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Degeling, Chris; McEwin, Eliza J.; Moynihan, Ray; Carter, Stacy M.

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The introduction and demise of full-body computed tomography (CT) scanning in Australia: implications for preventing overdiagnosis

ABSTRACT

Full-body computed tomography (CT) screening came to Australia in 2002. Within a year, public access to self-referred full-body CT screening was withdrawn as a consequence of sustained professional and political pressure and legislative changes. We examine how self-referred full-body CT scans were made available to Australian consumers, and evaluate the social, cultural and system factors that contributed to their de-implementation. Using historical methodologies, insider accounts and an ethnographic content analysis of policy documents, statutory reports, grey and scholarly literatures, we show how the rapid de-implementation of full-body CT scans in Australia arose from interconnected social, cultural and system factors, and an unusual harm profile for the technology. In the Australian context, this case suggests that neither single actors nor robust health technology assessments are likely to be sufficient to protect people from the unwanted consequences of too much medicine. The coordinated interaction of multiple stakeholders achieved this unusual example of successful, early de-implementation. Each stakeholder exercised their authority within their respective remits to shape public perceptions of and access to the new CT screening service: it is possible that without the actions of each, the final de-implementation outcome may not have been achieved. These findings are timely, given growing concerns about overdiagnosis and the emergence of new forms of testing technologies. Against a background of technological optimism and commercial opportunism, a commitment to vigilance and cross-sectoral coordination across a range of decision-making roles and institutions will be key to efforts to prevent the harms of overdiagnosis.

Key words: Australia; full-body CT scan; de-implementation; screening technologies; overdiagnosis

INTRODUCTION

This paper describes the introduction of self-referred full-body computed tomography (CT) scans as a screening technology to Australia's privately-operated healthcare market in 2002. Dubbed 'yuppie scans' because of their appeal to wealthy, apparently healthy people, a 'full', 'whole' or 'total' body CT scan – from head to pelvis – produces a large amount of image data that may not be visible on a conventional X-ray (Mitchell, 2003). The scans were marketed as screening tests for healthy people, not as diagnostic tests for people with symptoms. With no need for a doctor's referral, and at a cost about \$900 AUD, anyone could purchase access to this technology to screen for a previously undiagnosed or asymptomatic disease (Pollard, 2003; Teutsch, 2002).

Enthusiasm about new health technologies among publics and health professionals tends to run ahead of the evidence of benefit, especially if a technology has not previously been in widespread use. The wider acceptance or rejection of a health technology can depend on how different technological attributes such as its plausibility, visibility, effectiveness, utility, and any attendant risks are perceived by implicated stakeholders. From this perspective, how a technology is used (or not) is an ongoing product of sociotechnical practices that iteratively create meanings around technologies, and direct them toward the pursuit of specific aims (Ulucanlar, Faulkner, Peirce, & Elwyn, 2013). In practice, these 'technology identities' can be constructed by interested actors (developers, regulators, service providers, consumers, etc.) to shape the purposes and contexts in which a technology is permitted to operate. As an example, for screening technologies used to detect prostate cancer risk, such as the PSA test and genomic profiling, Alex Faulkner (2012) has shown that regulators in the UK are increasingly diversifying their modes of governance to manage varied uncertainties and risks associated with screening technologies. For the PSA test, which attracts significant support from Men's Health advocates, effective governance has relied on the alignment of a rhetoric of consumer empowerment with mandated informed decision-making processes that make men responsible for their PSA testing choices. In the contrasting case of direct-to-consumer genetic screening, regulators have acted as a traditional evidence-driven gatekeeper of the technology, paired more innovatively with a media-focused response, relying on their epistemic authority to manage expectations, raise questions about the motivations of providers who are aggressively marketing their services, and resist the claims of benefits associated with new and unproven tests.

Informed by theory regarding the construction of technological identities (Ulucanlar et al., 2013), and regarding screening regulation as situated, flexible and tailored (Faulkner, 2012), we examine how self-referred full-body CT scans were made available to Australian consumers for medical screening, and then, just as rapidly, how they

were withdrawn. We evaluate and discuss the social, cultural and system factors and modes of resistance and governance that contributed to the de-implementation of this use of a technology. Our aim is to encourage discussion and debate regarding how to prevent new uses of testing technologies with a high chance of causing significant overdiagnosis.

BACKGROUND

While the value of early detection is intuitively appealing, participating in screening can cause harms (Woloshin & Schwartz, 2010). In this case, the harm is increased risk of radiation-induced cancer, not offset by likely benefits from screening. A full-body CT scan exposes people to a large amount of ionising radiation, which depending on the protocol and CT scanner used can exceed 24 milliSieverts. Regardless of the results, a full-body CT scan is thus likely to increase a person's overall risk of developing cancer. The risk is higher if a person has a CT scan at regular intervals because of the large cumulative lifetime dose of ionising radiation (Smith-Bindman, 2010). In 2002 there was already good evidence that each year 431 cancer cases in Australia were radiation-induced (de Gonzalez & Darby, 2004), leading to a basic rule for ionising radiation that 'if you don't need it, don't have it'.

