait Islander health research, the Lowitja Institute. This paper draws on the perspectives of the authors and from those gathered from semi-structured interviews and an online survey conducted with eight individuals - three researchers, three government health bureaucrats, one data clinician from a non-government organisation, and one chair of a research ethics committee who is also a researcher. All have extensive experience of data linkage in the Aboriginal and Torres Strait Islander health sector and a good understanding of the key issues and practical and ethical implications of utilising big datasets. These issues are further highlighted in the case study of a national multicentre cervical cancer project.

Key issues and practical implications

Indigenous identification

Not all datasets include a variable on indigenous status and in some historical datasets indigenous status was not gathered routinely or uniformly, making availability and reliability of data on indigenous identification particularly challenging. For example, indigenous status information may not be available for a baby and may be derived from the indigenous status of the mother. However, some datasets may not routinely include indigenous status information of both parents. This is changing now, but will take some time before the data become truly reliable.

Data linkage can improve Aboriginal identification as there is a greater likelihood that indigenous status will be recorded in one or more datasets. In the case of babies, if indigenous status of the mother was not captured at hospital admission, but she gave birth and received other services with Aboriginal status recorded, data linkage can increase confidence that the person/s involved are Aboriginal. The various Australian jurisdictions have developed different processes for data linkage that impact on the extent to which indigenous identification can be ascertained. Western Australia (WA) is held up as a national exemplar. For example, the WA Data Linkage System connects a wide range of datasets spanning up to 50 years. In collaboration with Telethon KIDS and Indigenous academics, a method to combine this information about indigenous identity has been developed so that a 'Getting Our Story Right' indigenous flag can be added to any approved data extract for analysis.

Federal fragmentation

A national approach to best practice in data linkage needs to be undertaken. It has been suggested that the varying jurisdictional approaches have contributed to the problem of under identification, leading to calls for more complementary and unity in the desire to use data that is collected from people for the benefit of the people. Under Australia's federal system of government, states/territories have control of health services, which has resulted in large amounts of data being collected and stored by them using divergent methods.

For national-scale research projects, the differing processes for accessing data between states/territories may also create additional issues. For example, there is fear that the fragmented approach will result in many silos making it difficult to streamline data access and linkage and thus impact on efforts to develop better access to data for all types of population based research.

There are also concerns about who owns and controls the data. Big datasets should be viewed in light of the potential benefits to Indigenous Australians and the current system, where government and/or state and territory departments hold and control these large datasets, can be a specific barrier to sharing information and linking data. Challenges in accessing and sharing these datasets may also lead to mistrust among the community which is completely understandable given past injustices. Systematic and ethical processes for sharing information must occur, but systems must be established that enable the use of these data to assist in the development of better policies, planning, management and delivery of health services to Aboriginal and Torres Strait Islander people.

National collaboration

In recent years there has been a concerted effort to build better linkages between datasets in different jurisdictions, and to make data collection more uniform. These include the establishment of the Population Health Research Network in 2009,[5] the publication in 2012 of national best practice guidelines for collecting indigenous status in health data sets,[6] and a subsequent evaluation of these guidelines released in 2013.[7] These initiatives are facilitating improvements in data linkage and strong support for their continuation within the existing system. For example, data linkage infrastructure is being developed across Australian states and territories through the Population Health Research Network. This includes technical development of data linkage systems modelled on those existing in WA and NSW. In addition, consistent access policies and research protocols have been developed and a secure data access environment is now operational through the Secure Unified Research Environment.

There are a number of other positive developments in linking and sharing data in the indigenous health context. For example, data custodians are increasingly aware of the importance of data linkage in enhancing indigenous identification across datasets with a view to generating reliable data for closing the gap in indigenous disadvantage.

National studies are likely to have more power for change in the long-run, but in the meantime there is a need to recognise the jurisdictional divide in order to work in the current climate.

Approvals processes

Ethical approval processes are time consuming and complex, adding additional challenges to linking datasets. All health research projects must go through ethical approval processes, and projects involving Indigenous Australians may also require additional approvals. Projects also need to be cleared by jurisdiction-based data custodians, all operating under different legislative regimes. The process may take several months to complete. For example, the NSW Ministry of Health has a partnership agreement with the Aboriginal Health and Medical Research Council. Under this agreement, projects that propose to use information on Aboriginal

people are referred to both the Aboriginal and Medical Research Council and also their Ethics Committee for approval prior to data release.

Although a centralised agreement for ethics applications and reporting of progress and outcomes would mitigate a lot of researcher fatigue and frustration, streamlining the approvals process must be balanced against the need to ensure cultural respect and that Indigenous people and communities are fully informed of research proposals using their health and health-related information. It is also important that Aboriginal people feel safe about providing their indigenous status with the knowledge that the data will be used for them with the aim of improving indigenous health and not against them (as in the past). There is a much greater possibility of data sharing and linkage if there is greater input and control of data by Aboriginal people.

Education and resourcing

More education and training around data collection and data linkage projects, and greater resourcing for a data linkage workforce would address, at least in part, some of the aforementioned obstacles and maximise opportunities to improve the health outcomes of Indigenous Australians. For example, data collection agencies should have culturally competent staff collecting data from Indigenous Australians and engage in respectful discussions regarding ownership of personal and community information with Aboriginal and Torres Strait Islander peoples and community organisations. Additionally, individuals should be informed about such data collections, their importance, how their data will be used, stored and the potential contributions it may add to improving health, planning and service delivery.

Case study

Cervical cancer incidence and mortality have halved in Australia since the introduction of the National Cervical Screening Program in 1991, yet Indigenous women remain twice as likely to get cervical cancer and four times more likely to die from it.[7] The program is unable to report on cervical screening participation for indigenous women as indigenous status is not universally recorded in the state Pap test registries which provide monitoring data to the program. In 2011, we commenced a national project to link Pap test registries datasets within each state and territory to health datasets containing an indigenous identifier, in order to assess participation of indigenous women in the program. Ethical approval was required from 10 state-based HRECs and three Aboriginal HRECs. In addition, regulatory approval was required from seven data linkage units (DLU) and the custodians of 24 datasets.

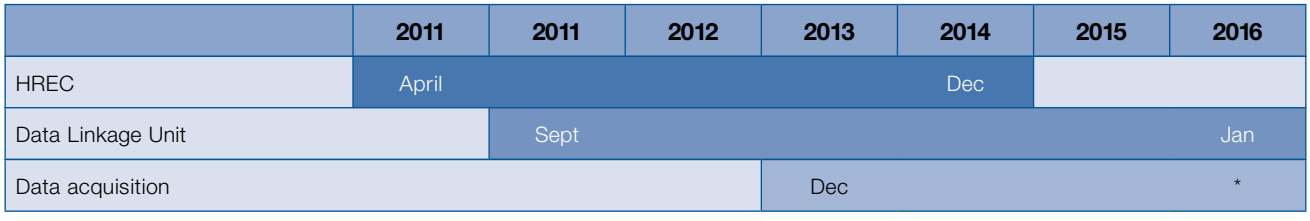
Unreasonable time and financial cost for ethical and linkage approval

The time from initiation to completion of the ethics committee approval process ranged from two to 32 months, and final approval to link and access all datasets took five years. In one jurisdiction, a data custodian provided conditional approval pending ethics committee approval; by the time the HREC approval was received, a new employee held the data custodian position and the conditional approval was deemed to be invalid, requiring the approval process to start afresh. The first set of data was obtained in December 2013 and one data set remains outstanding as of April 2016 (figure 1). While the professionalism, support and thoroughness of almost all individuals involved has been exemplary, the process has been fraught with duplication, ineffective regulation and delay.

Box 1: *Data linkage units in Australia*

The Public Health Research Network is a collaboration of six state/territory data linkage units in Western Australia, New South Wales, South Australia/Northern Territory, Tasmania, Queensland and Victoria, and two national linkage units, namely the Centre for Data Linkage based in Western Australia and the Australian Institute of Health and Welfare in Canberra.[5] The Data Linkage Unit (DLU) in WA has existed for more than 20 years and others have commenced in the past 10 years.[5,6] Researchers can apply for datasets related to the same individual to be linked and provided without identifiers, ensuring that privacy is not breached. The process requires initial approval from the data custodian, then ethical approval through various human research ethics committees (HRECs) in each state or territory and, in the case of research for Indigenous people, Aboriginal HREC approvals may also be required. The process of obtaining HREC approval differs in each jurisdiction— some require a national ethics application form; others accept a form if already approved in another jurisdiction, and still others require a specific application form.

Figure 1: *Time from commencement of application or data acquisition to completion*



* one state outstanding as of April 2016

Over 400 days of person time, at a cost in excess of $200,000, were spent obtaining HREC and DLU approval. Datasets contained different variables or the same variables with different naming conventions; the researchers worked with the DLU to obtain variables that were necessary to answer the project's research questions. In some jurisdictions, a request for each variable had to be justified and negotiated and, where changes to the original request were necessary (either researcher or DLU driven), an amendment was required by the relevant ethics committees and/or data custodians.

Results

The first results, based on population data (1,334,795 women aged 20-69 years) from one jurisdiction, show that Indigenous women have a 20-point lower screening participation rate than other Australian women, with no improvement over time,[8] and a higher rate of high-grade cervical abnormalities.[9] Had the process been more efficient and less protracted, results for the whole country would have been available by now, information which could have underpinned interventions to reduce cervical cancer occurrence in Indigenous women.

Discussion and conclusion

This paper highlights some of the obstacles encountered by researchers using data linkage to answer important research questions regarding the health of Indigenous Australians. Australia has many publicly funded data holdings, including clinical dataset registries, administrative databases and survey data, access to which can lead to improvements in public health. Although population level data exist, access is so complex that researchers are taking longer to achieve results that can underpin interventions and improve outcomes for Indigenous Australians. This is an ethical concern for many researchers.

Ethical implications

By its very nature, data linkage allows researchers to use data that has been de-identified and it is therefore highly unlikely that an individual's personal health data could be made public. The Privacy Act provides a mechanism to allow such research to go forward as long as the relevant HREC approvals are in place.[10] The use of big data and conduct of data linkage projects should also be guided by the values and ethics in conducting Aboriginal and Torres Strait Islander research.[11]

A recent National Health and Medical Research Council report stated: "It is particularly important that the use of Aboriginal and Torres Strait Islander data maximises opportunities to improve health outcomes for this population group."[12] While researchers must at all times respect the individuals whose information is contained within these data, and abide by the legislative structures governing their use, measures to streamline data linkage processes are required. Key to this is the critical need for researchers to establish and build relationships with indigenous groups to ensure that indigenous status is accurately recorded in health and census data in the first place and to facilitate/navigate/expedite approval and compliance requirements. Mistrust between indigenous people, communities, data custodians and researchers, which could be addressed through better education about why data are being collected, how data are being used and stored, who benefits and how findings will be disseminated.[13,14] Further, establishing a national set of guidelines for sharing de-identified data collected from indigenous communities has the potential to prevent unnecessary duplication in data collection and maximise health benefits for indigenous people.[15]

Multi-jurisdictional data linkage is in its infancy in most of Australia and the ability of services to provide linked data in a timely manner varies across the country. There is no doubt that data linkage projects have an increasingly important role to play in health care planning and providing a more complete picture of the health of Aboriginal and Torres Strait Islander health outcomes, without the time and cost burden of gathering additional and often duplicate data.

Notwithstanding length and complexity of data linkage projects, the case study presented here is an exemplar of what can be achieved to address a significant gap in reporting of indigenous people's participation in a national cancer screening program that has been in operation for 25 years. A firm foundation has been established – the challenge now is to build on it.

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ETHICAL ISSUES ARISING IN THE USE OF GENOMICS IN CANCER

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Abstract

This paper examines ethical issues in relation to genomics that arise in connection with their use in cancer, focusing primarily on the clinical context. The role of genomics in cancer is investigated through the lens of 'personalised medicine' or 'precision medicine', and the implementation of contemporary genomics into mainstream clinical practice. The paper explores the impact that 'next generation sequencing' (high throughput sequencing) is having, including whole genome sequencing, exome sequencing and the use of cancer panel testing. It also examines a number of ethical-legal issues which regularly arise in the context of next generation sequencing technologies, in particular: consent; privacy; management of clinical findings and results back; and the scope of a physician's/doctor's duty to a patient over time and whether there is a duty to recontact. This is an area where medical technology is rapidly developing and ethical, as well as legal principles need to be reassessed from time to time so we can recalibrate to take account of these advancements. While next generation sequencing holds remarkable potential, some caution in its deployment is warranted so that there is good preparedness for the outcomes. To this end, cancer panel tests appear to be a good compromise to address the clinical questions at hand while avoiding the problem of too much information.

This paper will examine ethical issues in relation to genomics that arise in connection with their use in cancer. The focus will primarily be on the clinical context, although it must be acknowledged that there are many clinicians who are also involved in genomic research and therefore the boundaries between clinical practice and research can become blurred. This exploration of the role of genomics in cancer must be understood in the broader context of the 'personalised medicine' era,[1] now referred to as 'precision medicine', and the implementation of contemporary genomics into mainstream clinical practice, including its use for diagnosis and treatment. Advancements in precision medicine are opening up new medical possibilities around personalised health care, that is, care tailored to the individual patient's genetic characteristics and medical history.[3] Also to be noted is the related field of pharmacogenomics, a form of genetic testing that determines the influence of genetic variation on drug response. This has seen the emergence of targeted therapies that provide benefit to particular cancer

patients as illustrated with the targeted use of Herceptin (trastuzumab),[2] a targeted therapy for HER2 positive metastatic breast cancer and HER2 positive gastric cancer.[4]

Developments in genetic testing: single gene tests to gene sequencing

The technological capacity for genetic testing to reveal changes in a person's genes, or gene mutations, to determine the risk of cancer and appropriate care strategies, has increased significantly over recent years. Predictive gene testing is usually undertaken where there is a family history of disease which suggests that there may be an inherited mutation. For example, where there is a family history of breast cancer, testing for BRCA1 and BRCA2 mutations may be recommended. Genetic testing may also be undertaken for people who already have a cancer diagnosis in an attempt to confirm a suspected gene mutation in the family which may influence the course of treatment. There is now also capacity for testing of cancer cells from a cancer tumour of a person with cancer, which may assist in determining prognosis and also inform treatment decisions. Genetic testing, facilitated with a genetic counsellor, enables better understanding of disease risk; identification of a gene mutation can ensure closer surveillance, with the likelihood of detecting the disease earlier, at a time when treatment is more likely to be effective.

Numerous hereditary cancers have been identified involving mutations inherited in a dominant fashion, including hereditary breast and ovarian cancer, lynch syndrome (hereditary nonpolyposis colorectal and endometrial cancer) and familial adenomatous polyposis. Predictive genetic testing for a range of cancers has been available for decades, initially taking the form of single gene tests using Sanger DNA sequencing. More recently, there has been a move away from single gene testing to high throughput sequencing – referred to as 'next generation sequencing' (NGS) involving massively parallel sequencing of exomes or even whole genome sequencing (WGS). This has occurred as a direct consequence of the dramatic decrease in the cost of NGS,[4,5] to the extent that it is becoming cheaper to undertake WGS then undertake a number of the individual genetic tests, although in practice, most laboratories are still targeting specific genes rather than using WGS. In January 2014, a media release announced that Sydney's Garvan Institute of Medical Research was one of the first in the world to acquire machines that can sequence a whole human genome at a base cost below $US1000.[6] Commentators have suggested that using NGS to identify the complete DNA sequence of cancer genomes has the potential to provide significant breakthroughs in understanding the origin and evolution of cancer.[4,7] The current trend towards NGS however, gives rise to questions about whether the availability of a more comprehensive, but less targeted form of testing, should be undertaken simply because it is more economical to do so. This is particularly the case for WGS given its far reaching scope, with potential for information overload, and greater likelihood of 'incidental findings' that is, unanticipated discoveries unrelated to the condition being treated or for which tests are performed, and the resulting legal and ethical challenges in relation to which results should be disclosed. At the heart of the problem is the reality that the capacity to generate data through massively parallel sequencing has outpaced our capacity to determine its functional significance.[8] There is high demand for bioinformatics in the implementation of NGS and anticipated workforce shortages.[4]

Cancer panel testing

Currently, the main focus of WGS in relation to cancer mutation detection is in the context of research. For clinical purposes, the preferred approach is the use of cancer panel testing. Cancer gene panels use next generation sequencing technology to assess inherited mutations in multiple genes simultaneously,[9] but seek to contain their analysis by focusing on a specific clinical question. Prior to next generation sequencing, genetic testing usually started with the most commonly involved genes and proceeded to less likely genes only when clinical suspicion was very high. However, cancer panels allow testing of all genes in parallel without substantially increasing the cost, leading to a different clinical algorithm in which all known contributing genes can be assayed at first evaluation.[9] Cancer gene panels can vary in size from just a few genes (e.g. BRCA1 and BRCA2) to panels comprising 50 or more genes. In June 2013, in a case involving Myriad Genetics, the United States Supreme Court overruled the Myriad patent for detection of breast and ovarian cancer, holding that merely isolating genes that are found in nature does not make them patentable.[10] Since that decision, there has been a rapid expansion of the clinical options for genetic testing and of commercial providers of cancer panel tests, and incorporation of this sequencing technology into a range of clinical oncologic settings. More recently, the Australian High Court, in the case of D'Arcy v Myriad Genetics Inc and Anor, also found the Myriad patent to be invalid on the basis that claims were not patentable subject matter,[11] however, as the patent had already expired this decision will not have an impact on the availability of BRCA1 testing in Australia.

There are limitations as well as advantages of the cancer gene panels, and there is considerable debate surrounding the clinical, ethical, legal and counselling aspects associated with NGS and gene panels. This contemporary technology presents challenges, as the clinical value of multiple gene panels for cancer susceptibility is not yet fully understood. One of the major drawbacks is the increased complexity of results. A major concern is the increased likelihood of identifying variants of unknown significance. The more genes subject to tests, the greater the chances that there will be uncertain results. For many genes, clear risk reduction strategies for mutation carriers are not established and there is, therefore, increased scope for misinterpretation of uncertain results, possibly leading to

unnecessary interventions.[9] Learned commentators have taken different views as to the appropriateness of WGS in preference to gene cancel panels in a given scenario.[12] Mark Robson lays down the following challenge:

"The rapid pace of technological innovation has driven multiple panel testing into the clinic, perhaps a bit before we have built a responsible framework to accommodate it. Counselling and clinical management paradigms that were developed to support single gene testing are not adequate to address the disruptive challenges presented by NGS and panel testing. The clinical cancer genetic community needs to respond to these challenges with a systematic program of collaborative research and clinical trials to realise the potential and minimise the risks of this exciting new technology."[13]

However, cancer panel testing also represents something of a compromise because compared with WGS, it is a far more targeted form of testing, thereby reducing the risk of revealing excess, extraneous information regarding, for example, untreatable conditions unrelated to that which is under investigation, or information which is not understood e.g. variants of unknown significance. This helps to reduce the risk of misinterpretation of uncertain results.

What is encouraging is that early research into patient experiences with gene panel tests based on exome sequencing found that most adults accepted and were satisfied with gene panels based on diagnostic exome sequencing, few reporting distress regardless of mutations found within known disease causing gene panels.[14] The authors suggest that there should be continued evaluation of patient experiences following exome-wide analysis.

There are a number of particular ethical-legal issues which regularly arise in the context of NGS technologies and which are the focus of the discussion which follows: consent; privacy, including the issue of sharing genomic test information with genetic relatives; management of clinical findings and results back; and the scope of a physician's/doctor's duty to a patient over time and whether there is a duty to recontact.

Consent

The vastness and complexity of data from high throughput technologies creates challenges in ensuring adequate understanding of what is involved and in particular, in securing 'informed consent' from patients. The consenting process could potentially take a number of hours if everything is gone through comprehensively due to the sheer scale of NGS sequencing.[15] The extensive nature of counseling required for NGS has been confirmed in practice due to the extent of the information to be covered in order for participants to make informed decisions, in particular in relation to return of incidental findings.[16] Yet consent is crucial to clarify expectations about the scope of the test, return of results, and the extent of clinicians' duty to disclose. Before testing is undertaken, there needs to be a clear understanding in regards to these matters and this all needs to be clearly communicated to the patient at the time of consent.

Relatively speaking, a key advantage of cancer panel testing over WGS, is its more limited scope, which reduces the potential of information that will be available. This makes the process of providing information to patients and obtaining consent less complex than is the case for WGS, but even with the more targeted approach of cancer gene panels, there are still challenges and the potential for difficult issues with regard to the return of incidental findings.

Ideally, as much as possible should be dealt with in the first instance so that patients know the range of testing undertaken and what results will potentially be available, and how these will be managed. Only then can they make a well-informed decision about whether to proceed with the genetic test.[17] Individual preferences regarding the return of incidental findings should be dealt with as part of the consent process, although questions have legitimately been raised as to whether patients can really appreciate the nature of this information and decide what they want.[18] Biesecker refers to 'informational saturation' with respect to return of results,[16] and argues that there is a difference between what patients want and what they can cope with in the context of a maximum of 20-40 minutes of counselling. In any event, various sources support the view that the patient's right of autonomy is not absolute and may have to give way to the clinician's fiduciary duty or professional responsibilities to the patient as indicated by United States Presidential Commission for the Study of Bioethical Issues Report, *Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in Clinical Research, and Direct-to-Consumer Contexts* December 2013,[19] or with reference to the patient's relatives. If there is potential for enforced disclosure of certain information, patients should be advised about this at the outset so that they can make an informed decision about whether to proceed with the testing.

