



Rannán na nOspidéal Ghéarmhíochaine
Aonad 4A, Áras Dargan
An Ceantar Theas
An Bóthar Míleata
Cill Mhaighneann
Baile Átha Cliath 8

Acute Operations
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20th April 2022

Deputy Denis Naughten,
Dáil Eireann,
Leinster House
Kildare Street
Dublin 2

PQ 19025/22* “To ask the Minister for Health the national clinical guidelines which exist for each rare disease to facilitate the optimal diagnostic and therapeutic management of the given rare disease which comply with the European Commission Cross Border Care Directive 2011/24/EU; and if he will make a statement on the matter”

Response:

Dear Deputy Naughten,

As outlined in the HSE ‘Model of Care for Rare Diseases’ (2019), clinical practice guidelines (CPGs) are ‘statements that include recommendations intended to optimise patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options’ (Institute of Medicine).

There are more than 7,000 known rare diseases. It is recognised internationally that there are a limited number of CPGs for rare diseases available or up to date. The Irish National Clinical Effectiveness Committee was established by the Minister for Health in September 2010. One of the responsibilities of the committee is to commission national clinical guidelines and national clinical audit. To date, the committee has not commissioned any clinical guidelines specific for rare diseases. Rare diseases present a challenge for the development of CPGs on a national member state basis, often with a lack of sound evidence, available national clinical expertise, and availability of clinical trials for small populations or national publications.

Since January 2022, Ireland is now a member of 18 European Reference Networks (ERNs). The European Commission Cross Border Care Directive 2011/24/EU requires that ERNs and healthcare providers wishing to join ERNs should have the capacity to develop good practice guidelines. Currently, all approved ERNs have declared that the development of clinical practice guidelines is a priority, with work ongoing.

As part of the HSE Scheduled Care Transformation Programme, a number of integrated scheduled care pathways are currently in development with the objective to reduce waiting times and improve access, patient flow and care delivery as aligned with the principals of the Sláintecare Implementation Strategy & Action Plan 2021 — 2023. This project includes the development of care pathways for Neurology Rare Progressive Diseases: Motor Neuron and Huntington's disease.

Furthermore, the HSE National Rare Diseases Office is currently leading out on the development of integrated care pathways for a number of the more common rare diseases. In Phase 1 of the project, preliminary care pathways were designed based on the guidelines identified in an evidence-based review, where specific guidelines existed and CPGs were identified for 26 of the 29 conditions. However, many were based on lower levels of evidence, focused on a single body system, represented the position of a specific professional group, were over 10 years old or were not written in English.

The development of CPGs continues to be a work in progress for each ERN. As a member of an ERN, our Health Care Providers will agree to adopt the ERN approved guidelines and clinical decision support tools. The development of CPGs will be a key objective for our ERN Clinical Leads. However, the provision of adequate national funding and resourcing of the ERN hosting hospitals is necessary to enable ERN integration and operationalisation of key ERN work packages such as CPGs.

I trust this answers your question to your satisfaction.

Yours sincerely,



Brian Dunne
General Manager
Acute Operations