Whole-body CT scanning did not offer significant benefits to offset these risks. Like other testing technologies, CT scan results can deliver false reassurance (Le Heron & Coakley, 2004). They can also produce false positives, it can lead to unnecessary, costly and potentially harmful follow-up investigations. Finally, full-body CT scanning carries significant risk of harm arising from overdiagnosis. Overdiagnosis occurs when people are diagnosed correctly with conditions, but this produces an unfavourable balance of benefits to harms (Carter, Degeling, Doust, & Barratt, 2016). Our interest in this case study is because it is a rare case of an overdiagnosis-causing technology that was successfully withdrawn from market. New technologies, or new uses of existing technologies, can often contribute to overdiagnosis (Pathirana, Clark, & Moynihan, 2017). When overdiagnosis is occurring, people are harmed by being diagnosed correctly but unnecessarily: they meet the criteria (pathological, radiological or otherwise) to be diagnosed with the condition, but the condition was unlikely to shorten their life or reduce its quality if it had gone undetected. New testing technologies tend to be more sensitive than old technologies, increasing the risk of overdiagnosis. The same is true if old tests are used in larger populations of people at relatively lower risk: it is likely that more people will be diagnosed with conditions that would never be clinically

significant. Because of this, monitoring and potentially withdrawing new screening technologies is one important strategy for optimising patient outcomes and healthcare delivery by preventing overdiagnosis.

In Australia, restricting public access to privately operated self-referred full-body CT scans is an oft-cited example of a screening technology that caused harm and which was successfully withdrawn. Most of the professional, media and political activity that surrounded the introduction of this service occurred in the state of New South Wales (NSW) which has a co-regulatory model such that responsibility for oversight of health care practitioners and providers is distributed across a few key bodies. Of these there are a number of agencies who were potentially relevant to the task of withdrawing self-referred full-body CT scanning from the market (see Supplementary Table 1). As we will see, some of these agencies were better able to contribute than others to both creating procedural barriers to consumer access to the technology, and establishing an unfavourable technological identity for full-body CT scanning services.

Australia's health system is a complex mix of public and private provision and funding. Australia has a universal healthcare funding system (Medicare). For services to be funded by Medicare, they must pass Health Technology Assessment (HTA) for safety, efficacy and cost effectiveness via the Medical Services Advisory Committee (MSAC). However Australia also has a thriving fee-for-service private healthcare sector which is less constrained by HTA; in that sector restrictions on offerings occur largely post-market, in response to complaints or surveillance, through medical professional and consumer regulation. CT scanning machines were already an established part of medical practice in Australia in the 2000s. Their fee-for-service private use for new indications such as screening was not a matter for HTA via MSAC, but for medical professional and regulatory bodies, so these services were able to be introduced without pre-market regulatory requirements.

The literature on the surveillance, introduction, failure and withdrawal of harmful or ineffective testing technologies is comparatively small (Faulkner, 2009). Although decisions about the introduction or removal of health care services and medical technologies are ostensibly based on assessment of the evidence of harms, benefits and costs, these decisions are as much shaped by how health care is organized, regulatory systems and the policy influence of strategic alliances between different implicated stakeholders such as healthcare professionals, regulatory bodies, industry groups, and consumers (Faulkner, 2009; May, 2013; Ulucanlar et al., 2013). As health care providers, consumers and policymakers become increasingly aware of the harms of too much medicine, there is a need for more scholarly work on how best to identify and limit the impacts of

problematic testing technologies that promote overdiagnosis. For these efforts to be effective, they must take seriously the agents, systems and processes that will inevitably be implicated in any change.

METHODS

Data Sources and Collection

Systematic searches of relevant databases were undertaken for the period January 1, 1995 to December 31, 2014. We identified 114 unique items of which 35 were germane to the topic (Supplementary Table 2). Preliminary analysis and secondary searches of these materials identified a further 13 items. When limited to sources or content pertaining to policies and events in Australia, a final set of 48 documents was produced (Supplementary Table 3). These were downloaded as full-text and manually catalogued.

Data Analysis

Materials in the sample were subjected to an ethnographic content analysis (Altheide, 1987). Drawing on both numerical and textual data, ethnographic content analysis is a qualitative research method for interpreting documents to generate insights through an iterative process of testing, revising and refining understandings against an emerging timeline and conceptual map (Krippendorff, 2004). Led by Author 2, this cycle of searching, mapping and critical analysis continued until new textual materials were not providing substantive new insights. The final stage of analysis took place during the course of writing, through discussion between authors while revising drafts. To verify our analyses and interpretations, a key informant from the NSW Ministry of Health who was familiar with these events took part in an unstructured interview in order to assess, and add context and nuance to our findings. A consumer advocate who reported extensively on these services then reviewed our results and interpretations as a triangulation exercise, and to give further feedback on research outcomes and our timelines. In what follows we draw on these textual analyses, and insider recollections and reflections to begin to map out the challenges, pathways and mechanisms for the de-implementation of new screening technologies. The study process was approved by the University of Wollongong Human Research Ethics committee.

