A case of misdiagnosed squamous cell carcinoma due to alternative medical misadventure—time for tightening regulation?

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Abstract

We present a patient with locally advanced squamous cell carcinoma that had grown significantly during 16 months of intensive alternative therapy. The alternative medicine practitioner allegedly repeatedly reassured the patient that her condition was benign and advised against seeking conventional medical treatment. Due to the delayed presentation, the patient required extensive surgery and postoperative adjuvant radiotherapy. This case highlights the risks of alternative therapy in the place of proven conventional medical treatment and emphasises the limitations of current regulation of complementary and alternative medicine in New Zealand.

Case report

A 65-year-old woman sought advice from an alternative medicine practitioner regarding a 3 cm ulcerated lesion on her scalp. The alternative medicine practitioner allegedly diagnosed the lesion as an ‘infected sebaceous cyst’ and reassured the patient that it was benign. The patient was commenced on a skin treatment regimen involving daily application of herbal poultice and dressing changes. After 6 months of treatment, the lesion had grown to 8 cm and developed a purulent discharge. When the patient’s family became concerned that the treatment was ineffective, the alternative medicine practitioner allegedly dismissed these concerns and reiterated that the lesion was benign and advised against seeking conventional medical advice.

After 16 months of treatment the lesion had grown to 20 cm and eroded through the calvarium to involve the dura. The pulsation of the exposed dura was noted by the family and mentioned to the alternative medicine practitioner who again allegedly dismissed and attributed to ‘the bones of the skull were flexible like the fontanelles of a newborn’. The patient’s pain was now severely debilitating leaving her housebound. Desperately concerned, her family took a photograph of the lesion and showed it to their family doctor who immediately referred the patient to the hospital.

On admission, there was a 20 cm ulcerated fungating lesion over the left fronto-temporo-parietal scalp (Figure 1). Culture of the purulent discharge grew *Staphylococcus aureus* and *Pseudomonas aeruginosa*. There was microcytic anaemia with a haemoglobin of 77 g/L and white cell count of 15.7×10⁹/L. CT and MRI scans confirmed widespread bony destruction of the underlying fronto-temporo-parietal skull with extension to the greater wing of the sphenoid and involvement of the dura including the area over the sagittal sinus (Figure 2 and 3).

Biopsies of the lesion demonstrated poorly differentiated squamous cell carcinoma. It was felt that a combined treatment with radical surgery and postoperative adjuvant...
radiotherapy would improve her quality of life with a small chance of cure. Surgery involved wide local excision of the tumour including the underlying skull, the greater wing of sphenoid, dura and part of the temporalis muscle. Reconstruction included dural repair with a dura substitute, split rib grafts to span the bony defect and an overlying free latismuss dorsi muscle flap covered with a split thickness skin graft. Eight months following surgery and radiotherapy, the patient experienced greatly improved quality of life but had developed parasthesia within the left trigeminal nerve distribution (Figure 4) although a repeat MRI scan failed to demonstrate a skull base lesion.

Figure 1. Photograph showing a 20 cm ulcerated fungating lesion on admission

Figure 2. A MRI scan showing extensive bony destruction and dural involvement
In this case, the perseverance with alternative medicine led to a delay of appropriate medical intervention with a resultant locally advanced disease. If the original lesion was managed timely and appropriately, treatment would have been simpler with a high likelihood of a cure. Instead, the patient required radical surgery and radiation therapy, with a remote chance of cure. In addition, the delay put the patient at significant risk of life-threatening complications such as meningeal infection and profuse haemorrhage.
Discussion

This case highlights the risks of delayed medical treatment and the limitations of current regulation of complementary and alternative medicine (CAM) in New Zealand. CAM is an umbrella term used to describe a range of health practices, modalities and therapies that exist outside of mainstream medicine. The National Centre for Complementary and Alternative Medicine (NCCAM) categorises CAM into five categories: alternative medical systems; mind-body interventions; biologically based therapies; manipulative and body based methods; and energy therapies.

Treatment can be further categorised as being complementary or alternative. Complementary medicine is that which is used alongside mainstream medicine, whereas alternative medicine is used in the place of mainstream medicine. In recent years, the popularity of CAM amongst the general population has increased significantly. Despite its widespread use, CAM practitioners are not subject to the same level of regulation as mainstream health practitioners.

In New Zealand, mainstream health practitioners are regulated by the Health Practitioners Competence Assurance Act (HPCAA). The HPCAA was enacted in 2003 and brings together all mainstream health practitioners under one piece of legislation. The purpose of the Act is to protect the health and safety of members of the public by providing mechanisms to ensure that health practitioners are competent and fit to practice their professions. Under the Act, practitioners must be overseen by a registration body (e.g. the New Zealand Medical Council).

Each registration body is responsible for defining their scope of practice and standards of competence. Practitioners are then required to undertake continuing professional development and quality assurance activities to maintain their annual registration. Failure to meet the required standards can result in loss of registration to practice. The HPCAA provides a system that ensures mainstream practitioners are competent and fit to practice. This system does not exist for CAM practitioners. At present, the majority of CAM practitioners in New Zealand lie outside the HPCAA or a similar legislative framework that regulates their practice.

Exceptions to this rule are chiropractors and osteopaths who are now regulated under the HPCAA. The remaining CAM practitioners are either under ‘voluntary regulation’ or ‘self regulation’. In other words, individual competency and fitness to practice is not regulated by statute. At present, there is no system to ensure that these CAM practitioners are competent and fit to practice.

