


Consent, capacity and compliance in concussion management: cave ergo medicus (let the doctor beware)

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ABSTRACT

While the acute effects of concussion and mild traumatic brain injury (TBI) are well understood, the certainty in the medical literature regarding the long-term outcomes of sports-related concussion is limited. Long-term deficits that may result from single, repeated concussions, and possibly subconcussive impacts, include cognitive dysfunction, depression and executive dysfunction. Perhaps most troublingly, repetitive head impacts have been linked to neurodegenerative diseases, including chronic traumatic encephalopathy (CTE), although the precise risk of long-term consequences remains unknown. CTE represents a distinct tauopathy with an unknown incidence in athletic populations; however, a cause and effect relationship has not yet been demonstrated between CTE and concussions or between CTE and exposure to contact sports, as no prospective longitudinal studies have been performed to address that question. Studies of high-school sports exposure and long-term outcomes have not demonstrated consistent findings.

Medical advice regarding return to play and the risk of acute and/or long-term consequences is therefore problematic. It is important that the individual's right to make their own choices regarding their health is respected. Team, coach, parental, peer or financial pressures should not influence this decision. The choice to return to play after a concussion or mild TBI injury is the athlete's decision once they have (1) recovered from their injury and have the legal capacity to make an informed decision; (2) been medically assessed and (3) been informed of any possible long-term risks in a language that they can understand.

Given the current lack of certainty in relation to long-term outcomes from concussion, is it possible to provide a framework to inform players of current evidence, as part of a consent process, even if the information upon which the decision to return to sport is based remains uncertain and evolving?

the medical literature regarding the long-term outcomes of SRC.^{7–9} Long-term deficits that may result from a single concussion and/or repeated concussions include cognitive impairment, depression and neurobehavioural dysfunction. Perhaps most troublingly, repetitive (subconcussive) head impacts have been linked to neurodegenerative diseases, including chronic traumatic encephalopathy (CTE), although the precise risk of long-term sequelae remains unknown.⁷ CTE represents a distinct tauopathy with an unknown incidence in athletic populations^{10–12}; however, a cause and effect relationship has not yet been demonstrated between CTE and concussions or between CTE and exposure to contact sports, as no prospective longitudinal studies have been performed to address that question.⁷ Studies of high-school age sports exposure and long-term outcomes have not demonstrated consistent findings.^{13–19}

Medical advice regarding return to play and the risk of acute and/or long-term consequences is therefore problematic. It is important that clinicians respect the individual's right to make their own choices regarding their health. Team, coach, parental, peer or financial pressures should not influence this decision. The choice to return to play after a concussion or mild TBI injury is the athlete's decision once they have (1) medically recovered from their injury, (2) have the legal capacity to make an informed decision and (3) been informed of any possible long-term risks using terms and language that they can understand.

Given the current uncertainty in relation to long-term outcomes from concussion, is it possible to provide a framework to inform players of current evidence, as part of a consent process, even if the information upon which the decision to return to sport is based remains uncertain and evolving? Can the principles of informed consent in healthcare be applied in this setting?

INTRODUCTION

In the days and weeks after injury, sports-related concussion (SRC) has been linked to cognitive deficits, neurological symptoms, sleep problems and mood impairment, as well as an increased risk of injury when resuming sport.^{1–4} More severe traumatic brain injury (TBI) is also associated with elevated risk of premature mortality in population studies.^{5,6}

While the acute effects of concussion and mild TBI are well understood, there is uncertainty in

MEDICOLEGAL ENVIRONMENT

Whenever sport is played, there is a complex interconnecting set of medicolegal relationships that must be considered in relation to the risk of injury. These include:

1. **Individual risk:** there is a long-standing legal principle in English common law of *'volenti non fit injuria'*—the assumption of risk by competent adults where it is understood that voluntary participation in contact sports, even when played by the rules, may have a risk of injury.



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This principle is a common defence for the torts of trespass against the person providing the physical contact did not go beyond what was expected in the usual nature of that sport (*R v Billingham* (1978) Crim LR 553) or that the injuries resulted from inadequate safety measures (see comment on *Watson v British Boxing Board of Control* (2001) QB 1134 below).

