



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Domiciliary invasive ventilation for adults with spinal cord injuries: Protocol for a Health Technology Assessment

Publication date: 21 February 2023

Contents

About the Health Information and Quality Authority (HIQA)	3
1. Introduction	4
2. Evidence synthesis approach	7
3. Epidemiology and burden of disease	8
4. Description of technology and outcomes	9
5. International practice and standards	10
6. Organisational considerations	16
7. Budget impact analysis	17
8. Social and ethical considerations.....	18
9. Conclusion.....	19
References	20
Appendix 1: Search strategy	23

About the Health Information and Quality Authority (HIQA)

The Health Information and Quality Authority (HIQA) is an independent statutory authority established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

HIQA's mandate to date extends across a wide range of public, private and voluntary sector services. Reporting to the Minister for Health and engaging with the Minister for Children, Equality, Disability, Integration and Youth, HIQA has responsibility for the following:

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.
- **Regulating social care services** — The Chief Inspector within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.
- **Regulating health services** — Regulating medical exposure to ionising radiation.
- **Monitoring services** — Monitoring the safety and quality of health services and children's social services, and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health technology assessment** — Evaluating the clinical and cost-effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.
- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland's health and social care services.
- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health services, in conjunction with the Department of Health and the HSE.

1. Introduction

1.1 Background

Spinal cord injury (SCI) is damage to the spinal cord that causes changes in its function, either temporary or permanent. These changes translate into the loss of muscle function, sensation, or autonomic function in parts of the body served by the spinal cord below the level of the lesion.^(1, 2) SCI can occur because of trauma (for example, a car crash) or from disease or degeneration (for example, degenerative disorders or neoplastic conditions).⁽³⁾

After a SCI, all the nerves above the level of injury keep working normally. At the level of injury, messages are blocked from being transmitted from above that level to below the level of injury. Damage to the spinal cord can result in partial or complete loss of function below the level of the injury. Therefore, the consequences of SCI depend on the severity and location of the injury on the spinal cord; injuries that occur high up the spinal cord (that is, the cervical spine) and that cause complete loss of function, result in the most serious sequelae (for example complete paralysis of all four limbs and torso).⁽³⁾

Evidence from a national database in the US indicates that tetraplegia (that is, paralysis caused by illness or injury that results in the partial or total loss of use of all four limbs and torso) is the outcome for approximately half of all patients with SCI, and the majority of these patients will have injuries to the cervical spine and consequently some degree of respiratory insufficiency.⁽⁴⁾ The data suggest that most patients with high cervical lesions are ultimately weaned from requiring long-term ventilator assistance. However, 3.5% of patients with tetraplegia require ventilation at one-year post-injury, which is indicative of lifelong dependency on ventilation assistance.⁽⁴⁾ Extrapolating these US data to 2015 Irish incidence data from the National Rehabilitation Hospital (NRH), clinicians have estimated there could be up to 62 patients presenting with tetraplegia annually in Ireland, and of these, one to two patients could potentially be dependent on lifelong ventilation.⁽²⁾

An integrated care pathway for patients with SCI has been developed in Ireland by the National Clinical Programme for Rehabilitation Medicine, in line with its model of care.⁽²⁾ Integrated care pathways are structured multidisciplinary care plans that detail essential steps in the care of patients with a specific clinical problem.⁽⁵⁾ As part of this integrated care pathway, patients with SCI are transferred to the NRH for post-acute rehabilitation once they are deemed to be ready to engage in rehabilitation. In 2019, the NRH commenced admission of ventilator-dependent

patients with SCI. The National Spinal Cord Injury team in the Mater Misericordiae University Hospital (MMUH) and the NRH Spinal Cord System of Care programme developed this specific pathway. Although the NRH can now admit and manage ventilated patients successfully, discharge planning for these complex patients remains a significant challenge for a range of reasons, including the current fragmented funding model for community services as well as the lack of suitably trained homecare staff in the community. As a result, these patients can remain in the NRH for a prolonged period of time, often several years, before being discharged home.⁽⁶⁾ These delayed discharges can have a detrimental impact on the patient, their family and caregivers, other patients that may require a bed in the NRH, and the wider healthcare system due to the significant cost of treating these patients in hospital.

In line with Sláintecare reforms, there is an ambition to achieve a universal single-tier health and social care system, which provides equitable access to services based on need, and not ability to pay. One of the key objectives of Sláintecare reforms is about delivering the right care, in the right place, at the right time by the right team.⁽⁷⁾ Specifically, a key aspect of the reform is the shift of care out of acute hospitals into the community and closer to a person's home, in situations where it is safe to do so. Where clinically appropriate and delivered in line with international best practice and guidance, domiciliary ventilation is considered the standard of care for ventilator-dependent adults with SCI.⁽⁸⁻¹¹⁾ Despite being consistent with the vision of Sláintecare,⁽⁷⁾ the service has only been provided to adults in a very limited number of circumstances in Ireland to-date.

