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Case Study

Safeguarding injured Victorians: development and implementation of an evidence-informed system to manage therapeutic uncertainty and decision making in a compensable environment

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Abstract. WorkSafe Victoria and the Transport Accident Commission are two Victorian government agencies that determine the policies that guide decisions to fund treatments and services provided to Victorians injured in transport or workplace accidents. These agencies identified that an internal system was required to manage requests for funding of new or emerging treatments. In particular, the agencies recognised a system that supported consistency in decision making in the context of therapeutic uncertainty and ensured the safety of injured Victorians was needed. The New, Emerging or Non-Established Treatments (NENETs) policy was launched in its current form by the agencies in 2013. The NENETs system includes a record of contemporary evidence for emerging treatments and an evidence-informed decision-making system to ensure consistency and information sharing. A system of recording decisions on emerging treatments was also implemented to ensure that funding decisions could later be reversed if necessary. The NENETs system has proved to be a robust and sustainable method of managing uncertainty for WorkSafe Victoria and the Transport Accident Commission and could be transferable to other funding bodies.

What is known about the topic? An algorithm to guide clinicians when prescribing off-label medications was developed in 2006, although it has not been used widely in everyday practice. In 2019 the Medical Board of Australia launched a discussion paper on 'complementary and unconventional medicine and emerging treatments' because no system for managing such treatments exists. Third-party payers have a responsibility to make objective and reliable decisions about new, emerging or non-established treatments to ensure high value care is offered to health consumers.

What does this paper add? This paper provides an overview of the policy and decision-making system implemented by WorkSafe Victoria and the Transport Accident Commission to managing requests for new, emerging or non-established treatments. The system is adaptable to other third-party payers, health service funders and regulators in Australia and internationally.

What are the implications for practitioners? It is important that practitioners caring for injured Victorians are aware of the systems used to inform decision making around requests for funding new, emerging or non-established treatments. Knowledge of the principles underlying this system may assist other funding bodies and the Medical Board of Australia to develop systems in other jurisdictions.

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Introduction

The Medicare Services Advisory Committee (MSAC), the Pharmaceutical Benefits Advisory Committee (PBAC) and the Prostheses List Advisory Committee (PLAC) make recommendations regarding items on the Medical Benefits Schedule (MBS), Pharmaceutical Benefits Scheme (PBS) and the

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Australian Department of Health's Prostheses List (PL), respectively. Interventions and medications not approved by the MSAC and the PBAC cannot be funded under Medicare, and prostheses not approved by the PLAC cannot be reimbursed by private health insurers. MSAC has an option of approving a new treatment for provisional funding, whereas the PBAC and PLAC only approve medicines and prostheses, respectively, of proven benefit and cost-effectiveness.[1] In this context, the PBAC operational guidelines have been criticised by some as being too stringent.[2,3]

WorkSafe Victoria (WSV) and the Transport Accident Commission (TAC) are Victorian government agencies that determine the policies that guide decisions to fund treatments and services provided to Victorians who have accepted claims for workplace or transport injuries, respectively. Although these agencies choose to follow the Medicare reimbursement criteria for clinical services as described above, they are not bound by them. Consequently, the compensable environment provides the opportunity to fund new, emerging or non-established treatments (NENETs). Processes for healthcare funders to manage therapeutic uncertainty around new and emerging therapies are essential to ensure transparent and reproducible decision making and ensure the delivery of high value care options.

Setting for this case study

In this case study we outline the development, implementation and performance of a policy and program initiated by WSV and the TAC to manage therapeutic uncertainty related to NENETs and guide decision making related to funding NENETs. The setting for this case study is therefore the workplace illness and injury and transport accident compensation systems in Victoria.

WSV and the TAC define NENETs as any treatment that has not been considered by the MSAC, PBAC or PLAC and is therefore ineligible for subsidy under the MBS, PBS or PL, respectively. Non-standard equipment or devices and programs of care are also included in the definition of NENETs.[4,5] Once WSV or the TAC identifies a request as a 'NENET', decision making is required about the appropriateness of funding the treatment(s) for the indication requested, such as platelet-rich plasma injections for knee osteoarthritis (93 requests received by WSV and the TAC between March 2013 and March 2019) or for tendinopathy (225 requests received by WSV and the TAC between 2013 and 2019).