2. **Sporting Club:** there is a duty of care owed to an athlete either employed by a sports club or when participating in an organised sporting fixture under the auspices of a sporting club. Sporting clubs have an obligation in law to take all reasonable steps to ensure that their medical staff, allied health staff and trainers assess and manage concussion in accordance with the prevailing rules and regulations of that sport. They must also take all reasonable steps to ensure that all the staff involved in medical care of the club's athletes are appropriately registered (if relevant in their jurisdiction) and resourced, and that players are educated regarding the importance of concussive injuries.
3. **Medical staff:** doctors and healthcare professionals must be registered or licensed to practise in the state or country and do so within the scope of their training, experience and competence. They should be familiar with current concussion management guidelines specific for the athlete's sport and there should be no financial or other conflict of interest that could potentially influence patient care. Like all other medical professionals, they are negligent if they fail to deliver the standard of care reasonably expected of someone in the medical profession (as held in the cases of *Wilsher v Essex Area Health Authority* (1988) 1 AC 1074 and *Bolam v Friern Hospital Management Committee* (1957) 1WLR 582 (1957)).
4. **Sports governing bodies:** sporting governing organisations or unions that impose regulations or guidelines to manage concussion, may take on an additional duty of care for their sports participants. Additional steps for governing bodies may include rule changes, education, medical guidelines and research into injury prevention. The Court of Appeal of England and Wales ruled in *Watson v British Boxing Board of Control* (2001) QB 1134 that even allowing for a voluntary assumption of risk, the British Boxing Board of Control as a governing body owed a duty of care to participants. It was in breach of this duty by failing to ensure that adequate resuscitation equipment and medical assistance was available at ringside in the event of the claimant suffering a serious head injury during the bout. This case was considered to be the first case where a regulatory body has been liable for the negligent failure to regulate. In *Australia* however, the case of *Agar v Hyde* (2000) HCA 41 examined the question of whether the board of control owed a duty to protect the players of the game in a case of a rugby player who sustained a broken neck while playing rugby. The High Court of Australia determined that the board did not owe a duty of care in circumstances where it lacked control over the rules in matches where the players were injured.

SPORTING CLUBS AND GOVERNING BODIES CONFUSING THE ROLE?

Even allowing for the voluntary assumption of injury risk, it would be reasonably foreseeable that the individual participants (who necessarily accept a risk of injury by participation in sport) would rely on their club for overall medical care and for sports governing bodies to ensure the personal safety of participants

(by providing rules and safety guidance, and by taking all reasonable steps to ensure their compliance).

Sporting organisations often fulfil this role through regulatory mechanisms that specifically require the team doctor to determine 'fitness to play' for injured players, without necessarily involving a formal process of informed consent, in the expectation that this unstated requirement will be satisfied by the doctor. An example of this approach is shown by the international sports medicine federation, FIMS, which states '*It is the responsibility of the sports medicine physician to determine whether the injured athletes should continue training or participate in competition*'.²⁰ Most of the governing bodies of sport do not have a specific medical ethical code but rather default to the doctors' country of licensing origin to provide an overarching ethical model in which to practise. Only the International Olympic Committee has a detailed and specific medical ethical code of conduct, which is recognisable as a process of informed consent related to participation between the athlete and doctor.²¹

An extension of this concept is that sporting clubs, and governing bodies, should provide concussion education, in an effort to inform athletes about the issues associated with this injury. The sporting bodies might then claim that the athlete is *knowingly* assuming the risks inherent in that activity. It is critical to recognise that this informed consent process begins, not at the professional sports level, but with parents who must evaluate risk on behalf of their children, who are legally minors until the age of 18. Moreover, the simple provision of information does not demonstrate that the individuals have actually received and understood the message. This is discussed further in the General principles section.

THE ROLE OF THE DOCTOR

Traditionally in sports medicine, the doctor assesses a concussed player and 'decides' when that player is fit to participate in sport after a SRC, or when it is sensible to retire when he or she has ongoing problems or has had 'too many' concussions. Nonetheless, the corollary goals of beneficence (*moral imperative to do the right thing*) and non-maleficence (*do no harm*) are fundamental to all ethical frameworks of medical practice and, when managing athletes who have sustained a concussion, physicians must consider the current and future best interests of the patient.