In light of the issues described above, in April 2021, the National Clinical Programme for Rehabilitation Medicine in the Health Service Executive (HSE) and the Spinal Cord System of Care Programme in the NRH requested a HTA of domiciliary invasive ventilation for adults with SCI. This request was prioritised for inclusion in the HIOQA HTA work plan in June 2021. In establishing which domains should be examined to inform the HSE's decision-making process, it was recognised that domiciliary ventilation is the standard of care for the patient cohort under consideration, and so a comprehensive assessment of the clinical effectiveness, safety and cost-effectiveness was not considered necessary for this HTA. However, there are important social and ethical issues arising from the provision of care in a home setting to these patients who have substantial needs. Furthermore, it is expected that significant organisational and resource implications may be associated with any reorganisation of how this service is funded and delivered at a national level.

This protocol presents the proposed methodology for estimating the epidemiology and burden of disease associated with SCI and for assessing the organisational

implications, budget impact, and social and ethical aspects associated with provision of a national domiciliary ventilation service for this population.

1.2 Aims and objectives

The purpose of this HTA is to assess the requirements for the national provision of care to adults (≥ 16 years old) with spinal cord injuries who require permanent mechanical invasive ventilation and in whom discharge home is deemed clinically appropriate. The focus of this HTA is on an individual's own (domestic) home as opposed to a nursing home or other residential care setting. This HTA will advise on the budget impact and resource implications as well as organisational, social and ethical aspects associated with the systematic provision of domiciliary invasive ventilation for this population.

For adults with spinal cord injuries who require permanent mechanical invasive ventilation and in whom discharge home is deemed clinically appropriate, the terms of reference of this HTA are to:

- describe the epidemiology and burden of disease for this population
- briefly describe the technology and outcomes associated with domiciliary invasive ventilation
- review international practice and standards relating to the provision of domiciliary invasive ventilation for this population
- examine the potential organisational and resource implications associated with providing domiciliary invasive ventilation for this population
- assess the budget impact of providing mechanical invasive ventilation for this population at home compared with in hospital or long-term care settings
- consider the social and ethical aspects associated with providing domiciliary invasive ventilation for this population
- based on the findings of this assessment provide advice to the Minister for Health and the HSE.

1.3 Establishment of the Expert Advisory Group

An appropriately represented Expert Advisory Group (EAG) will be convened as a source of expertise to inform the interpretation of the evidence and development of the advice to the HSE.

This group will comprise nominees from a range of stakeholder organisations, including patient representation, healthcare providers, and clinical and public health experts.

The terms of reference of the Expert Advisory Group (EAG) are to:

- contribute to the provision of high quality and considered advice by HIQA to the Minister for Health and the HSE
- contribute fully to the work, debate and decision-making processes of the group by providing expert guidance, as appropriate
- be prepared to provide expert advice on relevant issues outside of group meetings, as requested
- provide advice to HIQA regarding the scope of the analysis
- support the Evaluation Team led by HIQA during the assessment process by providing expert opinion and access to pertinent data, as appropriate
- review the project plan outline and advise on priorities, as required
- review the draft report from the Evaluation Team and recommend amendments, as appropriate
- contribute to HIQA's development of its approach to HTA by participating in an evaluation of the process on the conclusion of the assessment.

2. Evidence synthesis approach

HTA is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology. It does so in a systematic, transparent, unbiased, and robust manner. HTAs are designed to inform safe and effective health policies that are both patient-focused and achieve the best value.

The HTAs conducted by HIQA follow the HTA Core Model® proposed by the European Network for Health Technology Assessment (EUnetHTA).⁽¹²⁾ Aligned with the Core Model, HIQA HTAs typically include the following domains:

- epidemiology
- burden of disease

- description of the technology
- clinical effectiveness and safety
- costs and economic evaluation
- organisational, social and ethical implications.

The terms of reference for this HTA are limited to consideration of the budget impact and resource implications as well as the organisational, social and ethical implications of the national provision of domiciliary invasive ventilation; this is the case as domiciliary invasive ventilation is already considered standard of care for adults with spinal cord injuries who require permanent mechanical invasive ventilation and in whom discharge home is deemed clinically appropriate.⁽²⁾ The decision the HTA intends to inform is not whether domiciliary invasive ventilation should be provided for this population but to provide advice on how such a service is made available.

While not the primary focus of the HTA, the epidemiology and burden of disease, as well as the technology itself (that is, invasive mechanical ventilation) will be briefly described in order to provide context and also to inform parameter estimates for the budget impact analysis.

For the purpose of this HTA, evidence will be retrieved from a broad range of sources, including scientific literature, policy documents, epidemiological databases, resource and costing sources and expert opinion. A broad literature search comprising both electronic databases and grey literature will be conducted focusing on three main concepts: *spinal cord injury*, *mechanical ventilation* and *homecare*. Scoping work done by the evaluation team has identified limited literature on this topic. Hence any identified literature relating to any aspect of this topic may be important. In addition, members of the EAG will be requested to provide any other documents that they may be aware of that might be relevant. The search strategy is reported in detail in Appendix 1.

3. Epidemiology and burden of disease

The World Health Organization (WHO) estimates that globally between 250,000 and 500,000 people experience a SCI each year, with the majority of such injuries due to preventable causes such as road traffic accidents, falls or violence.⁽³⁾ People with a SCI are estimated to be two to five times more likely to die prematurely than people without such an injury. SCI is also associated with substantial morbidity, with many

affected individuals developing secondary conditions that can be debilitating and even life-threatening, for example:

- deep vein thrombosis
- autonomic dysfunction
- urinary tract infections
- pressure ulcers
- chronic pain
- respiratory, bowel and bladder insufficiency.