Attempts to regulate NENET requests can lead to Type 1 and Type 2 errors. A Type 1 error occurs when the treatment is funded and provided to the patient and later found to be low value (i.e. ineffective or potentially harmful).[6,7] A Type 2 error occurs when the agency denies funding of a treatment that is later found to be beneficial and safe (high value).[7,8] Accordingly, the delivery of high value care to appropriately selected patients requires the consideration of funding NENETs with rigorous evaluation of risk and benefit. A transparent and consistent decision making process is also desirable to reduce the risk of conflict and litigation, factors associated with suboptimal recovery in compensable systems.[9]

Background and sequence of events

NENET requests posed a frequent decision-making challenge for WSV and the TAC. In response, the agencies established a panel of independent, contracted clinicians (the Clinical Panel) in 1997 to assist with decisions regarding treatment requests, as well as to help with other clinical decisions. Initially each clinician on the Clinical Panel responded individually to requests, at times resulting in duplication of work and inconsistency in processes and decisions. The agencies identified that a more systematic approach was needed to ensure a valid and reproducible process undertaken by members of the Clinical Panel to evaluate the risks and benefits of NENETs.

In 2010, WSV and the TAC commissioned a scoping literature review on how health and compensation systems internationally make decisions about NENETs and whether guidelines exist for the same.[10] That review identified evidence for processes and systems in Australia (namely the MSAC and the PBAC and a consensus recommendation for evaluating the appropriateness of off-label use of medicines[11]), New Zealand, the UK and the US. Seven principles were derived from a metasynthesis of the available evidence to guide decision making about NENETs (Box 1).

Box 1. Principles to guide decision making for new, emerging and non-established treatments (NENETs)

1. Providing clear criteria as to the definition of NENETs and how these would be managed by funders
2. Ensuring, through appropriate clinical assessment, that the condition being treated is significant and warrants the treatment
3. Confirming that standard available treatment(s) are not appropriate and/or not effective
4. Guaranteeing safety and efficacy of the proposed treatment wherever possible
5. Using an evidence-based approach in decision making
6. Ensuring patients are appropriately consented to the proposed treatment and understand that the treatment is non-standard
7. Monitoring the outcomes of the decision-making process and the treatment provided through registries or research

Implementation of the NENETs system

Informed by the commissioned literature review and seven principles (Box 1),[10] the NENETs system was launched by WSV and the TAC in 2013, with supporting organisational policies, accessible to care providers.[4,5] The NENETs system is not restricted to requests from any discipline and includes operations, procedures, medications, prostheses, equipment and programs of care and services. Requests for medications may include those not on the PBS or on the PBS and used off-label. WSV and the TAC do not fund treatments that are part of a clinical trial.

The NENETS system was established with three components: (1) an algorithm to guide workflow for the Clinical Panel; (2) a database of evidence of previously considered NENETs to support the decision making processes of the Clinical Panel; and (3) a log of claim numbers affected by NENET decisions to enable tracking and potential reversal of decisions at a later date.

The database includes all NENETs requested from 2013 to the present, and contains synthesised evidence about the safety and efficacy of the treatment. The database provides the Clinical

Panel with information to guide its funding recommendations by offering two potential recommendations based on the evidence:

1. to *consider funding* where there is National Health and Medical Research Council of Australia Level 1 or 2 high-quality evidence of efficacy and safety, all other conventional treatment options have been exhausted or are deemed unsuitable, the provider is qualified to provide the NENET and positive advice from relevant clinical experts has been obtained, if needed;
2. to *reject funding* when all the criteria above are not met.

Where a NENET is recommended by the Clinical Panel for funding based on all the criteria under the 'consider' option having been satisfied and the insurer decides to accept the recommendation and fund the NENET, the provider is obliged to provide outcome measures to evaluate the treatment effect.