The physician's ethical duty to safeguard all athletes, particularly younger athletes, from the risks of additional concussions increases with each injury. Physicians should be sensitive to the many factors motivating an athlete to return to sport, regardless of the athlete's acknowledgement that there is a potential risk of neurologic impairment, which may be permanent. Additional factors motivating an athlete's desire for an early return to sport may include career aspirations, financial drivers, a commitment to a sport, school, or team, pressure to meet expectations from family or coach, intrinsic competitiveness and, particularly in team sports, a loyalty to teammates and the team culture.

Acute concussion injuries

Treatment of acute SRC occurs in game day situations when pressures exist that (1) limit the ability of the doctor to communicate treatment options effectively or (2) in the case of concussive injuries, where the capacity of the player to make their healthcare decisions cannot be easily or accurately determined.

In the acute situation, given that the clinical features of head injury evolve over time, it is not possible using current technology or clinical tools to accurately exclude a concussion injury when an athlete presents with neurological symptoms in that

setting.¹ Sideline assessment tools, such as the SCAT5 provide a standardised means of assessing potentially concussed athletes, however they do not provide a diagnosis per se which is a clinical judgement. In any case, no current assessment tool assesses capacity for decision-making or consent.¹

The doctor's role (either as a team doctor or independent doctor) is primarily one of beneficence. While medical ethics has rightly emphasised the importance of preserving patient autonomy, this principle is not absolute and does not outweigh all other ethical imperatives. A physician's commitment to beneficence and a duty to protect his or her patient from harm may occasionally supersede patient autonomy from an ethical perspective particularly when a concussed athlete may not have the capacity to make a competent decision regarding their own health. In this situation, the doctor determines fitness to play and hence removal from participation, when a concussion is suspected. See sections 4 and 5 of the attached template in online supplementary file 2 for examples of the independent medical assessment process and sign off.

Various international guidelines have repeatedly emphasised that only licensed medical professionals should provide care to concussed athletes²² and in such situations the other practitioners could be acting under the supervision or direction of the medical practitioner. A claim could be brought against the club, as well as the individual medical practitioner, trainer or allied health professional, as each may have their own insurance. Ultimately legal representatives for any injured athlete bringing a claim will want to ensure that the defendant's insurance will cover the claim being intimated. A trainer or allied health professional may have no insurance cover, or insufficient cover, and expect to be covered by the club. It is not unusual to see a claim brought against multiple parties by the claimant, or one defendant seeking to pass a claim onto another for example, a club saying that the medical practitioner and his or her own indemnifier should be responsible for responding to a claim.

Return to play and retirement decisions

In any return to play decision (following recovery from SRC, or where an athlete has sustained repeated injuries and concern exists as to the risk of long-term problems), there is an assumption that the athlete has (1) recovered from the acute injury of concern and (2) has the legal capacity to make a voluntary decision about his/her health. In this situation, there should be a full and frank discussion between the doctor and player, inline with the principles of informed consent, enabling the player to ultimately decide whether or not they should participate in future competitions.

Despite these important considerations, athletes, and particularly adolescent athletes, may not truly understand the risks or potential long-term sequelae of concussion. Thus, restricting concussed athletes from prematurely returning to play, or from returning to play after multiple concussions, is grounded in the physician's commitment to beneficence and protecting athletes from potential harm. From a legal perspective the physician will often be judged in terms of his or her clinical management in accordance with what a responsible body of medical peer opinion would do, and whether the practice in question would withstand logical analysis. When looking at what information is given to the athlete, to allow him or her to make a decision to accept treatment or return to play following a concussion injury, a court will look to see that informed consent has been obtained. In accordance with the principles in *Montgomery v Lanarkshire Health Board* (2015) UKSC 11 and *Rogers v Whittaker* (1992)

HCA58–AustL11, the court would not reference what risks a responsible body of medical opinion thinks the patient should be told about but, instead, what material risks the particular patient, or a 'reasonable' patient in the same position, would want to be told.

It is important to note that in both acute and long-term management situations, there is a clear legal duty of care owed by the doctor to the concussed athlete (either as an independent physician or through his club employer) and any breach of this legal duty may have significant consequences, including possible civil litigation and/or investigation by professional regulatory agencies.

