Hospitalisation and comorbidities in Parkinson's disease: A large Australian retrospect study

Michal Lubomski Dr.

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APPENDIX 1 – ETHICAL CONSIDERATIONS

Human Research Ethics Committee approval has been granted prior to the commencement of the research project:

- University of Notre Dame, Sydney School of Medicine – HREC Approval: #013067S. Approved 16th May 2013.

Attached are:

- HREC approval certificate

- Completed low risk application form requesting ethical clearance – UNDA HREC
16 May 2013

Dr Stephen Tisch
School of Medicine
The University of Notre Dame Australia
Sydney Campus

Dear Stephen,

Reference Number: 013067S
Project Title: “Parkinson’s disease hospitalisations and co-morbidities: a retrospective cohort study of NSW patients.”

Thank you for submitting the above project for Low Risk ethical review. Your application has been reviewed by a sub-committee of the university’s Human Research Ethics Committee in accordance with the National Statement on Ethical Conduct in Human Research (2007). I am pleased to advise that ethical clearance has been granted for this proposed study.

All research projects are approved subject to standard conditions of approval. Please read the attached document for details of these conditions.

On behalf of the Human Research Ethics Committee, I wish you well with what promises to be a most interesting and valuable study.

Yours sincerely,

Dr Natalie Giles
Executive Officer, Human Research Ethics Committee
Research Office

cc: Prof Christine Bennett, Dean, School of Medicine Sydney;
    Prof George Menzies, SRC Chair, School of Medicine Sydney.
HUMAN RESEARCH ETHICS COMMITTEE

Application for Low Risk Review of a Research Project involving Human Participants

Important Information for Applicants

1. This application form is to be used by researchers seeking a Low Risk review for individual projects.
2. To find out if you are eligible for Low Risk Review, you should complete a Low Risk Review Checklist and refer to Section 2 of the National Statement regarding risk and benefit. 
   Low Risk research describes research in which the only foreseeable risk is one of inconvenience and/or discomfort.
   In addition, if you are seeking a waiver of consent, you are required to fill in a Full Risk application form even if the foreseen risk is deemed “low”.
3. Download a new form from http://www.nd.edu.au/research/hrec/apply.shtml to ensure that you are using the most current version of this form.
4. Handwritten applications will not be accepted.
5. Please respond concisely to all applicable sections, using plain language wherever possible.
6. Type an ‘X’ in checkboxes that apply.
7. Please also provide all necessary attachments where indicated.
8. The National Statement on Ethical Conduct in Human Research (2007) provides the primary guidelines for this application. This and other national guidelines can be found at http://www.nd.edu.au/research/hrec/links.shtml
9. University of Notre Dame research policies can be found at http://www.nd.edu.au/research/hrec/policies.shtml
   In particular read Policy: Ethics Approval for Research Involving Humans and Guideline: Applying for Ethics Approval (Low Risk Clearance).
10. Your completed application must be submitted to your School Research Committee (SRC) for review together with the Low Risk Review Checklist. The SRC will then forward your application to the Research Office for HREC sub-committee review.
11. RESEARCH MUST NOT COMMENCE UNTIL WRITTEN APPROVAL HAS BEEN PROVIDED BY THE HREC SUB-COMMITTEE.
12. Please note: The HREC may decide the application is not Low Risk and will therefore require a Full Review application or may find the study requires substantial changes prior to the commencement of the study.
13. The HREC will not grant retrospective ethics approval.
HUMAN RESEARCH ETHICS COMMITTEE

Application for Low Risk Review of a Research Project involving Human Participants

Registration No. (HREC use only) □□□□□□□

PROJECT TITLE: Parkinson's disease hospitalisations and co-morbidity, a retrospective cohort study of NSW patients.

PROJECT SUMMARY: There is a paucity of understanding to the reasons for admission and related co-morbidities of patients with Parkinson's disease during their hospitalisations. The aim of this study is to examine Parkinson's disease patient hospitalizations in regards to various demographics, co-morbidities as well as clinical management. In this study, data will be extracted from the NSW Ministry of Health, examining various coded patient admissions details over the last five years. Epidemiological, demographic and clinical features will be examined to assess for trends over time, as well as analysing potential correlations of patient co-morbidities that may have predisposed to their hospitalisation. The results of this retrospective study will be analysed to determine whether there are differences or correlations in various health outcomes for PD patients that lead to hospitalisation.

PROJECT TYPE

[Mark X to those that apply]

Student Research Project
Staff Research Project
Project involving patients
Project involving students
Funded consultancy
Other (describe briefly)

PhD
Honours
X Masters
Postgraduate Diploma
Undergraduate
Other Doctorate

EXPECTED COMMENCEMENT DATE: 01.03.2013
EXPECTED COMPLETION DATE: DECEMBER 2014

SCHOOL/CENTRE: School of Medicine, Sydney

CHIEF INVESTIGATOR/SUPERVISOR: [A UNDA staff member with ultimate responsibility for the research]

Name Dr Stephen Tisch
Mailing Address 160 Oxford St, Darlinghurst. 2010. NSW
UNDA Email slisch@stvincents.com.au Phone 02 8382 3305

Describe what the researcher will do in the context of this project.

