What are clinical practice guidelines?

Clinical practice guidelines (CPGs) are a set of recommendations for clinical care, based on evidence gained from medical science and, where no evidence exists, expert opinion.

The CPGs help patients understand available treatment options – medicinal, surgical, etc. – and empower patients to have informed consent to work in partnership with their clinicians in developing their own clinical plan. For healthcare professionals, the CPGs are useful in recommending treatment for specific conditions based on generally recognised standard parameters, as well as help review treatment benefits and possible harms with their patient.

Where patient numbers are considered small, such as the case for rare diseases (e.g., Epidermolysis Bullosa – EB), CPGs are vital in providing internationally consistent standards of care. The CPGs also highlight situations where there is a lack of evidence, which identifies gaps in knowledge of the condition and could shape future research.

What is DEBRA’s involvement in the EB CPGs?

DEBRA International (DI) is one of the few patient organisations in the world leading the development of CPGs.

DI aims to produce guidelines for all the major clinical areas involved in the care of people with EB. These guidelines will help improve the clinical and social care of EB patients across the globe. Until there is a cure, there is probably no greater way to positively impact the lives of people with EB.

Other EB CPGs are available; however, the majority of current and future work to be produced is coordinated and collaborated internationally to reduce costs and duplication. Additionally, the CPGs produced with DEBRA involved, on average, have been more highly rated than others.

How are the topics chosen?

Because the EB CPGs are patient driven, the topics are chosen based on priorities set by the EB Community. The international EB Community was surveyed and more than 20 topics were chosen/requested. A total of 7 topics are prioritised and around 10 are active at any given time.

The priorities might be reset based on groundbreaking research, technological advances or concerns over safety.

<table>
<thead>
<tr>
<th>Current Selected Guideline Topics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral Health</td>
</tr>
<tr>
<td>Nutrition: Constipation</td>
</tr>
<tr>
<td>Laboratory Diagnosis</td>
</tr>
<tr>
<td>Pregnancy, Childbirth, and Aftercare</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
Future Selected Guideline Topics

<table>
<thead>
<tr>
<th>Anaesthetics and clinical procedure</th>
<th>Bone Health</th>
<th>Gastrostomy</th>
<th>Eye Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renal Disease</td>
<td>Oesophageal dilatation and Reflux</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

How are they developed?

Broadly, guidelines are developed by assembling an international multidisciplinary panel of relevant clinical experts and patents. This panel then:

- Agrees on the clinical question(s) the guideline should address
- Undertakes a systematic literature search for relevant evidence
- Draws on the expert opinion within the panel when no evidence exists
- Drafts recommendations for care
- Has these recommendations reviewed by other experts and patients
- Publishes the guideline in an open access journal
- Updates the guideline when substantial new evidence or changes in practice emerge (approximately every 3-5 years)

How many people are involved?

There are more than 260 volunteers from the EB Community – those directly impacted by EB or working with the condition – with a representation from over 20 countries involved in developing the CPGs. The diversity varies per guideline based on the relevance of the people selected; however, DI encourages 3+ countries to participate with the development of each guideline, with each panel having between 6 and 12 members.

How much does one CPG cost?

Each guideline’s cost varies; however, the average cost of all current and forecasted guidelines equates to roughly €37,400 (or approximately £33,000). The figure includes costs for: training, publishing, meetings, writing and coordinating, a patient version, as well as admin and other support.

How long does it take for a CPG to be completed?

The length of time to produce a guideline varies between 18 to 24 months. The start period is from the initial date the agreement letter is signed and completion date is classified as a submission for publication.

How does it benefit those involved in the process?

Volunteers on the CPG panels range from those living with EB to those with clinical and scientific backgrounds. Taking part in this process facilitates international networking and collaboration: sharing knowledge on a variety of subject areas, learning from the experiences of others, enhancing CVs, becoming an avenue to publish further research, and sharing workloads and responsibilities.