POTENTIAL FOR CONFLICT OF INTEREST

Ideally, all physician payments pertaining to SRC should be solely derived from patient evaluation, management and counselling activities. Physicians should disclose all financial arrangements that could influence patient care decisions to athletes and/or their legal guardians. This includes contractual relationships with teams, organisations or governing bodies, involvement (scientific or financial) in the development of diagnostic or protective equipment, and paid sponsorships. Physicians who have the potential to benefit directly (financially), or indirectly (by reputation from referrals, publicity or name recognition) from treating athletes with concussion, should disclose these potential conflicts of interest immediately and must ensure that their primary duty is to care for the health of the athletes.^{23 24} While it is assumed that treating doctors make decisions in the best interests of the patients, when a team employs the same doctor, the potential for a conflict of interest in decision-making exists (or may be perceived to exist). See sections 1 and 3 of attached template in online supplementary file 1 for examples of conflict of interest forms for both player and doctor.

For both acute injury assessment, as well as return to sport decisions, the role of an 'independent' or non-affiliated physician to assess the injured player may offer an opportunity to avoid such potential conflicts of interest. However, the downside of not 'knowing' the player, or having access to their full medical history, can make the assessment, especially pitch side, more difficult.

INDIVIDUAL COMPETENCE TO MAKE HEALTH DECISIONS

From a legal standpoint the terms *capacity* and *competence* to make decisions are often used interchangeably. Adults are presumed to be competent, unless it can be proved otherwise. From a practical standpoint, the law requires that the individual be able to understand and retain treatment information, weigh the information and reach a decision and be able to communicate his or her decision. Based on this common law approach, four jurisdictions in Australia (New South Wales, Queensland, Tasmania and Victoria) have formally enacted legislation that adopts a functional test of competence. For example, in Victoria, section 36(2) of the Guardianship and Administration Act 1986 states that a person is incapable of giving consent to the carrying out of a special procedure or medical or dental treatment if the person

1. is incapable of understanding the general nature and effect of the proposed procedure or treatment; or
2. is incapable of indicating whether or not he or she consents or does not consent to the carrying out of the proposed procedure or treatment.

It is important to note that an assessment of competence is not always simple or straightforward and may require input

from specialists such as neuropsychologists. In the setting of an individual following a concussion or mild TBI, that individual's ability to synthesise and retain information may be impaired and needs to be assessed formally as part of any consent process where a healthcare decision may be made. The law does not mandate any specific test to be passed, but instead leaves the decision to the discretion of the clinician.^{25–27} See section 6 of attached template in online supplementary file 3 for examples of the assessment of capacity to make health decisions.

In many legal contexts, a person is not termed an adult until they are 18 years of age. Therefore, a parent (or legal guardian) is required to consent to their child's medical treatment although Australian law recognises that teenagers become more competent as they get older and may be able to provide informed consent for themselves. In some jurisdictions the concept of a 'mature minor' is recognised, so that a person younger than 18 years of age, may nevertheless demonstrate competence to consent to or refuse treatment, without the consent of a parent or guardian. Competency is assumed unless there is clear evidence to the contrary. Under English law, 'Gillick competence' has established that someone under 18 can consent to treatment if they satisfy the necessary criteria to take on, retain and understand the information being given. This was a result of a 1985 decision of the House of Lords in *Gillick v West Norfolk and Wisbech Area Health Authority (AHA) (1986) UKHL 7* and is binding in England and Wales, and has been adopted to varying extents in Australia, Canada and New Zealand. This case related to the prescribing of contraceptive medication to a teenage girl, without the consent or knowledge of the mother, and the judge accepted that the girl was able to understand the information provided and use it to consent to treatment. It does not apply so readily however to decisions to refuse medical treatment especially where the treatment may be lifesaving treatment.

THE PROCESS OF INFORMED CONSENT IN RETURN TO SPORT DECISIONS

Informed consent is an agreement obtained from a competent patient to undertake a specific course of action and has ethical, legal and practical implications. Ethically, consent represents an individual's inherent moral right to make autonomous healthcare decisions. Legally, consent represents a process through which the individual's right to agree to, or refuse, medical treatment is upheld. Practically, consent represents the conversation in which the patient and clinician discuss the options, risks and benefits of treatment and any consequences of refusal. It is vital that people are given the information they need in order to choose what is right for them in a manner that they can understand. The patient, and parent/guardian, must be given an opportunity to ask questions and have them answered. It is essential that they not only hear, but also understand this information. Ensuring that they understand is a key aspect of consent and is the responsibility of the clinician obtaining consent, who should also ensure that this process is documented. See sections 8–10 of the attached template in online supplementary file 3 for examples of the consent process in decision-making.