Overall project supervisor, involved in the following roles:
- Research Project: Conception and design, organization and execution
- Statistical Analysis: Design, execution, review and critique
- Thesis: Review and critique
### Describe the relevant experience the researcher has specific to this project.

<table>
<thead>
<tr>
<th>Dr Stephen Tisch, MBBS PhD FRACP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staff Specialist, Department of Neurology, St Vincent’s Hospital</td>
</tr>
<tr>
<td>Consultant Neurologist, St Vincent’s Private Hospital and Clinic.</td>
</tr>
</tbody>
</table>

**Area Of Interest:**
- Movement disorders
- Deep brain stimulation
- General neurology
- Neurophysiology

Leading expert in Movement Disorders including Parkinson's disease. Widely published in this area and maintains an active interest in research into the field. Has supervised in the past several research projects including a current University of Notre Dame, School of Medicine, student research project. Clinical interests in this project focus towards epidemiological analysis of Parkinson’s disease.

### CO- INVESTIGATOR/STUDENT:

<table>
<thead>
<tr>
<th>Title and Name</th>
<th>Dr Michal Lubomski</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>1002/160 Goulburn St, Surry Hills. 2010. NSW</td>
</tr>
<tr>
<td>UNDA Email</td>
<td><a href="mailto:20084168@my.nd.edu.au">20084168@my.nd.edu.au</a></td>
</tr>
<tr>
<td>Phone</td>
<td>0410190830</td>
</tr>
</tbody>
</table>

**Describe what the researcher will do in the context of this project.**

Principle Researcher.

Directly involved in all the project’s activities, including the following:
- Research Project: Conception and design, proposal submission and presentation, HREC approval, organization and execution
- Statistical Analysis: Design, execution, review and critique
- Thesis: Report writing, review and critique
- Submission for publication

### Describe the relevant experience the researcher has specific to this project.

<table>
<thead>
<tr>
<th>Dr Michal Lubomski, MBBS(Hons)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Resident, St Vincent’s Hospital.</td>
</tr>
</tbody>
</table>

**Area Of Interest:**
- Movement disorders / Parkinson’s disease
- General neurology


Further interest in conducting a larger cohort study, focusing on epidemiological analysis of Parkinson’s disease within Australia. The aim of this study is to further investigate the above clinical interest, a follow on of previous research conducted within this field.

### CO- INVESTIGATOR/STUDENT:

<table>
<thead>
<tr>
<th>Title and Name</th>
<th>Associate Professor Louise Rushworth</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>160 Oxford St, Darlington. 2010. NSW</td>
</tr>
<tr>
<td>UNDA Email</td>
<td><a href="mailto:louise@chrispassociates.com">louise@chrispassociates.com</a></td>
</tr>
<tr>
<td>Phone</td>
<td>02 8204 4404</td>
</tr>
</tbody>
</table>

**Describe what the researcher will do in the context of this project.**

Co-supervisor / Researcher.

Involved project in the following roles:
- Research Project: Conception and design, organization and execution
- Statistical Analysis: Design, execution, review and critique
- Thesis: review and critique
1. PROJECT DETAILS

1.1 KEYWORDS

Provide a list of, and definitions for, any technical terms and acronyms which may assist the HREC to understand this application.

<table>
<thead>
<tr>
<th>TERM</th>
<th>LAY. EXPLANATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>PD</td>
<td>Parkinson’s disease</td>
</tr>
</tbody>
</table>
1.2 AIMS OF AND JUSTIFICATION FOR THE RESEARCH

State the aims and significance of the project. Where relevant, state the specific hypothesis to be tested. Provide a brief description of current research/literature review, a justification as to why this research is important and an explanation of any expected benefits to the community.

(Max 500 words)

This study has three aims. They are:

1. To examine the range of Parkinson's disease patient's hospitalisations in New South Wales over a 5 year period, to determine whether there are trends in patient demographics, reasons for admission as primary and secondary diagnosis, aspects relating to their clinical management and services accessed during an inpatient admission. A comparison of length of stay and inpatient mortality to age and gender matched control patients will also be undertaken.

2. To determine whether medical co-morbidities of patients with Parkinson's disease influence clinical management or health related outcomes during an inpatient admission.

3. To inform the cause of inpatient death, of patient's with Parkinson's disease as a primary and secondary diagnosis.

Hypothesis:

Patients with Parkinson's disease are likely to present with complaints characterised by their chronic neurological illness which are likely to directly influence their health related outcomes during an inpatient admission. Demographics, co-morbidities and management options are likely to differ between subdivided groups of PD patients as well as compared to controls. Patients with greater co-morbidities relating to their diagnosis of Parkinson's disease are likely to have a prolonged and complicated admission with a possible higher incidence of in-hospital mortality. Uncharacterised co-morbidities not related to Parkinson's disease are likely to result in complicated inpatient management and increase the length of patient stay. The cause of PD inpatient death is likely to result from complicated co-morbidities relating to patient treatment. These causes of death are expected to differ compared to age matched controls.

