

Introduction

The work of Ted Freeman and the local medical profession's response to it raise several critical issues that have ongoing relevance for Australian health consumers and health policymakers alike. The first is the capacity of the health system to respond appropriately to catastrophic disablement. Until the 1980s, at least, the conditions in which many people with severe disabilities were kept shocked most outside observers. Today, awareness is higher and more resources have been allocated, but long-term care institutions remain the subject of myriad complaints.

Another worrying issue that his story raises is the closure of some medical minds and the isolation of the Australian medical fraternity from the latest overseas developments in treatment. Dr Freeman was widely ostracised by colleagues who appear to have been unaware of the cutting-edge ideas and practices that were emerging in other countries where his work was highly respected. Since the 1980s, Freeman's hypotheses that the brain is plastic and has considerable capacity to repair itself have been validated by scientific observations and are now universally accepted. Australian health consumers might well ask whether mechanisms are in place to prevent a recurrence of such a travesty.

The issue of what constitutes evidence-based medicine is as relevant today as it was 30 years ago. In its bid to ensure legitimacy, medical practice has emphasised the scientific basis of that practice; however, a quick survey reveals that many practices have been introduced on the basis of empirical evidence long before modes of operation were understood. The reality that there was no scientific basis, in the 1980s, for the commonly accepted approach to the management of people with injured brains is a case in point.

The relationship between scientific hypothesis, including its validation, and empirical observation in developing potentially innovative medical therapies is a central issue in the Freeman story. Demonstration that a specific therapy can benefit a group of patients, without imposing a contingent risk, is not synonymous with an equally confident demonstration of how that therapy is actually achieving its goal.

The introduction of penicillin into clinical practice may be the best-known example of the reality that demonstration of clinical efficacy and safety is a question distinct from that of how an innovative therapy is actually achieving its results. Clinical proof of the value of this antibiotic was established by Howard Florey in the early 1940s and was sufficiently convincing that its use in the North African theatre of World War II was expedited. Understanding of the mechanism of action of penicillin, however, had to await the crystallographic

studies of its structure by Dorothy Crowfoot Hodgkin two decades later. This gap was reflected in the two decades separating the awarding of Nobel prizes to Florey (Medicine or Physiology, 1945) and Hodgkin (Chemistry, 1964).

In other instances, a therapeutic advance has been successfully introduced underpinned by a hypothesis of its mechanism of action that has subsequently been invalidated by further research with the result that this hypothesis has been discarded. Nevertheless, clinical efficacy, accompanied by safety, has ensured the continued use of the therapy, notwithstanding the abandonment of the theory that originally led to its development.

In 2013, successful new therapies are increasingly being produced by synthesis of molecules the detailed structure of which may be predicted in advance to act on highly specific cellular receptors in the human body. These receptors have, in their turn, been shown previously to be critical in disease development. On this basis, it is easy to assume, quite incorrectly, that empiricism had no place in twentieth-century medicine. Despite the elegance of therapeutic approaches developed by molecular strategies, it is unlikely that anything approaching the full range of human diseases will be so well understood in the foreseeable future. Acquired brain injury and the mechanisms responsible for recovery, at least at the molecular level, are likely to elude such precise understanding. The experience to date, including that of Freeman, implies that interventions that are much more basic and which defy precise measurement, such as human interactions, may continue to have more to offer.

Acquired brain injury and, more specifically, the potential for recovery from it, was very poorly understood at the time Freeman became interested in the subject. His initiatives, to be discussed in this book, were based on the limited understanding of normal function and capacity for repair following injury in the human brain available at the time. Understanding of these events, although it has advanced since the early 1980s, remains massively incomplete today. The truism that 'if the human brain was sufficiently simple that we could understand it using our own brains, we wouldn't have the ability to do so' remains substantially valid.

Freeman's hypotheses about which approaches might facilitate recovery of the injured brain were substantially based on the body of information that had been published to that time, with one notable exception—namely, that of the existence of neuroplasticity. Much of this information is likely to have been wide of the mark. One basis for opposition to his proposals by colleagues was undoubtedly that they conflated assessment of his hypotheses with his clinical outcomes. To the extent that some of his hypotheses could be associated with claims by others, which may have been of dubious validity, opposition was fuelled.