Acute care, rehabilitation services and ongoing lifelong health maintenance are essential for the prevention and management of these conditions. Depending on the location and severity of the injury, SCI may also result in a person becoming fully dependent on caregivers. Assistive technology is often required for people with SCI to facilitate mobility, communication, self-care or domestic activities. SCI can also negatively affect individuals' quality of life, with an estimated 20-30% showing clinically significant signs of depression, which in turn has a negative impact on improvements in functioning and overall health.⁽³⁾

A brief description of SCI, including its epidemiology, risk factors, classification, symptoms, management and impact, will be provided. Where available, national data will be presented from relevant datasets. Data relating to those with high cervical cord injuries (C1-3) will be disaggregated from other types of SCI, as this patient cohort is the most likely to require permanent invasive mechanical ventilation. Irish data will be supplemented with data from the international peer-reviewed literature, where appropriate. Clinical opinion will inform the latent demand in Ireland for domiciliary ventilation in adults with spinal cord injuries who require permanent mechanical ventilation.

4. Description of technology and outcomes

The national provision of care to adults with spinal cord injuries who require permanent mechanical ventilation and in whom discharge home is deemed clinically appropriate is the health technology under assessment in this HTA. There is an existing integrated care pathway for the management of SCI in Ireland, which includes attendant care guidelines.⁽²⁾ As part of the lifelong care phase of this pathway, a return to home is considered the ideal outcome for many patients. However, there are challenges in terms of providing the right homecare and

supports particularly for those who are ventilator dependant. There are many clinical considerations for the delivery of care to these patients in the home settings including:

- the need for invasive mechanical ventilation
- bowel and bladder care
- skin care
- management of nutrition.

There are also some additional risks and costs associated with the delivery of high-dependency care in the home compared with in a hospital setting. However, this may be balanced by the benefits to the person's quality of life by being at home and increasing the availability of intensive care unit (ICU)/ high dependency unit (HDU) beds in hospital.⁽²⁾ Using phrenic nerve stimulators in this population will also be described. Phrenic nerve stimulators can be used as an alternative to mechanical ventilation in some individuals with damage to the cervical spine who have intact phrenic nerves and functioning diaphragm muscles. The term 'phrenic nerve stimulator' applies to systems whereby an electrode is surgically implanted around the phrenic nerve(s), which are stimulated by a radiofrequency receiver usually implanted in the chest wall.⁽¹³⁾ This chapter will provide an overview of the:

- management of adults with spinal cord injuries
- current integrated care pathway and the challenges that exist within the system
- use of domiciliary ventilation in various populations and the evidence regarding benefits, harms and costs.

As part of the overarching literature review, relevant peer-reviewed studies and grey literature will be identified and summarised to address this domain. This will be supplemented by consultation with relevant stakeholders. Based on this information and the advice of the EAG, the description of the technology under assessment and associated outcomes will be outlined.

5. International practice and standards

Standards promote practice that is up-to-date, evidence-based, effective and consistent. Standards help health and social care providers to identify strengths and

highlight areas that may need improvement, while also aiming to show people what safe, high-quality care should look like and what to expect from a service.⁽¹⁴⁾

Domiciliary ventilation, comprising both invasive and non-invasive mechanical ventilation, has been used for decades as the treatment of choice for chronic respiratory failure in several countries (for example, Germany, the UK and Finland).^(2, 15)

Individuals with SCI generally account for a relatively small proportion of all domiciliary ventilation service users for a number of reasons: high complete cervical lesions are a rare event⁽¹⁶⁾ and within this population, of those that require ventilation, most (>95%) can be weaned from requiring long term ventilator assistance.⁽⁴⁾ Other patient groups that can avail of domiciliary ventilation include patients with amyotrophic lateral sclerosis (ALS), central hypoventilation syndrome (CHS), chronic obstructive pulmonary disease (COPD), kyphoscoliosis, obesity hypoventilation syndrome (OHS), Duchenne muscular dystrophy (DMD), other muscular dystrophies, myopathies, and myotonic dystrophy (Steinert's muscular dystrophy (SMD)).⁽¹¹⁾

The standards for the provision of a safe, high-quality domiciliary invasive ventilation service in particular are substantial and can vary between patient groups. Practice and standards with regards to the provision of domiciliary invasive ventilation for adults with spinal cord injuries also vary from jurisdiction to jurisdiction. While there are additional care needs associated with providing homecare to individuals with SCI that may be unique to this patient group (for example, bowel and bladder management, full assistance with personal care etc.), there may be some standards that are common to all domiciliary invasive ventilation service users.⁽²⁾ Hence it is important to describe practice and standards that are relevant for individuals with SCI who are domiciliary invasive ventilation service users.