Literature Summary:

Despite the manifest benefits to patients of early intervention and ongoing access to a range of specialised health services, there is a paucity of local New South Wales information relating to the reasons for PD patient hospital admissions, as well as patient associated co-morbidities. In 2009-10 there were 3179 hospitalisations for PD nationally. Although motor disturbances in PD are believed to be a significant cause for PD related admissions, other less defined causes are likely to influence hospitalisation, particularly non-motor complaints. Nationally it was estimated that in 2009-10, 2220 hospital admissions were recorded for accidental falls as well as 2138 admissions for pneumonia in the context of PD related complications. This was predicted to cost at least $79.6 million in addition to the health care system, as a result of PD related complications. Further, information regarding the types of health services that patients access as inpatients, along with the difficulty in tailoring focused neurological care are largely unknown within an Australian hospital setting.

Expected Benefits:

The findings of this study are expected to inform the development of recommendations to clinicians and support groups about optimising the pre-hospital care of patients with Parkinson's disease. Importantly this study's findings are expected to provide a well powered statistical analysis about the relevant reasons for admission that can guide resource allocation / funding within a local or state division. Further, publication of the common patient co-morbidities that lead to hospitalisation in PD may generate further awareness amongst clinicians and support the need for expanding activity based funding, based upon contemporaneous discharge summaries and admission documentation. Thirdly, the extended aim of investigating the cause of inpatient death for patients with a diagnosis of PD is believed to inform clinical governance in reviewing measures to prevent unexpected deaths as well as assisting in preparation for earlier end of life measures for the patient, family and clinicians. In addition it is believed that by providing direct feedback to Parkinson's Australia as well as other support groups, this study may offer many Australian sufferers with newly generated awareness to the importance of optimising outpatient PD management and improved chronic disease management through General Practice, avoiding unnecessary hospitalisations.
1.3 DESIGN OF THE STUDY

(a) What data collection technique(s) will be used? [Type X to all that apply]

Questionnaire(s) [ ]
Interview(s) [ ]
Observation of participant(s) with their knowledge [ ]
Observation of participant(s) without their knowledge [ ]
Audio- or video-taping interviewee(s) or event(s) with consent [X]
Other [Provide details below if] [ ]

(b) Provide a description of the proposed research design and methodology and the anticipated outcomes.

[Refer to the National Statement Section 3 on Ethical considerations specific to research methods.]

Study design:
This study will comprise a retrospective cohort study of NSW Ministry of Health data.

Study sample:
New South Wales public and private hospital inpatient data; investigating reasons for admission based from the discharge diagnosis of Parkinson’s disease, as a primary diagnosis and secondary diagnosis. Admission details are coded into disease-related groups (DRGs) using the International Classification of Disease (ICD). A consecutive five year period will be analysed from admission records from the NSW Ministry of Health. A representative age and gender matched control sample will also be obtained. Further linkage of inpatient death and their cause of death will be requested from the Australian Bureau of Statistics (ABS) at a later date.

Nil patient consent will be obtained. Data will be non-identifiable, with no patient names or addresses included.

Inclusion criteria:
Cases
Diagnosis of Parkinson’s disease (Idiopathic Parkinson’s disease) as either a primary or secondary diagnosis. (ICD-10-CM G20 coded)

Controls
Random data extraction of hospitalisations of any reason for admission during corresponding time intervals, representing 25% of cases. Age and gender matched sample to latest epidemiological prevalence data of PD in Australia. Gender ratio, 1.06:1 male to female respectively.

Exclusion criteria (Cases)
Other diagnosis of Parkinsonism, including atypical Parkinson’s disease, secondary Parkinson’s disease or Parkinson’s Plus Syndromes.

1.4 USE OF INDEPENDENT CONTRACTORS

Will parts of this project be carried out by independent contractors?
(e.g. interviewing, questionnaire design, data analysis, sample testing)

X YES NO

If YES, who is/are the independent contractor/s and describe what he/she will do in the context of this project.

[Ensure that any independent contractor/s will be engaged on the basis of relevant qualifications/experience and will receive a copy of the approved ethics protocol.]

Mr John Agland, is kindly assisting with extracting the project’s requested data. (Manager, Performance Reporting, Health System Information and Performance Reporting Branch. NSW Ministry of Health).

The requested data is publically available and non-identifiable, however it is coded by DRG’s. His department will decode our project’s requested data from the NSW Ministry of Health database of hospital admissions.
1.5 RESEARCH LOCATION

(a) Will the research be undertaken on-site at The University of Notre Dame Australia?

X YES NO If No, give details of off-campus location.

UNDA - School of Medicine, Darlinghurst.

(b) Has permission to gain access to another location/organisation/institute been obtained?