General principles

There are general principles that apply to all informed consent processes. These principles require:

- ▶ **Capacity:** a patient must be of sound mind and over 18 years of age in order to give or refuse valid informed consent.
- ▶ **Informed:** the patient must be provided with sufficient information on which to make a decision regarding his or

her own healthcare. This should include the details, nature, benefits, alternatives and material risks of the proposed health intervention or treatment. Information about the proposed health intervention or treatment must be provided in a way that the patient can understand. It is the clinician's responsibility to make sure the patient understands and is not just passively agreeing.

- ▶ **Voluntary:** consent must be given freely and voluntarily. The clinician may advise the patient what they believe is the best option for their care. A clinician must not exert pressure on, coerce, or force the patient to take their advice and the patient has the right to choose between available treatment options. This process should be documented and communicated to all involved.
- ▶ **Timing:** consent must occur prior to the commencement of any proposed procedure or treatment.
- ▶ **Specific:** consent given by the patient must be specific to the treatment for which the patient has been informed and is only valid for that medical treatment. The clinician must not exceed the 'scope of authority' given by the patient.
- ▶ **Consent in language that a player can understand:** many laws and sporting bodies may have policies that require athletes to acknowledge receipt of concussion-related information. One way to eliminate disputes involving the risks inherent in an activity is to provide participants with information regarding those risks and to require their acknowledgement of the risks. By providing athletes with concussion-related information and requiring their express acknowledgement of the inherent risk of concussion, as a part of the sport prior to participation, schools/coaches/leagues may be attempting to limit their liability in this area. It should be noted that the requirement and provision of athlete and/or parental signatures does not necessarily mean that the information provided has been read or understood. Particular care is required to ensure that the primary language of the athlete, and the family, has been taken into account. Although providing concussion-related information to athletes and/or their parent/guardian, and requiring them to acknowledge receipt of this information in writing, is included in a majority of approaches, there is relatively widespread variation in the ways in which these are structured and implemented. Data suggest that general concussion information provision among collegiate and club athletes can be variably implemented and largely ineffective in changing concussion knowledge or concussion reporting behaviour.²⁸

The area of consent carries significant medicolegal risk. Failure to properly discuss and advise of the short-term and long-term risks around returning to sport after a concussion injury could result in a legal suit being brought later. Important evidence a court will be asked to consider will include the medical records and, therefore, a clear contemporaneous note of the discussion that took place, including advice given, questions asked and so on, is critical. Consent should not be seen as a 'tick box' exercise (eg, is the athlete fit to return to sport following concussion? YES/NO). What is needed is clear evidence of a two-way dialogue, with the patient being given a chance to ask questions, consider information and have explained to them any material risks relevant to that patient in the patient's position.

The key point is that it is a subjective analysis and decision-making process. Both risks and what the athlete may want or choose to do could differ very much between a 20-year-old athlete breaking into a first team and a 33-year-old athlete coming to the end of his or her career. As the Australian consent case of *Rogers v Whittaker (Rogers v Whitaker) (1992) HCA 58*;

175 CLR 479) shows it is not just a matter of percentages on risk but what does this particular patient consider important. All discussions should be carefully documented and encapsulate the complexity of the case.

A recent English case (*Webster v Burton Hospitals NHS Foundation Trust* (2017) EWCA Civ 62, (2017)), which involved risks concerning obstetric management that were only identified in emerging medical understanding highlights this point. In determining factual causation, the judge ruled about individual willingness to take responsibility for health decisions. The court looked subjectively at the particular claimant (a university-educated patient with a degree in nursing), and deemed that she was capable of distinguishing what risks she would and would not take and had demonstrated ability to process medical advice about her health-care. Such a patient may reject medical advice and follow their own judgement. This issue becomes more complicated when the individual is uneducated, and/or has had no opportunity to demonstrate willingness to take responsibility for their health, but equally it does not mean that the clinician should disregard their obligation to provide sufficient information to the patient, including warning of material risks associated with the treatment. It is then for the patient to make an informed choice as to how they wish to proceed.