The following research question will be addressed within this chapter: *What practice and standards do international, national or regional guidelines, recommendations, position papers and standards specify for the provision of permanent domiciliary invasive ventilation in adults with spinal cord injury?*

Given the broad nature of the research question, a scoping review will be undertaken. A scoping review can be defined as a form of evidence synthesis that addresses an exploratory research question aimed at mapping key concepts, types of evidence, and gaps in research related to a defined field by systematically searching, selecting, and synthesising existing evidence.⁽¹⁷⁾

Scoping reviews are generally preferable to systematic reviews when the purpose is to provide a comprehensive overview of a broad topic, rather than to determine the efficacy or effectiveness of a specific intervention.⁽¹⁸⁾ Importantly, scoping reviews still provide a high standard of rigour and transparency.^(18, 19) The review will adhere to the Arksey and O'Malley six-stage framework.⁽²⁰⁾ The scoping review framework follows the main systematic reviewing principles. However, it allows for more flexibility in terms of inclusion and exclusion criteria, pays less attention to quality appraisal and is more focused on presenting a thematic overview of findings rather than determining any definitive effect estimate. Hence, quality appraisal will not be undertaken for this review.

The population, area of interest and context for this question are summarised in Table 1. For the purpose of this scoping review, the umbrella term 'guidance documents' will be used to describe the guidelines, position papers, recommendations and standards identified for inclusion in this review.

Table 1: PICO for Scoping Review of International Practice and Standards

Population	Individuals with SCI receiving permanent domiciliary invasive ventilation
Interest	<p>Practice and standards for provision of care including:</p> <ul style="list-style-type: none"> ▪ Pre-transition <ul style="list-style-type: none"> ▪ patient assessment ▪ room and environment requirements ▪ training requirements ▪ staffing requirements ▪ informed consent processes ▪ funding process and requirements. ▪ Transition phase <ul style="list-style-type: none"> ▪ process of transition ▪ transportation requirements ▪ liaison and other support staff. ▪ Technical requirements <ul style="list-style-type: none"> ▪ ventilators ▪ oxygen ▪ hoist ▪ wheelchair ▪ bed ▪ other equipment. ▪ Management of SCI complications <ul style="list-style-type: none"> ▪ ventilator management ▪ respiratory care and function ▪ autonomic dysreflexia ▪ emergency management ▪ bowel management ▪ bladder management ▪ medication administration ▪ nutrition and feeding ▪ skin integrity ▪ stoma care ▪ waste management ▪ telemedicine ▪ infection prevention and control ▪ psychosocial care ▪ end of life/palliative care ▪ rehabilitation ▪ education and training. ▪ Governance, quality assurance and legal issues <ul style="list-style-type: none"> ▪ governance structures and accountability ▪ escalation pathways ▪ care and referral pathways ▪ organisations responsible for providing care, funding and oversight

Context	<ul style="list-style-type: none">▪ safeguarding▪ ethics▪ quality assurance processes▪ other legal issues.
	Guidance documents: <ul style="list-style-type: none">▪ guidelines (international, national or regional)▪ position papers▪ recommendations▪ standards.

This scoping review will follow the broad search strategy outlined in Appendix 1. For data management purposes, the results of the search will be exported to Covidence (www.covidence.org) after de-duplication in Endnote. Two reviewers will independently review the titles and abstracts and subsequently full texts of the identified records. Those that meet the inclusion criteria for this scoping review (as per Table 2), will be included in this chapter. Any disagreement regarding the eligibility of documents will be resolved through discussion, and using a third reviewer where necessary. Clinical input will be sought from members of the EAG where the clinical applicability and/or relevance of identified standards and practice needs to be determined.

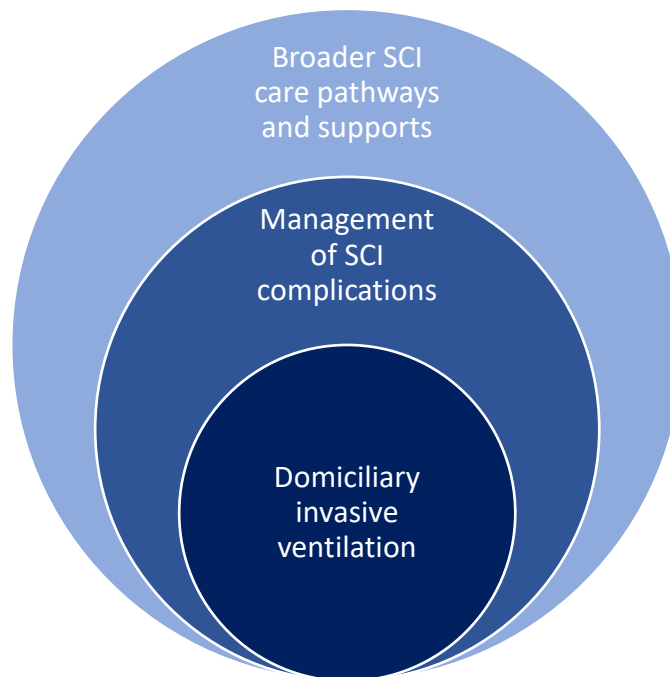
Table 2: Inclusion and exclusion criteria

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none"> ▪ guidance is provided regarding the provision of care to those availing of invasive mechanical ventilation at home. ▪ guidance is generally applicable to all invasively ventilated patients regardless of underlying diagnosis and/or is specific to patients with spinal cord injuries.* ▪ guidance is evidence-based (meets at least one of the following criteria <ul style="list-style-type: none"> – based on a literature review – based on expert consensus methods, which are described in the document – affiliated with a recognised society/organisation.)* 	<ul style="list-style-type: none"> ▪ guidance is specific to another patient group, or a paediatric population, with very limited, or no applicability to adults with spinal cord injuries* ▪ hospital or long-term care based ventilation ▪ acute or post-acute settings ▪ older guidance that has since been updated (or synthesised into a newer guidance document) ▪ guidance specific to an individual hospital/specialist centre/care provider ▪ guidance is focused on the management of SCI complications only, without reference to domiciliary ventilation ▪ guidance is focused on the broader structures of SCI care pathways and supports without reference to domiciliary ventilation.