RESULTS

Selling the benefits of a full-body CT scan

At the end of 1998, Toshiba, General Electrical and Siemens all launched competing models of the next generation of multi-slice CT scanner with a period of a few weeks. By the early 2000s, enthused by the falling price of the

technology and the uptake of direct-to-consumer CT body scanning services in the USA, a handful of medical entrepreneurs in Australia bought machines with funds raised through share issues with the aim of offering preventive screening services. Promotion of fully body CT scanning in Australia began several months before the businesses began to trade and focused strongly on the services' purported benefits: largely, that the details uniquely revealed by this technology would enable individuals to be informed about their state of health, both at the time of the scan and into the future. The promotion of this benefit was framed so as to imply that people who did not have a full-body CT scan were putting their health at risk (Le Heron & Coakley, 2004), and would be unable to make informed decisions about their health. For example, in Australia full-body CT scan providers advertised widely in daily newspapers, with slogans such as

In just 30 seconds we might find something your doctor may not find for ten years (Zinn, 2003).

The images obtained were promoted as a 'win-win' for informed decision making, regardless of the results, with this promise marketed especially to the wealthy and apparently healthy with no symptoms of disease. If the large amount of image data from the scan appeared to show that everything was as it should be – a normal result – this was a benefit, labelled as 'peace of mind' (Le Heron & Coakley, 2004; Teutsch, 2002). If the result was abnormal, this was also seen to be a benefit, the promise being 'improved outcomes' on the assumption that early intervention must be beneficial. The implication was that without the scan, the abnormality or disease may have gone unnoticed because there were no symptoms, perhaps until it was too late for a good outcome (Evans, 2003; Le Heron & Coakley, 2004).

Opposition, but continued marketing

In January 2002 – a few months before full-body CT scans became available in Australia – the Royal Australian and New Zealand College of Radiologists (RANZCR) issued a statement that there was no evidence that full-body CT scans were either cost-effective or effective in prolonging life (RANZCR, 2002). Despite RANZCR making these concerns public, there was no regulatory mechanism available to stop the roll out of commercial services. As noted by a key informant, in 2002:

...a lot more CT scanners came into Australia ... But there were clearly some gaps in both the advertising restrictions on those services and then the regulation of the radiation component of the services. (Key Informant Interview)

As a consequence, during the first few months of 2002 full-body CT scanning services were widely advertised in daily newspapers by at least 3 companies operating from a range of locations in Sydney, the most populous city in Australia. These ads portrayed full-body CT scans as a preventive health tool that gave people control over their health, with little to no indication of the potential for harm. Just before the launch, Dr Paul Condoleon, a GP and company director of a service provider called ProActive Medical Screening, noted in a media interview: ‘It’s always better to know if something is amiss...’ (Teutsch, 2002). In the same interview, Condoleon sought to play down RANZCR’s reservations about lack of benefit and radiation risks raised by claiming:

There is no evidence of any health problems, these scans are used day in day out... I think people want to be a little more proactive with their health. They don’t just want to go to a doctor and be told: ‘there’s nothing wrong with you’. (Teutsch, 2002)

Within a few months, media appearances and advertising campaigns asserting the value of full-body CT scanning drew a media response from health professionals and health professional bodies such as the Australian Medical Association (AMA) challenging the promises being made—implicitly or explicitly—by the screening services (AAP, 2002; Davies, 2002). Spurred by complaints from the AMA, the Office of Health Protection at NSW Health referred full-body CT screening service providers to the Therapeutic Goods Administration (TGA), for making misleading or false claims in advertising. At the same time citing the findings of the RANZCR report and rulings by the U.S. Food and Drug Administration, spokespersons from the NSW Ministry of Health and AMA raised concerns about the widespread uptake of these services leading to increased rates of radiation-induced cancer in the community, to try and dissuade people from using the new screening services (Pollard, 2002). There was also a direct attack from the National President of RANZCR on the claims being made and anecdotal evidence used by the new service providers:

It will always be possible to trot out someone who has had a cancer found early and removed as a result of a whole body [CT] scan. That’s wonderful for the individual but it hides the statistics about people who may have had unnecessary tests and had complications, or who have been mistakenly reassured. (Aisbett, 2002)

Notably, in these early media stories, environmental health authorities and other government bodies primarily focused on the risks of radiation while radiologists and epidemiologists sought to highlight the risks of unnecessary medical investigations. The differences in the framing of risk between these positions were matters of emphasis rather than conflict. Ruth Pollard, a respected journalist working for Fairfax-owned newspapers, took a different tack on this issue. She tended to portray the emergence of self-referred full-body CT scans as a symptom of a society heading towards troubling medicalization, asking:

Why are we so determined to see into our medical future? Why would someone with no symptoms or suspicion of illness turn to a full-body scan? (Pollard, 2002)

To recap, from the very outset of the introduction of this new fee-for-service offering, there was solid scientific evidence of an unfavourable balance of benefits and harms associated with full-body CT scans and consistently negative communication from a range of reputable medical authorities emphasizing this evidence. In addition, there was social commentary and ridicule as to the types of ‘healthy, wealthy and paranoid’ people who would want to avail themselves of such a service (Evans, 2003; Teutsch, 2002). Despite resistance from health authorities and a hostile discursive environment, privately-operated screening services began to perform full-body CT scans for willing members of the Australian public.