Privacy

Genetic and genomic information is, of its nature, sensitive information. Clinicians may seek to share information from WGS/NGS in order to maximise understanding of the patient's data and informing clinical advice, but data sharing inevitably has privacy implications, particularly if the patient's raw genomic sequencing data is to be placed in the public domain. Combining high throughput sequencing with the capacity of electronic health records creates unique opportunities to understand the genetic determinants of disease,[20] however the use of electronic health records in this context also raises concerns about privacy and data security.[21]

There are times where tensions arise in families regarding the extent to which genetic information about an inheritable mutation such as BRCA1 and BRCA2 mutations should be shared with other genetic relatives who may benefit from this knowledge by undertaking prophylactic measures or

regular screening. Guidelines in a number of jurisdictions, including Australia and the United Kingdom, help to guide the decision-making of clinicians in circumstances where a patient declines to consent for information to be shared with genetic relatives, but the clinician takes the view that the information should be disclosed.[22,23]

Management of clinical findings and results back/or 'return of incidental findings'

There has been evolving debate across clinical genetics specialities about the management of clinical findings. The American College of Medical Genetics and Genomics (ACMG) has issued guidelines, initially in 2013, and revised in 2014,[24,25] regarding what laboratories undertaking clinical sequencing should test for and report on. The initial 2013 recommendations required laboratories, regardless of the indication for which clinical sequencing was ordered, to explicitly seek and report on a minimum list of variants - 57 in total later revised down to 56, including for specific cancers.[22] Under the original recommendations, it was recommended that patients not be given the option of opting out of this information, and it was also recommended that this approach should be taken regardless of the age of the patient. This was justified on the grounds that many of the conditions could be prevented, treated or risk reduced and it was anticipated that approximately 1% of sequencing reports would include a variant from the list. The recommendations of the ACMG came under strong criticism from a range of sources, particularly in relation to overriding patient autonomy, also because it was in conflict with established guidelines on the genetic testing of children for late onset disorders. In April 2014, revised recommendations were announced, allowing patients to opt out of receiving certain incidental results before the test was undertaken, and where the patient was a child, parents would have the option of opting out of such analysis.[23]

In contrast, the European Society of Human Genetics (ESHG) has recommended a more conservative approach,[24] suggesting that whenever possible, testing should be targeted to genome regions linked to the indication and that wider testing requires a justification in terms of necessity, defined as the need to solve a clinical problem and proportionality, understood to be the balance of benefits and drawbacks for the patient. According to the ESHG, adding screening targets to a diagnostic test violates the criterion of necessity. The ESHG was of the view that imposing this extra testing on patients who need an answer to a clinical problem is at odds with respect for autonomy; people have the right to decline testing on the basis of their own assessment of the burdens and benefits.[26] Similarly, in Canada, a cautious approach has been recommended by, the Canadian College of Medical Geneticists.[27] The college position paper states that until the benefits of reporting incidental findings are established, the college does not endorse the intentional clinical analysis of disease-associated genes other than those linked to the primary indication.

In Australia, the Human Genetics Society of Australasia had expressed concerns in relation to the initial ACMG recommendations, in particular, in relation to the ethical principal of autonomy and testing in minors, which have since been amended.[28] The Royal College of Pathologists of Australasia, in the updated Massively Parallel Sequencing Implementation Guidelines, revised May 2015, notes that there is as yet no consensus on whether and what incidental findings should be reported to the patient. The guidelines recommend that patients should receive a clear written record of the policy regarding the reporting of incidental findings.[29]

The quite prescriptive nature of the proposed approach of the ACMG has fuelled debate in relation to the management of clinical findings and return of incidental findings to the patient. This has, in turn, had implications for the research context, where there appears to be growing support for the return of 'incidental findings' that meet certain threshold criteria - analytical validity, clinical validity and clinical utility,[30,31] and even, more controversially, suggestions that researchers may have an obligation to actively look for genetic incidental findings.[32] However, this area is by no means settled, and some commentators caution about the risks associated with return of incidental findings,[33] and others highlight the importance of recognising the difference between clinical and research contexts.[34]

Scope of duty of disclosure: duty to recontact?

When incidental information arising from genomic testing reveals a significant health risk for which a preventative or therapeutic intervention is available, the law may well require its disclosure by the laboratory to the clinician, who must then inform the patient. It should be noted that the United States and Canada recognise a legal duty to warn, which potentially extends also to relatives. This concept does not have direct authority to support it in Australia or the United Kingdom,[35] however general common law principles in relation to duty of care apply.

Accepting that there may be circumstances where a clinician is under a duty to disclose pertinent genomic findings, the question then arises as to the scope and duration of this duty, in particular, if the clinical relevance of incidental findings changes over time in light of new information? Is there an obligation to recontact the patient to share that new information, even though some time may have passed since the patient saw the clinician? Commentators have suggested that it is unlikely that liability would accrue for information, that was not known or knowable during the existence of the doctor patient relationship; once that relationship has ceased, that duty is generally concluded.[36] Ideally, the possibility of new information later coming to light should be raised with the patient at the time that consent for testing is obtained; if the dynamic nature of this area is explained, the patient can be empowered to be proactive and recontact the

clinician after a year or two to see if there is any relevant new information. This seems a more reasonable course than proposing that clinicians should have an ongoing duty to the patient, particularly given the vast amount of information involved with NGS and the rapid pace of change, which would very quickly render any such duty unmanageable.

Conclusion

The shift from single gene testing to clinical use of NGS has presented a range of ethical challenges which have demanded fresh thinking on key ethical principles. At a very practical level, a lack of genomic expertise in the health system generally has been highlighted, and the difficulty of interpreting the clinical implications of highly complex genomic data indicated. Education will inevitably be part of the solution – continuing education for clinicians to ensure that they are enabled to serve the interests of their patients in this fast moving area, as well as helping to improve the genetic literacy of the broader public.

In the application of genomics to cancer, the use of gene panel testing seems a reasonable compromise, focused on obtaining the information that is needed and managing the risk of too much information. Continued monitoring of patient experience and satisfaction with this form of testing will be important. Above all, it is vital that decisions about clinical care are evidenced-based.

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NEGOTIATING LIMITS TO THE FUNDING OF HIGH COST CANCER MEDICINES

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Abstract

The cost of pharmaceuticals is overwhelming health budgets around the world. A growing proportion of this burden stems from the ever-increasing demand for subsidisation of cancer medicines. Those making decisions about which cancer medicines should be subsidised are often criticised by patients, clinicians and the pharmaceutical industry for withholding life-saving treatments from patients in desperate need. While their arguments are emotionally compelling, these critics often fail to recognise the complexity of resource allocation decisions, and the challenges faced by those making such decisions. In this article we describe two of these challenges: 1) the need for decision-makers to balance their desire to rescue those in desperate need against their responsibility to consider population-level opportunity costs and to make decisions based on solid evidence of cost-effectiveness; and 2) their need to negotiate 'fair' prices for medicines when they lack negotiating power, and when prices seem to be more reflective of what the 'market will bear' than what the medicines are really 'worth'. We conclude that, while there is no easy solution to these challenges, there is a need for greater transparency and procedural fairness, so that stakeholders are both more alert to the complexity of decisions about funding high cost cancer medicines, and more willing to accept the outcomes of these decisions.

Cancer is one of the most active areas of contemporary drug development. According to the Pharmaceutical Research and Manufacturers of America, there are 98 drugs currently being developed for lung cancer, 87 for leukemia, 78 for lymphoma, 73 for breast cancer, 56 for skin cancer and 48 for ovarian cancer. In total, 3137 clinical trials for cancer drugs are being conducted in the US alone.[1] Patients and clinicians often have high hopes that these new cancer therapies will be safe and effective, particularly because many of these medicines are 'targeted,' or 'personalised' and therefore appear to be 'designed' with particular patients in mind.[2] Success stories, such as imatinib for chronic myeloid leukemia,[3] and trastuzumab for early, that is, non-metastatic, breast cancer,[4] bolster these hopes.

Driven by this optimism, patients and clinicians focus much of their attention on the need for regulators to approve cancer therapies as quickly as possible, and for public and private insurers (henceforth 'payers') to subsidise them.[5,6] Governments have responded to this demand by establishing programs such as the UK's Cancer Drugs Fund,[7] and Australia's Herceptin Program,[8] which provide access to cancer medicines that have not been deemed to be cost-effective according to the usual standards applied by organisations such as the UK's National Institute for Health and Care Excellence or Australia's Pharmaceutical Benefits Advisory Committee.

In Australia, growing expectations for access to expensive cancer therapies has also led to increased pressure on hospital therapeutics committees to provide access to expensive cancer medicines that are not listed on the Pharmaceutical Benefits Scheme or, alternatively, on the pharmaceutical industry to provide 'compassionate access' (also referred to as 'patient access,' 'compassionate use,' 'named patient' and 'expanded access'), which makes cancer medicines available, either for free or at a discount, to patients who meet specific inclusion criteria.[9] For example, for hematological malignancies, approximately 21% of patients receive non-Pharmaceutical Benefits Scheme funded drugs. Of these, 31% receive access through industry or hospitals, 61% through clinical trials, and 37% have to draw on savings, sell assets, take out loans, or fundraise to help pay for their treatments.[10]

There has also been a recent growth in calls for 'coverage with evidence development,' a type of 'managed entry' in which payers subsidise cancer therapies that have not been conclusively demonstrated to be safe and/or effective, with a view to subsequently generating evidence to support either ongoing subsidisation or disinvestment. Coverage with evidence development arrangements is already in place for selected cancer therapies in the US, UK, Europe and Australia.[11]

Complexity and conflict in decisions about access to cancer medicine

There is of course, nothing wrong with patients and clinicians lobbying for access to cancer therapies, or with policymakers changing their processes to facilitate such access. But health systems globally are struggling to cope with this demand. A prediction that global spending on cancer medicines would reach $100 billion by 2018 saw this threshold passed in 2014, with almost 50% of this spending associated with new, targeted therapies.[12,13]

The economic challenges associated with funding cancer medicines are evident in the recent streamlining of the UK Cancer Drugs Fund,[14] and ongoing concerns about its viability.[15] Similar concerns have been expressed about Australia's capacity to cope with the growing demand for cancer medicines, with a recent Senate report acknowledging that expensive cancer medicines are a major challenge for governments attempting to balance affordable access while maintaining a sustainable health budget.[16]

Given the strain placed on health systems by cancer medicines, it is crucial that those advocating for access to cancer medicines have a sophisticated understanding of the values that regulators and payers have to consider when they make their decisions. That they have a good understanding of why cancer medicines cost what they do, and why it can be so difficult for payers to negotiate fair prices is also important.

Competing values in decisions about access to cancer medicines

Those making these decisions about access to cancer medicines need to contend with a number of competing moral, clinical, economic and scientific values. Broadly speaking, these can be summarised as the desire to:

1. provide benefit to patients, without harming them, and to fulfill the related 'rule of rescue', which is the moral and psychological imperative to help those in desperate need, irrespective of cost or scientific uncertainty;[17]

2. achieve equity - that is, ensuring that patients are not disadvantaged simply because they have rare cancers or, in the case of targeted cancer therapies, rare subsets of cancers;

3. allocate resources efficiently - that is, producing the 'greatest good for the greatest number' in an affordable and cost-effective manner, and paying a 'fair' price for medicines, based on their clinical value; and

4. make decisions based on sound scientific evidence of effectiveness, safety and cost-effectiveness.

Each of these values can be particularly difficult to fulfill in relation to cancer medicines. First, cancer medicines are not always as safe and effective as hoped. In many cases, decisions to provide access to cancer medicines are based on surrogate outcomes such as progression-free survival,[18] so prediction of their true clinical benefit can be difficult. Cancer medicines also have serious and costly side-effects. For instance, up to 22% of cancer patients treated with chemotherapy are estimated to require hospitalisation for neutropenia.[19] Even targeted cancer therapies, which are touted as being both safer and more effective than standard chemotherapies have their risks. For example, trastuzumab has been found to be associated with serious cardiotoxicity when combined with adjuvant chemotherapy.[20]

Efficiency and affordability can be difficult to achieve because, as discussed above, cancer therapies are often so expensive, stretching health systems to their limits, and creating enormous opportunity costs. Achieving equity can also be challenging because, unless medicines are subsidised nationally, access to medicines is contingent on ad hoc decision-making by hospital therapeutics committees or by pharmaceutical companies.[9] In the absence of these mechanisms, only the wealthiest patients, or those with the necessary connections for personal fundraising, can afford to pay for their own cancer therapies.

The desire to make decisions based on sound scientific evidence of effectiveness, safety and cost effectiveness, that is, to adhere to the principles of evidence-based medicine, can also be extremely challenging in relation to cancer medicines. One reason for this is that patients are often desperately ill and are often not willing to be subjected to the 'control' treatment in cancer clinical trials, or want to 'crossover' to the active treatment when their disease progresses.[21,22] The increasing number of targeted cancer therapies in development exacerbates these difficulties because there is often a lack of evidence of their safety and efficacy from systematic reviews and meta-analyses of large, placebo-controlled randomised control trials (RCTs). This is primarily because RCTs and meta-analyses of targeted therapies can only be conducted when diseases and/or biomarkers are common, exemplified by the BCR-ABL translocation in chronic myeloid leukaemia, the HER-2 mutation in breast cancer or the EGFR mutations in lung cancer.[23-26] In many cases, however, populations with specific biological profiles are very small, which means that, unless effect sizes are very large, the conduct of trials of targeted therapies comparable in power to the standards demanded by conventional RCTs can be challenging. There are also a number of other challenges associated with conducting RCTs of targeted cancer therapies, including the need to evaluate companion diagnostics alongside targeted therapies, and the difficulties associated with determining which patient group to select as the comparator in trials of targeted therapies.[21,22] While there is currently a concerted effort to develop epidemiological and statistical methods for dealing with these challenges,[21,22,27,28] regulators and payers are still challenged by calls to soften their commitment to the

principles of evidence-based medicine in order to allow access to targeted cancer therapies.[29]

The abovementioned moral, clinical, economic and scientific principles are not only difficult to achieve in isolation, but can also be in tension with each other. These tensions are evident in the frequent news reports of patients who have been 'refused' access to the 'only' cancer therapy that could have 'saved their life.'[30,31] In these accounts, narratives of benefit, rescue and equity are typically countered by arguments about avoiding harm, ensuring affordability and cost-effectiveness, and adhering to the principles of evidence-based medicine. Similar competing principles are evident in the efforts of some pharmaceutical companies and disease advocacy groups to persuade regulators and payers to be more supportive of cancer medicines, and to facilitate access to them even if they are not, or have not been shown through RCTs to be, effective or 'cost-effective' according to the criteria usually used by regulators and payers.[5,32]

The challenges of negotiating fair prices for cancer medicines

While those conducting health technology assessments of high cost cancer medicines have traditionally focused most of their attention on evidence of effectiveness and cost-effectiveness, payers are becoming increasingly concerned about the price of new cancer medicines. One example of a high cost cancer medicine recently approved is pembrolizumab (Keytruda), used to treat patients with melanoma, which is expected to cost approximately US$120,000 per patient per year.[33,34]

While payers who question high drug prices are often criticised by the pharmaceutical industry for being naïve about the costs associated with drug development, they are in fact more concerned about whether the prices being asked for new medicines are 'fair.' In this context, a fair price is one that reflects the amount that a company needs to charge in order to for it to recoup the costs of drug development, continue to innovate, and make a reasonable profit for its shareholders.

Payers who want to negotiate such fair prices find themselves in a difficult position because there is currently no agreement as to how much development really costs a new medicine. Researchers from the Boston-based Tufts University Centre for the Study of Drug Development have recently estimated that it costs $2.6 billion to bring a new drug to market, with $1.4 billion attributed to direct costs of development and $1.2 billion attributed to investment returns necessary to attract investors. This estimate also accounts for drugs that have failed at some stage during development.[35] This figure has, however, been contested by a number of people who claim that it does not account for public contributions to R&D, exaggerates the return on investment required to attract investment, and ignores experience showing that drugs can be developed for much less than the Tufts figure suggests.[36,37]

In addition, although pharmaceutical companies often complain about the enormous risks and costs they bear, the industry remains highly profitable in comparison to other industries highly dependent on R&D, while up to three to 37 times more profitable according to some.[38] Only 1.3% and 13% of revenue is channelled back into basic and clinical research respectively.[39] There is, of course, nothing wrong with companies making profits, but the pharmaceutical industry receives extensive public support in the form of incentives and tax breaks. In return for this, there is the expectation that the industry will not exploit its success, but many people question whether the pharmaceutical industry is upholding its end of the bargain.

Sceptics thus believe that medicines are priced not according to what they cost to develop or what would constitute a fair return to shareholders, but rather according to what the 'market will bear.'[40] Given that the market for cancer medicines is dominated by a few regions, most notably the US and Europe, and characterised by lack of consumer autonomy, unlike other consumer goods, patients cannot simply choose whether to partake of cancer therapy, price insensitivity on the part of patients and clinicians,[41] and information asymmetry regarding the cost of developing medicines, simply 'letting the market work' does not necessarily lead to fair prices for cancer medicines.

Negotiating limits to the funding of high cost cancer medicines

When values conflict and there is no obvious means of resolving them, and when policy decisions are complex, focusing on procedural justice becomes extremely important. This entails educating all stakeholders so they can participate in, and critique decision-making. It also entails having clear frameworks in place for specific decisions. A useful framework that can be applied is that of 'accountability for reasonableness,' which emphasises 1) public access to decisions and transparency about reasons for decisions (publicity); 2) relevance of reasons to 'fair minded' participants (relevance); 3) mechanisms for challenging or disputing decisions (appeals); and 4) regulation of the process (enforcement).[42]

For such a process to be possible for the funding of high cost cancer medicines, far greater transparency will be required. At present, decisions about access to cancer medicines are often not made transparently, largely because of the perceived need to maintain commercial confidentiality.[43] While it is understandable that companies would not want to completely reveal their commercial interests, especially about prices, without greater openness,[43] it may be impossible to achieve accountability for reasonableness and, rightly or wrongly, people will be left with the feeling that their values are not being respected.

Conclusion

New cancer medicines hold great promise, but the demand for these medicines places enormous strain on health systems. Those making decisions about funding cancer medicines face two key challenges: 1) balancing their desire to rescue those in desperate need with their responsibility to make decisions based on solid evidence of cost-effectiveness and to consider population-level opportunity costs; and 2) their need to negotiate fair prices for medicines when they lack negotiating power and when prices seem to be more reflective of what the market will bear than what the medicines are really worth. If their decisions are to be understood and have legitimacy, then they need to adhere to the principles of procedural justice and 'accountability for reasonableness.' As a starting point, companies and payers will need to be far more transparent about both the cost of drug development and the process of resource allocation.

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WHAT CONSENT MODEL IS ETHICALLY JUSTIFIABLE IN CANCER POPULATION RESEARCH?

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Abstract

The important role that explicit informed consent plays in the conduct of research cannot be denied. Inhumane medical research has prompted over many decades the articulation of guidelines, legislation, and codes to ensure that research participants are protected from the harms inherent in some forms of research. However, there are now certain kinds of research, such as large epidemiological studies or data linkage studies, which offer potentially great benefits for whole populations but which, at the same time pose minimal, if any, harms to those included. These forms of research should not be required to adhere to the traditional informed consent requirements for the reasons articulated in this paper. The paper focuses on consent options for cancer population studies and examines the ethical issues associated with each model.

'Treating research differently is harmful to public health because it slows progress on solving important problems. In this regard, our focus on privacy protection has become a hindrance to scientific progress, which cannot be justified on ethical grounds.'[1]

The number of newly diagnosed cancer cases in Australia increased from 66,393 in 1991 to 114,137 by 2009.[2] Predictive modelling for the period 2007 to 2036 suggests that the impact of cancer is expected to increase dramatically, with approximately 110% in cumulative incidence of cancer in New South Wales alone.[3] While such long-term predictions are tentative,[3] it would be imprudent not to use routinely collected cancer data in large epidemiological and data linkage studies to identify priorities, to better plan and evaluate treatment strategies and screening programs, as well as care outcomes.[4,5] Such large-scale research can also guide the development of more efficient and effective systems, and more effective evidence-based policies in a context where resources are limited.[4] A key consideration, however, is what consent model should be adopted in such research.

Facts and myths about informed consent

In any discussion about consent models, it is instructive to bear in mind important historical facts that influenced and prompted the regulation of research by ethics committees.[1,6] The inhumane Nazi experiments and the publicly funded Tuskegee Study (cdc.gov/tuskegee/timeline.htm) suffice to remind us that human experimentation was conducted over extensive periods without the ability for participants to choose whether or not to participate, without accurate information regarding the nature of the research, and with no regard for the devastating harms inflicted on human beings in the name of science.

The default position enabling participation in research is rightly explicit informed consent, as it confers numerous benefits on research participants. Protections arise from a participant's ability to decline to participate without penalty, as well as from the conditions that consent processes impose on the research, such as the provision of appropriate information and reporting requirements. Obtaining informed consent provides protections against infringements of people's privacy and ensures that the trust that must exist between the public and the research community is promoted and protected. In addition, obtaining informed consent from participants demonstrates researchers' respect for people's autonomy, thus enabling them to make the choices they consider appropriate for themselves. Gaining greater importance as vast amounts of information are gathered about us is the role that informed consent plays in providing greater levels of control over the uses to which our information will be put. Informed consent, however, is also sought to satisfy institutional or legislative requirements.[7] This is an important motivator for researchers to engage in consenting participants, but if it is the sole motivation, the spirit and effectiveness of the whole process is undermined and it simply becomes a procedural exercise underpinned by necessity rather than respect for research participants.

The importance of obtaining consent from research participants is undisputed. However, its role and function can sometimes be overstated. For example, some assert that informed consent enables participants to control the risk to which they are exposing themselves as a result of information received and their ability to withdraw from the research.[8] This sounds appealing but, in practice, may not be so clear-cut. How informed consent, the process of

which culminates in an informed decision to participate, can itself truly provide any protection against unforeseen and unintended harms is unclear. Participants in clinical trials, for example, may receive all the information required for them to make an informed choice about the level of risk they are willing to assume, but their consent does not and cannot protect them from harms that may arise during the course of the research, such as unexpected adverse events. O'Neill argues that seeking informed consent '… reduces the possibilities of deception and coercion'[9] It may be that deception is reduced, but it is difficult to argue that coercive influences are completely eradicated through the provision of informed consent, given the impact that the framing of information can have on how information is received and understood. Potential participants may, in fact, still be coerced to participate during the consent process even if '…additional accurate information is reliably available as demanded…'[9] simply as a result of *how* it is presented.

Informed consent: not the right model for all research

The requirement for explicit informed consent arose in relation to unethical human experimentation and primarily aimed to ensure that no research participant was involuntarily included in harmful research, and that associated research risks were transparently made known so participants could determine their willingness to assume certain risks.[10] The same kinds of risks are not involved in large epidemiological studies and insistence on this model has significant ethical implications relating to the ability to conduct sound research and the appropriate use of limited research funds.

Numerous considerations support the view that explicit informed consent in certain kinds of research is both inappropriate and harmful.

Impact of stringent consent requirements on population research

The constraints that stringent consent requirements impose on large-scale population research have been articulated in the literature at length.[4,11] In addition to leading to lower participation rates, the opt-in consent model also results in biased samples.[12,13] An example of the dire consequences on epidemiological cancer research is seen in Europe. The impact of additional protections imposed on registry data to align with the European data protection directive (95/46/EC) was crippling, as research and other key functions of cancer registries were severely impacted or halted in some jurisdictions.[4] Having considered the impact on epidemiological research and other key areas such as quality control, the European Commission is now in the process of replacing the directive.[4]

Protections surrounding uses of data

The articulation of multiple protections afforded to individuals' data in large epidemiological or data linkage research has also been extensive.[4,11,14] Such protections are greater guarantees for research participants than any consent process could provide and include, but are not limited to: legislation and regulation; ethics committee oversight; technical, physical and personal security protections the data are subject to; as well as the broader data sharing systems developed, all of which ensure that participants are exposed to minimal risks.[4,11,14] Participants in an Australia-wide study indicated that they had a strong preference for opt-in consent for any secondary use of their health information (92%).[15] Interestingly, this finding was not linked to concerns about privacy, as 89% of these individuals indicated. It was also shown however, that the greater the assurances about the de-identification of data, the greater the support for use of health information in research.