Key: *as determined by clinical experts on the EAG.

Inclusion and synthesis will be framed around three main concepts (Figure 1). Domiciliary invasive ventilation guidance will be considered as essential for inclusion and as such will be the primary outcome of interest for this scoping review. Guidance relating to the management of SCI complications will be considered a secondary outcome, and for example, this may include guidance in relation to mental health issues, prevention of venous thromboembolisms, or bowel and bladder management. Guidance in relation to the broader SCI care pathway and supports will be considered a tertiary outcome, and for example, this may include guidance in relation to referral pathways or financial supports for individuals with SCI and caregivers.

Figure 1: Conceptual framework for the Scoping Review



Data extraction will be performed by a minimum of one reviewer and double-checked by another. A data extraction tool will be developed and piloted before implementing. As this is a scoping review aiming to provide an overview of a diverse range of standards and practice, no quality appraisal will be undertaken. Google translate will be used to obtain translations of non-English language documents, where possible.

The collated standards and practice will inform advice regarding the requirements for the national provision of care to adults with spinal cord injuries who require permanent mechanical ventilation and in whom discharge home is deemed clinically appropriate.

This scoping review will be reported in accordance with the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist.⁽²¹⁾

6. Organisational considerations

The assessment of necessary organisational changes associated with the provision of domiciliary ventilation to patients with SCI on a national footing will be carried out in accordance with the EUnetHTA Core Model.⁽²²⁾

The delivery of homecare services in Ireland is complex with a mixture of public (HSE), private, voluntary and not-for-profit entities providing such services. There are substantial organisational barriers to the provision of such services. Currently, the funding of homecare packages is a challenge as these are funded out of various different budgets including local budgets; the funding of high-dependency patients may overwhelm local budgets in particular. There is also no consistent national response to requests for care in the community; this can significantly delay or even prevent the transition of such patients to their home.⁽²⁾

There are important regulatory issues that need to be considered regarding the provision of homecare services in Ireland. There is currently no independent oversight and regulation in the provision of homecare in Ireland, though the Irish Government has indicated that it intends to develop an appropriate, bespoke regulatory framework for this setting.⁽²³⁾ In addition, there is currently no statutory scheme for homecare in Ireland, and so there is no obligation on the HSE to provide 'home help' services which makes the provision of domiciliary ventilation a challenge (though there is a commitment to implement such a statutory scheme as part of the Sláintecare reforms).⁽²³⁾ There are also some uncertainties regarding governance and accountability in community settings, with clarity needed over who is ultimately responsible for the care of these patients in the home setting.

As part of this chapter, the overall pathway of the patient from complex discharge planning in the NRH to home will be examined, with due regard to the underpinning regulatory framework (or lack thereof). This will include the process for requesting care packages, the funding model, the tendering process, staff recruitment and retention in the community, the delivery and monitoring of services, and the involvement of primary care teams and healthcare services.

Additional considerations relating to capacity will also be described. These include the potential impact of a national domiciliary ventilation service on waiting times for patients seeking rehabilitation in the NRH, as well as its potential impact on other homecare services in the community. The impact of delivering domiciliary ventilation services at a national level on the resilience, governance, and continuity of care of the service will also be explored, as well as the potential to extend this service to other patient groups that can potentially avail of domiciliary ventilation.

7. Budget impact analysis

A budget impact analysis (BIA) of the direct healthcare costs associated with the national provision of care to adults with spinal cord injuries who require permanent mechanical ventilation and in whom discharge home is deemed clinically appropriate

will be carried out from the perspective of the HSE. This will be conducted over a five-year time horizon in line with national guidelines.⁽²⁴⁾

In the baseline scenario, the comparator for the analysis will be routine care in Ireland. Though domiciliary invasive ventilation has been provided to some patients with SCI in Ireland its provision is ad hoc and so is not considered routine care for the purpose of this BIA. This means the comparators for domiciliary invasive ventilation are long-term invasive ventilation in a:

1. hospital setting
2. residential care setting.

There are substantial capital (for example, hospital bed, hoist, ventilator), labour (for example, 24/7 nursing and personal care) and technology (for example, medications, stoma products, nutrition) costs that fall on the HSE that are associated with providing care at home for patients with complex needs that include ventilation.