Setting the stage for regulatory actions

It took more than medical protest and media commentary to achieve successful de-implementation. Restricting access to full-body CT scans involved a number of other key people, groups and decision makers, many of whom were outside the institutions and practices of medicine, but it took some prompting. The services at issue were offered in the state of NSW, but as Table 1 shows, their de-implementation involved several national bodies.

As media attention focused on the medical professions’ response to self-referred full-body CT scanning, the NSW Chief Health Officer – the most senior health official for the government of NSW – publicly expressed his view that one of the likely consequences of allowing self-referred full-body CT scanning services to continue to operate was an increase in radiation-associated cancers in the community (AAP, 2002). Shortly after full-body CT scans became available in Australia, the Radiation Health and Safety Advisory Council (the expert body established to advise the Australian Radiation Protection and Nuclear Safety Agency on ‘emerging issues’ in radiation protection

and nuclear safety) declared publicly that there was no evidence to support the use of self-referred full-body CT scans for mass screening. In August 2002, the Council advised that such a service was potentially harmful because: *“the radiation dose involved is not insignificant”* (ARPANSA, 2002). The national Australian government’s primary authority on radiation protection and nuclear safety, an organisation with a remit including but beyond human health, now officially held a view concordant with the position taken in January 2002 by the RANZCR (2002), the key national organization of relevant health professionals.

According to a key informant who held a senior position at the NSW Ministry of Health at the time, a loose coalition of government agencies, medical professional and environmental bodies were now aligned against the full-body CT scanning service providers. However they lacked a clear and immediate mechanism to stop these companies trading. Senior representatives from both the Health and Environment Ministries met regularly on the Radiation Advisory Council (RAC) of the NSW Environment Protection Agency (EPA). During an unstructured interview this key informant confirmed:

A series of discussion on the Radiation Advisory Council that brings health regulators and the EPA together - that was where that response about tightening the regulation came from ... (Key Informant Interview)

As a statutory authority – a body set up by law – the EPA has primary responsibility for environmental regulation in NSW, in areas including waste, pollution, and environmental degradation. They have a broad scope of action, including issuing licenses, setting conditions for operation of environmentally sensitive activities, monitoring compliance, mounting prosecution, creating environmental policy and educating the public. According to our informant, key to the decision to use environmental health regulations to restrict direct consumer access to CT scanning technologies was a concern that:

...the other types of regulatory response we considered might have restricted that valid access for patients who needed an investigation (using a CT scanner). (Key Informant Interview)

To limit mixed messaging and continue to effectively counter any claims of benefit from full-body CT scanning service providers, the public face of these actions would continue to be NSW Health. Because of its early role in fielding the concerns of stakeholders such as the AMA and RANZCR and bringing the issue of self-referred full-body CT scans to the attention of other government agencies such as the TGA, the Office of Health Protection would act as overseer so that the response was as coordinated as possible. This is arguably the point at which effective de-implementation of full-body CT scans began in NSW.

In September 2002 the then NSW Minister for Health Craig Knowles advised the NSW state parliament that he would exercise a legislative lever: that there would be an investigation under the NSW Radiation Control Act 1990 (Legislative Assembly Hansard, 2002). The objects of this Act included protecting people and the environment from exposure to ‘ionising and harmful non-ionising radiation to the maximum extent that is reasonably practicable’, considering possible benefits and social and economic factors (Government of New South Wales, 1993). Broadly then, this was a set of environmental regulations, and thus a framework for formal investigation, designed to focus on allowing radiation exposure only in situations where there was sufficient benefit to justify any possible risks. The investigation would assess radiation exposures from CT scan machines in use at the clinics offering the service. Based on the findings, the NSW EPA’s Radiation Advisory Council would consider and draft a suite of conditions to be attached to licenses for CT scanning machines (Legislative Assembly Hansard, 2002). Even though the EPA’s Radiation Advisory Council includes representatives from NSW Health, the key regulator in the de-implementation of a service offered in the private health sector was not a body primarily charged with the oversight of human health services, but a body charged with managing environmental health risks, defined in such a way as to include human radiation exposure.