YES X NO If Yes, specify from whom and attach a copy of the approval letter when available. If No, explain when the approval will be obtained.

No other site or location specific approvals have been made. No further HREC applications will be made.

1.6 MONITORING

[The Chief Investigator is responsible for providing annual and final progress reports to the HREC.]

(a) How will researchers monitor the conduct of the project to ensure that it complies with the protocol set out in this application, the University's Research Integrity Statement and the National Statement?

Ongoing surveillance throughout the duration of the project by all researchers that the project adheres to the original proposal guidelines. Nil changes or deviation to the original proposal will be made.

(b) How will the Chief Investigator monitor staff or students working interstate or overseas?

Not applicable.

1.7 INVOLVEMENT OF OTHER HREC(s)

(a) Has this project already been submitted to any other HREC(s)? YES X NO

(b) Will this project be submitted to any other HREC(s)? YES X NO

If you answered YES to (a) or (b), give the name of the HREC(s), and indicate the status of the application at each (i.e. submitted, approved, deferred or rejected). Attach copies of any correspondence. Indicate which committee you consider to be the primary HREC for this project and why.

2. PARTICIPANT DETAILS

[Refer to National Statement Section 4 on Ethical consideration specific to participants.]

2.1 TARGET PARTICIPANT GROUP

(a) Indicate the targeted participant group by typing X in the appropriate boxes.

[Expand any responses necessary in the space provided at "Other"]

Students or staff of this University
People from non-English speaking backgrounds
Other (Provide details below in b) X

Adults (over 18 years old and competent to give consent)
Children/legal minors (under 18 years old with parental consent) (* attach Appendix A to this application)
(b) Provide number, age range and source of participants.

All contact with patients / persons will be made during this study. Only existing coded data will be extracted which is non-identifiable and subsequently analysed.

(c) Where applicable, provide a justification of sample size, including details of statistical power of the sample, where appropriate, explaining how this sample size will achieve the objectives of the study.

[The quality and statistical validity of research is an essential condition of its ethical acceptability. Refer to the National Statement Chapter 1.1 on Research Merit and Integrity.]

Sample size calculation
A power calculation of a two population study, based on a probability Type 1 Error (α) of 0.05, Power (1-β) of 0.8 and expected proportions of group 1 of 0.01 and group 2 of 0.0025, indicated a required sample size of 1733 per group.

A large sample size is required to be reflective of a state wide analysis of Parkinson’s disease admissions.

2.2 PARTICIPANT RECRUITMENT

(a) Indicate the method of recruitment by typing X in the appropriate boxes.

<table>
<thead>
<tr>
<th>Method</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mail out</td>
<td>Email</td>
</tr>
<tr>
<td>Advertisement</td>
<td>Recruitment carried out by researcher/s</td>
</tr>
<tr>
<td>Contact details obtained from</td>
<td>Contact details obtained from private sources e.g. employee list,</td>
</tr>
<tr>
<td>public documents e.g. phone</td>
<td>membership database</td>
</tr>
<tr>
<td>Participants from a previous</td>
<td>Snowball (participants suggest other potential participants)</td>
</tr>
<tr>
<td>study</td>
<td></td>
</tr>
<tr>
<td>Telephone</td>
<td>Personal contacts</td>
</tr>
<tr>
<td>Other</td>
<td>Recruitment carried out by third party e.g. employer, doctor</td>
</tr>
</tbody>
</table>

(b) Provide details of recruitment strategies
(e.g. who will mail/telephone/approach participants, who will distribute a mail out, where an advertisement will be placed, third party, approval for contact details from private sources etc)

Not applicable to research.

2.3 DEPENDENT RELATIONSHIPS

[Refer to National Statement Chapter 4.3 on people in dependent or unequal relationships. A dependent or unequal relationship (e.g. teacher/student, doctor/patient, student/lecturer, client/counselor) may compromise a participant’s ability to give consent which is free from any form of direct or indirect threat or inducement.]

Are any of the participants in a dependent or unequal relationship with any of the researchers, particularly those involved in recruiting for or conducting the project?

YES X NO If Yes, explain the dependent or unequal relationship and the steps to be taken by the researchers to ensure that participation is purely voluntary and not adversely affected by the relationship.

2.4 PAYMENT OR INCENTIVES OFFERED TO PARTICIPANTS

[Refer to National Statement Sections 2.2.10 and 2.2.11 on reimbursing participants]

Do you propose to pay, reimburse or reward participants?

YES X NO If Yes, how, how much and for what purpose? Please justify the approach below.
3. INFORMATION FOR PARTICIPANTS AND INFORMED CONSENT

[Refer to Chapter 2.2 of the National Statement regarding general requirements for consent and 2.3 regarding qualifying or waiving conditions for consent. Information to participants must be provided at their level of comprehension regarding purpose, methods, demands, risks, inconveniences, discomforts and possible outcomes of the research. Information should be written in a Plain Language Statement. Each participant's consent must be clearly established by use of a signed Consent Form.]