Comparable resource use estimates for the delivery of this service will be informed by the current integrated care pathway and attendant care guidelines (Section 4),⁽²⁾ international practice and standards, (Section 5) other organisational considerations (Section 6) and by using other data sources, including the Hospital Inpatient Enquiry (HIPE) reporting system of the HSE, input from the EAG, and the international literature. Additional resources associated with delivering domiciliary invasive ventilation, such as staff training and healthcare utilisation (for example, the use of Mobile Intensive Care Ambulance Service for transfers), will also be accounted for. Applicable cost data will be obtained in the first instance from relevant departments within the HSE, the Department of Health consolidated pay scales for the health sector,⁽²⁵⁾ and the HSE Activity-Based Funding price list.⁽²⁶⁾ In the absence of Irish data, cost data from the NHS⁽²⁷⁾ and the published literature may be used, where appropriate. Costs will be adjusted in line with national guidelines.⁽²⁴⁾

8. Social and ethical considerations

This chapter will focus on the social and ethical aspects associated with providing ventilation in a home compared with a hospital or long-term care setting. Domiciliary invasive ventilation involves intensive round-the-clock care in the home setting and places a known burden on patients and their families.^(28, 29) Patients with high cervical cord injuries who are receiving ventilator support are completely physically dependant on others and this impacts significantly on the person's ability to undertake everyday tasks, communicate with others, and integrate with their community and wider society. Many challenges need to be overcome in order for

these individuals to adapt to their new reality.⁽³⁰⁾ Successful transitioning of patients with SCI to their home is heavily reliant on strong family and caregiver support - physical, emotional, financial, housing and transportation-related.⁽³⁰⁾ The increased demands on families and caregivers can lead to the need for psychological support and a decrease in their health and quality of life.⁽³¹⁾

There are important ethical aspects that need to be considered when providing such high-dependency, lifelong care for vulnerable patients outside of regulated environments.^(23, 32, 33) An understanding of the ethical concepts supporting the patient pathway is an important element of this assessment. For example, from an autonomy perspective there may be issues if the patient wishes to move home to receive care and is clinically assessed to be fit for domiciliary ventilation, but the family are unable or unwilling to provide this care. Inequity issues will also be addressed as there is evidence of different regions within Ireland responding differently to requests for homecare services.

Methods outlined in the EUnetHTA Core Model will be used to guide the analysis.⁽²²⁾ Patient groups and healthcare workers supporting them will be consulted for their perspectives on their experience of domiciliary ventilation. Input may be sought from HIQA regulation and standards representatives and ethicists regarding the ethical aspects of this topic. This will be supplemented by a literature review as part of the overarching search strategy for this HTA (Appendix 1).

9. Conclusion

This HTA is intended to inform a decision by the HSE regarding the requirements for the national provision of care to adults with spinal cord injuries who require permanent invasive mechanical ventilation and in whom discharge home is deemed clinically appropriate.

Systemic changes to the way that domiciliary ventilation for these individuals is funded, organised and delivered may represent a feasible and affordable alternative to the current ad hoc system which often leads to prolonged stays in hospital and residential care settings. It may also reduce inequity in the current provision of services by enabling a standardised national approach and may expand access of domiciliary ventilation service in Ireland to other patient groups.

Considering the current care pathway already provides domiciliary invasive ventilation to these patients (although in an ad hoc and unsystematic manner), a HTA comprising a scoping review of international practice and standards, an analysis of the organisational, social and ethical considerations, and a budget impact analysis will be conducted to inform decision-making by the HSE.

References

1. United Spinal Association. What is Spinal Cord Injury/Disorder? 2022 [cited 2022 2 Sep]. Available from: <https://unitedspinal.org/what-is-spinal-cord-injury-disorder-scid/>.
2. Health Service Executive. Integrated Care Pathway for the Management of Spinal Cord Injury 2018 [cited 2022 2 Sep]. Available from: <https://www.hse.ie/eng/services/publications/clinical-strategy-and-programmes/integrated-care-pathway-spinal-cord-injury.pdf>.
3. World Health Organization. Spinal Cord Injury 2013 [updated 19 Nov 2013; cited 2022 1 Sep]. Available from: <https://www.who.int/news-room/fact-sheets/detail/spinal-cord-injury>.
4. US National Spinal Cord Injury Statistical Center. 2018 Annual Report – Complete Public Version 2018 [cited 2022 2 Sep]. Available from: <https://www.sci-info-pages.com/wp-content/media/NSCISC-2018-Annual-Report.pdf>.
5. Campbell H, Hotchkiss R, Bradshaw N, Porteous M. Integrated care pathways. *Bmj*. 1998;316(7125):133-7.
6. National Rehabilitation University Hospital. 39th Annual Report (2019): Moving Forward Together 2019 [cited 2022 2 Sep]. Available from: https://www.nrh.ie/wp-content/uploads/2020/05/9457_NRH_Ann_Rep_2019_FA9.pdf.
7. Government of Ireland. Slaintecare Action Plan 2022 2022 [cited 2022 5 Sep]. Available from: <https://assets.gov.ie/226519/9aefe8a9-9e85-4bbd-8876-458301609db8.pdf>.
8. Kotanen P, Kreivi H-R, Vainionpää A, Laaksovirta H, Brander P, Siirala W. Home invasive mechanical ventilation in Finland in 2015–2019. *ERJ Open Research*. 2020;6(4).
9. Harlid R, Andersson G. The Swedish experience in the organisation of domiciliary ventilation for patients with a high spinal cord injury. *Paraplegia*. 1993;31(3):157-9.
10. van den Biggelaar R, Hazenberg A, Cobben N, Gommers D, Gaytant M, Wijkstra P. Home mechanical ventilation: the Dutch approach. *Pulmonology*. 2022;28(2):99-104.
11. McKim DA, Avendano M, Abdool S, Côté F, Duguid N, Fraser J, et al. Home mechanical ventilation: a Canadian Thoracic Society clinical practice guideline. *Canadian Respiratory Journal*. 2011;18(4):197-215.
12. EUnetHTA Joint Action 2 Work Package 8. HTA Core Model ® version 3.0 (Pdf) 2016 [cited 2022 1 Sep]. Available from: www.htacoremodel.info/BrowseModel.aspx.
13. NHS Commissioning Board. Clinical Commissioning Policy: Phrenic Nerve Pacing Following Spinal Cord Injury 2013 [updated Apr 2013; cited 2022 25 Oct]. Available from: <https://www.england.nhs.uk/wp-content/uploads/2013/04/d13-p-a.pdf>
14. Health Information and Quality Authority. Standards and Quality 2022 [cited 2022 7 Sep]. Available from: <https://www.hiqa.ie/areas-we-work/standards->