ANOTHER COMPLICATION—LEGISLATION AND PRIVACY LAWS

In addition, in US State concussion laws, physicians who perform concussion evaluations must take into account federal and state privacy laws. The US Federal Health Insurance Portability and Accountability Act, as well as many state privacy laws, restricts providers from sharing personal health information without specific patient consent. These restrictions can present challenges for physicians in the context of athlete—patients who want to return to play contrary to medical advice. The athlete may also request that the physician's evaluation and denial for clearance to return to play remain confidential. Thus, the evaluating physician could find himself or herself in the difficult position of being legally restricted from sharing a concussion evaluation with the athlete's coaches and school personnel, even though making such a disclosure might be in the best interest of the athlete's health.

In English law, such considerations reference the General Data Protection Regulation 2016/679 (GDPR). All health organisations will have a GDPR policy and staff should be aware of their obligations under this. In Australia, health practitioners should be aware of their obligations under the various state health records legislations (eg, the Victorian *Health Records Act 2001*) and the Australian privacy principles under the Australian *Privacy Act 1988*.

If it is a club doctor who is making an assessment of an athlete, it is arguable that they have to share the data within their club (ie, to a manager or high-performance coach) if a failure to do so could put the athlete at risk. This may be more complex when a player is referred to an outside specialist.

NEXT STEPS

The authors have discussed the medicolegal issues related to concussion assessment above and propose a framework or template for clinicians to assess decision-making in acute concussions, as well as for athletes with multiple concussions

or persistent symptoms. This is shown in Sections 1-10 of the online supplementary files 1–3 .

The overall concept of the template is that the individual sections can be used in a modular fashion as needed in the clinical assessment and then incorporated into the medical record.

This template also provides a contemporaneous medicolegal documentation of the process undertaken by the doctor and patient. In some jurisdictions, consideration of video-taping the discussion may be worthwhile with copies retained by both doctor and patient.

While this template provides guidance for the discussion between a doctor and patient, it is important to understand that practitioners should monitor the literature as clinical and research evidence evolves and incorporate this information into their discussion and document this as required. As indicated in the text, as well as in the template, it is critical that in order to make an informed decision, athletes receive information in a language that they can understand and have the opportunity to have all their questions answered. We would also argue that an additional step of a 'cooling off' period is valuable before career ending decisions are made. This gives the athlete additional time to process the discussion, talk with friends, family or advisors and reconvene for further discussion and additional questions. A 'second opinion' should be offered as another option to assist the decision process, where necessary.

What is already known/What are the new findings?

- ▶ Sport related concussion is associated with short-term and long-term neurological sequelae
- ▶ Current research does not provide an accurate risk of the long-term problems resulting from single or repeated concussive impacts
- ▶ Informed consent is a basic legal requirement for all medical interventions and treatments
- ▶ A framework based on the medicolegal principles of informed consent is provided to assist clinicians in the management of sports related concussion

How might it impact on clinical practice in the near future?

- ▶ The authors propose a framework with which to assess return to play decisions in acute concussions as well as for athletes with multiple concussions or persistent symptoms. This framework provides a medicolegal documentation of the process.

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Competing interests DM is a coinvestigator in research on long-term follow-up of neuropsychological function in former Australian Rules Footballers, funded through the Florey Institute of Neuroscience and Mental Health. He has a legal practice in medical law and has provided legal advice to professional sporting clubs and the Australian Football League (AFL). He is a member of the AFL Grievance Tribunal and the AFL Concussion Working Group. PM is a coinvestigator on competitive grants relating to mild TBI funded by several governmental and other organisations. He is funded under a Fellowship awarded by the National Health

& Medical Research Council of Australia and is employed at the Florey Institute of Neuroscience and Mental Health. He has a clinical consulting practice in neurology, including medicolegal work. He has been reimbursed by the government, professional scientific bodies and commercial organisations for discussing or presenting research relating to MTBI and sport-related concussion at meetings, scientific conferences and symposiums. He acknowledges unrestricted philanthropic support from CogState Inc (2001–2016). He is the chair of the scientific committees of the International Concussion and Head Injury Research Foundation in London and the Sports Surgery Clinic in Dublin. MT is employed by ICHIRF as CEO and Medical Director. He has been reimbursed by universities, scientific bodies, and commercial organizations for travel and accommodation related to presenting research relating to concussion at meetings, scientific conferences, and symposiums.

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