One medical practitioner (appointed as the Clinical Lead in Research Translation) was tasked with establishing the database and now maintains and expands the NENETs database through searching for, appraising and synthesising scientific evidence and published clinical guidelines. This critical role is funded at 4 h per week. The NENETs database ensures all clinicians on the WSV and the TAC Clinical Panels have access to the most contemporary evidence summary pertaining to a NENET.

The NENETs log is used to record all claims affected by a NENET funding decision from 2013 to the present time. By keeping these records, Type 1 and 2 errors can be corrected if new research supports or refutes the treatment. From March 2017 to March 2019 there were 21 (3.9%) Type 2 errors and 5 (0.9%) Type 1 errors identified from the 539 NENETs on the database. Of the Type 1 errors, two were corrected and three were related to procedures that had already taken place. One example of a Type 1 error was the approval of hyaluronic viscosupplementation for hip osteoarthritis in 2017. A 2010 Canadian Health Technology Assessment suggested that this was a treatment that could be considered.[12] Subsequently, the 2018 Royal Australian College of General Practitioners (RACGP) clinical guideline for management of knee and hip osteoarthritis made a strong recommendation against this treatment, and consequently it is no longer funded by WSV or the TAC.[13] An example of a Type 2 error is the use of high-frequency spinal cord stimulators for pain management. Requests for this prosthesis were initially denied based on a lack of high-level evidence. When supporting evidence became available, the providers of recently denied claims were contacted and the funding decision reversed.[14]

In the period from March 2013 to March 2019, 539 unique treatment requests have been recorded on the NENETs database, each with an evidence summary. Each entry has a start date and updates are also dated to ensure that the evidence synthesis remains contemporary and can be reviewed retrospectively. In each year, WSV alone receives an average of 330 requests for NENETs. To March 2019, there have been 2545 requests logged to WSV and the TAC. Often multiple requests are received for the latest 'fad'. Overall, 50% have been medication requests, 29% have been requests for procedures, 17% have been requests for equipment and 4% have been requests for prostheses.

The NENETs system has operated in its current form since 2013 and has been an effective approach for internally managing uncertainty through systematically guiding clinical decision making around effectiveness and safety of interventions. Prior to 2013, the system was in a beta development phase. Each time new evidence emerges, the database entry is updated accordingly. Further, if a NENET becomes mainstream (i.e. funded through the MBS, PBS or PL), it is removed from the database.

Challenges and opportunities with the NENETs system

As the volume of NENET requests to WSV and the TAC continues to increase, the organisations are faced with a need to continually evolve operational and governance arrangements, including upskilling other Clinical Panel members to maintain the database, implement delegation processes to ensure volume does not exceed capacity and refine and improve appraisal and recording processes for evidence reviews. There is an opportunity to further enhance the evidence appraisal and recording processes, including peer review of decision making.

At this stage, the database of 539 unique entries has not been made available to external clinicians or researchers, but a process to enable this is currently being considered to better facilitate transparency and to enable surveillance and outcomes research, as well as mediation of disputes over treatment options.

Discussion

The NENETs policy[4,5] and its guiding principles are easily adaptable to other third-party payers, health service funders and regulators in Australia and internationally. Although the NENETs system has similarities to the New Zealand Accident Compensation Corporation system, it is able to respond to requests at the claims level without the need for an advisory group. The NENETs system is particularly relevant to the current draft guidelines developed by the Medical Board of Australia on 'complementary and unconventional medicine and emerging treatments'.[15] The draft guidelines propose informed consent but do not mention exceptional circumstances and the application of best evidence. These parameters reflect a strength of the NENETs system.

The NENETs policy provides an important framework for WSV and the TAC in clinical decision making regarding requests for new and emerging therapies. It is anticipated that the agencies will continue to support the NENETs system and consider opportunities for enhancement and expansion as they arise, including the potential for public access to the resource.

Competing interests

All authors work as clinical consultants for WorkSafe Victoria. No other competing interests are declared.

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