ISSUE 1 – July 2010

PHBE NEWSLETTER

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1. PHBE UPDATE

The evaluation has made good progress, most notably with the recruitment of 65 participants and interviews with PHB leads about *early implementation* experiences.

The final interim report on the early implementation experiences is now on the PHBE website.

Different sites are at different stages in the implementation process, but as you roll-out PHBs don't forget to invite them to participate in the evaluation.

The rest of this edition provides more detail on different aspects of the evaluation.

2. CONSENT FORMS AND INFORMATION SHEETS

We have developed a series of consent forms and information sheets to suit different situations. Each form will be included in each documentation pack. If you would like to personalise them we can email them to you:

- Does the user have the capacity to consent? If not, we have versions to allow a consultee (e.g. a relative /carer) to consent on their behalf.
- Can the user/proxy consent using a 'full' information sheet? If this information is too much to take in, then 'accessible' versions are available.
- Is the individual part of the PHB or Comparison Groups? We have different forms for each.
- Does the participant have a carer? If yes, we will ask participants if we can contact their carer. This form will be included in the PHBE documentation packs.

Please remember that it is very important that the key points of the consent form are explained carefully to the individual (or carer, consultee as appropriate) so that the consent they give is well informed.

If they have any questions you cannot answer, individuals are very welcome to contact the PHBE team (contact details are on the information sheet)

3. KEEPING IN TOUCH

The first point of contact between sites and PHBE is through Karen Jones (email: K.C.Jones@kent.ac.uk ; telephone 01227 827953). This will help PHBE to coordinate communication with you and ensure we give out consistent messages, whilst keeping one person as the main contact. Please keep us informed with where you are up to in the evaluation process, and let us know of any concerns if they arise.

4. ETHICS AND RESEARCH GOVERNANCE

The PHBE project has already received a favourable opinion from the National Research Ethics Committee (NRES). We also have initial approval from all of your R&D offices.

The substantial amendment has been given a favourable opinion from NRES and is currently being reviewed by your R&D offices. We will inform you when the document has been approved, as information from medical records can be collected and data can be extracted from HES once we have the necessary paperwork in place.

If you have any queries regarding the ethics or research governance process – contact Karen Jones: K.C.Jones@kent.ac.uk.

5. DATA COLLECTION

The grid below outlines the data collection process depending on the two different processes:

1. A group of health professionals offer PHBs and recruit to the PHB Group. In same site, a different group of HPs decide who is approached to be in the Comparison Group **(Process 1)**
2. Same group of health professionals to recruit to both the comparison and PHB Group **(Process 2)**

Process 1

Stage 1	**Different groups of health professionals (HPs) to recruit to the comparison and PHB group** A group of HPs offer PHBs and recruit to the PHB Group. In same site, a different group of HPs decide who is approached to be in the Comparison Group. A minimum of 75 should be recruited to each group	
Stage 2	**Comparison Group** Invite the individual to participate in the evaluation. Individual continues to receive conventional services for the next 12 months PCT to send the following data to the evaluation: Signed consent form Baseline data Medical record information Evaluation team extract HES data	**PHB Group** Individual is offered a PHB and is invited to participate in the evaluation. An individual can accept the offer of the personal health budget but refuse to participate in the evaluation. PCT to send the following data to the evaluation: Signed consent form Baseline data Medical records information Evaluation team extract HES data
Stage 3		Care plan **(Informed consent needs to be asked on the plan for data sharing).** PCT to send a copy of the care plan itself
Stage 4		A small sample of PHB holders will be interviewed at three and nine months after the PHB has been agreed.
Stage 5	Twelve months after allocation to the comparison group, all participants will be interviewed by a fieldwork agency. PCT to send the following data to the evaluation: Medical record information Evaluation team extract HES data	Twelve months after allocation to the PHB group, all participants will be interviewed by a fieldwork agency. PCT to send the following data to the evaluation: Medical record information Evaluation team extract HES data

Process 2 – Process to follow until we have ethical approval to randomise on the NHS number