The NSW EPA finalized its draft conditions in the second half of 2002 (Radiation Advisory Council, 2003). The draft was then sent to the Australian Health Minister’s Advisory Council (AHMAC) and the Australian Competition and Consumer Commission (ACCC) to obtain advice as to whether the new conditions would unnecessarily encumber the use of CT scanning technologies in other contexts and settings. Notably the EPA and ACCC are not the authorities through which medical practices are governed in NSW. Even though the NSW Health Care Complaints Act (1993) and Australian consumer law could conceivably have jurisdiction over the activities of self-referred CT scanning service providers such as Life Span Medical Imaging and ProActive Medical Screening, neither the Health Care Complaints Commission (HCCC) or Fair Trading Commission took an active role in de-implementation. According to testimony at the Inquiry into the Promotion of False and Misleading Health-Related Information and Practices (Committee on the Health Care Complaints Commission, 2014), ambiguity as to whether self-referred full-body CT scanning for screening could be defined legally as a ‘health’ or ‘consumer’ service meant that it fell into the cracks between the remits of these two statutory organizations, and was therefore unregulated (see Supplementary Table 1). On this basis, a decision was made

that the most effective pathway was to change the conditions under which a radiation license holder was legally able to operate CT equipment in NSW.

Policy implementation and provider resistance

In November 2002, the NSW Minister for Health accepted the EPA's recommendations and would trial them for 6 months as a first step in tightening the rules around full-body CT scans (see Figure 1). Each recommendation covered a different entry point in the process of someone accessing a full-body CT scan. The first recommendation—requiring an independent referral—created several barriers. People had to make the time, and often an appointment, to see a medical doctor not employed by the CT scanning service provider, and the doctor should in almost all cases refuse. The second recommendation aimed to ensure people would be better informed, on the assumption that this should diminish demand. Of this the NSW Health Minister noted during a speech in the NSW parliament:

At stake in this issue is the right of the consumer to be fully informed and for medical treatments to be based on evidence, rather than on hope” (Legislative Assembly Hansard, 2002).

The third recommendation of requiring a declaration of consent from patients was intended to function to force people to carefully consider the information provided to them. Together, these recommendations were designed to synergistically drive down the numbers of people accessing full-body CT scans, and—if operators did not comply—to be only the first step in a tightening series of controls. The NSW Government sent letters to operators who advertised full-body CT scans advising that licensing conditions were changing and they had 30 days from notification to put the new protocols in place (see Box 1). In a subsequent interview the Health Minister justified the government's response by arguing:

These machines have a place in the medical world, and should be used in accordance with professional medical advice, they are not money-making toys. (Pirani, 2002)

When the trial of the amendments ended and they were formally legislated in June 2003, breaches automatically became subject to the penalties contained in the Radiation Control Act. Both the Premier and Health Minister of NSW took to the media again to inform the public that operators and companies who failed to comply could be

financed up to \$165,000 AUD and/or imprisoned for a maximum of two years (Anderiesz, Elwood, McAvoy, & Kenny, 2004). In these media interviews opponents of the CT scanning services increasingly sought to frame users of these services as the “worried well”, a class of hyper health-conscious individuals who would be better served by taking their concerns to a General Practitioner. When interviewed about the impact of these changes, the director of the rebranded Total Health Screening (formerly ProActive Health Screening) told the media:

It's an absolute overreaction... to try and show the government is potent and actually doing something when the health service is a shambles... The level of our Xrays is just the same as medical imaging. We regularly detect cancers and a whole range of other conditions patients have no idea they have. (Zinn, 2003)

In the Australian Financial Review, the journalist Jill Margo (2003) reported that despite the concerted media campaign making sweeping claim of benefits, the uptake of self-referred full-body CT scanning services by the Australian public was much lower than in the USA. Now that this source of clients was no longer available, service providers sought to stay in business by offering different types of CT scans as alternatives to standard screening services. In October 2003, Life Span Medical Imaging advertised virtual colonoscopy and angiogram CT scanning as the safer and pain-free option for patients. These activities triggered further responses from the NSW Ministry of Health who threatened to refer the company's advertisements to the Therapeutic Goods Administration (TGA) because it made significant and misleading claims about the evidence for using CT scanning to screen for serious illnesses (Pollard, 2003). According to media reports, service providers had also begun to mail and letterbox drop standardized referral forms to people to take to their doctor to sign so that they could access the services (Lavelle, 2004). Concerned that too many GPs were succumbing to patient pressure, an editorial was published in the *Medical Journal of Australia* warning their readership of the radiation risks of unnecessary CT scans, and the lack of evidence that it was an effective screening technology (Anderiesz et al., 2004). Unable to generate a volume of referred patients sufficient to sustain a viable business, by the end of 2005 Life Span Medical Imaging, Heart & Body Scanning and Total Health Screening had all ceased to trade.

DISCUSSION

The de-implementation of full-body CT scans involved a diverse range of stakeholders exercising varied influence and authority within the state of NSW and nationally across Australia. The available evidence suggests that this

policy success might have occurred in part because each stakeholder exercised their influence and/or authority within their respective remits, while engaging in collective collaborative consultation and communication. In his examination of PSA and genetic tests, Alex Faulkner (2012) identified that UK health system regulators have employed at least two strategies to manage the risk and uncertainty entailed by different screening technologies. For PSA testing regulators relied on ‘responsibilising’ consumers through shared decision making. For new genetic and genomic tests, regulators used their epistemic authority to justify restricting access to testing, while moderating public expectations of new testing technologies via a media strategy. In this case, Australian health authorities employed a strategy similar to that described by Faulkner in response to genomic testing, with the added complication that there was no clear agency or pathway to regulation.

