Response ID ANON-GFK1-Z4VC-G

Submitted to Proposed refinements to the requirements for medical device patient information materials
Submitted on 2021-08-30 17:46:43

Privacy and your personal information

Introduction

1 What is your name?

Name:
Miriam Norman

2 What is your email address?

Email:
[redacted]

3 What is your organisation?

Organisation:
The Royal Hobart Hospital

4 Are you a manufacturer/sponsor/consumer/health care professional?

Health Care professional

Refinement 1: Provision of patient information materials

5 Should patient information materials be provided in range of formats including:

Yes

Yes

Yes

Do you agree that the proposed wording of 'made available with' provides clarity for the format of and timing of when PICs and PILs are to be supplied?:

Yes and No.
Implant card info should be included in hospital discharge forms, MyHealth Record etcetera, but the patient should still be issued with a hard copy Implant Card.
This is important for airport security, and for adequate care at clinics or hospitals in other countries or states and territories within Australia.

6 Do you have any other comments/suggestions that we should consider in relation to how PILs and PICs are made available?

Do you have any other comments/suggestions in relation to how Patient Information Leaflets and Patient Implant Cards are to be supplied?:

Ideally there should be both written and audible forms of the PIL.
I have previously recorded video material for education of pacemaker and defibrillator recipients, where the info was presented in text (PowerPoint style) and audio formats. We never used it, because we realised that it needed to be broken down into smaller videos (e.g. wound management, travel, precautions re electromagnetic interference etc need their own short videos). I parked the project, but would be happy to revisit. Hearts 4 hearts would be a good organisation to host this material (and is endorsed by CSANZ).

7 As a manufacturer/sponsor/consumer do you foresee any regulatory or cost implications or burden if the PICs and PILs are provided in more than one format?

Do you foresee any cost implications as a manufacturer/sponsor/consumer should the proposed change occur?:

Material might have to be updated from time to time.
for example, my handout re Implantable Loop Recorders needed adjusting because new technologies came out.
Material provided by the manufacturers is often unsuitable - for example the remote monitoring consent forms for CIEDs are in far too small a font for our elderly, and are written in lawyer-language. I've found the key messages just get lost, and consider them totally inappropriate and unhelpful for our patients. We might have a hard time getting the companies to approve a patient-appropriate version.

Refinement 2: Devices exempt from the requirements of patient information materials

8 Do you agree that it is unnecessary to provide Implant Cards if the device is going to be absorbed by the body within a certain timeframe? Should a PIL still be available?

Yes

7) Do you agree that devices absorbed within a certain timeframe should be exempt from providing PICs?:

9 If you answered yes to the above question, tell us what would be a reasonable timeframe (e.g. devices absorbed within 3months/6 months), and why?

8) If yes, what is a reasonable timeframe (e.g. 6 months), and why?:

I can only comment on CIEDs and associated technology.
tyrx pouch would be an example of an absorbable product. I don't see any need for a PIL in that instance.

10 If you are a manufacturer, describe the evidence that you could provide to demonstrate that the device will be absorbed within the stated timeframe.

9) If you are a manufacturer, what evidence could you provide to demonstrate that a device is absorbed within a certain timeframe?:

N/A

11 Do you agree that it is unnecessary to provide Implant Cards for each pedicle screw, given that many screws could be used in one surgery. Should a PIL still be available? Please explain why?

Not Answered

Do you agree that an extra 18 month transition period is sufficient to allow the correct provision of PICs for non-exempt, non-sterile implants such as pedicle screws?:

Not my area

Other questions

12 Are there any other devices that could have implementation issues which are outside the control of the medical device sponsor and manufacturer? Please give examples.

Are there any other devices that could have implementation issues which are outside the control of the medical device sponsor and manufacturer? Please give examples.:

Yes.
Mobile phone technology for remote monitoring of CIEDs.
Hard to implement and maintain connection when patients may not have the technical skills to keep the required app up and running. Easy to lose monitoring when a patient changes to a new phone or forgets to leave their Bluetooth "on".
Important to have low tech options for patients (e.g. a bedside accessory that requires only a one off "set and forget".
Though these bedside accessories should get a formal mandatory label "Medical Equipment - keep plugged in at patient bedside" so they don't get disconnected in nursing homes, or by the cleaner.

13 Do you have any other comments in relation to patient information materials?

Do you have any other comments in relation to the above issues around patient information materials?:

Some advice lacking - for example we don't have an Australian standard for pacemaker wound care post op.
Local handouts cover local policies - but there is research to be done to back-up a national policy.
for example - driving instructions post pacemaker replacement are poorly covered (defibrillators are specifically given 2 weeks, and I think that it is implied that pacemakers are 2 weeks also, but this isn't actually stated).
Some centre require a 2 week appointment, some severely restrict arm movement for 2 weeks, others 6 weeks.

Required - Final step - Publishing my response

14 Do you consent to the Department collecting the information requested in Citizen Space about you, including any sensitive information, for the purposes of this consultation?

I consent:
Yes

15 I consent to the submission made by me being published on the Department's website, and accessible to the public, including persons overseas, in accordance with the following preference:

Publish response, including both my name and organisation's name

16 If there are questions that you don't want published, please indicate those below

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17 May we contact you for further information or to seek feedback about how the consultation was undertaken?

Yes

18 By making a submission, I acknowledge that:

I acknowledge the above:
No