- [and-quality](#).
15. Kotanen P, Kreivi HR, Vainionpää A, Laaksovirta H, Brander P, Siirala W. Home invasive mechanical ventilation in Finland in 2015–2019. *ERJ Open Research*. 2020;6(4):1-8.
 16. Smith É, Fitzpatrick P, Lyons F, Morris S, Synnott K. Prospective epidemiological update on traumatic spinal cord injury in Ireland. *Spinal cord series and cases*. 2019;5(1):1-4.
 17. Colquhoun HL, Levac D, O'Brien KK, Straus S, Tricco AC, Perrier L, et al. Scoping reviews: time for clarity in definition, methods, and reporting. *Journal of clinical epidemiology*. 2014;67(12):1291-4.
 18. Munn Z, Peters MDJ, Stern C, Tufanaru C, McArthur A, Aromataris E. Systematic review or scoping review? Guidance for authors when choosing between a systematic or scoping review approach. *BMC Medical Research Methodology*. 2018;18(1):143.
 19. Tricco AC, Lillie E, Zarin W, et al. Prisma extension for scoping reviews (prisma-scr): Checklist and explanation. *Annals of Internal Medicine*. 2018;169(7):467-73.
 20. Arksey H, O'Malley L. Scoping studies: towards a methodological framework. *International journal of social research methodology*. 2005;8(1):19-32.
 21. Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMA-ScR): Checklist and Explanation. *Annals of Internal Medicine*. 2018;169(7):467-73.
 22. European Network for Health Technology Assessment (EUnetHTA). HTA Core Model Version 3.0 2016 [Available from: <https://eunethta.eu/wp-content/uploads/2018/03/HTACoreModel3.0-1.pdf> Accessed 05/01/2021].
 23. Health Information and Quality Authority. REGULATION OF HOMECARE: Research Report 2021 [updated Dec 2021; cited 2022 6 Sep]. Available from: <https://www.hiqa.ie/sites/default/files/2021-12/Regulation-of-Homecare-Research-Report-Long-version.pdf>.
 24. Health Information and Quality Authority. Guidelines for the Budget Impact Analysis of Health Technologies in Ireland. Dublin: HIQA, 2018 17 January 2018. Report No.
 25. HSE. Pay scales: HSE; 2022 [Available from: <https://healthservice.hse.ie/staff/benefits-services/pay/pay-scales.html>].
 26. Healthcare Pricing Office. ABF 2022 Admitted Patient Price List. HSE, 2022.
 27. NHS. 2019/20 National Cost Collection Data Publication 2022 [Available from: <https://www.england.nhs.uk/publication/2019-20-national-cost-collection-data-publication/>].
 28. Martinsen B, Dreyer P. Dependence on care experienced by people living with Duchenne muscular dystrophy and spinal cord injury. *Journal of Neuroscience Nursing*. 2012;44(2):82-90.
 29. Huang J, Pacheco Barzallo D, Rubinelli S, Münzel N, Brach M, Gemperli A. Professional home care and the objective care burden for family caregivers of persons with spinal cord injury: Cross sectional survey. *International Journal of Nursing Studies Advances*. 2021;3:100014.
 30. Hall AG, Karabukayeva A, Rainey C, Kelly RJ, Patterson J, Wade J, et al.

- Perspectives on life following a traumatic spinal cord injury. *Disability and Health Journal*. 2021;14(3):101067.
31. Maitan P, Frigerio S, Conti A, Clari M, Vellone E, Alvaro R. The effect of the burden of caregiving for people with spinal cord injury (SCI): a cross-sectional study. *Annali dell'Istituto superiore di sanita*. 2018;54(3):185-93.
 32. Kelly BD. The Assisted Decision-Making (Capacity) Act 2015: what it is and why it matters. *Irish Journal of Medical Science (1971 -)*. 2017;186(2):351-6.
 33. Priebe MM, Chiodo AE, Scelza WM, Kirshblum SC, Wuermsler L-A, Ho CH. Spinal Cord Injury Medicine. 6. Economic and Societal Issues in Spinal Cord Injury. *Archives of Physical Medicine and Rehabilitation*. 2007;88(3, Supplement 1):S84-S8.