Reinforcing the opposition to Freeman engendered by scepticism about his theories, divorced from the question of whether the clinical outcomes of people who had participated in programs designed by him were successful, was an attitude that can only be categorised as therapeutic nihilism. Details of this will be given in a later chapter but its basis may be summarised here. The prevailing mind-set (I do not consider that an unduly denigratory term in this context) among medical professionals at the time when Freeman set out to attempt rehabilitation of people with severe brain injury held that any recovery could only occur as a result of a natural process. Furthermore, it held that the speed and extent of any recovery would not be affected by medical intervention. As succinctly expressed at the time, the medical attendants were no more than spectators during the return of consciousness. This firmly held opinion, which Freeman would not accept, was buttressed by the scientific conviction that new neurons could not be formed after birth in the human brain.

Controversially at the time, Freeman hypothesised that brain repair was possible, whether by the production of new cells, by the assumption of new responsibilities by existing networks of cells or by other, unanticipated mechanisms. These processes fell into the description, disparaged at the time, of 'neuroplasticity'. Freeman's records indicate that he was actively promoting the concept of plasticity as a contributor to functional recovery in the early 1980s. The term 'neuroplasticity' and the concept underlying it are now universally accepted. One type of observation facilitating this acceptance has been the repeated demonstration of the formation of new neurons. Whether, and to what extent, the generation of new neurons contributed to the recoveries that ensued among many of Freeman's patients is unknown but, by analogy with the history of the introduction of penicillin into practice already referred to, that is not a valid reason to preclude clinical application.

Background

The outlook for a patient with acquired brain injury in 1980 was a reflection of rapid progress in one field of medical practice, unaccompanied by comparable progress in associated fields. Advances in intensive care, and in radiological technology capable of very accurately localising injury within the brain in anticipation of emergency neurosurgery, permitted the survival beyond the acute stage of many patients with traumatic injury who would not formerly have done so. A majority of these patients were young persons involved in motor vehicle accidents. By the time that their need for intensive care had been replaced by a need for rehabilitation, some of these people would not have regained consciousness and, of those who had done so, many remained very severely disabled.

Existing rehabilitation services were not usually equipped to meet the needs of patients who remained severely disabled by brain injury when they were discharged from an intensive care unit. Furthermore, because of budgetary constraints, rehabilitation services commonly imposed minimal entry standards, which were unattainable by these patients. Consequently, patients who had sustained severe traumatic brain injuries in the first three decades of life, along with those who had sustained other types of severe neurological impairment, were frequently destined for admission to aged-care facilities at an early stage, sometimes within a few weeks of the event occasioning their injury. This major deficiency in provision of continuity of health care required that patients conformed to the established system or were excluded from it. An alternative—namely, that of introducing systemic flexibility, for example, in the form of slow-stream rehabilitation strategies—was not accepted, at least in Australia, in the 1980s. Having witnessed the fate of young adults consigned to nursing homes for the remainder of their lives (which most of his colleagues are unlikely to have done), Freeman felt compelled to intervene on their behalf. Many of the patients whom Freeman attended under the auspices of the National Brain Injury Foundation conformed to this description.

Medical tribalism (or the dominance of the curative medical model)

The disconnection between the acute care provided to patients with an acquired brain injury and that available in the longer term serves to highlight a second general issue exposed by Freeman's experience—namely, the consequences for a patient of medical tribalism. This was manifest in segmentation of different aspects of a patient's care and accompanied by an emphasis on cure at the expense of care. An example of this, discussed below, was the setting of fixed time boundaries between the care to be provided by different medical specialties, irrespective of an individual patient's progress along the recovery path. Patient transfer from one speciality to another was likely to follow the systemic rules rather than the specific patient's needs. These demarcation issues came to the fore in the course of trialling Freeman's practices in a hospital setting. Tribalism certainly came to the fore in the personal hostility directed towards Freeman by some of his medical colleagues. Being neither a neurologist nor an accredited rehabilitation specialist, he could not be taken seriously, it was suggested.

Before considering the nature of the issues raised in the course of attempts to trial Freeman's ideas, another source of antagonism towards him should be noted. An approach that he commonly adopted may be categorised as 'domiciliary rehabilitation'. This entailed the conduct of rehabilitation measures in the

patient's home. Primary participants in such programs were family members, frequently assisted by large groups of volunteers. Not only did family members undertake procedures with their patient but also, not unnaturally, they often made observations. Freeman invariably took account of family observations, a practice with which some colleagues strongly disagreed. Moreover, the shifting of responsibility for rehabilitation from healthcare professionals to laypersons tended to generate hostility among healthcare professionals.

The basis cited by many practitioners for disparaging the reports from family members ranged across issues such as their lack of training and the risk that they would see what they hoped to see. Freeman's emphatic response to these objections was that he found family members to be accurate observers. It was also relevant that they had 24/7 access to patients rather than a few minutes in the course of a ward round. As discussed later, inconsistency in patient responsiveness is a characteristic feature during the early stages of regaining consciousness after brain injury. Several decades after Freeman stressed this inconsistency in responsiveness, some objective validation of it is now available.