Previous work on medical expertise, institutional jurisdictions and the exercise of power in regulating medical activities has pointed to a blurring of the roles of governments, medical professionals, device and drug manufactures and consumers – and how this creates markets for individuals who want to assume control of their health risks (Hogle, 2002; Petersen, 1997). In the case of self-referred full-body CT scanning services, these forces were resisted through public advocacy and regulatory change. The events described in this study occurred against a background of recent Australian health system funding reform. With debate on the introduction of government subsidies for private health care in the background, two opposing social identities for CT scanning technologies were being constructed. Both appealed to widely held norms of prevention and avoidance of unnecessary risk. Service providers attempted to tap into deeply culturally embedded logics of prevention to portray full-body CT screening as a responsible measure that allowed savvy consumers to take control of their health and prevent future disease. Drawing on institutional authority, the campaign to counter this framing focused on highlighting the long-term risks of unnecessary radiation exposure and questioning the underlying pecuniary motivations of service providers and self-obsessions of their customers. Explicitly linking the use of CT scanning technologies as a consumer service to the financial interests of the business owners likely reflected the prevailing public discourse regarding privatization. The federal government put in place measures that incentivized private healthcare provision (Hall, de Abreu Lourenco, & Viney, 1999), even though public support for maintaining funding for the public system was strong (Shiell & Seymour, 2002). Service providers found themselves alone in fighting against the move to shut them down – as regulatory measures began to be imposed, there was no public controversy, and no natural constituency emerged to defend direct private access to full-body CT health scans.

Forming and sustaining policy coalitions among diverse sets of stakeholders can be difficult because of the need to balance conflicting values and agendas (Heaney, 2006). However, in this case all policy stakeholders could promote their varied interests in service of the same goal: achieving the de-implementation of self-referral to CT scanning services. The AMA and RANZCR maintained the position of GPs and radiologists as, respectively, the gatekeepers to, and expert interpreters of, diagnostic imaging; the TGA, HCC and EPA fulfilled their public mandates by protecting the public, respectively, from misleading medical advertising, unethical medical practices, and unnecessary exposure to high levels of radiation. Regulatory changes needed to be justified through undertaking a series of reviews and consultations such that medico-administrative processes were instituted involving diverse professional and federal and provincial government bodies, including authorities on radiation safety (Radiation Advisory Council, 2003; RANZCR, 2002). The aim was to create and validate a body of evidence that was robust enough to withstand political or legal challenge. As soon as these reports were finalized and tabled in the NSW Parliament, the regulatory loophole was closed through the NSW EPA enacting legislation which effected several entry points at which people could access a full-body CT scan.

Attempts by the CT Scanning providers to reframe their offerings as alternatives to established screening services were thwarted by the TGA enforcing strict guidelines on the claims made in medical advertising. In contrast to the case of direct to consumer marketing of pharmaceuticals in the United States, CT scanning service providers in NSW were unable to sustain claims they were providing meaningful options to responsible health consumers, or to authorize themselves in ways that would convince others to accept them (Hogle, 2002). To limit further the potential for attempts at market entry in the future, a process was established to develop principles to assess and manage new applications of ionizing radiation in medical facilities and other occupational settings (ARPANSA, 2017). The final outcome was that full-body CT screening providers could buy the machines – but could not successfully embed them in everyday practices. Without direct access to otherwise healthy members of the public, providers were unable to legitimate new sets of medical practices, activate a consumer base, or integrate themselves into, and, thereby reconfigure, existing systems (May, 2013).

We began by noting our interest in self-referred access, by apparently healthy people, to full-body CT scans because this is very likely to contribute to overdiagnosis. Full-body CT scanning in Australia is a rare example among overdiagnosing technologies: rapidly identified as harmful, and equally rapidly and decisively removed. Because our work is based on a single case study, we cannot offer systematic comparative analysis to suggest

why this might have been, but we can draw out the characteristics of this case that appeared instrumental to regulatory success.

First, since the practice had been condemned internationally before it was introduced in Australia, local authorities had an opportunity to take action before it arrived. When full-body CT scanning providers pointed to the popularity of this type of service in the USA and sought to reinforce the intuition that individuals can proactively prevent potentially fatal diseases by having more information about their health, statutory authorities and institutional actors such as the AMA Ministry of Health and ARPNSA were quickly able to draw on scientific studies and reports from US regulatory agencies to begin to prosecute a case that the public needed to be protected from increased levels of radiation exposure.

Second, the practice involved advertising a service directly to consumers, which not only bypassed the usual checks and balances of the Australian healthcare system but perhaps more significantly, created a threat to the usual channels of medical professional authority and autonomy. Medical professional bodies sought to reinforce their institutional authority, maintaining their position as gate-keepers to diagnostic technologies while reassuring the public that CT scanning technologies were safe to use in appropriate circumstances. This was accomplished by asserting the importance of clinical expertise in deciding when CT scanning was appropriate, and questioning the motivations of the new screening service providers. These providers' attempts to depict the technology as a demand-driven service for health-conscious consumers were scuttled by opponents, who were successful in reinforcing the medical identity of CT scanners and publicly positioning the technology as an important but potentially dangerous diagnostic tool that required expert hands (Ulucanlar et al., 2013).