Another important regulatory framework governing health care practitioners in New Zealand is the Health and Disability Commissioner Act (HDCA). The HDCA was enacted in 1994 following the Cartwright Inquiry and applies to all health and disability care providers in New Zealand, both mainstream and CAM practitioners. The HDCA makes provision for the Code of Rights, which represents the accepted standard of care within New Zealand.

The purpose of the Act is to promote and protect the rights of health and disability service consumers, and, to that end, to facilitate the fair, simple, speedy, and efficient resolution of complaints related to infringements of those rights. In the event of a breach, a formal investigation is undertaken by the Health and Disability
Commissioner. Options upon finding a breach include making recommendations to the provider, appropriate authorities (e.g. the registration body or professional college), the Minister of Health, the Director-General of Health, District Health Boards, Accident Compensation Corporation, and consumer and provider groups. These recommendations range from a written apology, undertaking specific training, and implementing and reviewing systems to prevent further breaches.

If there are concerns about the competency of a registered health practitioner, the Commissioner may recommend review by their registration body (e.g. the New Zealand Medical Council). If disciplinary and/or other proceedings are deemed necessary, the Commissioner may refer the case to the Human Rights Review Tribunal (HRRT). The HRRT has a range of actions that it can take including awarding compensatory and punitive damages, and ordering health care providers to undergo remedial training.6

While the HDCA and the HPCAA are both enacted to protect health and safety of the public, there are fundamental differences between these two Acts. The HDCA is based on the Code of Rights and is geared towards complaints resolution. In contrast, the HPCAA is focused on ensuring that health practitioners are competent and fit to practice and therefore preventing adverse events from occurring. At present, mainstream health practitioners in New Zealand are subject to both statutes. Thus they provide the confidence that they are both competent and fit to practice and the assurance of a formal complaints resolution process should a negative outcome occur. This is not the case for CAM practitioners in New Zealand.

With the exception of chiropractors and osteopaths, the remaining CAM practitioners are subject only to the HDCA. While the HDCA is an important pathway to resolve complaints, it is limited in its ability to prevent cases such as one presented in this report from occurring. There is no HPCAA-equivalent statute regulating CAM practitioners’ competency and fitness to practice.

In this case, the alternative medicine practitioner appears to have breached the HDCA Code of Rights. Namely, the right to services of an appropriate standard and the right to be fully informed6 and working beyond the scope of practice. While it may have been reasonable for an alternative medicine practitioner to manage the lesion initially, when it was noted the lesion was not responding to therapy but rather progressing, appropriate referral should have been sought. Also, from the time of the initial consultation and throughout the duration of alternative therapy the patient was allegedly repeatedly reassured that the lesion was “not cancer” and advised against seeking a second opinion.

This advice was allegedly given despite the patient and her family’s repeated enquiries in the face of continued clinical deterioration. To determine if a practitioner has breached the Code of Rights, the individual must be measured against the practice of a reasonably careful practitioner within his/her relevant profession. As such, the care provided by this alternative medicine practitioner must be compared with that of a reasonably careful alternative medicine practitioner.7 It is doubtful that a reasonable alternative medicine practitioner would have undertaken the same practice when faced with the same deteriorating clinical scenario.
The issue of regulating CAM practitioners has been widely debated in the literature.\textsuperscript{7–11} Arguments in favour of regulating CAM practitioners centre around the need to ensure public health and safety. The cost of unsafe health care (both personal and economic) to the individuals, families, communities, and the country is huge. As illustrated in this case, the practice of CAM is not without risk.

General risks include making misleading claims, lack of appropriate referral resulting in delays in treatment, and lack of first aid knowledge. More specific risks associated with particular CAM therapies can include tissue, nerve or organ damage, infection, poisoning, allergic reaction or interaction with other treatments.\textsuperscript{12} Regulation has the potential to contain these risks by defining the scope of practice and the standard of competence.

Throughout the health care sector there is increasing pressure to ensure that treatments are evidence-based. To date, research into the safety and efficacy of CAM is still rudimentary compared with mainstream medicine. As such, there is little high quality evidence for many CAM treatments. Critics of CAM argue that this is a true reflection of the lack of validity of CAM. Proponents of CAM argue that it is difficult to apply standard research methods to CAM. It is argued that methodologies such as randomised-controlled trials have too much emphasis on quantifiable outcomes.\textsuperscript{8}

There are also a number of arguments opposing regulation of CAM. One such argument is that regulation would restrict access to CAM practitioners, through its effect on compliance costs and on the number of practitioners. Another concern is that statutory regulation may appear to give CAM official endorsement for treatments that, so far, are not evidence based. This unwarranted status may run counter to achieving consumer and public safety.\textsuperscript{8,12}

In 2001, the Ministerial Advisory Committee on Complementary and Alternative Health (MACCAH) was established.\textsuperscript{12,13} The goal of the Committee was to review the issues surrounding CAM regulation in New Zealand and provide advice to the Minister of Health. In 2004, the MACCAH published their recommendations.\textsuperscript{13} The Committee recommended that CAM practitioners should be regulated according to the level of inherent risk involved in the modalities they practice. They recommended high-risk CAM modalities should be regulated under the HPCA.

To date, the only CAM practitioners to be identified as high-risk in New Zealand are osteopaths and chiropractors. It was felt that the remaining CAM practitioners were of low-risk and could continue to self-regulate.\textsuperscript{13}

We argue that self-regulation of these so-called low-risk CAM practitioners is inadequate. We have presented a case which demonstrates the need for closer scrutiny of all CAM practitioners. One avenue for achieving this is statutory regulation. We recommend review of current regulations to prevent further similar cases from occurring.
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