The issue of formally showing whether Freeman's proposals for rehabilitation after severe brain injury, especially when followed by prolonged unconsciousness, were actually successful was very significant. As mentioned already, there was some tendency for this question to be intertwined with the question of whether Freeman's explanation of the responsible mechanism(s) was correct. As suggested above, the question of success should be separated from that of its mechanism.

A strong case can be made that the methodology that it was sought to apply to testing the success or otherwise of Freeman's rehabilitation strategies—namely, a double-blind randomised control trial—was utterly inappropriate in that situation. This point is examined in some detail in Chapter 6. Even the most sophisticated, 'state-of-the-art' technology may be rendered useless, and sometimes dangerously misguided, when applied in circumstances for which it is unsuited. Whilst such trials can be an essential aid in the evaluation of many new pharmaceutical agents and surgical procedures, it is not feasible to conduct them, nor will they provide any information of value, when applied to studies of the effect of intervention by family members on an unconscious patient. One size, most emphatically, does not fit all.

The deferral of this account until the second decade of the new century has provided the opportunity to revisit some of Freeman's practices in the light of an accumulating body of information gained by the application of novel imaging technology to patients who have been diagnosed as comatose. As a result, it can be confirmed that some of the clinical procedures that Freeman advocated and applied can actually initiate and influence brain activity in these people.

Recalling the caveat, already expressed, that there can be considerable value in observations even if their meaning is not fully understood, some reservations legitimately remain about the meaning of observations of electrical activity demonstrable in the brain. Whether a specific form of activity represents the actual mechanistic correlate of consciousness, rather than being an epiphenomenon, closely linked to but separate from that correlate, is probably unknowable and more likely to be a question for metaphysics than for medicine. Nevertheless, such observations offer much for improving the lot of individuals who have been incorrectly diagnosed as clinically unconscious.

There are two topics underlying the story of Freeman's battle, already dealt with in earlier publications, the details of which have not been introduced into this account. Whilst Freeman's philosophy relating to rehabilitation following brain injury and its practical application are frequently referred to, anyone seeking a comprehensive practical account is referred to his two handbooks on this subject.¹ Many of the patients who benefited from Freeman's advice, probably a majority, had been dismissed by others as 'vegetative'. This term was frequently inaccurate and invariably pejorative. I have refrained from any examination of the concept of vegetative states in this text but have previously pursued this subject in some depth.²

Three decades of achievement and controversy

Ted Freeman has had an interesting career, notable for its contrasts. Having left school, he worked as a barrow boy in the Sydney Markets but, 20 years later, was admitted as a Fellow of the Royal College of Surgeons of Edinburgh. While caring, as a general practitioner, for people whose lives had been disrupted by traumatic brain injury, his daily observations led him to propose major changes in attitudes towards their disabilities, and consequent modifications in their management. As a result of his achievements, he was to receive considerable international recognition. Notwithstanding that recognition, he was shunned by some of his Australian colleagues. He was defamed under parliamentary privilege, but went on to be recognised for his contributions to medicine in the Order of Australia awards.

In retrospect, most achievements may be traced, at least partially, to the experiences of the individual responsible for them. Chapter 1 contains Ted

1 Edward Freeman (1987) *The Catastrophe of Coma—A Way Back*. David Bateman, Buderim, Qld. (Available free online from the National Brain Injury Foundation: <<http://nbif.org.au>>); Edward Freeman (1998) *Brain Injury and Stroke—A Handbook to Recovery*. Hale & Iremonger, Sydney.

2 Peter McCullagh (2004) *Conscious in a Vegetative State? A Critique of the PVS Concept. Volume 23, International Library of Ethics, Law and the New Medicine*. Kluwer Academic Publishers, Dordrecht.

Freeman's account of some formative experiences. The personal experience of being unable to communicate following Freeman's inadvertent isolation after a hospital admission with meningitis afforded him an insight into the predicament of many individuals with brain injuries that was to stay with him. A chance observation of communication between a child with cerebral palsy and its mother, although that communication remained inaccessible to others, aroused his interest in the possibility of retention of undetected abilities in people with severe brain injury. As a response to these incidents, Freeman redirected his career, deliberately seeking to discover all that he could about the impact of brain injury on patients and their families. That concern led him to embark, in the first instance, on visits to relevant clinics overseas and then into related employment in Australia.

When he proposed and implemented substantial changes from existing practice, Freeman was warned by some of his colleagues, and unreservedly criticised by others. The declared basis for criticism was that the scientific backgrounds of some of the therapists from whom he sought to learn were regarded as suspect.