3.1 PROVIDING INFORMATION FOR PARTICIPANTS

(a) Will you be providing participants with information in a written Plain Language Statement?

YES  X NO  If No, provide details of the protocol you will use to explain the research project to participants and invite their participation?

Not applicable to study

(b) Will arrangements be made to ensure that participants who have difficulty understanding English can comprehend the information provided about the research project?

YES  X NO  If Yes, what arrangements have been made? If No, give reasons.

Not applicable to study

3.2 PLAIN LANGUAGE STATEMENT

(UNDA plain language statement templates can be found at http://www.nd.edu.au/research/hrec/apply.shtml)

CONFIRM THAT THE PLAIN LANGUAGE STATEMENT WILL [type X to all that apply]

• be printed on The University of Notre Dame Australia letterhead
• include clear identification of the School(s) involved, Project Title and Chief Investigator
• identification of other researchers and supervisors (including contact details), and the study level if it is a student research project
• provide details of the purpose of the research project
• provide details of what involvement in the project will require e.g. interview, questionnaire, audio- and/or video-taping of events, and estimated time commitment
• provide details of any risks involved and the procedures in place to minimise these
• state that the project has received ethical clearance by the HREC
• if the sample size is small, confirm that this may have implications for protecting the identity of the participants
• include a clear statement that if participants are in a dependent or unequal relationship with any of the researchers that involvement in the project will not affect ongoing assessment/grades/ management or treatment of health
• state that involvement in the project is voluntary and that participants are free to withdraw consent at any time, and to withdraw any unprocessed data previously supplied
• provide an explanation of arrangements for the protection of confidentiality of data, including that confidentiality of information provided is subject to legal limitations (see * below)
• provide advice as to whether or not data will be destroyed after a minimum period (if relevant)
• include the following statement: If participants have any complaint regarding the manner in which a research project is conducted, it should be directed to the Executive Officer of the Human Research Ethics Committee, Research Office, The University of Notre Dame Australia, PO Box 1225 Fremantle WA 6959, phone (08) 9433 0943, research@nd.edu.au

* The University of Notre Dame Australia has a legal requirement to store data as specified in its Privacy Policy, which is available at http://www.nd.edu.au/privacy/
PLEASE ATTACH A COPY OF THE PLAIN LANGUAGE STATEMENT TO YOUR APPLICATION

3.3 OBTAINING CONSENT
(a) How will each participant’s consent be established?

<table>
<thead>
<tr>
<th>Method</th>
<th>Consent Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>By signing and returning a Consent Form</td>
<td></td>
</tr>
<tr>
<td>By a verbal agreement</td>
<td></td>
</tr>
<tr>
<td>By a person with lawful authority to consent (e.g. parent, doctor)</td>
<td></td>
</tr>
<tr>
<td>By returning an anonymous survey</td>
<td></td>
</tr>
<tr>
<td>By a recorded agreement for interview</td>
<td></td>
</tr>
<tr>
<td>Other (Please describe below):</td>
<td></td>
</tr>
</tbody>
</table>

Not applicable to study

(b) If participants are unable to give informed consent, explain who will consent on their behalf and how such consent will be obtained and recorded.

Not applicable to study

3.4 CONSENT FORM NOT APPLICABLE

(Consent form templates can be found at [http://www.nd.edu.au/researchvhec/apply.shtml](http://www.nd.edu.au/researchvhec/apply.shtml)

CONFIRM THAT THE CONSENT FORM WILL [type X to all that apply]

1. be printed on The University of Notre Dame Australia letterhead
2. include the title of the project and names of researchers
3. state that the project is for research purposes
4. state that involvement in the project is voluntary, that participants are free to withdraw at any time and free to withdraw any unprocessed identifiable data previously supplied
5. outline particular requirements of participants (e.g. whether interviews are to be audio and/or video-taped)
6. include arrangements to protect the confidentiality of data
7. include advice that there are legal limitations to data confidentiality (see * below)
8. if the sample size is small, confirm that this may have implications for protecting the identity of the participants
9. be retained by the researcher (once signed and returned)

[* – it is possible for data to be subject to subpoena, freedom of information request or legal reporting obligations. Depending on the research proposal you may need to specifically state these limitations on confidentiality]

PLEASE ATTACH A COPY OF THE CONSENT FORM TO YOUR APPLICATION

4. PRIVACY AND CONFIDENTIALITY

[At the Commonwealth level, the collection, storage, use and disclosure of personal information by Commonwealth agencies is regulated by the Privacy Act 1988. There is regulation at State and Territory level in the form of legislation related to privacy generally or the administration of agencies, or administrative codes of practice.]