Third, within public communications from government and health agency spokespersons, the framing of who is at risk from full-body CT scans gradually shifted from 'healthy people' to the 'worried well'. This media strategy moderated the early derision against these services by journalists as 'yuppie scans' (at a time when mocking yuppies was a well-established national sport), but also effectively sustained an unfavourable discursive environment. Finally, because the test was not designed to facilitate early detection of a particular condition (e.g. in contrast to the Men's Health advocacy that surrounds the PSA test) there was no obvious group of suffering patients to become a social movement defending the service.

From the perspective of de-implementing overdiagnosing technologies, perhaps the most significant thing about this particular case, however, was the role of radiation exposure. Most overdiagnosing technologies cause harm by exposing people to unnecessary and damaging treatments, which are triggered by, but separate from, the test itself. Overdiagnosis mostly begins with tests for biomarkers, ultrasounds, relative simple and low-dose x-rays or genome testing (Welch, Schwartz, & Woloshin, 2011), investigations that do not physically harm the body at all, or not to any great extent. The test is the entry point through which the patient commences a cascade of intervention that can cause significant harm, but the test itself is fairly benign – PSA testing being a well-known example. Full-body CT scanning was different. The amount of radiation exposure from the test itself was large, amplified by the possibility that consumers might attend for multiple scans and so have that exposure multiple times. The test itself clearly increased health risk, and it was this risk which mobilised the arguably pivotal agency, the Environmental Protection Agency, to act quickly against a practice that was clearly in its remit. Most arguments against overdiagnosing technologies rest on the clinical non-significance of the findings and the non-necessity of the harmful treatments that follow. These arguments were potentially relevant to full-body CT scanning too, but they did not provide the main lever for change.

CONCLUSION

There are several key lessons from this historical case study for efforts to reduce the harms of testing technologies, including overdiagnosis. Health technology assessment processes are vitally important, but tend to focus on applications of new technologies rather than new applications of existing technologies. This episode shows that new applications can be just as dangerous, and need just as much oversight, including assessment of their benefits and harms at a population level. Once potential problems do emerge, the role of media becomes critically important for alerting people, suggesting a need for ongoing educational engagement with media about the risks of overdiagnosis associated with testing technologies. And perhaps most important – and the most difficult thing to achieve unless existing institutional stakeholders have their interests aligned – is a strong collaborative regulatory, legislative and government response, guided by a combination of good evidence and the precautionary principle. As we have shown, full-body CT scanning had the unusual characteristic of being a potentially harmful test, as well as being a test that can trigger harmful and unnecessary investigations and treatments. Our appraisal (later confirmed by our informants) is that the health risk posed by the test itself motivated implicated stakeholders to effect de-implementation. Opponents to the introduction of the new service were able to construct a public profile for CT scanning technologies that was nuanced to distinguish between self-referred and medically

indicated applications. The key intervention was to mandate the need for a referral and an informed consent process. Once medical professionals were the gatekeepers to customers, service providers had limited ability to reshape consumer expectations or established clinical pathways. Future research focused on other comparative case studies will provide better understanding of how feasible de-implementation is when the test itself is relatively benign, consumers and advocates are strongly invested in access to the technology, or both.

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Figure 1: The Environmental Protection Authority's recommendations for licensing the use of CT equipment as accepted by the NSW Government*

1. Operators will require [a patient to have] a referral from an independent doctor for a full body CT scan
2. All patients are to be fully informed about the risks and uncertain value of a full body CT scan. They are to be given a clear explanation of what the scans are both capable of detecting, and perhaps more importantly, are not capable of detecting.
3. Should patients wish to proceed with a full body CT scan, they are to sign a declaration stating they have received the advice but wish to proceed.

Supplementary Table 1: Key Australian stakeholders in the de-implementation of full body CT scans

