**Call for evidence to all registered stakeholders**

**Updated NICE guidance on the diagnosis and management of Parkinson's disease in adults**

Dear Stakeholder

The National Institute for Health and Care Excellence (NICE) has commissioned its Internal Clinical Guidelines team (ICG) to update guidance on the diagnosis and management of Parkinson's disease in adults.

Your organisation is invited to submit data that meets the requirements set out below to assist the guideline development process.

We have already carried out extensive searches to cover published clinical literature. Upon reviewing the literature, we have reason to believe there may be relevant evidence in addition to that identified by the searches that is not yet available in published form.

We are evaluating the following review question:

**What is the comparative clinical effectiveness and cost effectiveness, for people with Parkinson's disease whose symptoms are no longer controlled by existing pharmacological treatment(s), of:**

- **deep brain stimulation surgery (of any surgical target) or**
- **levodopa and carbidopa intestinal gel or**
- **best medical treatment (which may or may not include apomorphine infusion).**

We are interested in data covering the following areas:

1. Unpublished data from any randomised controlled trial comparing 2 or more of the above interventions
2. Unpublished non-randomised data detailing long-term follow-up (1 year or longer) of any of the above interventions (to inform our original health economic analysis)
3. Existing health economic data or models comparing any 2 or more of the above interventions.

We require data reporting any of the following outcomes:

- Patient-reported outcomes:
  - EQ-5D (summary index score)
  - PDQ-39 (at domain and summary level)
  - PDQ-8 (at domain and summary level)
  - ON and/or OFF times (reported as hours per day or quartile percentages)
- Markers of disease progression (in ON and/or OFF states):
  - UPDRS (total score and/or subscores for parts III, IVa IVb and IVc)

- Hoehn and Yahr stages
- Resource use (including concomitant medication and care requirements)
- Rates of entry to full-time institutional care (e.g. time-to-event data)
- Any adverse events (rates or numbers of events and people)

Data can be submitted in aggregate (with appropriate measures of dispersion) or appropriately anonymised individual form. In addition to the outcomes listed, supporting data covering the number of participants, baseline participant characteristics and any concomitant medication(s) taken should be submitted.

Data should be submitted in Microsoft Word, Microsoft Excel, Adobe PDF or comma-separated value formats. Health economic models may also be submitted as R, WinBUGS or TreeAge files. If you wish to submit data in any other format, please get in touch to discuss with us.

You should ensure that any data you wish to submit:

- Directly addresses the review question listed
- Fits into 1 of the 3 categories of data required
- Reports outcomes listed and supporting data
- Are in the format(s) listed.

There is no need to submit data that have already been published.

Please note that all evidence submitted will be reviewed against the inclusion criteria indicated here. Only evidence that is eligible will be presented to the Guideline Development Group for consideration. All such evidence will be subject to the same process of critical appraisal that applies to published evidence identified in our reviews. We are in no way bound to use submitted data.

Please read the instructions below to identify the types of information that can be accepted. A full description of NICE's guideline development process and guidance of stakeholders is available from the NICE website.

If you wish to make a submission please email it to stephanie.mills@nice.org.uk. Alternatively, submissions can be posted to Stephanie Mills, National Institute for Health and Care Excellence, Level 1A City Tower, Piccadilly Plaza, Manchester M1 4BD. Submissions should arrive by **12 noon on Monday 20 July 2015.**

Please acknowledge receipt of this letter by email, indicating whether your organisation will be submitting evidence for consideration

Yours sincerely

Stephanie Mills

Project Manager

**Instructions to stakeholders for submitting evidence for a call for evidence**

Before submitting details of suggested evidence, please check the relevance of the information against the review question, interventions, required data and outcomes listed above and also against the criteria detailed below:

- Relevant, published, peer-reviewed reviews or cost-effectiveness analyses that appropriately address the question posed by the scope of the guideline will be found by ICG by systematic literature searching. Generally there is no need to submit such papers unless you are aware that the journal in question is not indexed on any of the main databases or that the specific data we seek are not reported within the published paper.
- Submissions should include sufficient information about methods to allow them to be quality assessed. Abstracts, posters or data tables alone will be considered to provide insufficient methodological information and should be accompanied by a technical report or draft paper.
- Relevant 'academic in confidence' or 'commercial in confidence' data can be submitted, however it must be clearly labelled as such and a completed checklist submitted (please see checklist attached). Its submission must adhere to the principles contained within the guidelines manual.

Evidence which generally will *not* be considered by NICE includes:

- promotional material
- unsubstantiated or non‑evidence‑based assertions of effectiveness
- opinion pieces or editorial reviews
- potentially unlawful or other inappropriate information.