Benefits arising from population research

Examples of the benefits of large population studies abound, and some of these have been mentioned in the above sections.[16-20] Roder and colleagues provide a detailed account of the traditional, recent, and emerging role that cancer registries play in producing wide ranging benefits, including when these are employed in research.[19]

Harms of not using routinely collected data to benefit large populations

Cancer alone will burden communities significantly in years to come and healthcare systems will increasingly be functioning under greater constraints due to increased demands for treatments.[3] Additional resources will go towards caring for increased numbers of cancer survivors and at the same time there will be an impact from lost productivity.[3] Often not considered is the fact that our attempts to provide the best consent process results in poor quality research, poor quality outcomes from the application of biased findings, an inability to conduct certain research, and ultimately a waste of precious resources which should be used to address pressing emerging health needs.

Our difficulty seems to lie in shifting consent paradigms, not only to match the new research capabilities and the multiplicity of safeguards applied in such research, but also to respond to the new demands on health systems around the world. This paradigm shift from our excessive commitment to individual rights, to the exclusion of other important values, to a more balanced consideration of communal benefits has not yet fully occurred, despite clear statements from highly regarded research declarations and guidelines.

There may be exceptional situations where consent would be impossible or impracticable to obtain for such research

i.e. medical research using identifiable human material or data. In such situations the research may be done only after consideration and approval of a research ethics committee.

Declaration of Helsinki, Article 32, 2013 [21]

However, when the research design involves no more than minimal risk and a requirement of individual informed consent would make the conduct of the research impracticable (for example, where the research involves only excerpting data from subjects' records), the ethical review committee may waive some or all of the elements of informed consent.

CIOMS [22]

Opt-out consent model

Refusal to consent is not necessarily an indication of people's objection to the research or concern about the risks involved. In fact, one study has shown that non-involvement was primarily a result of recipients of research information failing to understand key research facts, even though the initial reason provided was a lack of interest in the study.[23] Reasons for non-participation relate to disinterest, which was by far the most prominent reason in another study, feeling too ill or too old, or simply being too busy.[24] The defining features of the opt-out consent model relate to a) people not having to take action to be part of the study; b) the fact that some participants may be missed because of change of address and are therefore included without their knowledge; and c) the fact that people are unlikely to take action not to be involved unless they have strong objections to participating. Therefore, the fact that the opt-out consent model increases research participation compared to the opt-in consent model is not surprising.[12] Opt-out consent is viewed as an ethically appropriate consent model where the risks from participation are negligible, because it appears to better balance the need for information provision to potential participants and the ability to decline, but also enables important research to proceed when complete and representative samples are required. For this reason population studies rely on this model for appropriate sample sizes that will ultimately lead to reliable research findings.

The Prostate Cancer Registry, for example, was established in Victoria in 2009 in recognition of the rising incidence in prostate cancer in Australia and the human and economic impact of this.[25] The registry uses an opt-out consent model to increase recruitment capability and aims to 'monitor quality, benchmark outcomes and to assist clinical research'[25]. The opt-out consent model has also applied to research using registry data, such as a study that enrolled men diagnosed with prostate cancer, which aimed to evaluate patterns of care.[26] Likewise, the Victorian Lung Cancer Registry was also set up in recent years using the opt-out consent model and, while not set up primarily for research, it will nevertheless enable research to be conducted using the same opt-out consent process.[27] A large UK study on prostate cancer reported on the difficulties they encountered in the conduct of their low risk research,[28] which was delayed by almost two years while approvals were being sought. Faced with these difficulties, the research group concluded that an opt-out consent process would be suitable for public health research.[28]

Numerous studies in other areas of health research have also acknowledged the need to use the opt-out consent model. For example, it was both argued for and used successfully in a study examining the link between the prescription of antibiotics and antibiotic resistance of E. coli urinary tract infection.[29] This study achieved a participation rate of 85.5% and an opt-out rate of 14.5%,[29] which may be higher than usual opt-out rates as a result of urine samples being submitted not by participants, but by the participating practices.

When asking research participants about their preferences in a study relating to vaccine safety surveillance (n=1129),[30] there was evidence that participants were not as committed to the opt-in model as might have been expected. Support for opt-out consent and no consent were favoured in this study, with 40% of participants preferring opt-out consent and 30% preferring no consent for the linkage of their child's vaccination records with their hospital records in the context of vaccine safety surveillance.[30] Other studies have shown that even if people do not believe that explicit consent is required, they often prefer to have some knowledge about how their information is used for research purposes.[31-33]

Justification for a no consent model

The opt-out consent model is generally preferred in large epidemiological research, but there are ethical issues relating to opt-out consent that have not been explored. Firstly, most researchers and ethics committees that approve research employing the opt-out consent model do not view as ethically questionable the fact that information about such studies may never reach a large proportion of the intended research participants,[34] who are therefore simply included in the research without their knowledge. The fact that some of the intended participants are aware of the research while others are not, and that some have the opportunity to decline to participate while others do not, introduces a level of inequity in research. The opt-out consent model may therefore be regarded as superficially functioning as an ethically appropriate model but, in fact, may be a model that simply aims to appease our concerns about consent. Secondly, it has been argued that applying the opt-in consent model for uses of medical records in research may undermine the principle of fairness, as it is unfair for some to refuse to participate yet reap the benefits of such research.[35] This same argument also applies to the use of data in large data sets for any

consent process that enables non-participation. Those reluctant to provide consent (whether opt-in or opt-out) may not fully appreciate at the time of refusal that in the future they or their loved ones may well be beneficiaries of research conducted. In addition to the above issues, the extensive amounts of research time and funding used to engage in prolonged consent processes given the large cohorts is not a mere inconvenience to researchers, but more worryingly, a poor use of limited public research funds, which, if used more efficiently, could yield greater benefits for the public.

Numerous studies have identified that the public lack an understanding of research processes and the multiple safeguards ensuring that research participants are protected, as shown in a systematic review of public opinion to secondary uses of existing health records.[36] The same study conducted two focus groups comprising 19 men with prostate cancer. These men also lacked considerable knowledge about research and safeguards. They became even more accepting of their information being used without consent after considering the effects of stringent consent requirements on the quality of research due to selection bias. Those men who continued to support the view that consent was required, despite the clarifications provided, were satisfied that an opt-out consent model was appropriate.[36]

Another study focusing on lay people's consent preferences relating to data linkage revealed that when people are provided with adequate information regarding both research process and safeguards, and are made aware of the impact of inflexible consent requirements, they weigh up the potential risks (including, for example, loss of privacy, loss of control over uses of their information, as well as not being respected) against the public benefits arising from large data linkage studies.[37] Most participants supported the non-consensual use of their information and none of these participants were concerned about the initial use of identifying information, as they were satisfied that the best practice processes involved provided adequate safeguards.[37] Some felt that information no longer identifying them did not have the same moral dimension as identifying information and should therefore be used without consent, provided safeguards are in place.[37]

With regard to cancer research specifically, a large scale UK study (n=2872) found that members of the British public show strong support for the confidential use of identifiable data by the National Cancer Registry for purposes other than treatment, including research.[38] Research has shown that there appear to be differences in views on sharing information for research purposes depending on the health status of those asked. For example, a 2011 US study showed that people affected by cancer are more willing to have their personal data accessed for research purposes, ranging from 59.4% to 70.4% depending on their status at the time of the study, as being survivors on treatment, living with cancer as a chronic illness, post-treatment survivors than those not affected by cancer and the general population, 55.9% and 32.4% respectively.[39]

The vast amounts of data available should be viewed as a valuable resource which can yield immeasurable benefits to large populations. Even though individual controls, such as consent, are not exercised in large scale research using existing data, increased external controls in the form of numerous safeguards are in place to ensure that harm is avoided.[40] Such protections are central to research where consent is not sought, precisely because the protection of individual privacy and minimisation of harm to individuals are regarded as being critically important.[11]

It is nevertheless also crucially important for the public to be aware of the kinds of research being conducted and the manner with which data are used. Transparency in this regard will ensure that the research community remains a trusted partner in finding solutions to the ever challenging health landscape now and into the future. Information regarding uses of health data can and should be provided at the point of collection of such data for treatment purposes, if not for any other reason, because this is a demonstration of respect towards those whose information may be used in research. Researchers and governments alike have a responsibility to educate the public about future health needs, the role that population research plays in finding solutions, the numerous safeguards that apply, the great contribution that each cancer patient makes to the development of cancer treatments and cancer care, and how information on advances can be accessed. Only when the public is armed with such insight can there be a shift away from the focus on individual needs and desires.

Conclusion

All consent models currently used have an important role to play in the conduct of research. However, discerning the correct model for the kind of research involved has proved challenging, as evidenced by the extensive literature over many decades. Our commitment to seeking consent, whether opt-in or opt-out is, in part, a result of important historical facts that must be borne in mind by researchers. However, current pressing health challenges, of which cancer is only one of many, urge us to use large population data sets wisely for the benefit of all, while ensuring that the highest levels of protection are available to all those whose information is used for secondary purposes such as population research.

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ETHICAL ISSUES AROUND PHASE I AND PHASE III CLINICAL TRIALS IN CANCER

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Abstract

The results of phase III (randomised) cancer clinical trials underpin evidence-based clinical practice. A standard comparator (control arm) is crucial so that the real value of an intervention can be tested. The goal of phase I trials is to assess the toxicity of a new drug and to determine the maximally tolerable dose to be recommended for subsequent studies to identify efficacy. Guidelines on informed consent intend to inform patients considering enrolment in clinical trials, but surveys of patients participating in cancer trials indicate that patient misunderstanding is common.

The current informed consent process commonly results in people enrolling in clinical trials without basic knowledge of the trials in which they are involved. Guidelines on informed consent intend to protect patients and promote ethical research conduct through full explanation of a proposed trial, including any possible harms and the requirement that participants freely consent. To give informed consent, participants should understand the purpose, process, risks, benefits and alternatives to research participation.[1]

Joffe et al measured the quality of understanding among participants in clinical trials of cancer treatments in Massachusetts to identify correlations of an increased understanding and to assess doctors' beliefs about clinical research.[2] They also reported evidence of therapeutic misconception in participants and doctors. They used an informed consent questionnaire (QuIC – Questionnaire Informed Consent) consisting of two parts to survey adult cancer patients who had consented to enrol in a clinical trial. Part A measures the knowledge of participants of informed consent specified in US federal regulations. Part B has 14 questions in which participants rate their understanding of important elements of the trial on a five-point scale. Response was averaged and normalised from 0-100 to generate a self-assessment score.

The QuIC was sent to 287 adult patients with cancer. Ninety per cent of respondents were satisfied with the informed consent process and most considered themselves to be well informed. Nevertheless, many did not recognise non-standard treatment (74%), the potential for incremental risk from participation (10%), the uncertain benefits to self (29%) or that trials are done mainly to benefit future patients (29%).

Methods of obtaining informed consent

Methods of obtaining informed consent evolved differently over the past 50 years without substantive information on the impact of these different practices on the patient. For clinical trials comparing randomised treatment, countries such as the UK and Australia in the 1980s allowed considerable latitude in what the patient was told. Simes et al undertook a prospective randomised study comparing two methods of obtaining consent for randomised trials of cancer treatment: a) an individual approach where the amount of information given to the patient was left to the discretion of each doctor and consent was verbal; and b) a uniform policy of total disclosure of all relevant information relevant to the clinical trial, both verbally and in a written consent form.[3] The main endpoints of the study were the effects of the two consent procedures on patients' willingness to participate in clinical trials, on their understanding of their illness and treatment, on their anxiety levels, and on their perceptions of the doctor-patient relationship.

The main effects of total disclosure compared with an individual approach were: a better understanding of treatment and side-effects and of research aspects of the treatments; less willingness to agree to randomised treatment; and increased anxiety. A repeat questionnaire given three to four weeks later no longer showed significant differences between the groups. We concluded that results clearly indicated some trade-offs when patients are given all the relevant information compared with an individual approach to obtaining consent. We hoped that our result would stimulate similar control trials of consent practices at other hospitals where the style of seeking consent may differ, but this did not eventuate and detailed written consent is now required in almost all studies on humans in the western world.

Interventions aiming to enhance informed consent

Jefford and Moore analysed the written consent form and the discussions that had taken place between clinician or investigator and patient.[1] They reviewed strategies to improve consent forms, particularly the use of plain language. Recommendations were made on discussions between investigator and patient to improve patient comprehension and satisfaction. They comment that the discussion should first include a discussion of standard treatments, followed by discussion of potential treatment as part of a clinical trial. They recommend that the patient, according to their preference, be given written information or a recording of the conversation, or both. Delaying of consent (e.g. overnight to digest what has been said and to read the written consent documents) may increase satisfaction with participation and improve understanding. Checking of understanding and asking patients whether they have any questions and offering time to think about the information and discuss with others was recommended.

Resnick has argued that despite extensive critiques of informed consent documents, there are ethical and legal reasons why they cannot be replaced by conversations with study personnel as the chief vehicle for obtaining seeking consent from patients.[4] The possible role of patient decision aids to complement the consent documents and to inform the conversation with the potential clinical trial participant has been advanced.[5] We developed a cancer clinical trial question prompt list (Question Prompt List, Clinical Trials, QPLCT) Brown et al to inform the clinical trial conversation and empower the patient to ask questions.[6] We have conducted a randomised clinical trial of a QPLCT, and the manuscript is under review.

Outcomes reported in trials of interventions to enhance the informed consent process have focused on understanding of trial information. Outcome measures and issues such as decisional conflict, trust, coercion, honesty and patient involvement have been largely ignored. The wider features of randomised trial decision-making and interventions intended to improve them merit more extensive investigation.

Audio recording informed consent discussions

We audiotaped 59 consultations in which 10 participating oncologists sought informed consent.[7] Transcripts were analysed using a coding system to identify the presence or absence of aspects of four domains for ethical communication about phase II and III clinical trials, namely: shared decision, sequencing information; type and clarity of information; and disclosure/coercion. Oncologists rarely addressed aspects of shared decision making, other than offering to delay a treatment decision. Moreover, many of those discussions scored poorly with respect to ideal content. Oncologists were rarely consistent with the recommended sequence of information provision. A rationale for randomising was only described in 46% of consultations. In 29% of consultations, oncologists made implicit statements favouring one option over another, either standard or clinical trial treatment.

Jenkins et al analysed 82 audiotaped discussions during which consent was sought for enrolment in a randomised clinical cancer trial.[8] In most interviews the concept of the trial was introduced by describing uncertainty about treatment decisions – all oncologists used the word 'trial,' but randomisation was used in only 62% of discussions. The median duration of 'consent' interviews was less than 15 minutes, and most patients signed the consent document at the first consultation when the clinical trial was discussed.

Audiotaping informed consent consultations has informed development of interventions to assist oncologists in seeking informed consent to cancer clinical trials.[9] The notion that patients receive a copy of the taped informed consent discussion merits investigating, particularly now that a high proportion of patients carry their own smart phone.[10]

The consensus opinion of ethicists, linguists, health professionals and consumers was that standard treatment options (including no treatment) should be discussed first and the doctor's recommendation should be provided before the clinical trial is introduced as another treatment option. Furthermore, doctors should routinely explain the sources of medical knowledge and the levels of evidence for the standard treatment options.[11]

Phase I trials of new cancer treatments

The first evaluation of new cancer treatments in human subjects occurs in phase I trials. Phase I trials are not designed to demonstrate tumour response. Their aim is to define the safety profile and to identify appropriate phase II trial drug doses and schedules. The rate of tumour response in phase I trials is estimated at less than 6%, with a toxicity related death rate of about 0.5%.

Tomamichel et al reported the process by which patients were informed and their consent obtained in phase I trials.[12] The procedure consisted of three consecutive conversations in which the investigator, the clinical trial research nurse and the patient's relatives or friends also participated, followed by the patient signing of a written consent form. Thirty two conversations were audio-recorded, transcribed and evaluated by one psychiatrist and one psychologist. A quantitative analysis of information provided was undertaken by calculating the percentage of patients to whom six items of information considered essential by the team had been conveyed. The qualitative analysis was performed by rating on a five-point scale (1-5, bad to excellent) the three dimensions

of the informing process for each patient. Complete information about the characteristics of the phase I drug and treatment and follow-up was given to 80% of the patients. All but one of the information items scored well (>3.5), with the one related to the assessment by the doctor of the patient's understanding at the end of the consultation scoring <3 in 53% of patients. The authors concluded that physicians should become more skilful in providing adequate information and improve the delivery of information.

People enrolled in phase I clinical trials often equate medical research with medical care. Meropol et al described and compared the perceptions of cancer patients and their oncologists regarding phase I clinical trials in the US.[13] Three hundred and twenty eight patients enrolled in phase I trials and 48 oncologists completed surveys, with domains including perceptions of potential benefits and harms from treatment, both experimental and standard, relative value of quality and length of life, and perceived content of patient oncologist consultations. Patients had high expectations regarding the outcome of treatment, with a median 60% benefit from experimental therapy. Patients predicted a higher likelihood of both benefits and adverse reactions than their oncologists. The authors concluded that the discordant perceptions of patients and oncologists may be explained by patient optimism, but there is also the possibility that communication between oncologist and patient is suboptimal. Jenkins et al evaluated the communication and informed consent process in phase I clinical trial interviews in the UK.[8] In several important areas, information was either missing or was interpreted incorrectly by patients. Discussion of prognosis was frequently absent, but alternatives to phase I treatment were explained.

Catt et al recruited patients considering phase I cancer trial enrolment to complete a 19 item study specific 'accept or decline' measure exploring hope, expectations of benefit, altruism, concerns and general perceptions of the trial information.[14] Patients were generally optimistic, and 90% consented to trial entry. However, 51% thought the trial was the only treatment option available. The four main reasons for trial entry were expectation of some medical benefit (21%), trial the best available option (21%), to maintain hope (15%) and to help research (13%). The authors concluded that achieving genuine informed consent and avoidance of therapeutic misconceptions in phase I trial patients may be difficult.

Pentz et al interviewed and surveyed phase I trial participants at an academic centre in the US and explored therapeutic misconception – misunderstanding of the research purpose or how research differs from individualised care, and therapeutic misestimation – and found misestimates of the chance of research trial benefit as greater than 20% or underestimates of risk as 0%.[15] Sixty five of 95 respondents (68%) had therapeutic misconception. Risks novel to research of requiring biopsies were rarely mentioned (3%). Most respondents thought their chance of benefit was higher and risks lower than the population chance, with 55% optimists, and 38% pessimists.

It seems that patients enrolled in phase I clinical trials often equate medical research with medical care and misunderstand the risks and potential benefits of participation in a phase I trial. Although clinical trial consent forms explain how a clinical trial will differ from standard care, the details are not succinctly addressed in the consent form.

Miller and Joffe discuss the ethical concerns raised about the quality of informed consent by participants in phase I cancer trials.[16] These concerns revolve around three dimensions: therapeutic misconception; therapeutic misestimation; and unrealistic optimism. They consider whether the observed defects in understanding and appreciation call for improvements in the process of obtaining informed consent for phase I trials. Do these defects invalidate consent? They agree that although investigators must enhance participants understanding of what phase I trials involve, the three types of misunderstanding concerning the "purpose, methods and personal risk-benefit ratio of the trials - do not necessarily render the consent of trial participants invalid."

Phase I trials in children with cancer

The informed consent process for research trials can be particularly difficult in children and adolescents. Miller et al describe hopeful and persuasive messages by paediatric oncologists during informed consent conferences.[17] Participants were children with cancer who were offered a phase I trial along with their parents and physician. The conferences were audio-recorded, and coded for physician communication of hope and persuasion. Parents completed an interview (n=60). The most frequently hopeful statement related to expectation of positive outcome, and mention of treatment options. Physicians did not mention 'no treatment' or palliative care in 68% of the conferences, nor that the disease was incurable in 85% of the conferences. Hopes and goals other than cure or longer life were rarely mentioned. A minority of the physicians stated that the disease was incurable. The authors comment that physicians have an important role helping families develop alternative goals when no curative options exist. Questions for investigation include the variability in how physicians describe phase I trials, and the relationship between the content and process of communication during informed consent conferences. Strategies to reduce physicians' 'unbalanced' presentation of the purpose and benefits of phase I trials are necessary. They observe that tempering hope with realism is one way to be compassionate with patients and families while supporting informed decision making at the end of life.

Baker et al completed interviews with a total of 57 parents and 20 patients aged 14-21, who had the option of participating in a phase I paediatric oncology clinical trial.[18] The transcribed interviews were studied using established content analysis methods. Twenty one unique suggestions for improvements were made in three themes: provision of more information, structure and presentation of the informed consent process, and suggestions conducting the process. Physician investigators should be familiar with these recommendations and interventions incorporating them should be investigated.

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CURRENT ETHICAL ISSUES IN ADVANCED CANCER CARE

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Abstract

Despite continuing advances in treatment, cancer continues to be a major cause of suffering and death, and so symptom management and end of life care will continue to be an important aspect of cancer care for the foreseeable future. An integral part of providing this care, for all clinicians involved, is understanding and managing the ethical dimensions of such care, and meeting the challenges of patient and public expectations - for relief of pain and other suffering, and for dignity and control at the time of death. This paper will highlight two aspects of care of patients with advanced cancer which are current, ethically contentious and need to be considered by all health professional working with these patients. These are medical use of cannabis and terminal sedation.

There have been many studies investigating the experiences, fears and desires of patients with advanced cancer.[1,2] These studies clearly show that some patients in this situation wish not only to have relief of pain, but to hasten their own death, for reasons related to both physical and emotional/psychological suffering.[3] Discussion of these issues inevitably raises the question of euthanasia, in particular active voluntary euthanasia, where a patient requests a doctor to give a lethal dose of a drug to end their life. Active voluntary euthanasia is not legally permitted in any state or territory of Australia (its legalisation in the Northern Territory some years ago was short-lived),[4] but there is considerable evidence that some doctors perform euthanasia anyway.[5] There is continuing pressure from patients and the public for legal access to euthanasia.[6] Euthanasia has been legalised in a number of countries world-wide,[7] notably the Netherlands, where it was officially tolerated, though still illegal, for many

years, and became fully legalised in 2002.[8] The question of euthanasia in the context of advanced cancer arises constantly and will only become more pressing with time. Physician-assisted suicide, which is legally permitted in a number of jurisdictions which do not permit active voluntary euthanasia, is also on the horizon. Physician-assisted suicide is often seen as an ethically preferable alternative to euthanasia, although it comes very close in ethical terms to actually constituting euthanasia.[9]

In Australian, questions of euthanasia and physician-assisted suicide, although important to be aware of and consider, are still theoretical. This paper highlights two aspects of care of patients with advanced cancer which are current, ethically contentious and need to be considered by all health professionals working with these patients. These are medical use of cannabis, and terminal sedation.