My reading of his own account of these events is that he was overwhelmingly influenced, primarily, by the care and concern for their patients manifest by those therapists. The contrast was indeed considerable when placed alongside his observations of attitudes prevalent in some Australian facilities towards those severely disabled by a variety of conditions including brain injury. In the absence of any accepted alternatives in mainstream medical practice, he was captured by the challenge of attempting to help, even in the most desperate situations.

Students are taught at an early stage in medical school that a good practitioner learns from his patients, an experience that Freeman has repeatedly recounted. That being so, it is natural that any account of the philosophy and practices that he refined over the course of his career should be based on his patients' stories. Chapter 2 provides descriptions of some patients from his clinical records. These case histories are presented uncut as Freeman wrote them for a general audience.

It should be stressed that, when one is dealing with traumatic brain injury, no two patients are identical. In this respect, such injuries differ from many medical conditions in which it is possible, on the basis of clinical observation and laboratory investigation, to gain a comprehensive understanding of the nature of the pathological changes underlying those conditions. The likelihood of heterogeneity in pathology among patients who present similar clinical features of brain injury may impede such understanding. Limitations in understanding the natural history of repair in the injured brain presented another obstacle

to any attempts to undertake scientifically plausible and interpretable clinical trials of Freeman's practices. Any clinical trial, if its results are to be subject to interpretation, requires that like is being compared with like.

The clinical histories to be recounted each illustrate a number of features of the experiences of patients with brain injury. The selection of the term 'experience' in relation to these patients is quite deliberate, notwithstanding a commonly expressed opinion that they are, *by definition*, incapable of experience. Reading of some patient histories, I suggest, cannot fail to raise doubts about the value of 'commonly expressed opinion'. None of the patients whose stories are to be recounted will exemplify exclusively the point that she or he has been selected to illustrate. After reading two dozen histories, I have selected a group because their stories provide a good account of particular aspects.

The points chosen for presentation and emphasis include the frequent inadequacy of clinical assessment of the patient's level of awareness and the resultant precipitate consignment of affected individuals to aged-care facilities. A consequence of these events has been the aggravation of co-morbidities that are likely to confound any belated attempts at neurological rehabilitation. Attention will also be directed in the case histories to the essential requirement of a highly motivated family when embarking on rehabilitation and to provide examples of the manner in which family commitment can enable rehabilitation of a disabled member.

Freeman learnt much, not only from his patients, but also from their families. The most cursory reading of his case histories will reveal the extent to which unstinting commitment of immediate family members, accompanied frequently by scores of volunteers, to home-based rehabilitation programs designed and overseen by Freeman was critical. On one occasion in the mid 1990s, a large group of people who had participated in such programs wrote individual letters recounting their experiences. Chapter 3 contains extracts from some of these letters. They have been composed by people with a broad range of educational and socioeconomic backgrounds, but they display, in common, a 'hands-on' comprehension of the realities of living with acquired brain injury over many years. Notwithstanding this ongoing burden, they contain many examples of the triumph of the human spirit.

The carers' stories, being a thoroughly realistic lay account of brain injury, include many details of non-medical aspects such as financial perils, litigation over accidents and intra-familial stress. Whilst these accoutrements merit wide exposure in the community, the present account will generally be restricted to extracts dealing with more clinical aspects.

Chapters 4 and 5 deal with two discrete issues that require a separation that they frequently have not been accorded. The loosely applied expression ‘coma arousal’ misleadingly lumps the detection of an individual’s retained or regained level of awareness after a brain injury together with the outcomes of subsequent efforts at rehabilitation that aim, among other goals, to enhance that awareness. To emphasise the importance I attach to drawing the distinction between the implications of the first return of consciousness (or, more accurately, its ascertainment by others) and subsequent stages of recovery, the two issues are dealt with in separate chapters.

The inevitable connection between the two topics is that the attitudes of others towards the individual, and the course of management to be adopted, will be strongly influenced by the prevailing impression about the patient’s level of awareness. There are abundant and uncontested reports in the medical literature of the considerable incidence of incorrect diagnosis of vegetative states. The adjective ‘vegetative’ had already been conferred by other medical practitioners on many of the people coming under Freeman’s care. His experience—much of it reported in peer-reviewed, overseas medical journals—was that both the nature and the usual circumstances of a conventional neurological examination were inappropriate to detect or exclude awareness. The strategy of the clinical examination that he developed to detect any signs of awareness is presented in Chapter 4. With the benefit of a quarter-century of research, especially that based on technologically refined brain scanning, it is possible to gain an insight into the scientific basis of some of Freeman’s observations.