ORGANISATION	DESCRIPTION	MAIN ROLE(S)
Health professional bodies		
RANZCR The Royal Australian and New Zealand College of Radiologists http://www.ranzcr.edu.au/	Professional college for clinical radiologists and radiation oncologists in Australia, New Zealand and Singapore.	Training, professional accreditation, continuing professional development, policy, advocacy, quality and standards, research activities. Promote clinical radiology and radiation oncology.
Australian Medical Association https://ama.com.au/	Professional association for Australian doctors and medical students (all specialties).	Advocacy, influence, professional resources, member benefits, workplace advice, professional networks. Does not regulate or certify doctors.
NSW Cancer Council https://www.cancercouncil.com.au/	Non-profit state cancer organisation (has branches in every state and a National umbrella organisation)	Leading cancer charity focused on support, research funding, advocacy and fundraising.
National Health and Medical Research Council https://www.nhmrc.gov.au/	Australia's leading scientific authority on health and medicine.	The major national publicly funded competitive research-granting institution for health and medicine; also provides authoritative health advice.
Regulatory bodies		
Radiation Health and Safety Advisory Council of the Australian Radiation Protection and Nuclear Safety Agency https://www.arpsa.gov.au	The Australian Federal Government's primary authority on radiation protection and nuclear safety.	Advise the Australian Radiation Protection and Nuclear Safety Agency on 'emerging issues' in radiation protection and nuclear safety.
NSW Environment Protection Agency (EPA) http://www.epa.nsw.gov.au	A statutory authority with an independent governing Board.	Manage environmental issues in the state collaboratively with the other two levels of government in Australia's federated system; primary responsibility for environmental regulation in the state of NSW.
Australian Competition and Consumer Commission https://www.accc.gov.au	An independent Commonwealth statutory authority	Enforces the Competition and Consumer Act 2010 and a range of additional legislation to promote competition and fair trading.
Therapeutic Goods Administration https://www.tga.gov.au	A regulatory agency within the Department of Health of the Commonwealth Government	Responsible for regulating the import, supply, manufacture, export and advertising of therapeutic goods
The Health Care Complaints Commission http://www.hccc.nsw.gov.au/Home	Independent statutory body in NSW	Established under the Health Care Complaints Act (1993), the commission investigates complaints about health service providers in NSW
Fair Trading Commission http://www.fairtrading.nsw.gov.au/ftw/home.page?	Consumer complaints service within the NSW Government Department of Finance, Services and Innovation	Acts to safeguard the rights of all consumers and advises business and traders in NSW on fair and ethical practice
Government bodies, departments, authorities		
NSW Minister for Health	The minister responsible for human health in the state government of the day	Broad portfolio responsibilities for human health, oversees the majority of health service delivery in the state, which is co-funded by state and federal governments
NSW Chief Health Officer	Senior bureaucrat with lead responsibility for health matters within the NSW public service	Oversees a range of functions within the department responsible for health in the NSW government, including health protection, epidemiology, medical research
Australian Health Minister's Advisory Council http://www.coaghealthcouncil.gov.au/AHMAC/Introduction	Advisory and support body to the Coalition of Australian Governments' Health Council.	Increase coordination between state and national health ministers and their departments.

Supplementary Table 2: Data Sources and Search Terms

Data Sources
PubMed, Factiva, ANZ ProQuest, Informit, AustLii, and Pandora/Trove.
These databases catalog news and popular media reports, advertising materials, websites and online content, legal judgements, parliamentary proceedings, peer-reviewed science and medical journals, and government and corporate grey literatures.
Search Terms
“full body CT scan*”; “full body scan*”; “whole body CT scan*”; “whole body CT screen*”; “whole body CAT scan*”; “full body diagnostic scan*”; and, “yuppie scan*”

Supplementary Table 3: Ethnographic Content Analysis Sample Characteristics

Type of Source	Intended Audience	Number
<i>Mainstream media</i>		
Examples of advertorial in newspaper print media	General public	2
Examples of articles in newspaper print media	General public	18
Examples of articles on national broadcaster website	General public	2
Examples of articles on newswires	General public	2
Examples of transcripts of radio programs	General public	1
<i>Consumer organisations</i>		
Examples of articles in consumer news magazine	General Public	1
<i>Medical and scientific literature</i>		
Research articles in peer-reviewed medical journal	Medical practitioners	2
Editorials in peer-reviewed medical journal	Medical practitioners	1
News article in peer-reviewed medical journals	Medical practitioners	4
News articles in online medical news website	Medical practitioners Medical researchers Regulatory agencies	1
College or association newsletters	Medical practitioners Regulatory agencies	1
Report by medical research institute	Medical practitioners Medical researchers Regulatory agencies	1
<i>Government, court and health agencies</i>		
Parliamentary Hansard	NSW Parliament	2
Report by statutory agency	Regulators Professional associations	3
Legal ruling	Regulators Professional associations	1
Health agency webpage	General public Regulators Professional associations	4
<i>Private Individuals</i>		
Examples of activist websites / Blogs	General public	2
Examples of letters to newspapers	General public	1

Supplementary Table 4: Full body CT scans summary timeline

Jan 2002	The Royal Australian and New Zealand College of Radiologists took the position that there was no evidence to justify recommending full body CT scans.
Apr 2002	Full body CT scans became available in Australia.
Aug 2002	The Radiation Health and Safety Advisory Council took the position that there was no evidence to support full body CT scans.
Sep 2002	The NSW Chief Health Officer ordered an investigation under the Radiation Control Act 1990 to assess radiation exposures in CT machines being used and inform an assessment by the NSW Environment Protection Agency (EPA). The EPA proposed draft suite of conditions to be attached to licenses for CT machines (Box 1).
Nov 2002	The NSW state government accepted the EPA's recommendations and instituted a 6-month trial of the new licensing conditions.
Jun 2003	The new licensing conditions are legislated within the NSW Radiation Control Act