Medical use of cannabis

Patients with advanced cancer are one of the main groups to use cannabis for symptom relief in places where its use for medical purposes has been legalised, or at least decriminalised.[10] The claimed benefits of cannabis include pain relief,[11] relief of nausea and stimulation of appetite,[12] and in some cases relief of psychological suffering.[13] Use of cannabis for medical purposes is not currently legal in any Australian state. Even where marijuana is decriminalised for ordinary personal use, those caught with it are fined, and there is no exception for those using it for a medical condition. However, the landscape is changing quickly and Australian clinicians will soon have to deal with some significant ethical questions. Two Australian states, NSW and Victoria, will begin trials of medical cannabis in 2016-2017.[14]

These trials will involve doctors 'authorising' the use of cannabis for patients with specific medical diagnoses, with cancer being one of these. Although the term 'authorising' is used to avoid saying that doctors are prescribing cannabis,[15] the process will be very similar to prescribing, and arguably will have all the ethically significant features of prescribing. That is, it will involve a doctor making a clinical assessment that cannabis would have benefits for this patient, outweighed by possible side-effects and risks, and recommending this to the patient. In other countries, for example in Canada, not all doctors have been willing to do this.[16] There are a number of reasons why doctors might be hesitant to authorise medical cannabis, including concerns about lack of evidence about safe dosage levels, let alone robust evidence of benefit, possible short-term side-effects for those who are already unwell, and lack of knowledge about interactions with other medications which cancer patients typically take.[17] The reason for lack of evidence is primarily that medical use of cannabis has not evolved through the usual pathway of regulatory approval for clinical trials of drugs developed by pharmaceuticals, but been driven largely by patients using a (usually illicit) recreational drug for their own medicinal purposes.

Discussion of the ethics of medical use of cannabis can easily get tangled up with the broader question of the proper legal and ethical status of marijuana and other mind-altering substances, but in the medical literature, this is mostly avoided, and the debate focuses on potential benefits and risks to patient.[18] In the context of advanced cancer, this debate is significantly hampered by lack of evidence about short-term use. Evidence about side-effects such as psychosis and cognitive damage comes overwhelmingly from long-term use of marijuana, mostly by young people, in circumstances where use is illegal and the chemical constitution of the drug is not controlled.[19] This evidence is not necessarily relevant to the situation of patients with advanced cancer, who might be much older, and use a known and consistent type of cannabis over a period of months only, dying from the cancer before any long-term effects of cannabis use could become problematic.

In this regard, it is vital to consider the role of informed consent, or perhaps better, informed decision-making by the patient about use of cannabis for symptom relief. The ethical basis for informed consent is respect for patient autonomy,[20] which is closely linked to responsibility. When a patient makes an informed choice to take a drug, even when prescribed by a doctor, the patient is also taking on responsibility for that choice. It is not solely the responsibility of the doctor. This is the whole point of respect to autonomy. In a terminal situation, the ethical principle of respect for autonomy has particular significance, because life cannot be prolonged to any great extent, leaving the ethical obligations of beneficence and non-maleficence focused on prevention of the very subjective matter of suffering. Respect for the patient's autonomous decisions in relation to whether and how they are suffering, and what brings them relief of suffering, is surely central. Doctors do not need to see themselves as bearing full responsibility when a well-informed patient chooses to use cannabis for symptom relief, despite the unknowns and possible risks.

Requiring doctors to authorise medical use of cannabis by patients, as will happen in the upcoming Australian trials, is a complicating factor, making it harder for doctors to give the dignity of making choices and taking responsibility for those choices as their patient's death approaches. As noted above, authorising is very close to prescribing, and doctors would be asked to authorise something which they know has not been as rigorously tested as all other drugs that they prescribe. A possible alternative approach to legally permitting use of medical cannabis would be a system where doctors certify a patient's medical condition, and a government sets in place a system to determine whether an individual meets the criteria that have been set for medical use. In this way, a doctor does not have to make a judgement about relative benefits and risks according to usual medical standards; rather, the patient makes their own choice to seek access to medical cannabis.

It will be interesting to see how the trials of permitting medical use of cannabis play out in Victoria and NSW, and in particular what lessons can be learned about the appropriate role for doctors and other health professionals in this.

Terminal sedation

Terminal sedation is another approach to the management of refractory symptoms in advanced cancer - one that is currently part of accepted medical practice, although it continues to be somewhat ethically contentious. Palliative sedation more generally is the use of medication to decrease or completely remove awareness, either intermittently or continuously, in order to relieve suffering due to refractory symptoms at the end of life.[21] Palliative sedation is particularly relevant in advanced cancer, the reported prevalence of refractory symptoms is often quite high.[22] The contentious form of palliative sedation is continuous deep sedation until death, or 'terminal sedation'.[23] Terminal sedation is practised in a number of countries worldwide,[24] including Australia.[25]

There are a number of concerns discussed in the palliative care literature. Most guidelines on terminal sedation imply or state that it is only appropriate as a last resort, for 'intolerable suffering' due to 'refractory physical symptoms'[26] - indeed the European Association of Palliative Care (EAPC) framework describes terminal sedation when symptoms are not refractory as 'an abuse'.[27] The basis for this position would appear to be that awareness and capacity to interact have such high objective value that should not be given up when there are any other options. The EAPC framework acknowledges that 'refractoriness' and 'intolerability' are subjective, but still defines refractory symptoms as those which a clinician judges unable to be relieved.[28] This leaves open the ethically problematic possibility of a patient who wants continuous deep sedation being denied it, because a doctor does not believe that the patient's symptoms are bad enough. The second condition often put on terminal sedation is that it be used only for physical symptoms, but not for psychological or existential suffering.[21] The motivation for this concern again seems to be making sure that awareness is not taken away except as a last resort. Perhaps psychological or existential suffering is seen as more amenable to intervention than physical suffering; just needing the right personal support or psychiatric treatment. However, in the end all suffering, whether it is in response to physical or emotional stimuli, is psychological because it is related to the meaning that the patient attaches to their symptoms.[29] Given this as well as the ethical importance of respect for patient autonomy, the claim for reserving terminal sedation only for physical suffering is on shaky ethical ground.

Another concern often discussed in the literature is whether terminal sedation might be a form of euthanasia.[9] In an early paper, Billings and colleagues described terminal sedation as 'slow euthanasia'.[30] The official medical position, as succinctly stated in the ANZSPM Position Statement (2013) on The Practice of Euthanasia and Assisted Suicide, is that "Palliative sedation for the management of refractory symptoms is not euthanasia".[31] It references this statement to the EAPC framework. But for a number of reasons, the discussion continues. One concern sometimes expressed is that terminal sedation may hasten death, especially when the patient is not provided with artificial nutrition and hydration. This concern, however, is misplaced, both ethically and empirically. Empirically, a number of studies have shown that terminal sedation does not in fact hasten death.[32] Ethically speaking, the defining feature of euthanasia is that it involves an intention to cause death. It has long been accepted that medical treatment provided to relieve pain does not necessarily involve such an intention, even if it known that there is a risk of hastening death.[33] In this sense, terminal sedation is the same as use of opiates in end of life care, and clearly does not constitute euthanasia as that practice is standardly defined. As Materstvedt and colleagues argue, terminal sedation and euthanasia differ at least three crucial elements: intention, procedure and outcome.[34]

Those who take the position that terminal sedation is a form of euthanasia tend to base their case on the fourth element which Materstvedt and colleagues highlight, which is the concept of 'personhood', and the related question of when a person counts as having died. Lipuma, for example, argued recently in the *Journal of Medicine and Philosophy* that terminal sedation is ethically equivalent to euthanasia because the state of deep continuous sedation which it causes is ethically equivalent to death.[35] Terminal sedation clearly involves the intention to cause a deeply sedated state, so if that state counts as death, then terminal sedation involves the intention to cause death, and is indeed a slow form of euthanasia. The contentious step in the argument is the claim that the deeply sedated state is ethically equivalent to death. Materstvedt and colleagues base this claim on higher-brain definitions of death, in which a person is held to have died when they have lost the cognitive capacities for personhood, even if their body continues to be alive in some sense. Higher brain definitions of death have been proposed by many philosophers, ethicists and some doctors over the years, but have never been taken up by the medical profession or the law in any country. For this reason, Materstvedt's argument that terminal sedation is a form of euthanasia is unlikely to be accepted and acted upon by clinicians. However, it is important in prompting reflection about what the state of deep continuous sedation actually is, ethically and personally, and whether all patients would find it an acceptable alternative to death by euthanasia or physician-assisted suicide.

This is an important question in the on-going debate over legalisation of physician-assisted suicide and euthanasia in Australia. If terminal sedation is an effective alternative, it could be argued that these practices are unnecessary, and should not be legalised, when there are risks that

they might expand to situations which are not fully voluntary. And if they are legalised, what will be the ethical responsibility of clinicians to patients who want euthanasia, when terminal sedation is available? These are matters worth further consideration.

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SUPPORT FOR RESEARCH FUNDING 2016

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CANCER COUNCIL AUSTRALIA

Externally Funded Research Programs

New research grants			Cancer Council charitable funding amount 2016	Other funding amount for 2016	TOTAL	Research focus
Name of research program	*Recipients*	*Name of research grant*				
Priority Driven Collaborative Cancer Research Scheme	Prof Danielle Mazza Monash University	LEAD – Lung cancer diagnostic and treatment pathways: a comparison between CALD and Anglo-Australian patients.	$200,000	$0	$200,000	Lung cancer
TOTAL RESEARCH FUNDED (new program)			**$200,000**	**$0**	**$200,000**	

Continuing research grants

Priority Driven Collaborative Cancer Research Scheme	Prof Michael Friedlander Prince of Wales Hospital	An international multi-stage randomised phase III trial of dose-fractionated chemotherapy compared to standard three-weekly chemotherapy for women with newly diagnosed epithelial ovarian cancer.	$5,241	$0	$5,241	Ovarian cancer
Priority Driven Collaborative Cancer Research Scheme	Assoc Prof Sandi Hayes Queensland University of Technology	ECHO Trial: exercise during chemotherapy for ovarian cancer.	$98,000	$0	$98,000	Ovarian cancer
Priority Driven Collaborative Cancer Research Scheme	Prof Linda Mileshkin The University of Melbourne	RECUPERATE: can REaltime molecular profiling in Carcinoma of Unknown Primary improvE tReAtment ouTcomEs?	$196,000	$0	$196,000	All cancers
Priority Driven Collaborative Cancer Research Scheme	Prof Jane Young University of Sydney	Quality of life outcomes and cost effectiveness of pelvic exenteration for people with advanced rectal cancer.	$3,209	$0	$3,209	Rectal cancer

Name of research program	*Recipients*	*Name of research grant*	**Cancer Council charitable funding amount 2016**	**Other funding amount for 2016**	**TOTAL**	**Research focus**
Priority Driven Collaborative Cancer Research Scheme	Assoc Prof Trevor Leong University of Sydney	Randomised phase II/ III study of preoperative chemo-radiotherapy versus chemotherapy for resectable gastric cancer.	$924	$0	$924	Gastric cancer
Priority Driven Collaborative Cancer Research Scheme	Prof Derek Hart University of Sydney	RNA Loading of Tumour Associated Antigens and the Activation of Blood Dendritic Cells for Prostate Cancer Immunotherapy.	$4,958	$0	$4,958	Prostate cancer
International Agency for Research on Cancer	Dr Eleonora Feletto	Research Fellowship	$55,642	$0	$55,642	All cancers
TOTAL RESEARCH FUNDED (continuing program)			**$363,974**	**$0**	**$363,974**	
TOTAL RESEARCH FUNDED CANCER COUNCIL AUSTRALIA			**$563,974**	**$0**	**$563,974**	

CANCER COUNCIL ACT

Externally Funded Research Programs

New research grants

Name of research program	*Recipients*	*Name of research grant*				
Ellestan Dusting Cancer Research Bequest Grant	Prof Ross Hannan The Australian National University	Development of broad spectrum, non-genotoxic cancer treatments for acute myeloid leukaemias and multiple myeloma.	$113,334	$0	$113,334	AML, Multiple myeloma
TOTAL RESEARCH FUNDED CANCER COUNCIL ACT			**$113,334**	**$0**	**$113,334**	

CANCER COUNCIL NSW

Externally Funded Research Programs

New research grants

Name of research program	*Recipients*	*Name of research grant*				
Program Grant	Prof Murray Norris Children's Cancer Institute	PG 16-01 Improving outcomes for children with leukaemia through molecular targeted therapies.	$449,998	$0	$449,998	Leukaemia

Name of research program	*Recipients*	*Name of research grant*	**Cancer Council charitable funding amount 2016**	**Other funding amount for 2016**	**TOTAL**	**Research focus**
The Harry McPaul Program Grant	A/Prof Claire Wakefield University of New South Wales	PG 16-02 The Harry McPaul Program Grant - Development and implementation of real-world, sustainable, interventions to prevent chronic physical and mental health conditions in paediatric cancer survivors and their families.	$448,701	$0	$448,701	Childhood cancer
Program Grant	Prof John Wiggers University of Newcastle	PG 16-05 Community prevention of cancer: building the evidence base for translation into policy and practice.	$447,106	$0	$447,106	All cancers
Program Grant	Prof Rob Sanson-Fisher University of Newcastle	PG 16-09 Improving and maintaining holistic cancer survivor outcomes. A system-based program.	$446,990	$0	$446,990	All cancers
The Kay Stubbs Project Grant	Prof Susan Clark Garvan Institute of Medical Research	RG 16-02 The Kay Stubbs Project Grant - Exploring and Exploiting the DNA Methylation Profile of endocrine resistant breast cancer.	$120,000	$0	$120,000	Breast cancer
The Kay Stubbs Project Grant	Prof Peter Croucher Garvan Institute of Medical Research	RG 16-03 The Kay Stubbs Project Grant - Anti-sclerostin- a novel, dual action agent to treat multiple myeloma.	$120,000	$0	$120,000	Myeloma
Project Grant	Prof David Gottlieb University of Sydney	RG 16-04 Co-administration of malignancy and infection specific T cells after allogeneic stem cell transplant for acute leukaemia with CD34+ stem cells.	$120,000	$0	$120,000	Leukaemia
Project Grant	Prof Philip Hansbro University of Newcastle	RG 16-05 Identification of genomic mutations associated with the development and progression of lung cancer for use in early diagnosis.	$120,000	$0	$120,000	Lung cancer
Project Grant	Dr Phoebe Phillips University of New South Wales	RG 16-08 Reprogramming the tumour microenvironment by therapeutically targeting heat shock proteins in pancreatic cancer.	$120,000	$0	$120,000	Pancreatic cancer
Project Grant	A/Prof Hilda Pickett Children's Medical Research Institute	RG 16-09 Developing treatment strategies to target telomere maintenance in cancer.	$119,004	$0	$119,004	All cancers

Name of research program	*Recipients*	*Name of research grant*	**Cancer Council charitable funding amount 2016**	**Other funding amount for 2016**	**TOTAL**	**Research focus**
Project Grant	Prof Roger Reddel Children's Medical Research Institute	RG 16-10 G-quadruplex DNA: a molecular target for treatment of cancers using the Alternative Lengthening of Telomeres (ALT) mechanism.	$120,000	$0	$120,000	All cancers
The Susan and James Freeman Project Grant	A/Prof Stuart Tangye Garvan Institute of Medical Research	RG 16-11 The Susan and John Freeman Project Grant - Mechanisms underlying impaired anti-EBV and anti-tumour immunity causing B-cell lymphoma in primary immunodeficiencies.	$120,000	$0	$120,000	Lymphoma
Project Grant	Prof Xu Dong Zhang University of Newcastle	RG 16-12 Co-targeting CD47 and the MAPK pathway in melanoma.	$118,928	$0	$118,928	Melanoma
Project Grant	Dr Mustafa Khasraw University of Sydney	RG 16-13 VERTU - Veliparib, Radiotherapy and Temozolomide trial in Unmethylated MGMT Glioblastoma.	$119,959	$0	$119,959	Brain cancer
Priority-driven Collaborative Cancer Research Scheme	Prof Finlay Macrae Melbourne Health	RGPd 16-16 CaPP3: a randomized double blind dose inferiority trial of aspirin in Lynch Syndrome.	$96,780	$96,780	$193,560	Lynch syndrome
Priority-driven Collaborative Cancer Research Scheme	A/Prof Manish Patel University of Sydney	RGPd 16-17 Developing a Patient-Reported Symptom Index for Non-muscle Invasive Bladder Cancer.	$77,720	$77,720	$155,439	Bladder cancer
TOTAL RESEARCH FUNDED (new program)			**$3,165,186**	**$174,500**	**$3,339,685**	

Continuing research grants

Priority-driven Collaborative Cancer Research Scheme	Dr Lorraine O'Reilly The Walter and Eliza Hall Institute of Medical Research	RGPd 13-01 Understanding the role of NF-KB in the progression of gastric adenocarcinomas and assessment of new therapies.	$9,544	$0	$9,544	Stomach cancer
Project Grant	Prof Christopher Liddle University of Sydney	RG 14-02 Novel approaches to target cancer stem cells in liver cancer.	$119,757	$0	$119,757	Liver cancer
Project Grant	Prof Jacqui Matthews University of Sydney	RG 14-03 Developing inhibitors of the LMO4 oncoprotein.	$119,037	$0	$119,037	Breast cancer
Project Grant	Dr Jeremy Henson Lowy Research Institute UNSW	RG 14-04 Development of the C-Circle biomarker as a cancer diagnostic.	$116,149	$0	$116,149	Bone (50%), All cancers (50%)

Name of research program	*Recipients*	*Name of research grant*	**Cancer Council charitable funding amount 2016**	**Other funding amount for 2016**	**TOTAL**	**Research focus**
Project Grant	Prof John Rasko Centenary Institute	RG 14-05 Consequences of CTCF haploinsufficiency in endometrial carcinoma.	$120,000	$0	$120,000	Uterine cancer
Project Grant	Dr Lionel Hebbard University of Sydney	RG 14-06 Metabolic drivers of liver cancer progression.	$120,000	$0	$120,000	Liver cancer
Project Grant	Prof Peter Croucher Garvan Institute of Medical Research	RG 14-07 Defining the critical role of osteoclasts in multiple myeloma cell growth and activation in bone.	$120,000	$0	$120,000	Bone cancer
Project Grant	Dr Paul Timpson Garvan Institute of Medical Research	RG 14-08 Optimising ECM-targeted therapy in cancer using live intravital FRET biosensor imaging.	$119,037	$0	$119,037	Pancreatic cancer
Project Grant	Prof John Rasko Centenary Institute	RG 14-09 Consequences of CTCF mutation in acute lymphoblastic leukaemia.	$119,899	$0	$119,899	Leukaemia
Project Grant	Prof David Thwaites University of Sydney	RG 14-11 Do treatment delivery uncertainties limit the effectiveness of advanced technology radiotherapy treatments?	$119,909	$0	$119,909	All Cancers
Project Grant	Prof Michael Rogers Garvan Institute of Medical Research	RG 14-12 A new use for old drugs: Anti-tumour effects of bisphosphonates via tumour-promoting myeloid cells.	$120,000	$0	$120,000	Breast cancer
Project Grant	Dr Megan Chircop Children's Medical Research Institute	RG 14-13 Defining the cellular determinants that drive dynamin inhibitor induced cell death and in vivo efficacy against glioblastoma.	$120,000	$0	$120,000	Brain cancer
Project Grant	Dr Scott Byrne University of Sydney	RG 14-14 Skin cancer prevention and treatment by targeting sunlight-activated regulatory B cells.	$120,000	$0	$120,000	Skin (50%), Melanoma (50%)
Project Grant	Dr Hilda Pickett Children's Medical Research Institute	RG 14-16 Altered teleomeric chromatin and its role in Alternative Lengthening of Telomeres.	$106,149	$0	$106,149	All Cancers
Project Grant	Dr Glen Reid Asbestos Diseases Research Institute	RG 14-17 MicroRNA replacement: A novel therapeutic approach for malignant mesothelioma.	$114,380	$0	$114,380	Lung cancer

Name of research program	*Recipients*	*Name of research grant*	**Cancer Council charitable funding amount 2016**	**Other funding amount for 2016**	**TOTAL**	**Research focus**
Project Grant	Prof John Mattick Garvan Institute of Medical Research	RG 14-18 Modular RNA structures guiding epigenetic differentiation.	$117,719	$0	$117,719	Breast cancer
Strategic Research Partnership Grant	Prof Rob Sanson-Fisher University of Newcastle	CSR 11-02 Behavioural Science Strategic Research Partnership.	$0	$0	$0	All Cancers
Strategic Research Partnership Grant	A/Prof Gail Garvey Menzies School of Health Research	SRP 13-01 Strategic Research Partnership to improve cancer control for Indigenous Australians (STREP Ca-CIndA).	$397,529	$0	$397,529	All Cancers
Strategic Research Partnership Grant	Dr Gillian Mitchell University of Melbourne	SRP 13-02 The Inherited Cancer Connect (ICon) Partnership.	$391,952	$0	$391,952	All Cancers
Strategic Research Partnership Grant	Prof Andrew Grulich University of New South Wales	SRP 13-11 Preventing morbidity and mortality from anal cancer.	$392,796	$0	$392,796	Anal cancer
45 and Up	Prof Sally Redman Sax Institute	45 and Up Study	$400,000	$0	$400,000	All Cancers
Project Grant	Dr Nicole Verrills University of Newcastle	RG 15-03 A novel biomarker for luminal B breast cancer.	$119,859	$0	$119,859	Breast cancer
The Robyn Trinder Cancer Council NSW Project Grant	Dr Jeff Holst University of Sydney	RG15-04 Starving cancer cells: Developing nutrient uptake inhibitors as prostate cancer therapeutics.	$120,000	$0	$120,000	Prostate cancer
The Clement Saxton Cancer Council NSW Project Grant	Prof Xu Zhang University of Newcastle	RG15-05 RIP1 as a novel therapeutic target in melanoma.	$119,269	$0	$119,269	Melanoma
Project Grant	A/Prof Andrew Spillane University of Sydney	RG 15-06 EvAluation of Groin Lymphadenectomy Extent For metastatic Melanoma (Inguinal or Ilio-inguinal Lymphadenectomy for metastatic melanoma to groin lymph nodes and no pelvic disease on PET/CT Scan - a randomised controlled trial); ANZMTG 01.12 EAGLE FM Study.	$120,000	$0	$120,000	Melanoma
Project Grant	Prof David (Neil) Watkins Garvan Institute of Medical Research	RG 15-07 Rational targeting of the Hedgehog pathway to treat osteosarcoma.	$120,000	$0	$120,000	Bone cancer