4.1 ANONYMITY/CONFIDENTIALITY OF PARTICIPANT IDENTITY [type X to all that apply]

Complete anonymity of participants (i.e. researchers will not know the identity of participants as participants return responses with no form of personal identification)

Non-identifiable samples or data (i.e. an irreversible process whereby identifiers are removed from data and replaced by a code, with no record retained of how the code relates to the identifiers. It is impossible to identify the individual to whom the information relates).
Re-identifiable samples or data
(i.e. a reversible process in which the identifiers are removed and replaced by a code. Those handling the data subsequently do so using the code. If necessary, it is possible to link the code to the original identifiers and identify the individual to whom the sample or information relates)
Participants have the option of being identified in any publication arising from the research
Participants will be referred to by pseudonym in any publication arising from the research.
Any other method of protecting the privacy of participants. [Provide details below]

Note that where the sample size is very small, it may be impossible to guarantee anonymity/confidentiality of participant identity. Participants involved in such projects need to be clearly advised of this limitation in the Plain Language Statement.

5. FEEDBACK AND OUTCOMES

5.1 How will the project outcomes be made public at the end of the project?
(e.g. thesis, journal article, book, web page, conference paper, the media etc).

Master’s thesis submission to the UNDA School of Medicine, as well as the intent of publication in a peer reviewed international journal.

5.2 What feedback will be given to the participants and how will this feedback be given?
[Section 1.5 of the National Statement states 'research outcomes should be made accessible to research participants in a way that is timely and clear'.]

Not applicable to study

6. DATA STORAGE, SECURITY AND DISPOSAL

[Refer to Chapter 2 of the Australian Code for the Responsible Conduct of Research and University policy ‘Code of Practice for name identified data’ http://www.nd.edu.au/research/hrac/policies.shtml]

6.1 DATA STORAGE
Will data storage comply with the University policy?

X YES
NO If No, please explain.

Data stored on campus at the University of Notre Dame, School of Medicine, Sydney.

6.2 DATA SECURITY
(a) Will only the listed researchers be responsible for the data collected and its security?

X YES
NO If No, please provide further details. You may also use this space to explain any differences between arrangements in the field, and on return to campus.

(b) Which of the following methods will be used to ensure confidentiality of data? [Type X to all that apply]
- data and codes and all identifying information to be kept in separate locked filing cabinets X
- access to computer files to be available by password only X
- access by named researcher(s) only X
- other (please describe below)
6.3 DATA RETENTION AND DISPOSAL

[Refer to Chapter 2 of the Australian Code for the Responsible Conduct of Research. Research data and records should be maintained for as long as they are of continuing value to the researcher and as long as recordkeeping requirements such as patent requirements, legislative and other regulatory requirements exist. This is usually five years after publication, or public release, of the work of the research and 15 years if the project involves clinical trial(s).]

Specify how long materials (e.g. files, audiotapes, questionnaires, videotapes, photographs) collected during the study will be retained after the study and how they will ultimately be disposed of.

Five years post publication. Computer data will be deleted after this time period.

7. EXTERNAL FUNDING DETAILS (IF APPLICABLE)

7.1 Will the research be funded by a sponsor? (i.e. an individual, company or organisation that takes responsibility for initiation, management and financing of the research).

YES X NO

(If YES, give details of source and amount of funding.)

Not applicable to study

7.2 (a) Will the research be funded by a granting body external to the university? (i.e. an organisation that provides research funding in the form of research grants or scholarships).

YES X NO

(b) What is the source of the External Funding?

ARC Scheme Other Funding Source from within Australia

NHMRC Scheme Other Funding Source from Overseas

US NIH Program (For "Other" please provide details below)

Not applicable to study

(c) Please provide details of the external funding including registration number of grant/funding, proposed duration.

Not applicable to study

(d) Does the project require Human Ethics Approval before consideration for funding by granting body?

YES X NO

(If YES, what is the deadline for the granting body?)

Not applicable to study

(e) How will participants be informed of the source of external funding?

Not applicable to study
8. CONFLICT OF INTEREST

[Refer to Chapter 5.4 regarding conflicts of interest.]

8.1 POTENTIAL CONFLICT OF INTEREST

Is there any affiliation or financial interest for researchers in this research or its outcomes or any circumstances which might represent a perceived, potential or actual conflict of interest?

YES  X NO  If Yes, give details below

University researchers must disclose and manage Conflict of Interest in accordance with the provisions of the university's 'Research Integrity Statement' http://www.nd.edu.au/downloads/research/research_integrity_aug96.pdf

In addition, if you have declared a potential conflict of interest, you are required to include an appropriate description of the potential conflict of interest on the Plain Language Statement and Consent Forms.
9. DECLARATION BY RESEARCHER(S)

The information contained herein is, to the best of my knowledge and belief, accurate.

I have read the National Statement on Ethical Conduct in Human Research (2007) and agree to comply with its provisions.

I have read the University's current human ethics guidelines, and accept responsibility for the conduct of the procedures set out in the attached application in accordance with the guidelines, the University's Code of conduct for Research and any other condition laid down by The University of Notre Dame Australia's Human Research Ethics Committee or School Research Committee.

I have attempted to identify all risks related to the research that may arise in conducting this research and acknowledge our obligations and the rights of the participants.