Appendix 1: Search strategy

Databases to be searched:

- Medline (EBSCO)
- Embase (OVID)
- The Cochrane Library
- ClinicalTrials.gov
- CINAHL (EBSCO)
- APA PsycInfo (EBSCO)

Registries to be searched:

- ClinicalTrials.gov

Grey literature sources to be searched:

- TRIP
- BMJ Best Practice
- UptoDate
- Guidelines International Network
- International HTA Database
- Core
- Google
- Google Scholar
- The Physiotherapy Evidence Database (PEDRO)
- Agency for Healthcare Research and Quality (AHRQ)

Websites of international/national societies and agencies to be searched

- WHO
- European Respiratory Society
- American Thoracic Society
- Canadian Thoracic Society
- American Association for Respiratory Care
- American Spinal Injury Association
- Paralyzed Veterans of America
- Multidisciplinary Association for Spinal Cord Injury Professions (MASCIP) UK
- Thoracic Society of Australia and New Zealand
- British Association of SCI Specialists (BASCIS)
- Respiratory Information for Spinal Cord Injury (RISCI)
- The International Spinal Cord Society (ISCOS)

Table A1: Example of Medline (EBSCO) search strategy:

S42 S32 OR S41

S41 S16 AND S31 AND S40

CONCEPT 4: QUALITY OF LIFE SEARCH FILTER

S40 S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39

S39 AB ("Quality of life" OR "Life quality" "personal satisfaction" OR "patient satisfaction" OR "Activities of Daily Living" OR "Quality adjusted life year*" OR "Personal autonomy" OR "Happiness" OR "Patient preference*" OR "fear of death" OR "family relation*" OR "Religion" OR "social support" OR "financial support" OR "positive experience") OR TI ("Quality of life" OR "Life quality" "personal satisfaction" OR "patient satisfaction" OR "Activities of Daily Living" OR "Quality adjusted life year*" OR "Personal autonomy" OR "Happiness" OR "Patient preference*" OR "fear of death" OR "family relation*" OR "Religion" OR "social support" OR "financial support" OR "positive experience")

S38 (MM "Personal Autonomy") OR (MM "Happiness") OR (MM "Self Concept") OR (MM "Family Relations") OR (MM "Religion") OR (MM "Social Support") OR (MM "Financial Support")

S37 (MM "Quality-Adjusted Life Years")

S36 (MM "Patient Satisfaction")

S35 (MM "Activities of Daily Living")

S34 (MM "Personal Satisfaction")

S33 (MM "Quality of Life")

S32 S7 AND S16 AND S31

CONCEPT 3: HOMECARE

S31 S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30

S30 AB home N3 discharge OR TI home N3 discharge

S29 AB (HMV OR HIMV) OR TI (HMV OR HIMV)

S28 AB domiciliary OR TI domiciliary

S27 AB ("assisted living" OR TI ("assisted living")

S26 AB (homecare OR 'home based' OR 'home-based') OR TI (homecare OR 'home based' OR home-based')

S25 TI home

S24 AB ("primary health" OR "primary healthcare" OR "primary health care" OR "primary care") OR TI ("primary health" OR "primary healthcare" OR "primary health care" OR "primary care")

S23 (MH "Primary Health Care+")

S22 (MH "Skilled Nursing Facilities")

S21 (MH "Long-Term Care")

S20 (MH "Community Health Nursing+")

S19 (MH "Home Nursing+")

S18 (MH "Home Care Services, Hospital-Based")

S17 (MH "Home Care Services+")

CONCEPT 2: VENTILATION

S16 S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15

S15 AB (respiratory N5 (fail* OR insufficienc*)) OR TI (respiratory N5 (fail* OR insufficienc*))

S14 AB ventilator OR TI ventilator

S13 AB mechanical respiration OR TI mechanical respiration

S12 AB (artificial N2 (ventilat* OR respirat*)) OR TI (artificial N2 (ventilat* OR respirat*))

S11 AB Tracheostom* OR TI Tracheostom*

S10 AB mechanical ventilat* OR TI mechanical ventilat*

S9 (MH "Tracheostomy")

S8 (MH "Respiration, Artificial+") OR (MH "Respiratory Insufficiency+")

CONCEPT 1 SPINAL CORD INJURY

S7 S1 OR S2 OR S3 OR S4 OR S5 OR S6

S6 AB (myelopath* N2 (post-traumatic OR posttraumatic OR post traumatic)) OR TI (myelopath* N2 (post-traumatic OR posttraumatic OR post traumatic))

S5 AB (Paraplegi* OR Paralysis OR Quadriplegi* OR Tetraplegi*) OR TI (Paraplegi* OR Paralysis OR Quadriplegi* OR Tetraplegi*)

S4 TX (spine OR spinal) N3 (injur* OR trauma* OR posttrauma* OR 'post trauma*' OR contusion*OR lacerat* OR transect*)

S3 (MH "Spinal Cord+") AND (MH "Wounds and Injuries+")

S2 (MH "Paraplegia+") OR (MH "Quadriplegia+") OR (MH "Paralysis+")

S1 (MH "Spinal Cord Injuries+")

Published by the Health Information and Quality Authority (HIQA).

For further information please contact:

Health Information and Quality Authority

George's Court

George's Lane

Smithfield

Dublin 7

D07 E98Y

+353 (0)1 8147400

info@hiqa.ie

www.hiqa.ie

© Health Information and Quality Authority 2023