Name of research program	*Recipients*	*Name of research grant*	**Cancer Council charitable funding amount 2016**	**Other funding amount for 2016**	**TOTAL**	**Research focus**
The Valerie Enid Legge Cancer Council NSW Project Grant	Prof Xu Zhang University of Newcastle	RG 15-08 Elevated INPP4B as a biomarker and therapeutic target in colorectal cancer.	$119,269	$0	$119,269	Colorectal cancer
Project Grant	Dr Jenny Wang University of NSW	RG 15-11 Identifying and targeting a novel self-renewal signalling cascade in leukemic stem cells.	$119,500	$0	$119,500	Leukaemia
Project Grant	Dr Anthony Cesare Childrens Medical Research Institute	RG 15-12 Kinsase signalling in the Intermediate-state Telomere cell cycle Arrest Pathway (ITAP) during human ageing and in disease.	$120,000	$0	$120,000	All Cancers
Project Grant	Dr Ian Johnston University of Sydney	RG 15-13 Ibudilast as a therapy for chemotherapy-induced neuropathic pain and cognitive impairments.	$119,383	$0	$119,383	All Cancers
Project Grant	Dr Catherine Caldon Garvan Institute of Medical Research	RG 15-14 Aneuploidy as a driver of endocrine resistant breast cancer.	$120,000	$0	$120,000	Breast (80%), Endocrine (20%)
Project Grant	Dr Kenneth Micklethwaite University of Sydney	RG 15-15 Gene modified T cells expressing a chimeric antigen receptor for a kappa light chain antigen to treat multiple myeloma.	$112,359	$0	$112,359	Haematological cancer
Project Grant	Dr Karen Mackenzie University of NSW	RG 15-16 Dyskerin as a novel therapeutic target in neoplastic cells.	$117,359	$0	$117,359	All Cancers
Project Grant	Prof Christine Clarke University of Sydney	RG 15-17 Role of progesterone in normal breast and its convergence with estrogen action in breast cancer.	$119,859	$0	$119,859	Breast cancer
Project Grant	A/Prof Marcel Dinger Garvan Institute of Medical Research	RG 15-19 Genetic stratification of tumours of the head, neck, pituitary and skull base - identifying prognostic and new therapeutic targets.	$120,000	$0	$120,000	Head & neck (70%), Endocrine (20%), Bone (10%)
Project Grant	Prof David (Neil) Watkins Garvan Institute of Medical Research	RG 15-20 Targeting innate chemoresistance in lung adenocarcinoma.	$106,859	$0	$106,859	Lung cancer
Project Grant	Professor Robert Baxter University of Sydney	RG 15-21 Breast cancer therapies that target IGFBP-3 signalling.	$120,000	$0	$120,000	Breast cancer

Name of research program	*Recipients*	*Name of research grant*	**Cancer Council charitable funding amount 2016**	**Other funding amount for 2016**	**TOTAL**	**Research focus**
Project Grant	A/Prof Bettina Meiser University of NSW	RG 15-22 When the stakes are high: Psychosocial and behavioural impact of genomic testing for cancer risk.	$118,923	$0	$118,923	Breast cancer
Project Grant	Prof Anna DeFazio University of Sydney	RG 15-23 Novel treatment targets in low-grade serous ovarian cancer.	$119,358	$0	$119,358	Endocrine (ovarian)
Priority driven Collaborative Cancer Research Scheme	Prof Jacob George University of Sydney	RGPd 15-18 HCC Outcomes mitigation and disease PrEvention through Clinical Partnerships (HOPE).	$170,000	$0	$170,000	Liver cancer
TOTAL RESEARCH FUNDED (continuing program)			**$5,665,854**	**$0**	**$5,665,854**	
TOTAL EXTERNAL FUNDED RESEARCH PROGRAMS (including new and continuing research grants)			**$8,831,040**	**$174,500**	**$9,005,539**	

Internally Funded Research Programs

New research grants

Name of research program			
Hepatocellular carcinoma (HCC) Outcomes mitigation and disease PrEvention through Clinical Partnerships (HOPE). Dr Monica Robotin, Mamta Porwal (Medical Scientific Issues Unit), Prof Jacob George (Westmead). Cancer Council NSW's share of Cancer Australia grant.	$0	$65,000	$65,000	Liver cancer
A phase II randomised controlled trial of high dose Vitamin D in localised prostate cancer cases with intermediate rish of progression (Pros-D). Dr Visalini Nair-Shalliker. Funded via a Prostate Cancer Foundation of Australia Grant.	$0	$58,581	$58,581	Prostate cancer
Proposal for outcome and cost-effectiveness modelling to support the Cancer Council Australia Colorectal Guideline Working Party. Prof Karen Canfell. Funded via a Cancer Council Australia Grant	$0	$100,765	$100,765	Colorectal cancer
Comparative Modeling to Inform Cervical Cancer Control Policies. Prof Karen Canfell. Funded via a US National Cancer Institute Grant.	$0	$211,906	$211,906	Cervical cancer
Effectiveness and Cost-Effectiveness of HPV Vaccination and HPV-Based Cervical Cancer Sreening Strategies in China. Prof Karen Canfell. Funded via an NHMRC Project Grant.	$0	$151,282	$151,282	Cervical cancer
Development of clinical management guidelines for the prevention of cervical cancer. Prof Karen Canfell. Funded via Cancer Council Australia Grant.	$0	$184,103	$184,103	Cervical cancer
Cancer Council NSW Prostate Cancer Group funding for core research projects and staff. A/Prof David Smith.	$192,718	$0	$192,718	Prostate cancer

Name of research program	**Cancer Council charitable funding amount 2016**	**Other funding amount for 2016**	**TOTAL**	**Research focus**
Cancer Council NSW Colorectal Group, core funding for research support staff to oversee and work on various projects. Prof Karen Canfell.	$92,954	$0	$92,954	Colorectal cancer
Cancer Council NSW Lung Group, core funding for research support staff to oversee and work on various projects.	$238,926	$0	$238,926	Lung cancer
Cancer Council NSW Methods Group, core funding for research support staff to oversee and work on various projects - Includes 45 and Up Cohort Study infrastructure funding, CLEAR Study, Linked Data Sets for Patterns of Care Study. Prof Dianne O'Connell.	$1,597,465	$0	$1,597,465	All cancers
Cancer Council NSW Health Economics Group, core funding for research support staff to oversee and work on various projects	$165,474	$0	$165,474	All cancers
Cancer Council NSW Vision 2040. Prof Karen Canfell	$25,000	$0	$25,000	All cancers
TOTAL RESEARCH FUNDED (continuing program)	**$2,312,537**	**$771,637**	**$3,084,174**	

Continuing research grants

Hepatocellular carcinoma Outcome improvements Through Translational research in WESTern Sydney (HOTTer-West) program. Dr Monica Robotin (Medical Scientific Issues Unit). Prof Jacob George (Westmead), Prof Greg Dore (The Kirby Institute). Funded by Cancer Insititute NSW.	$0	$31,000	$31,000	Liver cancer
Improve your long game campaign evaluation. Vanessa Rock (Skin Cancer Prevention Unit), Michelle Havill (Skin Cancer Prevention Unit), Christina Falsone (Hall and Partners) and Natalie McKinnon (Hall and Partners). Cancer Institute NSW Partnership funding.	$0	$150,000	$150,000	Melanoma and other skin cancers
Enhancing Community Knowledge and Engagement with Law at the End of Life. Angela Pearce (Evaluation Unit). Funded by Australian Research Council.	$0	$117,168	$117,168	All cancers
Who decides and at what cost? Angela Pearce (Evaluation Unit). NHMRC Partnership Grant with the University of Newcastle.	$0	$84,037	$84,037	All cancers
Supporting people with cancer – Locally led Aboriginal Cancer Support Networks. Kelly Williams (Policy and Advocacy Unit), Marion Carroll (Policy and Advocacy Unit); Rhian Paton-Kelly, Brenna Smith (Northern Regional Team, Community Engagement and Program Delivery Division), Kerri Lucas, Catherine Wood, Dr Jenny Hunt, Angela Nicholas (AHMRC Research team). Funded by Cancer Australia grant.	$0	$40,000	$40,000	All cancers

Name of research program	**Cancer Council charitable funding amount 2016**	**Other funding amount for 2016**	**TOTAL**	**Research focus**
An e-learning program in smoking cessation for health and community sector professionals who work with high-prevalence groups. Scott Walsberger and Amani Sobhan (Tobacco Control Unit). Funded via a Cancer Institute NSW grant.	$0	$85,380	$85,380	All cancers
Cost-effectiveness of a systems change intervention for smoking cessation in drug and alcohol treatment centres. Scott Walsberger (Tobacco Control Unit) in partnership with University of Newcastle. Funded via an NHMRC grant (Cancer Council NSW component).	$0	$5,788	$5,788	All cancers
Quantifying intake of food prepared outside home during emerging adulthood. Lyndal Wellard, Kathy Chapman, Clare Hughes, Wendy Watson (Nutrition Unit) in partnership with the University of Sydney (Prof Margret Allman-Farinelli). Funded via an Australian Research Council Linkage Grant (Cancer Council NSW's component).	$0	$24,900	$24,900	All cancers
Applying a logic model to link unhealthy food promotion to childhood obesity. Kathy Chapman, Clare Hughes (Nutrition Unit) in partnership with the University of Wollongong (Dr Bridget Kelly). Funded via an Australian Research Council Linkage Grant (Cancer Council NSW's component).	$0	$20,000	$20,000	All cancers
Healthy Living after Cancer - A Partnership Project between the NSW, WA and SA Cancer Councils and the Cancer Prevention Research Centre, University of Queensland. Liz Hing, Lorna O'Brien, Kathy Chapman (Cancer Support Unit). Funded via an NHMRC Partnership Grant with the University of Queensland (Cancer Council NSW's component).	$0	$55,575	$55,575	Localised cancer types (excluding Myeloma)
An randomised control trial (RCT) of online versus telephone-based information and support: Can electronic platforms deliver care for lung cancer patients. Lorna O'Brien (Cancer Support Unit). Funded via an NHMRC Partnership Grant with the University of Newcastle.	$0	in kind	$0	Lung cancer
Cancer Information and Support Webinar Series for the Chinese community. Annie Miller, Jill Mills, Bee Lim (Practical Support Unit). Funded via a Cancer Australia grant.	$0	$69,290	$69,290	All cancers
Internal general infrastructure funding for the operation of the Cancer Research Division - Includes Biobank. Prof Karen Canfell.	$696,009	$0	$696,009	All cancers
Learning how Australians deal with menapausal symptoms (Lady Study) - Dr Louiza Velentzis.	$19,653	$0	$19,653	Breast cancer
Cancer Council NSW Cervix, Breast and HPV group funding for core research projects and staff. Prof Karen Canfell.	$572,522	$0	$572,522	Cervical cancer
NHMRC IRIISS Funding - Independent Research Institutes Infrastructure Support Scheme 2016.	$0	$80,000	$80,000	All cancers
Testing and treatment for prostate cancer in Australia: Epidemiology and modelling. Prof Dianne O'Connell. Funded via a Prostate Cancer Foundation of Australia Grant.	$0	$122,173	$122,173	Prostate cancer
Effectiveness and cost-effectiveness of systematic screening for Lynch Syndrome in Australia. Prof Karen Canfell. Funded via an NHMRC Project Grant.	$0	$155,014	$155,014	Lynch syndrome
Evaluation of outcomes and cost-effectiveness of implementing next generation human papillomavirus (HPV) vaccination and associated primary HPV-based cervical cancer screening strategies in Australia. Prof Karen Canfell. Funded via an NHMRC Project Grant.	$0	$235,949	$235,949	Cervical cancer

Name of research program	Cancer Council charitable funding amount 2016	Other funding amount for 2016	TOTAL	Research focus
Evaluation of new screening strategies for prevention of cancer. Prof Karen Canfell. Funded via an NHMRC Career Development Fellowship Grant.	$0	$75,178	$75,178	All cancers
NZ consultancy HPV testing modeling. Prof Karen Canfell. Funded via a New Zealand Ministry of Health Grant.	$0	$384,337	$384,337	Cervical cancer
TOTAL RESEARCH FUNDED (continuing program)	**$1,288,184**	**$1,735,789**	**$3,023,973**	
TOTAL INTERNALLY FUNDED RESEARCH PROGRAMS (including new and continuing research grants)	**$3,600,721**	**$2,507,426**	**$6,108,147**	
TOTAL RESEARCH FUNDED CANCER COUNCIL NSW	**$12,431,761**	**$2,681,926**	**$15,113,686**	

CANCER COUNCIL QLD

Externally Funded Research Programs

New research grants

Name of research program	*Recipients*	*Name of research grant*	Cancer Council charitable funding amount 2016	Other funding amount for 2016	TOTAL	Research focus
Project Grant	Prof Mark Smyth - QIMR Berghofer Medical Research Institute	Checkpoint blockade and denosumab in the treatment of established primary and metastatic cancers.	$100,000	$0	$100,000	Skin cancer & Prostate cancer
Project Grant	Dr Eloise Dray - Queensland University of Technology	Deciphering the role of the protein phosphatase EYA4 in genomic maintenance and breast cancer avoidance.	$100,000	$0	$100,000	Breast cancer
Project Grant	A/Prof Raymond Steptoe - University of Queensland Diamantina Institute	Does lymphoma avoid immune destruction by inducing T-cell tolerance?	$100,000	$0	$100,000	Lymphoma
Project Grant	Dr Dominic Ng - The University of Queensland	Mitotic spindle regulation by a novel Aurora A control mechanism.	$100,000	$0	$100,000	Prevention
Project Grant	Dr Stacey Edwards - QIMR Berghofer Medical Research Institute	Identifying new breast cancer genes from GWAS.	$100,000	$0	$100,000	Breast cancer

Name of research program	*Recipients*	*Name of research grant*	**Cancer Council charitable funding amount 2016**	**Other funding amount for 2016**	**TOTAL**	**Research focus**
Project Grant	Dr Bryan Day - QIMR Berghofer Medical Research Institute	Advancing a novel therapy to target brain cancer stem cells.	$100,000	$0	$100,000	Brain cancer
Project Grant	A/Prof Vicki Whitehall - QIMR Berghofer Medical Research Institute	Sessile serrated adenoma prevention in a preclinical study.	$100,000	$0	$100,000	Bowl cancer prevention
Project Grant	Dr Michael Piper - The University of Queensland	Regulation of stem cell differentiation during cerebella development and medulloblastoma.	$100,000	$0	$100,000	Childhood Brain cancer
Project Grant	Prof Rajiv Khanna - QIMR Berghofer Medical Research Institute	Impact of immune contexture on clinical outcome of adoptive immunotherapy	$100,000	$0	$100,000	Prevention
Project Grant	Prof Lisa Chopin - Queensland University of Technology	The ghrelin receptor antisense long non-coding RNA, GHSROS, as a potential target for prostate cancer therapy.	$100,000	$0	$100,000	Prostate cancer
Project Grant	Dr Mathias Francois - The University of Queensland	SOX18-VEGF cross-regulation during angiogenesis and blood vascular development.	$100,000	$0	$100,000	Basic Science
Project Grant	Prof George Muscat - The University of Queensland	Elucidating the role of the nuclear hormone receptor RORy1 in breast cancer.	$100,000	$0	$100,000	Breast cancer
Project Grant	Prof Judith Clements - Queensland University of Technology	Targeting kallikrein proteases to improve treatment options for ovarian cancer.	$100,000	$0	$100,000	Ovarian cancer
Project Grant	Dr Kate Gartlan - QIMR Berghofer Medical Research Institute	RORyt inhibition as a novel therapeutic for the prevention of graft-versus-host disease after allogeneic stem cell transplantation.	$100,000	$0	$100,000	Leukemia
Project Grant	Dr Fares Al-Ejeh - QIMR Berghofer Medical Research Institute	The MEK5-ERK5 pathway in triple negative breast cancer: progression and therapy.	$100,000	$0	$100,000	Breast cancer
Travelling fellowships	By invitation		$65,000	$0	$65,000	All cancers

Name of research program	*Recipients*	*Name of research grant*	**Cancer Council charitable funding amount 2016**	**Other funding amount for 2016**	**TOTAL**	**Research focus**
Provision for special projects	By invitation		$56,306	$0	$56,306	All cancers
TOTAL RESEARCH FUNDED (new program)			**$1,621,306**	**$0**	**$1,621,306**	

Continuing research grants

Project Grant	Prof Geoffrey Hill - QIMR Berghofer Medical Research Institute	Understanding and optimizing Graft-versus-Myeloma effects after bone marrow transplantation.	$100,000	$0	$100,000	Blood cancer
Project Grant	Prof Kum Kum Khanna - QIMR Berghofer Medical Research Institute	The role of PC4 in the tumorigenesis and metastasis of breast cancer.	$100,000	$0	$100,000	Breast cancer
Project Grant	A/Prof Amanda Spurdle -QIMR Berghofer Medical Research Institute	Clinical classification of BRCA1/2 gene variants.	$100,000	$0	$100,000	Breast cancer
Project Grant	Prof Andreas Suhrbier - QIMR Berghofer Medical Research Institute	Regulation of mTORC2 and Ras signalling by Sin1 isoforms in pancreatic cancer.	$100,000	$0	$100,000	Pancreatic cancer
Project Grant	Prof Mark Smyth - QIMR Berghofer Medical Research Institute	A new checkpoint of cancer immunotherapy.	$100,000	$0	$100,000	Immunotherapy
Project Grant	Dr Michele Teng - QIMR Berghofer Medical Research Institute	The role of IL-23 associated cytokines in cancer immunology.	$100,000	$0	$100,000	Skin cancer
Project Grant	Dr Roberta Mazzieri - The University of Queensland	Targeting the proangiogenic and immunosuppressive tumour microenvironment in primary and metastatic breast cancer.	$100,000	$0	$100,000	Breast cancer
Project Grant	Dr Murugan Kalimutho - The University of Queensland	Cep55 is a determinant of aneuploidy cell fate in breast cancer.	$100,000	$0	$100,000	Breast cancer

Name of research program	*Recipients*	*Name of research grant*	**Cancer Council charitable funding amount 2016**	**Other funding amount for 2016**	**TOTAL**	**Research focus**
Project Grant	Dr Lachlan Coin - The University of Queensland	Using somatic copy number and methylation profiling of circulating tumour DNA to monitor heterogeneous tumour development in breast cancer.	$100,000	$0	$100,000	Breast cancer
Project Grant	Prof Thomas Gonda - The University of Queensland	A small molecule screen for inhibitors of the MYB oncoprotein.	$100,000	$0	$100,000	Leukemia
Project Grant	A/Prof Richard Sturm - The University of Queensland	Human pigmentation pathway in UV-protection and mechanisms of melanoma risk.	$100,000	$0	$100,000	Skin cancer
Project Grant	Prof Brandon Wainwright - The University of Queensland	A synthetic lethal based approach for the treatment of medulloblastoma.	$100,000	$0	$100,000	Childhood Brain cancer
Project Grant	A/Prof Helen Blanchard - Griffith University	Development of inhibitors targeting the cancer promoting protein galectin - 3.	$100,000	$0	$100,000	All cancers
Project Grant	Prof Judith Clements - Queensland University of Technology	PSA coding variants: functional analysis, multiethnic association and risk models for prostate cancer.	$100,000	$0	$100,000	Prostate cancer
Project Grant	Dr Elke Hacker - Queensland University of Technology	New technologies in skin cancer prevention.	$100,000	$0	$100,000	Skin cancer
Project Grant	A/Prof John Hooper - Mater Research Institute, University of Queensland	Targeting CDCP1 to reduce tumour burden and ascites in clear cell ovarian cancer.	$100,000	$0	$100,000	Ovarian cancer
Project Grant	Prof Peter Koopman, University of Queensland	Nodal/Cripto signalling in germ cell development and tumorigenesis.	$100,000	$0	$100,000	Testicular cancer
Project Grant	Prof Nigel McMillan, Griffith University	Novel therapeutic targets for HPV-driven cancers.	$97,000	$0	$97,000	HPV Cancers
Project Grant	Prof Colleen Nelson, Queensland University of Technology	Development of YB-1 as a therapeutic target in advanced prostate cancer.	$100,000	$0	$100,000	Prostate cancer

Name of research program	*Recipients*	*Name of research grant*	**Cancer Council charitable funding amount 2016**	**Other funding amount for 2016**	**TOTAL**	**Research focus**
Project Grant	Prof Kenneth O'Byrne, Queensland University of Technology	MyRIP and exosomes function to control genomic stability.	$100,000	$0	$100,000	Basic science
Project Grant	Dr Allison Pettit, Mater Research Institute, University of Queensland	Macrophages facilitate prostate cancer bone metastasis.	$100,000	$0	$100,000	Prostate cancer
Project Grant	Dr Pamela Pollock, Queensland University of Technology	Understanding FGFR2 activation in endometrial cancer: Novel mutations, differences in spatio-temporal signaling and alternative activating spliceforms.	$100,000	$0	$100,000	Endometrial cancer
Project Grant	Prof Alpha Yap, University of Queensland	Controlling the Rho off-switch: a novel target in breast cancer.	$100,000	$0	$100,000	Breast cancer
PhD Scholarship	Miss Arabella Youing, QIMR Berghofer Medical Research Institute	Targeted therapy and immunotherapy in breast cancer.	$30,000	$0	$30,000	Breast cancer
PhD Scholarship	Dr Matthew Roberts, University of Queensland	Improving the early detection of prostate cancer: a non-invasive, systems biology approach.	$30,000	$0	$30,000	Prostate cancer
Senior Research Fellowship	Prof Nicholas Saunders - University of Queensland	Translating basic science into better cancer treatments.	$159,845	$0	$159,845	Basic science
Senior Research Fellowship	A/Prof Sandi Hayes - Queensland University of Technology	Exercise is medicine: a non-pharmacological approach to cancer care.	$138,627	$0	$138,627	All cancers
Chair of Cancer Prevention Research	Prof Michael Kimlin - University of the Sunshine Coast	CCQ/Univ. Sunshine Coast Joint Professor of Cancer Prevention Research.	$100,000	$0	$100,000	Prevention

Name of research program	*Recipients*	*Name of research grant*	**Cancer Council charitable funding amount 2016**	**Other funding amount for 2016**	**TOTAL**	**Research focus**
CCQ/QCOG Cancer Clinical Trial Data Manager Grants	Gold Coast University Hospital Icon Cancer Care - HOCA Research Centre Mater Health Services - Medical Oncology & Palliative Care Nambour Hospital Oncology Research Australia Genesis Cancer Care Princess Alexandra Hospital - (Surgery,Haematology & Medical Oncology, Radiation Oncology) Radiation Oncology Services - Mater Centre Royal Brisbane and Women's Hospital - Gynaecological Cancer, Medical Oncology, Radiation Oncology, Brisbane Colorectal Group Lady Cilento Children's Hospital Townsville Hospital Wesley Research Institute		$459,051	$764,063	$1,223,114	All cancers
TOTAL RESEARCH FUNDED (continuing program)			**$3,214,523**	**$764,063**	**$3,978,586**	
TOTAL EXTERNAL FUNDED RESEARCH PROGRAMS (including new and continuing research grants)			**$4,835,829**	**$764,063**	**$5,599,892**	