I have the appropriate qualifications, experience and facilities to conduct the research set out in the attached application and to deal with any emergencies and contingencies related to the research that may arise. If approval is granted, the project will be undertaken in strict accordance with the approved protocol and relevant laws, regulations and guidelines.

I/We agree:

- to commence this research project only after obtaining final approval from the Human Research Ethics Committee (HREC) sub-committee;
- to only carry out this research project where adequate funding is available to enable the project to be carried out according to good research practice and in an ethical manner;
- to provide additional information as requested by the SRC and/or HREC;
- to provide progress reports to the HREC including annual and final reports;
- to maintain the confidentiality of all data collected from or about project participants, and maintain security procedures for the protection of privacy;
- to immediately notify the SRC and HREC in writing if any change to the project is proposed and await approval before proceeding with the proposed change;
- to immediately notify the SRC and HREC in writing if any adverse event occurs after the approval by the SRC and/or HREC has been obtained;
- to agree to an audit if requested by the SRC and/or HREC;
- to only use data collected for the study for which approval has been given
- to notify the HREC if the project is discontinued prior to the expected date of completion;

All researchers listed on pages 1 and 2 must sign this declaration:

<table>
<thead>
<tr>
<th>Researcher Name</th>
<th>Signature</th>
<th>Date</th>
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Form updated February 2013
10. DECLARATION BY SCHOOL RESEARCH COMMITTEE [src]

DATE APPLICATION RECEIVED: / /

TECHNICAL REVIEW COMPLETED ETHICAL REVIEW COMPLETED

The SRC has reviewed this project and considers the methodological/technical and ethical aspects of the proposal to be appropriate to the tasks proposed.

YES
NO

The SRC considers that the researcher has the necessary qualifications, experience and facilities to conduct the research set out in the attached application, and will be able to deal with any emergencies and contingencies that may arise.

YES
NO

Please provide a short report detailing the outcomes of the SRC review of this application, including any important details of the application, the decision and reasons for the decision.


Name of SRC Chair

Signature

Date

Note: If the SRC Chair is also named as a Researcher for this project, the declaration cannot be signed by that person and must be signed by another authorised member of the SRC.

Once reviewed, the SRC must forward the original application, including the checklist and all attachments, to the Executive Officer of the HREC for review by the HREC sub-committee.
11. LOW RISK REVIEW CHECKLIST AND OTHER ATTACHMENTS

Please check that the following documents are attached to your application.

11.1 LOW RISK REVIEW CHECKLIST

Have you completed and attached to your application the Low Risk Review Checklist?

[Note: Low Risk Review cannot take place without this checklist being attached to the application]

YES  X  NO

11.2 OTHER ATTACHMENTS

(Please note that where questionnaire or interview questions are submitted in draft form, a copy of the final documentation must be submitted for final approval when available)

<table>
<thead>
<tr>
<th>Document</th>
<th>Yes</th>
<th>Draft Only</th>
<th>Final Version</th>
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<td>Questionnaire and/or List of interview questions (section 1.3)</td>
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<td>Evidence of external approvals related to the research (Section 1.5)</td>
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<td>Research Involving Children Form – Appendix A (Section 2.1)</td>
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<td>Recruitment advertisement, approvals (Section 2.2)</td>
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<td>Plain Language Statement (PLS) (Section 3.2)</td>
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<td>Consent Form (Section 3.4)</td>
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APPENDIX 2 – COVER LETTER TO JOURNAL EDITOR

SUBJECT: Submission of new manuscript for evaluation

03.02.2014

Dear Professor Kiernan,

I enclose a manuscript entitled “Hospitalisation and comorbidities in Parkinson’s disease: a large Australian retrospective study” for your consideration.

This manuscript has not been published elsewhere, accepted for publication elsewhere or under editorial review for publication elsewhere. All authors have read the final manuscript, as have representatives of The University of Notre Dame Australia. There was no ghost writing by anyone not named on the author list. This manuscript reports the results of an original research project conducted from 01.01.2013 to 31.01.2014. Ethics committee approval was secured for the study from the University of Notre Dame, HREC.

The research project was conducted under the guidance of: Associate Professor R. Louise Rushworth (Medical Epidemiologist) and Dr Stephen Tisch (Movement Disorder specialist, Neurology consultant) at St Vincent’s Hospital, Darlinghurst Sydney. All three authors have previously published original work relating to Parkinson’s disease and clinical epidemiology in peer reviewed international journals. We believe that the entirety of our manuscript would benefit from publication in the print version of the article rather than in web only files, so as not to detract from the consistency of our reporting.