Chapter 5 will consider the evolution of the approach that Ted Freeman developed to facilitate the further rehabilitation of people who, after emerging from coma, remained severely limited. This evolution, underpinned by his conviction that hope remained after severe brain injury, even when this is followed by prolonged unconsciousness, impacted upon the Australian medical scene. Essentially, this entailed the interaction of a man and his ideas with an established system based on different beliefs.

In most instances, a medical practitioner espousing a philosophy and resultant clinical approach that is at variance with traditionally embedded practice (unless she or he had already attained a leadership position in the profession—clinical, academic or administrative) could find it difficult to apply beyond a personal medical practice. Several factors contributed to producing an exception in the case of Freeman: of these, the most influential undoubtedly was money.

The commonest cause of acquired brain injury among younger people remains motor vehicle accidents. Frequently, these generate large insurance claims, which, in the case of young individuals, may entail many decades of expensive high-care support. Any variation in management that offered the possibility

of lower levels of support for lesser periods clearly has the potential to reduce compensation costs. In fairness to insurance industry people who made the decision to fund the implementation of Freeman's ideas, it is likely that simple humanitarian precepts were also influential.

A second source of impetus for the introduction of his ideas into medical systems were the people who feature in Chapter 3—namely, families and friends of patients. By the nature of living with a family member afflicted with brain injury, this group had limited time to agitate for change. Finally, from his account of events, it is clear that some medical, nursing and paramedical personnel were appalled at the warehousing of patients with brain injury and sought any viable alternative.

An issue that ran alongside Freeman's work for two decades was that of conducting a trial to prove or disprove his claims. This history, which is central to any understanding of his experiences, is outlined in Chapter 6. Fundamental to the concept of evidence-based medicine is a requirement to establish the efficacy and safety of any proposed novel treatment irrespective of whether it is based on drugs, surgical intervention, physical therapy or whatever. Efficacy requires a demonstration of its superiority over the currently best available alternative measures.

The preferred strategy to establish superiority of novel therapies is to conduct a randomised control trial. Two attributes of such trials, insofar as they relate to recovery from coma, are examined—namely, their efficacy and their ethical soundness. The chequered history of proposals to mount such a trial of Freeman's practices is also reviewed. Whilst Freeman attracted opposition from some of his neurosurgical and rehabilitation colleagues for his views, he increasingly came to be at the mercy of some other, more academically positioned, colleagues who specialised in conducting clinical trials. To express it bluntly, such colleagues were often eager to obtain the funding that Freeman and his patients' families had secured but preferred not to involve him in the research to which it was to be applied.

Chapter 7 will examine the basis for, and the nature of, the opposition that Freeman encountered. The simplest interpretation for this opposition would appear to be that Freeman was treading on the patch of a number of medical specialties in which he lacked the requisite formal qualifications. He was also, by implication, condemning the systemic approach to patients deemed to be irreversibly unconscious. There existed, and still largely exists, a hiatus in medical responsibility for these people. To a considerable extent, this may reflect the dominance of a curative medical model that disdains evidence considered to be 'non-scientific'.

Australian neurosurgeons, and intensivists in their turn, generally maintain a standard comparable with the best in the world but, once the initial period after brain injury has passed, they are out of the game. A disconnect can arise between high-intensity procedures with curative goals and rehabilitative care. Rehabilitation services are of variable quality but, with few exceptions, their entry requirements for treatment cannot be met by many brain injured patients—a strategy colloquially referred to as picking winners. As to the form taken by opposition to Ted Freeman, this ranged from the decidedly petty to the most damaging form—namely, vigorous defamation under parliamentary privilege.

Chapter 8 presents another set of assessments of Freeman's work. In contrast with the preceding chapter, which recounts some of the Australian reactions against him, this chapter is largely concerned with international appraisal of his achievements. This contrasts again with Chapter 7 in that, overwhelmingly, these were very positive. Interestingly, the assessments of overseas clinicians were as instrumental in accomplishing the reversal of the parliamentary defamation referred to above as Australian assessments, frequently anonymous, had been in fuelling that defamation.

Chapter 9, a short postscript, reflects briefly on several factors that impacted on the evolution of Freeman's approach to rehabilitation after brain injury, especially the entrenched attitudes of some colleagues and their reticence to countenance alternative responses to this problem. The discussion will look forward towards opportunities to remedy the systemic failures of the medical system that were experienced by many families. These opportunities centre on the proposed Australian National Disability Insurance Scheme (NDIS). If the NDIS is successfully implemented, major beneficiaries are likely to be future patients and their families who are confronted with the situations that characterised Freeman's families.