Internally Funded Research Programs

Continuing research grants

Name of research program			
Viertel Cancer Research Centre	$4,319,683	$1,150,925	$5,470,608
Epidemiology - Cancer in Indigenous Australians - Cancer in Children - Breast Cancer Outcomes - UV Exposure, Vitamin D and Melanoma - Analysis and reporting of cancer statistics and patterns	$134,989	$144,172	$279,161
Psycho-oncology - Developing accessible and effective supportive care interventions - Identifying needs for patients and carers	$89,350	$305,754	$395,104
Community Engagement - Building capacity for cancer control agencies - Meeting the needs of regional and rural communities	$373,125	$37,106	$410,231

Name of research program	Cancer Council charitable funding amount 2016	Other funding amount for 2016	TOTAL
Australian Paediatric Cancer Registry	$57,032	$63,924	$120,956
Queensland Cancer Registry	$396,779	$939,000	$1,335,779
TOTAL INTERNALLY FUNDED RESEARCH PROGRAMS (continuing research grants)	**$5,370,958**	**$2,640,881**	**$8,011,839**
TOTAL RESEARCH FUNDED CANCER COUNCIL QLD	**$10,206,787**	**$3,404,944**	**$13,611,731**

CANCER COUNCIL SA

Externally Funded Research Programs

New research grants

Name of research program	*Recipients*	*Name of research grant*	Cancer Council charitable funding amount 2016	Other funding amount for 2016	TOTAL	Research focus
BEAT CANCER PROJECT - A joint initiative of Cancer Council SA, South Australian Health and Medical Research Institute, SA Health and University of Adelaide, University of South Australia and Flinders University						
Project Grant	Prof Richard D'Andrea, University of South Australia	The role fo the GADD45A gene in AML pathogenesis and response to therapy.	$37,500	$37,500	$75,000	Leukaemia
Project Grant	A/Prof Lisa Jamieson, University of Adelaide	The effectiveness and cost-effectiveness of oral cavity cancer screening among Aboriginal and Torres Strait Islander Australians.	$37,500	$37,500	$75,000	Oral
Project Grant	Dr Caroline Miller, SAHMRI	Sugar sweetened beverages and obesity - evidence to advance a public health response.	$37,500	$37,500	$75,000	Prevention
Project Grant	A/Prof Benedetta Sallustio, University of Adelaide	Prevention of heart damage during anthracycline cancer chemotherapy.	$37,500	$37,500	$75,000	All cancers
Project Grant	Dr Amanda Townsend, University of Adelaide	Genome-wide association study of single nucleotide polymorphisms as predictive biomarkers for sensitivity to anti-EGFR antibody therapy for metastatic colorectal cancer with wild-type RAS.	$37,500	$37,500	$75,000	Colorectal
Project Grant	Prof Eric Yeoh, University of Adelaide	Colonic and anal sphincteric dysmotility after radiotherapy for prostate cancer.	$37,500	$37,500	$75,000	Prostate

Name of research program	*Recipients*	*Name of research grant*	**Cancer Council charitable funding amount 2016**	**Other funding amount for 2016**	**TOTAL**	**Research focus**
Travel Grants		Travel Grants for 2016 yet to be awarded.	$15,000	$15,000	$30,000	All cancers
Infrastructure funding*	Mr David Walters, Breast Surgeons of Australia and New Zealand	Breast ANZ Surg Quality Audit	$40,000	$40,000	$80,000	Breast Cancer
Infrastructure funding*	Professor Bik To, SA Pathology	The establishment of the South Australian Cancer Research Biobank (SACRB) at the South Australian Health and Medical Research Institute (SAHMRI).	$248,000	$248,000	$496,000	All cancers
Infrastructure funding*	Professor Greg Goodall, Centre for Cancer Biology	Adelaide Cancer Discovery Accelerator Facility.	$125,000	$125,000	$250,000	All cancers
TOTAL RESEARCH FUNDED (new program)			**$653,000**	**$653,000**	**$1,306,000**	

Continuing research grants

BEAT CANCER PROJECT - A joint initiative of Cancer Council SA, South Australian Health and Medical Research Institute, SA Health and University of Adelaide, University of South Australia and Flinders University.						
Cancer Council SA Chair in Cancer (Behavioural Science)	Professor Carlene Wilson		$250,000	$0	$250,000	All cancer
Research Chair*	Professor Tim Hughes, University of Adelaide		$125,000	$375,000	$500,000	All cancer
Research Chair*	Professor David Roder, University of South Australia		$125,000	$375,000	$500,000	All cancer
Research Chair*	Professor Ross McKinnon, Flinders University		$125,000	$375,000	$500,000	All cancer
Principal Research Fellow*	Dr Daniel Worthley, University of Adelaide	Identifying and targeting the important supportive cells in cancer.	$105,000	$315,000	$420,000	All cancer
Principal Research Fellow*	Professor Shudong Wang, University of South Australia	New therapeutics for cancer treatment.	$105,000	$315,000	$420,000	All cancer
Principal Research Fellow*	Dr Caroline Miller, South Australian Health and Medical Research Institute (SAHMRI)	Packaging and labeling of tobacco products, food and alcohol	$105,000	$315,000	$420,000	All cancer

Name of research program	*Recipients*	*Name of research grant*	**Cancer Council charitable funding amount 2016**	**Other funding amount for 2016**	**TOTAL**	**Research focus**
Cancer Council SA Research Fellow (cancer support)	Dr Kate Fennell		$65,000	$0	$65,000	
Hospital Packages*	Professor Guy Maddern, The Queen Elizabeth Hospital	Individualised Risk Assessment and Therapeutic Intervention for Colorectal Cancer in South Australia.	$187,500	$562,500	$750,000	Colorectal Cancer
Hospital Packages*	Professor David Watson, Flinders University	Flinders Centre for Gastrointestinal Cancer Prevention.	$187,500	$562,500	$750,000	Gastrointestinal Cancer
Hospital Packages*	Professor Tim Hughes, Royal Adelaide Hospital	Advancing T-cell therapy for leukaemia and glioblastoma.	$187,500	$562,500	$750,000	Leukaemia
Partnership Grant*	Professor Alex Brown, University of South Australia	Cancer Data and Aboriginal Disparities Project.	$125,000	$375,000	$500,000	All cancer
Infrastructure Funding*	Awarded to 9 recipients	Data manager and microarray support.	$97,500	$97,500	$195,000	All cancer
Infrastructure Funding*	Mr Andrew Stanley, University of South Australia	SANT DataLink	$151,425	$454,275	$605,700	All cancer
Infrastructure Funding*	A/Prof Caroline Miller, SAHMRI	Clinical Cancer Regitstry	$70,000	$250,000	$320,000	All cancer
TOTAL RESEARCH FUNDED (continuing program)			**$2,011,425**	**$4,934,275**	**$6,945,700**	
TOTAL EXTERNAL FUNDED RESEARCH PROGRAMS (including new and continuing research grants)			**$2,664,425**	**$5,587,275**	**$8,251,700**	

Internally Funded Research Programs

Continuing research grants

Name of research program				
Behavioural Research and Evaluation Unit*	$808,855	$105,321	$914,176	
TOTAL INTERNALLY FUNDED RESEARCH PROGRAMS (continuing research grants)	**$808,855**	**$105,321**	**$914,176**	

* Based on Financial Year to 30 June 2016

TOTAL RESEARCH FUNDED CANCER COUNCIL SA	**$3,473,280**	**$5,692,596**	**$9,165,876**	

CANCER COUNCIL TASMANIA

Internally Funded Research Programs

New research programs			Cancer Council charitable funding amount 2016	Other funding amount for 2016	TOTAL	Research focus
Name of research program	*Recipients*	*Name of research grant*				
Cancer Council Tasmania Small Grants 2016	Dr Brettingham-Moore	Michael Johns in Memoram Research Grant.	$20,000	$13,000	$33,000	Cancer control
Cancer Council Tasmania Small Grants 2016	Dr Dale Kunde	The Lynne and James Cretan Research Grant.	$15,000	$13,000	$28,000	Cancer control
Cancer Council Tasmania Clinical Traials Data Management 2016 - South	To be allocated - THS (South)	Employ cancer trials data manager.	$37,500	$0	$37,500	Cancer control
Cancer Council Tasmania Clinical Traials Data Management 2016 - North	To be allocated - THS (North)	Employ cancer trials data manager.	$32,500	$0	$32,500	Cancer control
Jeanne Foster Scholarship 2016	TBA - Closing date 15 April 2016	Jeanne Foster Scholarship 2016.	$5,000	$0	$5,000	Cancer control
Evelyn Pederson Honours Scholarship 2016	Kristof Wing	Cancer Council Tasmania Evelyn Pederson Honours Scholarship 2016.	$10,000	$0	$10,000	Cancer control
TOTAL RESEARCH FUNDED (new program)			**$120,000**	**$26,000**	**$146,000**	

Continuing research programs

Name of research program				
Cancer Council Tasmania / University of Tasmania Health Science Research Fellowship 2014 - Dr Mai Frandsen - 'Reducing the burden of lung disease: using self-affirmation to reduce defensiveness towardshealth risk information among smokers (SACO)' and 'supporting expectant mother to quit (SEMQ).'	$92,446	$0	$92,446	Cancer control
Evelyn Pederson Elite Research PhD Scholarshiop 2013 - Jessica Phillips - Regulation of imtegrins by RUNX transcription factors in cancer.	$7,500	$0	$7,500	Cancer control
TOTAL RESEARCH FUNDED (continuing program)	**$99,946**	**$0**	**$99,946**	
TOTAL RESEARCH FUNDED CANCER COUNCIL TASMANIA	**$219,946**	**$26,000**	**$245,946**	

CANCER COUNCIL VICTORIA

Externally Funded Research Programs

New research grants

Name of research program	Recipients	Name of research grant	Cancer Council charitable funding amount 2016	Other funding amount for 2016	TOTAL	Research focus
Grant-in-Aid - Girls Night In	Dr Yuan Cao Peter MacCallum Cancer Centre	Blocking the spread of breast cancer spread using a protein-based therapy.	$98,837	$0	$98,837	Breast cancer
Grant-in-Aid	Dr Nicole Haynes Peter MacCallum Cancer Centre	Targeting HER2+ breast cancer with novel combination therapies.	$99,771	$0	$99,771	Breast cancer
Grant-in-Aid	Dr Peter Janes Monash University	Developing new therapies to fight drug resistant breast cancers.	$99,661	$0	$99,661	Breast cancer
Grant-in-Aid	Prof Stephen Nutt The Walter and Eliza Hall Institute of Medical Research	Exploring new molecular targets on plasma cells as therapies for multiple myeloma.	$99,800	$0	$99,800	Multiple Myeloma
Grant-in-Aid	Dr Gretchen Poortinga Peter MacCallum Cancer Centre	Understanding how cancer cells become resistant to a novel treatment of blood cancers.	$99,483	$0	$99,483	Leukaemia, Lymphoma
Grant-in-Aid	A/Prof Louise Purton St Vincent's Institute of Medical Researc	Identifying better treatments for blood cell cancers.	$100,000	$0	$100,000	Leukaemia
Grant-in-Aid	Prof Jamie Rossjohn Monash University	Exploring how tumour cells are recognised by Natural Killer cells.	$100,000	$0	$100,000	Leukaemia, Lymphoma and Haematological malignancies
Grant-in-Aid	Dr Karen Sheppard Peter MacCallum Cancer Centre	Understanding why melanomas stop responding to therapy that inhibits cells from growing.	$98,921	$0	$98,921	Melanoma
Grant-in-Aid	Prof Andreas Strasser The Walter and Eliza Hall Institute of Medical Research	How does competition between cells impact tumour development.	$100,000	$0	$100,000	Leukaemia, Lymphoma

Name of research program	*Recipients*	*Name of research grant*	**Cancer Council charitable funding amount 2016**	**Other funding amount for 2016**	**TOTAL**	**Research focus**
Grant-in-Aid	Prof Jose Villadangos The University of Melbourne	Improving cancer killing with live cell therapy.	$100,000	$0	$100,000	Leukaemia, Lymphoma
Grant-in-Aid	Dr Florian Wiede Monash University	Defining a novel immunotherapy for more effective cancer treatment.	$100,000	$0	$100,000	All cancers
Postdoctoral Fellowship	Dr Kelan Chen The Walter and Eliza Hall Institute of Medical Research	Understanding the molecular basis of how Smchd1 deficiency accelerates blood cancer progression.	$73,661	$0	$73,661	Blood cancer, B-cell lymphoma
Postdoctoral Fellowship	Dr Amy Winship Hudson Institute of Medical Research	Developing a new therapeutic for uterine cancer.	$73,661	$0	$73,661	Endometrial, Uterine
Postdoctoral Fellowship	Two fellowships to be appointed mid-year		$73,661	$0	$73,661	
Vacation Studentships	16 summer Vacation Studentships to be awarded		$30,000	$0	$30,000	
TOTAL RESEARCH FUNDED (new program)			**$1,347,456**	**$0**	**$1,347,456**	

Continuing research grants

Colebatch Fellowship	A/Prof Sherene Loi Peter MacCallum Cancer Centre	Advancing personalised medicine for breast cancer patients.	$300,000	$0	$300,000	Breast cancer
Dunlop Fellowship	A/Prof Clare Scott The Walter and Eliza Hall Institute of Medical Research	Improvement of ovarian cancer models to support preclinical development of new therapies for ovarian cancer.	$299,744	$0	$299,744	Ovarian cancer
Mesothelioma Grant	Dr Thomas John Olivia Newton-John Cancer Research Institute	Melbourne Mesothelioma Research Collaborative. A collaboration to drive clinically meaningful research into mesothelioma.	$100,000	$0	$100,000	Mesothelioma
Venture Grant	Prof Roger Daly Monash University	Identification of Novel Therapeutic Targets for Triple Negative Breast Cancer Through Integrative Kinomics.	$250,000	$0	$250,000	Breast cancer

Name of research program	*Recipients*	*Name of research grant*	**Cancer Council charitable funding amount 2016**	**Other funding amount for 2016**	**TOTAL**	**Research focus**
Venture Grant	A/Prof Mark Dawson Peter MacCallum Cancer Centre	Genome Editing of Leukaemia Stem Cells to Identify Novel Epigenetic Therapies.	$250,000	$0	$250,000	Leukaemia
Venture Grant	Prof Ricky Johnstone Peter MacCallum Cancer Centre	New treatments for multiple myeloma.	$250,000	$0	$250,000	Multiple Myeloma
Venture Grant	Prof Andreas Strasser The Walter and Eliza Hall Institute of Medical Research	Novel method to find genes that control cancer development.	$250,000	$0	$250,000	Breast, Leukaemia and Lymphoma
Grant-in-Aid	Dr Jeffrey Babon The Walter and Eliza Hall Institute of Medical Research	Inflammation and cancer.	$99,705	$0	$99,705	All cancers, Leukaemia
Grant-in-Aid	Dr Colin Clyne Hundson Institute of Medical Research	Understanding how LRH-1 controls breast cancer development.	$100,000	$0	$100,000	Breast cancer
Grant-in-Aid - Bruce Ward	A/Prof Phillip Darcy The University of Melbourne	Harnessing the immune system against cancer.	$100,000	$0	$100,000	All cancers
Grant-in-Aid	Dr Andrew Deans St Vincent's Institute of Medical Research	A new target in the chemosensitisation of tumour cells.	$100,000	$0	$100,000	Breast cancer, Leukaemia
Grant-in-Aid	Dr Walter (Doug) Fairlie Olivia Newton-John Cancer Research Institute	The molecular basis of cancer development and drug resistance.	$100,000	$0	$100,000	All cancers
Grant-in-Aid - Girls Night In	Prof Peter Fuller Hudson Institute of Medical Research	The aldosterone receptor in breast cancer.	$100,000	$0	$100,000	Breast cancer
Grant-in-Aid	Dr Stephan Glaser The Walter and Eliza Hall Institute of Medical Research	Cell death and leukaemia.	$100,000	$0	$100,000	Leukaemia

Name of research program	*Recipients*	*Name of research grant*	**Cancer Council charitable funding amount 2016**	**Other funding amount for 2016**	**TOTAL**	**Research focus**
Grant-in-Aid	A/Prof Simon Harrison The University of Melbourne	New ways to treat blood cancers.	$125,000	$0	$125,000	All cancers
Grant-in-Aid	A/Prof Kieran Harvey Peter MacCallum Cancer Centre	Upstream signalling in the Hippo tumour suppressor pathway.	$100,000	$0	$100,000	All cancers
Grant-in-Aid	Prof Ygal Haupt The University of Melbourne	Treating prostate cancer by protecting the mechanism for cancer suppression.	$100,000	$0	$100,000	Prostate cancer
Grant-in-Aid	Dr Duangporn Jamsai Monash University	Defining the role of RBM5 gene in lung cancer.	$99,418	$0	$99,418	Lung cancer
Grant-in-Aid	Prof Brendan Jenkins Hudson Institute of Medical Research	Role of the TLR2 gene in stomach cancer.	$92,149	$0	$92,149	Stomach cancer
Grant-in-Aid	Dr Gemma Kelly The Walter and Eliza Hall Institute of Medical Research	Investigating the role of the Epstein-Barr virus in certain types of lymphoma.	$100,000	$0	$100,000	Lymphoma
Grant-in-Aid	A/Prof Michael Kershaw Peter MacCallum Cancer Centre	Turning the immune system against cancer.	$100,000	$0	$100,000	Breast cancer
Grant-in-Aid	Dr James Murphy The Walter and Eliza Hall Institute of Medical Research	How does necrotic cell death contribute to colorectal cancer?	$99,826	$0	$99,826	Bowel cancer
Grant-in-Aid	A/Prof Richard Pearson The University of Melbourne	Treating cancer by arresting cancer cell growth.	$100,000	$0	$100,000	All cancers
Grant-in-Aid	Dr Leonie Quinn The University of Melbourne	Identifying new pathways driving cell growth which is fundamental to cancer initiation and progression.	$100,000	$0	$100,000	All cancers
Grant-in-Aid	Dr Mark Shackleton The University of Melbourne	Hippo pathway molecules as new targets for cancer treatment.	$100,000	$0	$100,000	Melanoma

Name of research program	*Recipients*	*Name of research grant*	**Cancer Council charitable funding amount 2016**	**Other funding amount for 2016**	**TOTAL**	**Research focus**
Grant-in-Aid	Dr Oliver Sieber The Walter and Eliza Hall Institute of Medical Research	Discovery of new colon cancer genes predictive for outcome.	$100,000	$0	$100,000	Bowel cancer
Grant-in-Aid	Dr Jake Shortt The University of Melbourne	Non-chemotherapy drug combinations to turn on suicide genes in lymphoma cells.	$99,805	$0	$99,805	Leukaemia, Lymphoma
Grant-in-Aid	Dr Michaela Waibel The University of Melbourne	Tailored therapies for blood cancer.	$99,805	$0	$99,805	Leukaemia, Myeloproliferative neoplasms (MPN), paediatric leukaemia
Postdoctoral Fellowship	Dr Jue Er (Amanda) Lee The University of Melbourne	Finding drug targets for improving glioma diagnosis and treatment.	$36,180	$0	$36,180	Glioblastoma
Postdoctoral Fellowship	Dr Julia Marchingo The Walter and Eliza Hall Institute of Medical Research	Understanding how the immune response against cancer can be enhanced.	$36,180	$0	$36,180	All cancers
Postgraduate Scholarship	Miss Hendrika Duivenvoorden La Trobe University	The role of myoepithelial proteins in blocking breast cancer invasion.	$14,776	$0	$14,776	Breast cancer
Postgraduate Scholarship	Miss Emma Nolan The Walter and Eliza Hall Institute of Medical Research	Identification of novel breast cancer genes using a transposon-based mutagenesis screen in mice.	$14,776	$0	$14,776	Breast cancer
Postgraduate Scholarship	Miss Antonia Policheni The Walter and Eliza Hall Institute of Medical Research	Discovery of cancer genes in lymphomas.	$14,776	$0	$14,776	Lymphoma
Support for medical and scientific activities			$169,000	$0	$169,000	
TOTAL RESEARCH FUNDED (continuing program)			**$4,101,140**	**$0**	**$4,101,140**	
TOTAL EXTERNAL FUNDED RESEARCH PROGRAMS (including new and continuing research grants)			**$5,448,596**	**$0**	**$5,448,596**	

Name of research program	Cancer Council charitable funding amount 2016	Other funding amount for 2016	TOTAL	Research focus
Internally Funded Research Programs				
New research programs				
(Cancer Council Victoria core funding towards these two research groups reported under 'Continuing Research Programs')				
Cancer Epidemiology Centre	$0	$72,254	$72,254	Epidemiology
Nigel Grey Fellowship Group	$0	$652,785	$652,785	Tobacco Control
TOTAL RESEARCH FUNDED (new program)	**$0**	**$725,039**	**$725,039**	
Continuing research programs				
Cancer Epidemiology Centre	$4,928,000	$3,818,155	$8,746,155	Epidemiology
Behavioural Science Division	$1,296,000	$1,615,346	$2,911,346	Behavioural Science, Prevention
Nigel Grey Fellowship Group	$242,000	$74,680	$316,680	Tobacco Control
Victorian Cancer Biobank	$0	$2,042,500	$2,042,500	Tissue Bank
Victorian Cancer Registry	$1,078,993	$2,053,809	$3,132,802	Registry
TOTAL RESEARCH FUNDED (continuing program)	**$7,544,993**	**$9,604,491**	**$17,149,484**	
TOTAL INTERNALLY FUNDED RESEARCH PROGRAMS (including new and continuing research grants)	**$7,544,993**	**$10,329,530**	**$17,874,523**	
TOTAL RESEARCH FUNDED CANCER COUNCIL VICTORIA	**$12,993,589**	**$10,329,530**	**$23,323,119**	

CANCER COUNCIL WESTERN AUSTRALIA

Cancer Council WA

Externally Funded Research Programs

New research grants

Name of research program	*Recipients*	*Name of research grant*	Cancer Council charitable funding amount 2016	Other funding amount for 2016	TOTAL	Research focus
Research Project Grants	A/Prof Pilar Blancafort Harry Perkins Institute of Medical Research	Discovery of a new genetic factor linked to a novel type of breast cancer.	$100,000	$0	$100,000	Breast cancer