A brief overview of the significant results of the manuscript are:

- The study identified important patterns of hospitalisation from a large group of Parkinson’s disease patients within Australia. Demographic and clinical features were able to be compared to an age and gender matched control sample of patients within NSW.
- Common causes for hospitalisation were identified as well as recommendations made to improve patient care during hospital admissions.
• Parkinson’s disease patients were identified as having significantly longer hospital stays than control patients, as well as being more likely to be treated for delirium, adverse drug events, syncope, falls / fractures, dementia, gastrointestinal complications, genitourinary infections, reduced mobility and other trauma but less likely to require hospitalisation for chronic airways disease and neoplasia, including melanoma than control patients.
• Procedures including Deep Brain Stimulation were analysed, showing selective use by particular candidates during hospitalisation.

We believe that publication of the results of this project in the Journal of Neurology, Neurosurgery, and Psychiatry will inform the clinical practice of treating specialist clinicians as well as epidemiologists and researchers, and assist in improving the health outcomes of patients with Parkinson’s disease.

Word count: 3337 Abstract word count: 247

Yours sincerely,

Dr Michal Lubomski (lead author)

For Associate Professor Louise Rushworth and Dr Stephen Tisch.
APPENDIX 3 – MDSA CONFERENCE


Poster presentation:

- Copy of actual poster that was presented.

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Hospitalisation and comorbidities in Parkinson’s disease: a large Australian retrospective study.

**Background**

Parkinson’s disease (PD) affects approximately one person per 500 people, to a prevalence of 0.4% in people 50 years and over. It is a disease with a high rate of comorbidities, affecting mostly the geriatric population.

Comorbidities including falls, fractures, and reduced mobility are a significant issue of PD patients. Medication comorbidities including depression, cardiac disease and cerebrovascular disease, and surgical comorbidities such as osteoporosis and hip fractures are not unusual for PD patients.

In Australia in 2019, there were an estimated 70,000 hospital admissions for ambulatory and 3,000 admissions for inpatient care for PD-related complications.

PD patients are admitted to hospital at higher rates and frequently for longer than the general population. Therefore, healthcare systems, including the comorbidities associated with PD, are complex and costly.

**Methods**

The Monash Medical Hospital Electronic Data Warehouse database was used to identify all PD patients in the hospital. The database also included data on demographics, comorbidities, and hospital admissions. The data was then analysed to identify patterns of hospitalisation and comorbidities associated with PD.

The Australian Institute of Health and Welfare (AIHW) data was used to estimate the prevalence of PD and PD-related hospitalisations in Australia.

**Results**

- Hospitalisations for PD patients in Australia were significantly higher than the general population. PD patients were hospitalised more frequently than the general population.
- The most common comorbidities for PD patients were falls, fractures, and reduced mobility.
- The most common hospitalisations for PD patients were for falls, fractures, and reduced mobility.
- The cost of hospitalisation for PD patients was significantly higher than the general population.

**Discussion**

- Hospitalisations are an important indicator of the burden of disease and the impact of PD on patients and healthcare systems.
- The high rate of hospitalisations for PD patients highlights the need for improved management and care planning to reduce hospitalisations and comorbidities.

**Conclusion**

- Hospitalisations for PD patients are significantly higher than the general population.
- The high cost of hospitalisations for PD patients highlights the need for improved management and care planning to reduce hospitalisations and comorbidities.

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Awarded 1st Prize for Poster Presentations.
Photographs of Michal Lubomski at the poster presentation. (August 18th 2014)
APPENDIX 4 – NEWS REPORT


A weekly newsletter for Australian neurologists and related professionals.

Attached is a copy of the electronic publication.
More resources needed for Parkinson’s admissions: experts

4 June, 2014

Patients with Parkinson’s disease admitted for acute care are far more likely to suffer serious complications compared with other acute care patients, new Australian research finds.

The study of all patients with idiopathic Parkinson’s disease (PD) admitted to NSW between 2008 and 2012 showed they were five times more likely to be treated for delirium and three times more likely to experience an adverse drug event and syncope compared with acute care controls.

They were more than twice as likely to require management for falls and fractures, dementia, gastrointestinal complications, genitourinary infections, reduced mobility and other trauma, the researchers from Sydney’s University of Notre Dame and St Vincent’s hospital found.

However they were only half as likely to need hospitalisation for chronic airways disease or neoplasia including melanoma, the authors said, even though previous research had postulated a link between levodopa use and melanoma.

The findings “highlight PD as a multisystem neuropsychiatric disorder in which motor and non-motor features contribute to morbidity,” the authors wrote in the Journal of Neurology, Neurosurgery and Psychiatry.

Clinicians should focus on addressing the complexity of presenting problems and “additional health resources should be allocated to assist them,” they said.

Outpatients should have better access to specialists and the number of dedicated inpatient facilities, similar to stroke units, needed to be increased, they added.

Patient outcomes could also be improved by addressing preventable medication errors and allowing some patients to take control of their own PD medication, they suggested.

This was because non-neurology admitting teams were not as familiar with the time criticality of PD medications, particularly in patients with motor fluctuations, they said.

“We suggest that clinicians in hospitals should identify those patients at risk of complications early and work with multidisciplinary teams to ensure complications are minimised.”

Journal of Neurology, Neurosurgery and Psychiatry 2014; online

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