<table>
<tr><td>Stage 1: When pilot sites already have the PHBE documentation packs</td><td colspan="2">Same group of health professionals to recruit to both the comparison and PHB group
Each site will be sent documentation packs containing a unique ID number on each consent form and questionnaire.
The first number of the ID denotes whether the individual has been randomised into the PHB (number 1) or the Comparison Group (number 2).
Use the last 5 digits to randomise individuals into either the PHB or Comparison Group.
• If the individual has been randomised into the PHB Group use the documentation pack containing the unique ID number beginning with 1 (e.g. 189001)
• If the individual has been randomised into the Comparison Group use the documentation pack containing the unique ID number beginning with 2 (e.g. 289001)
• The same unique ID number can only be used once.
A minimum of 75 should be recruited to each group</td></tr>
<tr><td>Stage 1: When pilot sites do not have the PHBE documentation packs</td><td colspan="2">The evaluation team will randomise a sample of participants using their own unique IDs for each site. The PHB and Comparison Group documentation packs will be sent to each pilot site containing the relevant unique IDs. While it is tempting to select particular individuals into each group, please try to avoid doing so as this will have an impact of the evaluation.</td></tr>
<tr><td>Stage 2</td><td>Comparison Group
Invite the individual to participate in the evaluation. Individual continues to receive conventional services for the next 12 months

PCT to send the following data to the evaluation:
Signed consent form
Baseline data
Medical record information
Evaluation team extract HES data</td><td>PHB Group
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6. STAFFING NEWS

PHBE would like to welcome three new members to its research team:

Elizabeth Welch (University of Kent, E.Welch@kent.ac.uk), is currently working on Research and Development approvals for the wider cohort and setting up data collection files.

Annie Irvine (University of York, aj513@york.ac.uk) and Jacqueline Davidson [University of York, jd527@york.ac.uk) are involved in conducting interviews with PHB holders and carers.

7. PHBE WEBSITE

We have included a number of documents on the website. Please take a look at the documents within two folders: About the Evaluation and Data Collection. There are also a number of new FAQs on the website. Below are the new additions

Q. Do I need to keep a record of the unique IDs and NHS numbers?

Yes, please keep a record of which unique ID is related to the NHS number of each participant. If we need to contact you about a participant, we will be using the unique ID in emails.

Q. When will participants receive the voucher as a thank you?

Participants will receive the £10 voucher after 6 months from date of consent. They will receive an additional £10 voucher after they have completed the 12 month follow-up interview.

Q. Can a consultee give consent for information from medical records and HES data to be collected?

There has been concern about this issue. The evaluation team and the Department of Health would recommend that only a representative who has the appropriate power of attorney or has been appointed as a deputy can give consent for information from medical records and HES data to be collected.

Q. I really want to offer a personal health budget to one of my clients, but the randomiser has put them into the comparison group. Can I include them?

No. If one set of health professionals are recruiting to both the PHB and Comparison Group, it is absolutely critical to the success of the evaluation that the randomiser alone decides who is to be offered PHBs immediately. This would jeopardise the rigour of the evaluation, and would mean that the Department of Health makes decisions about the future of the policy based on unreliable information.

Q. We are worried that recruitment is going very slowly

The evaluation team are aware that sites are trying to overcome many issues which could be having an impact on recruitment. If you are concerned, please contact the evaluation team.

Q. Can we manually randomise participants?

No. Please contact the evaluation team to discuss the issue

Q. Is it necessary to complete the interview on one occasion?

It is OK for the participant to stop the interview and ask the interviewer to return on another day to complete the form.

Q. Will identifiable information be needed to be included on the care plans?

Please remove all identifiable information on the care plans before sending a copy to the evaluation team. We only need the unique study participant number. Please send the forms back securely to the evaluation team and keep a record of sending it.

Q. Will individuals need to consent for data to be extracted about their secondary care service use from HES?

They definitely will need to give permission for the data to be extracted.

Q. Can we gain consent and interview the participant on the same day?

No, there needs to be a gap of 24 hours between gaining consent and interviewing the participant.

Q. Can you remind me what information the evaluation needs on the care plan?

The evaluation needs the following information:

1. The budget per year and the total level of funding in terms of health service expenditure, recurrent annual and one-off payments (where applicable)
2. The cost of planning health support
3. The formal organisation of the budget in terms of deployment options
4. The activities (interventions, services, etc.) included in the care plan that the budget is to be spent on
5. The cost of the individual services identified within the care plan