Name of research program	*Recipients*	*Name of research grant*	**Cancer Council charitable funding amount 2016**	**Other funding amount for 2016**	**TOTAL**	**Research focus**
Research Project Grants	Prof Charles Bond The University of Western Australia	Understanding how a specific human protein molecule acts in neuroblastoma.	$95,246	$0	$95,246	Neuroblastoma
Research Project Grants	Prof Ruth Ganss Harry Perkins Institute of Medical Research	Can we make cancer blood vessels more normal?	$100,000	$0	$100,000	Brain and pancreatic cancers
Research Project Grants	Dr Elin Gray Edith Cowan University	Blood based test to guide treatment of metastatic melanoma.	$99,591	$0	$99,591	Melanoma
Research Project Grants	Dr Juliana Hamzah Harry Perkins Institute of Medical Research	Breaking the tumour stiffness to improve anti-cancer therapy.	$100,000	$0	$100,000	Solid tumours
Research Project Grants	Prof Prue Hart Telethon Kids Institute	Towards better outcomes after bone marrow stem cell transplantation for blood cancers.	$99,989	$0	$99,989	Blood cancers
Research Project Grants	Prof Y C Gary Lee The University of Western Australia	Australasian Malignant Pleural Effusion (AMPLE) Trial-2.	$100,000	$0	$100,000	Mesothelioma
Research Project Grants	Dr Alison McDonnell The University of Western Australia	Tracking the T cell repertoire at the tumour site in mesothelioma and lung cancer.	$99,752	$0	$99,752	Mesothelioma and lung cancer
Research Project Grants	Prof Anna Nowak The University of Western Australia	Combining radiotherapy and the immune system to fight cancer.	$97,103	$0	$97,103	Mesothelioma
Research Project Grants	A/Prof Oliver Rackham Harry Perkins Institute of Medical Research	Manipulating oncogenic non-coding RNAs to understand and treat cancer.	$100,000	$0	$100,000	All cancers
Research Project Grants	Dr Andrew Woo Harry Perkins Institute of Medical Research	Therapeutic reprogramming of metastatic tumour cells.	$100,000	$0	$100,000	Breast cancer
Suzanne Cavanagh Early Career Investigator Grant	Dr Mark Agostino Curtin University	Discovery of new anticancer drugs based on noscapine.	$14,000	$0	$14,000	All cancers

Name of research program	*Recipients*	*Name of research grant*	**Cancer Council charitable funding amount 2016**	**Other funding amount for 2016**	**TOTAL**	**Research focus**
Suzanne Cavanagh Early Career Investigator Grant	Dr Carlos Aya-Bonilla Edith Cowan University	Isolation and study of circulating melanoma cells from the blood of patients diagnosed with metastatic melanoma.	$35,000	$0	$35,000	Melanoma
Suzanne Cavanagh Early Career Investigator Grant	Dr Samantha Bowyer The University of Western Australia	The role of immune cells in blood to predict response to immunotherapy in melanoma and lung cancer.	$34,739	$0	$34,739	Melanoma and lung cancer
Suzanne Cavanagh Early Career Investigator Grant	Dr Jonathan Chee Telethon Kids Institute	'Sentinel' T cells in the skin protect against melanoma growth.	$35,000	$0	$35,000	Melanoma
Suzanne Cavanagh Early Career Investigator Grant	Dr Nicolas Hart Edith Cowan University	Is exercise safe and effective in reducing tumour activity, growth and spread for advanced prostate cancer patients with bone metastases?	$34,742	$0	$34,742	Prostate cancer
Suzanne Cavanagh Early Career Investigator Grant	Dr Annette Lim The University of Western Australia	New blood based markers for monitoring oral cancers.	$35,000	$0	$35,000	Oral cancers
Research Felllowship	Clin/A/Prof Nicholas Gottardo Telethon Kids Institute	Improving the cure rates for the childhood brain cancer, medulloblastoma.	$100,000	$0	$100,000	Brain cancer
Postdoctoral Fellowship	Dr Yi Huang The University of Western Australia	To develop blood tests that can predict the risk of primary liver cancer.	$45,000	$0	$45,000	Liver cancer
Postdoctoral Fellowship	Dr Rajesh Thomas Institute of Respiratory Health	Improving fluid removal methods to optimise benefits in patients with cancer-related fluid collection in the chest.	$45,000	$0	$45,000	Mesothelioma
PhD Top Up Scholarship	Ms Meenu Chopra Harry Perkins Institute of Medical Research	Improving tumour detection using multimodality imaging.	$12,000	$0	$12,000	Breast and liver cancer
Honours Scholarship	Mr Aaron Beasley Edith Cowan University	Markers in single tumour cells within the blood for determining the spread of uveal melanoma.	$7,500	$0	$7,500	Melanoma
Honours Scholarship	Ms Lelinh Duong Curtin University	Investigating changes in the function of key immune cells, known as macrophages, during aging to determine if they become enablers of tumour growth in the elderly.	$7,500	$0	$7,500	All cancers

Name of research program	*Recipients*	*Name of research grant*	**Cancer Council charitable funding amount 2016**	**Other funding amount for 2016**	**TOTAL**	**Research focus**
Honours Scholarship	Ms Katherine Landwehr The University of Western Australia	Chemotherapy and the immune response in malignant mesothelioma.	$7,500	$0	$7,500	Mesothelioma
Honours Scholarship	Ms Emma Port The University of Western Australia	Using pleural effusion to track anti-cancer immune responses in patients with mesothelioma and lung cancer.	$7,500	$0	$7,500	Mesothelioma and lung cancer
Vacation Scholarship	Ms Lelinh Duong Curtin University	Investigating the impact of aging on the role of the immune system during tumour growth.	$3,000	$0	$3,000	All cancers
Vacation Scholarship	Ms Angela Farmer Curtin University	Melanoma cell adhesion molecule contributes to melanoma invasion.	$3,000	$0	$3,000	Melanoma
Vacation Scholarship	Ms Saumya Rajgopal Harry Perkins Institute of Medical Research	Developing targeted drug delivery for cancer therapy.	$3,000	$0	$3,000	Solid tumours
Vacation Scholarship	Ms Benedicta Santoso Edith Cowan University	Role of the receptor activator of NFKB on resistance of melanoma cells to treatment with vemurafenib and dabrafenib.	$3,000	$0	$3,000	Melanoma
Vacation Scholarship	Ms Joanna Tedeschi The University of Western Australia	New blood based markers for monitoring oral cancers.	$3,000	$0	$3,000	Oral cancers
Vacation Scholarship	Ms Helen Tucker Curtin University	Improvement of pre-operative assessment of renal cell carcinoma with use of a 3D CT visualisation tool.	$3,000	$0	$3,000	Renal cancer
Vacation Scholarship	Ms Jinglin Yao Curtin University	What education do radiation therapists provide to patients undergoing radiation therapy for breast cancer.	$3,000	$0	$3,000	Psycho-oncology
Vacation Scholarship	Mr Gary Zhang Telethon Kids Institute	The effects of sun exposure on the health and wellness, in particular body fat and fitness levels, of breast and prostate cancer patients who have undergone an exercise intervention.	$3,000	$0	$3,000	Breast and prostate cancer
James Crofts Hope Foundation Vacation Scholarship	Ms Clare Tancabel The University of Western Australia	New tools for better neurosurgery: techniques to quantify tumour fluorescence to guide surgical resection.	$3,000	$0	$3,000	Brain cancer
Travel Grants			$15,000	$0	$15,000	

Name of research program	*Recipients*	*Name of research grant*	**Cancer Council charitable funding amount 2016**	**Other funding amount for 2016**	**TOTAL**	**Research focus**
Cancer Epidemiology Initiative	Prof Lin Fritschi Curtin University	Cancer Council Western Australia Cancer Epidemiology Network.	$115,000	$0	$115,000	Prevention
John Nott Cancer Fellowship Travel Support Fund	A/Prof Guatham Sethi National University of Singapore	Visiting Perth to collaborate with researchers at UWA and Curtin.	$5,000	$0	$5,000	
Awards	Dr Belinda Guo The University of Western Australia	Early Career Cancer Researcher of the Year.	$10,000	$0	$10,000	
Awards	Prof Wallace Langdon The University of Western Australia	Cancer Researcher of the Year.	$20,000	$0	$20,000	
Awards	A/Prof Steven Mutsaers The University of Western Australia	Cancer Research Career Achievement Award.	$20,000	$0	$20,000	
TOTAL RESEARCH FUNDED (new program)			**$1,724,162**	**$0**	**$1,724,162**	

Continuing research grants

Capacity Building and Collaboration Grant	Prof Eric Moses, Dr Iris Lansdorp-Vogelar, Dr Hooi Ee, Prof Rob Donovan, Prof David Preen, Ms Delia Hendrie, Prof Jack Goldblatt, A/Prof Mark Jenkins; Prof Peter O'Leary Curtin University, The University of Western Australia, King Edward Memorial Hospital and Sir Charles Gairdner Hospital	Integrating personalized genomics into risk-stratification models of population screening for cancer.	$400,000	$0	$400,000	
Strategic Research Partnership (STREP) Grants	A/Prof Gail Garvey Menzies School of Health	To improve cancer control for Indigenous Australians.	$100,000	$0	$100,000	
Infrastructure Grant	Curtin University	WA Cancer Prevention Research Unit (WACPRU).	$160,000	$0	$160,000	
Professorial Chair	Prof Michael Millward The University of Western Australia	Chair in Clinical Cancer Research.	$362,079	$0	$362,079	

Name of research program	*Recipients*	*Name of research grant*	**Cancer Council charitable funding amount 2016**	**Other funding amount for 2016**	**TOTAL**
Research Felllowship	Dr Pilar Blancafort Harry Perkins Institute of Medical Research	Epigenetic tailoring of the cancer genome: novel targeted strategies for the treatment of aggressive breast cancer.	$20,000	$0	$20,000
Research Felllowship	Prof Lin Fritschi Curtin University	Occupational cancer epidemiology.	$20,000	$0	$20,000
Research Felllowship	Prof Daniel Galvao Edith Cowan University	Improving health outcomes after cancer through exercise: a survivorship program.	$80,000	$0	$80,000
Research Felllowship	A/Prof Oliver Rackham Harry Perkins Institute of Medical Research	Correcting gene expression in pancreatic cancer.	$100,000	$0	$100,000
Youngberg Women's Cancer Research Fellowship	A/Prof Vincent Wallace The University of Western Australia	Improving breast cancer surgery with a tool that helps the surgeon remove all of the tumour in one go.	$100,000	$0	$100,000
Clinical Research Fellowship	Dr Andy Redfern Fiona Stanley Hospital	Clinical Research Fellowship in Cancer.	$100,000	$0	$100,000
Postdoctoral Fellowship	Dr Belinda Guo The University of Western Australia		$75,000	$0	$75,000
Postdoctoral Fellowship	Dr Angela Ives The University of Western Australia	Upper gastro-intestinal surgery as treatment for cancer: what influences its use and outcomes?	$60,000	$0	$60,000
Postdoctoral Fellowship	Dr Carolyn McIntyre Edith Cowan University	Exercise as medicine in the management of mesothelioma.	$75,000	$0	$75,000
PhD Top Up Scholarship	Ms Britt Clynick The University of Western Australia	Investigation of carcinomas of unknown primary.	$12,000	$0	$12,000
PhD Top Up Scholarship	Ms Olivia Ruhen The Unversity of Western Australia	A holistic approach to improve breast cancer care.	$12,000	$0	$12,000
Lions Cancer Institute PhD Top Up Scholarship	Ms Tracy Seymour The Unversity of Western Australia	The role of stem cell genes in aggressive human brain tumours.	$12,000	$0	$12,000
TOTAL RESEARCH FUNDED (continuing program)			**$1,688,079**	**$0**	**$1,688,079**
TOTAL RESEARCH FUNDED CANCER COUNCIL WA			**$3,412,241**	**$0**	**$3,412,241**

BEHAVIOURAL RESEARCH AND EVALUATION UNIT (BREU), CANCER COUNCIL SA

Social work service at Cancer Council SA lodges: an evaluation of the impact on distress and support provided to rural cancer patients

Cancer Council SA operates two accommodation lodges for rural Australians who require cancer treatment in Adelaide. An on-site social work service assists guests to manage the dislocation of travel and the psychosocial impact of their diagnosis and treatment. The social work service prioritises guests with high needs. The main objective of the evaluation was to describe the impact of the social work service on the ability of guests to manage the challenges associated with their cancer diagnosis and treatment.

Guests who stayed at the lodges during June 2015 were mailed a questionnaire collecting information about their experience of support and level of distress upon arrival to and departure from the lodge. Awareness of the service was also assessed. The sample comprised 149 guests. Contact with a social worker (n=88) was associated with greater perceived support in several areas (e.g. managing difficult emotions, feeling more able to ask questions of their health care team) and a greater reduction in distress between arrival and departure, compared with no contact. Just over half (52%) of guests who did not see a social worker were unaware of the service. The demographic characteristics of guests who did and did not have contact with the service were comparable. The study concluded that the social work service provided effective psychosocial support to high needs guests receiving treatment away from home. Further research could investigate the impact of a social work service in the acute care setting and explore other ways to provide information and support, including group programs.

Physical activity program at the lodges

In 2016, Cancer Council SA will commence a 'Physical activity and cancer' program at the Cancer Council SA lodges. The program is designed for long-stay guests (i.e. four weeks or more) who are receiving cancer treatment, but will be open to all guests who wish to participate. The key objectives of the program are to:

- educate guests on the importance, safety and benefits of maintaining physical activity and avoiding too much sedentary behaviour during (and after) treatment
- inform guests about how they can be physically active during their stay at the lodge
- provide information, equipment and activity opportunities within the lodge environment to support guests to be physically active.

The program will include two sessions run by a qualified exercise physiologist. The first session will include an educational component, functional testing, discussion about ways to be active, and demonstration of simple exercises that can be performed at the lodges (or at home). Guests will be provided with a pedometer to track their step count. The follow-up session will include functional testing (with feedback on changes in function), discussion about progress, barriers and concerns, reinforcement of key messages from the initial session, and encouragement to continue with any changes made. Our aim is to increase awareness of the importance of physical activity during cancer treatment, and to encourage uptake of physical activity and avoidance of too much sedentary behaviour among long-stay guests at the lodges.

CENTRE FOR BEHAVIOURAL RESEARCH IN CANCER (CBRC), VICTORIA

Implementing sun protective policies and actions in Victorian secondary schools study

Sun exposure during childhood and adolescence is a strong predictor of lifetime skin cancer risk, including for melanoma, which is a leading cancer among adolescents. SunSmart has been working with schools to support their sun protection practices since 1989. Over 90% of Victorian primary schools have joined the SunSmart member program, under which schools that meet a minimum set of standards (including a written policy) are recognised as SunSmart schools. The SunSmart team has been actively engaging with Victorian secondary schools for the last five years to ensure that the policies and practices established in primary school carry over to the secondary years. There is currently little published literature to inform best practice in skin cancer prevention in the secondary

school setting. The SunSmart team is conducting a mixed methods study on sun protective policies and actions in Victorian secondary schools, which will inform the future support that SunSmart offers to secondary schools. One of the aims is to better understand what actions secondary schools are currently taking to help students and staff to achieve a healthy UV balance. To answer this question, 250 schools were randomly selected to participate in a short online survey. The team also aims to explore barriers, opportunities and successes in sun protection in this setting, using a series of focus groups and interviews with staff members. Analysis of these results is underway.

NEWCASTLE CANCER CONTROL COLLABORATIVE (NEW-3C), NSW

Improving and maintaining holistic cancer survivor outcomes

New-3C has recently celebrated the award of a five year Cancer Council NSW program grant to undertake translational research across the cancer trajectory, from diagnosis to end of life care. The research will be undertaken by an experienced, multi-disciplinary team. The program has a strong focus on building capacity of early-mid career researchers and meaningful engagement of consumers in research development.

Cancer survivors face a myriad of challenges to their physical, emotional and social wellbeing from diagnosis through to the end of life. Research has highlighted a gap between what occurs and what should occur in relation to the care of survivors. For example, cancer care providers do not always recognise or manage the survivors' physical, emotional and social concerns. Many survivors are not involved in decisions about their care, and do not receive enough information about their disease, prognosis and treatment. Previous research has focused on trying to change the behaviour of survivors and individual cancer care providers in order to improve the quality of care received by survivors and their psychosocial wellbeing. However, this work has not achieved the desired improvements. If all survivors are to receive high quality care that meets their needs, we must modify the system in which care is provided.

This program will determine the effectiveness and cost effectiveness of a multi-faceted, system-based intervention in improving cancer survivors' levels of anxiety, depression, unmet needs and quality of life. Adult cancer survivors will be recruited from participating medical oncology outpatient units during the study period. Survivors attending their outpatient clinic appointment will be asked, by a trained research assistant, to complete an electronic survey while they wait to attend their clinic appointment. Each oncology unit will receive a 12-month system-based intervention, designed to improve the delivery of high-quality patient centred care. The intervention includes: quality assurance working parties of consumers, cancer care providers and hospital administrators at each oncology unit; a pre-intervention workshop at each unit, which will involve setting goals, identifying factors that might prevent best-practice care, and training staff on how to provide the best psychosocial care possible; web-based resources (one for staff and one for survivors) providing information and support; and monthly feedback reports of the unit's performance using the data collected from survivor surveys. The impact of the intervention on anxiety, depression, unmet needs and quality of life outcomes will be examined. Quality of care will be assessed across 12 domains: treatment decision making; continuity of care; preparation for potentially threatening procedures; prognosis disclosure; psychological screening; self-management and follow-up; end-of-life care planning; palliative care; communication and information provision; involvement of supportive others; financial impact of cancer; and peer support. If successful, the intervention could be applied to clinics across Australia. The study acknowledges the need for a holistic, patient-centred approach to care that addresses the issues that are important to survivors from diagnosis to end-of-life, with the potential to result in immediate benefits for survivors.

WESTERN AUSTRALIAN CANCER PREVENTION RESEARCH UNIT (WACPRU), CURTIN UNIVERSITY

We're more SunSmart, but more sunscreen dependent

In collaboration with Cancer Council WA, WACPRU recently completed a longitudinal analysis of Western Australians' sun protection behaviours. Over a five year period (2007/08 to 2011/12), more than 2000 adults reported how often they engage in specific sun protection actions including wearing a hat, wearing protective clothing, applying sunscreen, and using sunglasses. They were also asked to nominate which sun protection strategy they thought would be most effective in protecting their skin from the sun. The results showed increasing sunscreen use over time and consistently high usage levels of sunglasses. Around two-thirds of respondents nominated sunscreen as the most effective skin-protection strategy. Although current evidence suggests that wearing protective clothing and staying in the shade are the most efficacious strategies when outside in the middle of the day, reported participation in these activities did not improve over time. These results suggest that the sunscreen message is being heard, understood, and enacted, but this may be at the expense of other, potentially more effective, sun protection strategies.

There are practical implications of these results. In the first instance, it may be time for health promotion campaigns to focus on sun protection strategies other than (or in addition to) sunscreen to ensure Australians understand the need for a multi-pronged approach to being SunSmart. Second, while 'no hat, no play' and standard uniform policies in schools can increase sun protection among children, there is a need to translate these outcomes among the adult population. Creative strategies are required to make wearing hats and other protective clothing desirable and comfortable for adults.

The results of this study have been reported in the *Journal of Cancer Education* and the *Australasian Journal of Dermatology*.

How do we do surveys now that many people don't have home phones?

Historically, if we wanted to know what Australians think and do about cancer prevention, we could just use the White Pages to select random telephone numbers and call people at home. Today things are much more complicated. Many people do not own a landline, and those who do often screen their calls with an answering machine. This makes it very difficult to access the random samples required for valid and reliable statistical analysis. There are various other options available, such as using web panels to survey people who have registered as being interested in completing surveys for small monetary incentives. WACPRU and Cancer Council WA ran an experiment to assess whether those individuals responding to a telephone survey provide different responses to those responding to an online survey delivered via a web panel. The results, published in the *Journal of Public Health*, showed that where there were differences between the samples, the online respondents tended to report more favourable outcomes (e.g. awareness of a health campaign and subsequent behavioural improvements). This suggests that rather than migrating entirely to online samples, it may be prudent to combine telephone and online data collection methods to minimise losses in data comparability over time.

CANCER COUNCIL AUSTRALIA

Cancer Council publishes clinical guidelines for PSA testing

Health professionals in Australia now have access to evidence-based recommendations for using the prostate specific antigen (PSA) blood test to assess prostate cancer risk and manage test-detected patients, following the publication of new clinical practice guidelines.

Developed by Cancer Council Australia's Clinical Guidelines Network through a partnership with the Prostate Cancer Foundation of Australia, the guidelines' recommendations have been approved by the National Health and Medical Research Council.

Published on Cancer Council's Cancer Guidelines Wiki, the guidelines support health professionals involved in localised prostate cancer risk assessment, surveillance and treatment. Recommendations also cover matters such as retesting, active surveillance, watchful waiting and biopsy.

Though not recommended as a population screening program, the PSA test remains in widespread use. The guidelines aim to help health professionals navigate the dilemma of informing men about the risks and benefits of testing, prevent scenarios where PSA tests are conducted without patient consent and reduce over-treatment.

The recommendations were developed throug asystematic review of the evidence and consensus on its interpretation by a working group of leading epidemiologists, medical

and radiation oncologists, urologists, GPs, allied health professionals and consumers.

Cancer Council and the Prostate Cancer Foundation are currently working on a decision aid based on the guidelines, to assist GPs to discuss the appropriateness of PSA testing with their patients.

New guidance on sun protection and vitamin D

Cancer Council has published new guidance on how to balance sun protection to reduce skin cancer risk with maintaining vitamin D levels for good health.

Jointly developed by Cancer Council, The Australasian College of Dermatologists, Australian and New Zealand Bone and Mineral Society, Osteoporosis Australia and The Endocrine Society of Australia, the position statement aims to provide clearer and simpler advice for the public.

Mixed messaging in recent years has resulted in some uncertainty in the community about how to get the right balance of sun protection and vitamin D intake. According to Cancer Council's latest National Sun Survey, 28 per cent of Australian adults expressed concern about their vitamin D levels and a quarter had been advised by their GP to get more vitamin D.

The recommendations state that protection from the sun's UV rays is not required when the UV Index is below 3, which is the case during winter in southern areas of Australia such as Hobart, Melbourne, Adelaide, Perth, Canberra and Sydney. During those periods Australians are encouraged to spend some time outdoors, preferably being physically active, in the middle of the day.

The position statement contains specific guidance for people considered at higher risk of vitamin D deficiency, for example those: with naturally very dark skinned; who live largely indoors; who have conditions causing poor absorption of calcium and vitamin D; or who cover up for religious or cultural reasons.

The position statement is available at www.cancer.org.au/VitaminDposition. Cancer Council's SunSmart app for mobile devices provides advice on when you do and don't need sun protection for locations across Australia.

Australian cancer prevalence exceeds one million

More than one million Australians are now living with cancer or have survived a diagnosis of cancer.

The new estimate, released by Cancer Council for World Cancer Day, reflects progress in healthcare but also highlights new challenges.

Around 130,000 Australians will be diagnosed with cancer this year, with 65 per cent expected to survive more than five years and many going into permanent remission.

