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Hilfe für die Schmetterlingskinder.

Übergeleitete Auslegung durch Epimedis - Europäische Plastik- und Ausvermedien GmbH

Patient involvement in research: who needs it?

Public & patient involvement

- *Video:* Introduction to PPI
- What patients think – *Mike Jaega*
- What DEBRA International has done – *Avril Kennan*
- Thoughts from a father
- Thoughts from someone who lives with EB

Introduction to PPI

medical
research
charities
group
Unity is our Strength

What patients think – *Mike Jaega*:

I think, though clinician's are listening to people with EB more, there needs to be more work done in this area. If you have a clinical trial for EB for, say, a topical treatment for EB in which dressings need to be changed daily. This is much easier said than done with EB. Many people with EB have dressings changed just a few times per week or half one day, half the next etc. This is often due to the extreme pain that dressing changes can cause.

What patients think – *Mike Jaega*:

Plus, it's often the case that people with EB have dressings changed by either a family member or regular carer. So there is also a stress and comfort factor if they are suddenly told that dressings for the trial must be changed by a nurse who doesn't know that individuals dressing change routine. So, to summarise, factors such as being away from home, dressing changes everyday, other people/nurses changing dressings and even dietary issues can be factors when a EB patient undertakes a clinical trial.

What patients think – *Mike Jaega*:

Though trials will never be a perfect situation I think it's important to understand and address as many factors as possible and make life as easy as possible for the trial participant. Just showing an understanding and empathy for that individuals situation can be a massive help.

What DI has done – *Avril Kennan*:

Process:

- 11 patient reviewers from 10 countries were recruited; reviewers either have EB or are parents to a child with EB and span all major types of the condition
- Patient reviewers were provided with full, stage 1 applications for the proposals they were invited to review. Where possible, reviewers were matched with projects focusing on their type of EB
- They were requested to complete a review form, answering a series of questions, including, how understandable the lay section of the application was, whether they believed the proposed research was of potential benefit to patients and whether they felt patients would be willing to participate in the research. They were not asked to comment on scientific quality or feasibility (scientific reviewers were recruited for this purpose).
- Each of the 18 applications was reviewed by one (or, in a small number of cases, two) of the 11 patient reviewers.
- Each applicant was provided with the patient reviewers' comments (which were anonymised), to guide them in their stage 2 application (for those invited) and/or their future EB research plans

What DI has done – *Avril Kennan*:

Outcome:

- patient reviews were, in general, of a very high standard. They are highly informed, carefully considered and provided very valuable insight from the patient perspective
- The patient reviewers were broadly supportive of all 18 applications submitted, stating in every case that the research has the potential to make a difference to patients' lives
- Although patient reviews might be helpful in aiding decisions on which projects to fund in future calls, their greatest value in this call is the provision of a patient perspective to help applicants shape the future direction and design of the research
- In general, the lay summaries were understandable to the patient reviewers. Many also drew on information provided in other sections of the proposals, in preparing their reviews
- Many of the patient reviewers expressed a desire to know more about the following areas for the proposals they reviewed:
 - How the proposed clinical intervention would work/be administered in practice
 - How much time patients would need to commit, to participate in the study (e.g. the number of follow-up visits required)
 - The potential risks/side effects for patients
 - Whether the costs to the patients participating would be covered

What DI has done – *Avril Kennan*:

Future Plans:

- We will provide all patient reviewers with the opportunity to say what they felt worked well or didn't work well and consider their responses in shaping future plans
- We will consider whether there is the possibility to offer training or access to supportive resources to patient reviewers, to help them in their role
- We would like to further expand the pool of reviewers, for future calls. This would help to reduce the burden on any one reviewer, would engage additional, interested people in the research funding processes and would facilitate the matching of research proposals with patient reviewers with the same type of EB
- We will modify the research funding application form for future calls, to provide details on the areas the patient reviewers requested more information on
- In future appropriate calls, a patient representative on the MSAP will be invited to channel the comments from the patient reviews into the MSAP meetings, where they can be considered by MSAP members in their deliberations

Thoughts from a father:

- EB patients are EB experts
 - Don't talk about, talk with them
 - There are only a few, be nice to them
- Negotiations with regulators – before the study
 - Patient involvement? EMA / FDA etc.
 - Patient – level of specific knowledge (EUPATI, EURORDIS summer school)
 - Rigid study protocols will NOT attract patients and might lead to small numbers of participants
 - We will provide all patient reviewers with the opportunity to say what they felt worked well or didn't work well and consider their responses in shaping future plans
- Recruitment
 - Encourage patients – we need them (empowerment) → joint effort (clinicians, patient organisations)
 - Inform patients pro-actively about the process (manage expectations)
 - Anticipate problems with logistics: travel, hotel stays, dressing changes, access to medication, need for help (out of home)
- During the Study
 - Clinical care – self-evident
 - Psychological care – esp. if results are disappointing for patients?
 - How to communicate negative results without frustrating the patient group?

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Thank you