While survival is improving, incidence is also on the rise due to population growth and population ageing. As more people are diagnosed with and live with cancer, the health system has come under increasing pressure, not just in terms of treatment issues like the cost of medicines, but meeting the ongoing physical and emotional needs of patients and survivors.

The burden of life years lost to cancer is also increasing relative to other disease groups, while inequity remains a major issue, with Australians who have certain types of cancer or fall within particular demographic/socioeconomic groups faring worse overall in treatment and care outcomes, as well as early detection and prevention.

Cancer Council will be increasing its focus in coming years on working with governments and the health professions to address system and equity issues, particularly health system efficiencies and more targeted expenditures to reduce the cancer burden in Australia.

Cancer Council and Australian Cancer Survivorship Centre – On the Road to Recovery CALD project

On the road to recovery is a collaboration designed to produce translated booklets to assist cancer patients and survivors from cultural and linguistically diverse communities.

Developed by Cancer Council in conjunction with the Peter MacCallum Cancer Centre, the project has been supported with funding from Cancer Australia.

Stage one of the project saw production booklets on cancer survivorship in Cantonese, Mandarin and Greek, drawing from Cancer Council's 'Understanding Cancer' series, including: *Living well after cancer*; *Emotions and cancer*; *Coping with cancer fatigue*; *Cancer, work and you*; *Cancer care and your rights*; and *Understanding complementary therapies*.

Stage two is now complete with publication of bilingual booklets for the Arabic and Vietnamese speaking communities.

Booklets are available from the Australian Cancer Survivorship Centre, Peter MacCallum Cancer Centre, through Cancer Council 13 11 20 Information and Support, or online in PDF format at cancer.org.au/publicationsCALD.

For details contact Jane Roy on 02 8063 4100 or jane.roy@cancer.org.au

Clinical Guidelines Network

Cancer Council Australia aims to produce concise, clinically relevant and up-to-date electronic clinical practice guidelines for health professionals, accessible on its wiki platform at wiki.cancer.org.au

For more information or to be added to the mailing list for notification of guidelines open for public consultation or guidelines launches, please email guidelines@cancer.org.au.

Guideline news

Following their publication in January, *Clinical practice guidelines for PSA testing and early management of test-detected prostate cancer* have been endorsed by a number of professional colleges and societies.

Endorsements to date include The Royal Australian College of General Practitioners, The Royal College of Pathologists of Australasia, Urological Society of Australia and New Zealand, The Royal Australian and New Zealand College of Radiologists and Australian College of Rural and Remote Medicine.

Health professional organisations interested in endorsing the guidelines can contact the Head, Clinical Guidelines Network, on 02 8063 4100 or email guidelines@cancer.org.au

Guidelines in development

Guideline	Status
National Cervical Screening Program: Guidelines for the management of screen detected abnormalities, screening in specific populations and investigation of abnormal vaginal bleeding	Finalisation of guidelines post public consultation. Email guidelines@cancer.org.au to be notified when the guidelines are published.
Clinical practice guidelines for the prevention, diagnosis and management of lung cancer	Systematic reviews in progress
Clinical practice guidelines for the diagnosis and management of melanoma	Systematic reviews in progress
Clinical practice guidelines for the prevention, early detection and management of colorectal cancer	Systematic reviews in progress
Clinical practice guidelines for the management of sarcoma in AYA	Systematic reviews in progress

Cancer Council Australia guidelines

Guideline	Last updated
Clinical practice guidelines for PSA testing and early management of test-detected prostate cancer	August 2015
Clinical practice guidelines for the diagnosis and management of Barrett's oesophagus and early oesophageal adenocarcinoma	September 2014
Clinical practice guidelines for the treatment of lung cancer	December 2012 (update in progress)
Management of apparent early stage endometrial cancer	March 2012
Clinical practice guidelines for surveillance colonoscopy	December 2011
Clinical practice guidelines for the management of adult onset sarcoma	February 2015
Clinical practice guidelines for the management of locally advanced and metastatic prostate cancer	April 2010

Clinical Oncology Society of Australia guidelines

Guideline	Last updated
Clinical practice guidelines for teleoncology	December 2015
Diagnosis and management of gastroenteropancreatic neuroendocrine tumours guidance	August 2012
Evidence-based practice guidelines for the nutritional management of adult patients with head and neck cancer	August 2013
Early detection of cancer in AYAs	May 2012
AYA cancer fertility preservation	September 2012
Psychosocial management of AYA cancer patients	June 2012

Other guidelines

Guideline	Last updated
Cancer pain management	August 2013

CLINICAL ONCOLOGY SOCIETY OF AUSTRALIA

COSA Annual Scientific Meeting (ASM)

In 2016, COSA is partnering with the ANZ Breast Cancer Trials Group to host a joint breast cancer focused conference, 15-17 November 2016 at the Gold Coast Convention and Exhibition Centre. The Organising Committee has made excellent progress with the program, with a draft available on the conference website www.cosa2016.org

The invited international speakers confirmed to date are:

- Dr Laura Esserman – Professor of Surgery and Radiology at the University of California. Internationally recognised as one of the leading experts in breast cancer research and treatment, Dr Esserman's work in breast cancer spans the spectrum from basic science to public policy issues and the impact of both on the delivery of clinical care.
- Dr Deborah Fenlon – Associate Professor in the Faculty of Health of Sciences, at the University of Southampton. With a background in nursing women with breast cancer, Dr Fenlon interest is in researching and promoting health and wellbeing in people who have had cancer.
- Dr Jay Harris – Professor and Chair of the Department of Radiation Oncology at Dana-Farber Cancer Institute, Boston. Dr Harris' principal research interest is the use of radiation therapy in the multidisciplinary management of breast cancer. In particular, the development and optimisation of breast-conserving therapy for patients with invasive breast cancer and ductal carcinoma in situ.
- Dr Melinda Irwin – Professor of Epidemiology at Yale University. Dr Irwin is a prominent leader in the field of behavioural lifestyle factors and cancer risk and mortality.

Among the many local Australian experts, we have also secured the participation of Dr Ranjana Srivastava – an eminent oncologist from Melbourne. Dr Srivastava is a regular columnist for *The Guardian* newspaper, and presenter of a monthly health segment on ABC television and Radio National. Her writing has been published worldwide, including in *Time Magazine* and *The Week*, *The New England Journal of Medicine*, *Lancet*, *Journal of the American Medical Association* and *Journal of Hospice and Palliative Care Management*. In 2008, her story 'Ode to a Patient' won the Cancer Council Victoria Arts Award for outstanding writing.

Venues and dates for future COSA ASMs are as follows; themes are yet to be determined:

- 2017, 13-15 November, Sydney International Convention Centre.
- 2018, 13-15 November, Perth Convention and Exhibition Centre.
- 2019, 12-14 November, Adelaide Convention Centre.

Other educational opportunities

In addition to the ASM, COSA is hosting a number of other educational events for members in 2016.

- ATOM – the Advanced Trainees Oncology Meeting is a unique annual educational symposium for medical oncology trainees with a program developed by the trainees. Held in March and attended by over 50 delegates, this program provides a comprehensive review of current oncology practices and incudes presentations not covered in traditional meetings.

- ACTNOW – the ACT and NSW oncology weekend is a biennial educational opportunity for training and practising oncologists across ACT and NSW. This meeting is intended to enhance delegate professional development and workshop local issues which are not discussed at traditional oncology conferences. This popular event held in May saw registration oversubscribed before the closing date.
- Pharmacology of cancer chemotherapy workshops – following the success of these workshops in 2015, COSA will once again host them throughout June and July in Brisbane, Melbourne and Sydney. The workshops are designed to provide education on the pharmacology of cancer chemotherapy and targeted therapies specifically for advanced trainees in oncology and haematology.
- COSA advanced trainees weekend – "Everything you need to know about breast cancer" is an intensive two day course for advanced trainees in surgery, medical and radiation oncology, junior medical staff and allied health professionals, including nurses. This event will be held on 12-13 November 2016 at the Gold Coast Convention and Exhibition Centre prior to the COSA ASM.

Cancer care coordinator position statement

COSA's position statement on the role of the cancer care coordinator was approved by COSA Council and published in November 2015. The paper outlines COSA's position on the role of cancer care coordinators and provides guidance for consumers, health professionals, health service managers and funders on the effective integration of these roles into cancer care delivery. COSA is also pleased to have recently received the endorsement of the Cancer Nurses Society of Australia for the position statement. It is available to download at cosa.org.au

Marie Malica
Executive Officer, COSA

FACULTY OF RADIATION ONCOLOGY

Targeting Cancer and our first documentary on radiation therapy

The Targeting Cancer campaign team driven by clinical lead, A/Prof Sandra Turner, has worked with respected health journalist Dr Norman Swan and his team at Tonic Health Media to produce a documentary titled 'Below the Radar.'

The 28-minute documentary shows real patient stories about the value of radiation therapy and delivers the campaign messages about safety, effectiveness, cost effectiveness and the sophisticated technologies involved with radiation therapy. 'Below the Radar' was broadcast on ABC News24 on 6 and 7 February 2016.

The documentary has been edited into four shorter videos, which will be played in the waiting rooms of general practitioners across Australia, through the Tonic Health Media Network, for the next two years.

The four videos are now available on the Targeting Cancer website. Please visit targetingcancer.com.au to watch and share within your network to spread the word on radiation therapy.

Please like Targeting Cancer on Facebook, or follow @targetingcancer on Twitter, and help us promote radiation therapy as a safe and cost-effective cancer treatment option.

Targeting Cancer 'City to Surf' – call for expression of interest

Do you want to challenge yourself and have fun while promoting radiation therapy and Targeting Cancer? The 2016 City2Surf will be held on Sunday, August 14, and we are looking for participants to join our Targeting Cancer team.

The City2Surf is 14km in distance starting from Sydney's CBD, before heading through Rose Bay, then up 'Heartbreak Hill' (the toughest part of the course) and finishing at the spectacular Bondi Beach.

For details visit city2surf.com.au. If you are interested in participating in this fun event as part of the Targeting Cancer team, please contact us on info@targetingcancer.com.au.

Funding for radiation oncology

The Medicare Benefits Schedule Oncology Clinical Committee (which will include surgical, medical and radiation oncology) is currently being established, and we are pleased that a number of faculty members (from both radiation oncology and radiology) have been invited to participate. The Faculty has established a working group, which will lead our work in responding to and participating in the Medicare Benefits Schedule review process, to help ensure the ongoing provision of accessible and affordable quality radiation oncology services to our patients.

The Department of Health is also undertaking a review of Radiation Oncology Health Program Grants – a Commonwealth capital funding initiative (outside of Medicare) for radiation oncology equipment.

The Faculty made a written submission to the Department on 18 March, in response to a few specific areas of interest of the program grants review e.g. the purpose, benefits and limitations of the scheme, equipment eligibility and alternative funding models. The submission is available on the College website.

It is the Faculty's position that Radiation Oncology Health Program Grants play a vital role in maintaining radiation therapy capital equipment, especially the nation's fleet of linear accelerators, within its agreed lifespan, and it should be maintained.

Dr Dion Forstner
Dean, Faculty of Radiation Oncology

MEDICAL ONCOLOGY GROUP OF AUSTRALIA INCORPORATED, MOGA

The first quarter of 2016 has been a busy period for the Medical Oncology Group of Australia. A new group of trainees has commenced speciality training in medical oncology and those trainees who recently completed their training, have been awarded fellowships and are moving ahead with their career plans.

MOGA membership continues to grow and currently there are 172 trainees and 450 consultant members. Dr Zarnie Lwin, Deputy Chair and I have been progressing the new Workforce Study, having completed a pilot project in late 2015. An extensive online survey will be distributed to all MOGA members in the coming months to gather important new data on our workforce to assist with long term services, facilities and workforce planning.

Oncology drugs and treatments

The Oncology Drugs Group, Chaired by Dr Deme Karikios, continues to make good progress in advocating for access to oncology drugs, recording a number of notable achievements. Late in 2015, in response to advice from MOGA breast cancer experts, the Pharmaceutical Benefits Advisory Committee (PBAC) amended the Pharmaceutical Benefits Schedule listing of medicines for HER2 positive metastatic breast cancer and recommended a change to the listing of lapatinib for HER2 positive metastatic breast cancer. The restriction for trastuzumab emtansine will be amended to allow patients to access following treatment with lapatinib. PBAC also recommended that the restriction wording for nab paclitaxel be updated to be consistent with the restriction for trastuzumab.

The group has also made submissions for priority approvals for a number of oncology drugs considered at the PBAC March meeting, including: nivolumab in non-small cell lung cancer; bevacizumab in cervical cancer; lenvatinib in thyroid cancer; olaparib in ovarian cancer; and tamoxifen in breast cancer prevention. At the same time, the group indicated support for submissions on: cetuximab in metastatic head and neck cancer; nintedanib in non-small cell lung cancer; and vismodegib in basal cell carcinoma. These listings will address important areas of unmet need for cancer patients, those at increased risk of cancer, and their clinicians. The listings are supported by strong randomised clinical trial data and are in keeping with international clinical best practice.

A successful submission supporting the change to the listing for tamoxifen for the primary prevention of breast cancer in patients with moderate or high risk has resulted from a unique collaboration. In 2011, MOGA tabled a position paper prepared by leading Australian breast cancer specialist, Prof Kelly-Anne Phillips - 'The use of tamoxifen for the prevention of breast cancer: implications of recent research.' This paper presented strong research data supporting approval and listing of tamoxifen through the Therapeutics Goods Administration and the PBAC and its placement on the Pharmaceutical Benefits Scheme for reduction in the risk of invasive breast cancer in women at moderate or high risk. Since then, Prof Phillips and Prof Fran Boyle, Chair, MOGA Breast Cancer Group and ANZ Breast Cancer Trials Group, have worked with MOGA, the TGA, PBAC, Department of Health and Ageing and AstraZeneca, to enact this change.

Education and professional education

Plans are well advanced for the 2016 Australia and Asia Pacific Clinical Oncology Research Development Workshop (ACORD): 11-17 September. Applications have been reviewed and participants offered places on this career enhancing program (acord.org.au).

Communication Skills for Early Career Oncologists, a new program developed by the Young Oncologist Group of Australia (YOGA) was held in April. This program included a series of workplace related role plays with trained actors and related plenary sessions on burnout, mindfulness and other communications' challenges, that could assist medical oncologists in day-to-day clinical practice. Dr George Au-Yeung, YOGA President, reports: "Good communication is core to our profession as medical oncologists. This innovative educational initiative provided young oncologists with a challenging and valuable learning opportunity that helped build their professional communications skills."

The MOGA Annual Scientific Meeting - Implementation + Innovation in Immunotherapy - will be held on the Gold Coast (3-5 August). Immunotherapy has become an increasingly important therapeutic strategy for cancer patients and medical oncologists, with clinical trials demonstrating significant clinical advantages in an array of cancer streams. Convenor, Prof Ken O' Byrne, is planning a scientific program that will focus on innovative approaches to implementing immunotherapy in practice, including a major immuno-oncology forum convened by Prof Grant MacArthur and Dr Alexander Menzies. Prof Justin Stebbing, from the Imperial College in London, will present the keynote address at the meeting to share his insights on the future of medical oncology.

A/Prof Rosemary Harrup
Chair, Medical 0ncology Group of Australia

AUSTRALIA AND NEW ZEALAND

Date	Name of Meeting	Place	Secretariat
July			
10-12	ANZUP Annual Scientific Meeting	Brisbane, Queensland	ANZUP Cancer Trials Group Limited Website: anzup.org.au Email: info@anzup.org.au Phone: +61 2 9562 5033
August			
3-5	MOGA Annual Scientific Meeting	Gold Coast, Queensland	MOGA Website: moga.org.au Email: projects2@moga.org.au Phone: +61 2 9256 9656
9-9	HGSA 40th Annual Scientific Meeting	Hobart, Tasmania	HGSA Website: hgsa.org.au Email: secretariat@hgsa.org.au Phone: +61 (0)2 9669 6602
18-20	6th Australian Lung Cancer Conference	Melbourne, Victoria	Lung Foundation Australia Website: alcc.net.au Email: info@alcc.net.au Phone: +61 (0)7 3251 3600
21-26	International Congress of Immunology	Melbourne, Victoria	Arinex Pty Ltd Website: ici2016.org/ Email: ici2016@arinex.com.au Phone: +61 3 9417 0888
September			
11-17	ACORD Workshop 2016	Magenta Shores, New South Wales	MOGA Website: acord.org.au Email: projects2@moga.org.au Phone: Phone +61 2 9256 9656
11-15	9th COGNO Annual Scientific Meeting	Sydney, New South Wales	COGNO Website: cogno.org.au Email: cogno@cogno.org.au Phone: +61 (0)2 9562 5000
14-16	AGITG 18th Annual Scientific Meeting	Melbourne, Victoria	AGITG Website: agitg.org.au Email: agitg@ctc.usyd.edu.au Phone: 1300 666 769
22-23	Sydney Cancer Conference	Sydney, New South Wales	Arinex Pty Ltd Website: sydneycancerconference.com.au/ Email: scc2016@arinex.com.au Phone: +61 2 9265 0700
October			
10-11	Australian Gastroenterology Week Satellite Symposium 2016	Adelaide, South Australia	GESA Website: agw2016.org.au/ Email: agw2016@gesa.org.au Phone: +61 3 9001 0279
11-14	ALLG Scientific Meeting	Sydney, New South Wales	ALLG Website: allg.org.au Email: dilupa.uduwela@allg.org.au Phone: +61 3 8373 9702
13-16	Royal Australian and New Zealand College of Radiologists' Annual Scientific Meeting	Gold Coast, Queensland	Waldron Smith Management Website: ranzcr2016.com Email: ranzcr@wsm.com.au Phone: +61 3 9645 6311

Date	Name of Meeting	Place	Secretariat
15-16	The Annual Sarcoma Conference	Sydney, New South Wales	Australasian Sarcoma Study Group Website: australiansarcomagroup.org Email: TBA Phone: TBA
25-27	ANZHNCS Annual Scientific Meeting and IFHNOS 2016 World Tour	Auckland, New Zealand	ANZHNCS Website: ifhnosauckland2016.org/ Email: anzhncs.asm@surgeons.org Phone: +61 3 9249 1273
November			
15-17	COSA's 43rd Annual Scientific Meeting	Gold Coast, Queensland	ASN Events Website: cosa2016.org Email: TBA Phone: +61 0 3 8658 9530

INTERNATIONAL

Date	Name of Meeting	Place	Secretariat
July			
4-5	ESER Annual Scientific Meeting 2016	Naples, Italy	European Society of Emergency Radiology (ESER) Website: eser-society.org Email: office@eser-society.org Phone: TBA
9-10	International Cancer Congress	Nagpur, India	Raju Andulkar Website: internationalcancercongress2016.com Email: admin@aemevents.in Phone: +91 9823280081
16-20	AHNS 9th International Conference on Head and Neck Cancer	Seattle, USA	AHNS Website: ahns2016.org/ Email: registration@ahns.info Phone: 310-437-0559
August			
31-3	16th World Congress on Cancers of the Skin and 12th Congress of the European Association of Dermato-Oncology	Vienna, Austria	MCI Deutschland GmbH Website: wccs2016.com Email: wccs2016@mci-group.com Phone: +49 0 30 20 45 93 29
September			
8-11	2nd World Congress on Controversies in Breast Cancer (CoBrCa)	Barcelona, Spain	CongressMed Website: congressmed.com/cobrca Email: cobrca@congressmed.com Phone: +41 22 33 99 985
16-20	16th Biennial Metastasis Research Congress	Chengdu, China	Metastasis Research Society Website: 2016mrsmeeting.org Email: mrs_secretariat@sina.com Phone: +86 28 86298147
29-1	15th International Workshop on Multiple Endocrine Neoplasia and Other Rare Endocrine Tumours	Utrecht, Netherlands	Congress by Design Website: worldmen2016.org/ Email: worldmen@congressbydesign.com Phone: TBA

CALENDAR OF MEETINGS

Date	Name of Meeting	Place	Secretariat
October			
7-11	ESMO Congress 2016	Copenhagen, Denmark	ESMO Website: esmo.org Email: registration@esmo.org Phone: +41 0 91 973 19 26
13-16	9th China Conference on Oncology & 15th Cross-strait Academic Conference on Oncology	Tianjin, China	Medcon Website: cco2016.org Email: cco2016@126.com Phone: TBA
17-21	18th IPOS World Congress	Dublin, Ireland	IPOS Website: iposdublin2016.com Email: Iposdublin2016@abbey.ie Phone: +00 353 1 648 6278
22-25	10th International Symposium on Hodgkin Lymphoma (ISHL)	Cologne, Germany	German Hodgkin Study Group (GHSG) Website: hodgkinsymposium.org Email: info@hodgkinsymposium.org Phone: +49 0 2102 66936
29-31	16th Biennial Meeting of the International Gynecologic Cancer Society	Lisbon, Portugal	TWT Events and Tours Planner Website: igcs2016.com Email: gfrontani@twt-team.it Phone: +0039 06 44249321
31-3	UICC World Cancer Congress	Paris, France	UICC Website: worldcancercongress.org Email: congress@uicc.org Phone: +41 22 809 1834
November			
14-16	AICR Research Conference on Nutrition, Physical Activity, Obesity and Cancer	North Bethesda, USA	AICR Website: aicr.org Email: research@aicr.org Phone: TBA
17-19	SIOG 2016 Annual Conference	Milan, Italy	SIOG Website: siog.org Email: info@siog.org Phone: +41 22 552 3305
17-20	Society for Neuro Oncology (SNO) Annual Meeting	Arizona, USA	SNO Website: soc-neuro-onc.org Email: TBA Phone: TBA
December			
4-7	17th World Conference on Lung Cancer	Vienna, Austria	ICS Website: iaslc.org Email: wclc2016@icsevents.com Phone: +1604 681 2153
6-10	40th Annual San Antonio Breast Cancer Symposium	San Antonio, USA	Website: sabcs.org/ Email: sabcs@uthscsa.edu Phone: +210 450 1550

CANCER COUNCIL AUSTRALIA

Cancer Council Australia is the nation's peak independent cancer control organisation.

Its members are the leading state and territory Cancer Councils, working together to undertake and fund cancer research, prevent and control cancer and provide information and support for people affected by cancer.

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Cancer Council Northern Territory
Cancer Council Queensland
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CLINICAL ONCOLOGY SOCIETY OF AUSTRALIA

The Clinical Oncology Society of Australia (COSA) is a multidisciplinary society for health professionals working in cancer research or the treatment, rehabilitation or palliation of cancer patients.

It conducts an annual scientific meeting, seminars and educational activities related to current cancer issues. COSA is affiliated with Cancer Council Australia.

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MEMBERSHIP

Further information about COSA and membership applications are available from:

www.cosa.org.au or cosa@cancer.org.au

Membership fees for 2016-2017
Medical Members: $205
Non Medical Members: $120 (includes GST)

COSA Groups

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