FORM 2 – FULL RESEARCH PROPOSAL

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Research title[3]
Health in Nepalese and Foreign Nationals during travel to altitude

Lay summary[4]
The purpose of this project is to document the health Nepalese staff and porters employed to support expeditions and treks, particularly in remote regions. It is anticipated that this will of raise the awareness of foreign nationals in their duty of care for the people they employ. The project will build on experience gained during the 2010 Medex/PPUK project published in High Altitude Medicine and Biology (Drew *et al.*, 2011; 12:349-56). Remote regions of Nepal have fewer infrastructures to support expeditions/treks, requiring more Nepalese support and reduced access to assistance in the event of accidents and illness. We hypothesize that there will be a high risk of medical mishap to Nepalese nationals when supporting expeditions/treks in remote regions.

Scientific proposal, background[5]
Travel to high altitude requires careful preparation to minimize medical issues. This includes appropriate equipment and valid evacuation insurance, as well as understanding the common or serious illnesses that may be encountered. Rapid ascent to high altitude, with insufficient acclimatisation may lead to illness (1). From self limiting symptoms of acute mountain sickness, to life threatening High altitude Pulmonary Oedema and High Altitude Cerebral Oedema (2,3,4,5,6). Other conditions not unique to high altitude also occur commonly, including bronchitis, gastroenteritis, snow blindness, and lacerations (7,8).

Many foreign nationals who participate in trekking employ the services of Nepalese nationals, such as porters (load carrying personnel) and staff (who may include trekking guides and cooking staff). Compared with Nepalese staff, porters are often from lower socioeconomic backgrounds, reside at lower altitudes outside of the trekking season, and are paid less for their trekking services. These factors may make them vulnerable to medical problems at high altitude, particularly in remote regions and if insufficiently prepared. Furthermore, cultural differences in symptom and illness reporting may mean that foreign nationals are less able to care for their staff because they are not aware of the medical problems.

The 2010 project revealed in almost half of the trekking groups surveyed, one or more individuals encountered medical problems (9). Although Nepalese national reported fewer medical problems, then foreign nationals, a significantly higher proportion of

porters were evacuated from high altitude (9). This is particularly important when considering that, according to foreign nationals, approximately 40% of all trekking groups would not pay for helicopter evacuation of a Nepalese national, and approximately 40% of the trekking groups reported insufficient resources to be enable them to carry a severely ill Nepalese member of staff or porter down from an altitude (9). The 2010 project highlighted that Nepalese staff are dependent on the prior preparation and resources of the trekking group to reduce the risk of medical problems (9). This is more essential in remote trekking regions with no medical facilities, when the medical supplies carried by the group is their only access to health care.

Foreign nationals and Nepalese nationals in trekking groups have a duty of care towards each other; recognizing that trekking group preparedness relies not only on a comprehensive first aid kit, but also on knowledge of acclimatization and individuals' insurance that may improve the health, safety, and welfare of individuals taking part in trekking activities in the Nepal Himalaya. The aim of our project is to document the number of medical mishaps in Nepalese staff and porters, and foreign nationals on expeditions/treks in remote areas.

Scientific proposal, aims and hypotheses[6]

Primary aim:

To document of the number of medical mishaps in Nepalese staff and porters, and foreign nationals on expeditions/treks in remote areas.

Secondary aims

1) To evaluate the impact of previous altitude exposure on frequency of medical incidents
2) To evaluate the impact of previous experience of being a porter / staff member on frequency of medical incidents
3) To evaluate the impact of age on frequency of medical incidents
4) To evaluate the preparedness of the expedition
5) To evaluate the awareness of responsibility for trek safety by Foreign Nationals

Hypotheses

We hypothesize that there will be a high risk of medical mishap to Nepalese nationals when supporting expeditions/treks in remote regions.

Scientific proposal, methods[7]

Participants

Nepalese staff and porters who are taking part in the Medex trek. Group members taking part in the Trek. Other groups with Nepalese staff and porters Foreign Nationals trekking in Nepal will also be surveyed.

Data Collection

- Questionnaires, modified from those used in the 2010 survey, will be completed by trek volunteers and Nepalese experienced in expedition/trek logistics.
- It is envisaged that the Nepalese will better able to obtain information from the expedition/trek sirdars and head porters. The volunteers will be able to obtain information from the foreign national expedition/trek members.
- A team of volunteers (initially 8-10) and Nepalese expedition/trek experts will

interview foreign nationals and Nepalese staff on the Medex Expedition.
- Further questionnaires will be given to expeditions/treks passing through the trail region. The data collection will be in Spring 2015.

Data Analysis

- A repeated analysis will be undertaken on the data from the Nepalese staff and porters taking part in the Medex trek. It is anticipated that in each trekking group data will be collected at multiple data points.
- Quantitative data from other trekking groups will be compared (likely to be unpaired, non-parametric). The significance of the data will depend on the number of incidents and the populations surveyed. The ratio of Nepalese staff/porters to foreign nationals is expected to be higher than for data collected during 2010 as we will be in a more remote region.
- The qualitative data from both sources will be used to assist in interpretation of the statistical results and to enable a descriptive presentation of the study.

Scientific proposal, expected results[8]

This is a hypothesis generating study and although we have outlined our aims, previous experience suggests that we need to be flexible in our approach in order to gain the most accurate data.

Dissemination plan, target journal(s)[9]

Consider first submission to High altitude Medicine and Physiology

Dissemination plan, timeline[10]

- Develop Protocol with Medex and PPUK – August 2014
- Resubmission of ethics applications – September 2014
- Discussion and fine tuning of Protocol – ODG Nov 2014
- Finalise arrangements – January 2014
- Data Collection – March-April 2015
- Data analysis – May 2015 (the plan is to set up the data sheets so data can be entered at base camp)
- Data Interpretation, results and discussion – May / June 2015
- Final report formulation – July / Aug 2015
- Presentation of findings at PPUK meeting – Oct 2015
- Submission of manuscript – Nov 2015

Research requirements, participants[11]

- 20-30 minutes from participants for data collection at baseline, basecamp and at two points along the route.
- There is no known risk for those completing the survey.

Research requirements, personnel[12]

- 2 researchers per trekking group - we are especially keen to have people who can speak multiple languages, as we want to speak to other trekking groups when we meet them - particularly Japanese

Research requirements, equipment[13]

- Pre-printed questionnaires and information sheets
- Pens
- Note pads
- Laptop at base camp to enter data
- Medex high altitude books in Nepalese
- Socks or baseball caps to give out to helpers

Research requirements, consumables[14]

- As above

Research requirements, logistics[15]

• A lead data collector will be based in each trekking group to direct the other volunteers. • Data will be collected from each Medex Group at baseline, at two points on route and base camp. At baseline and base camp Nepalese data will be collected with the help of an interpreter. • Additional data will be collected from any other trekking groups we contact whilst trekking.
Research requirements, research cost[16] • Cost of printed paperwork and stationary – these costs will be met by PPUK • Computer at basecamp to enter data – computer will be supplied by our group

[Print full name of principle investigator and collaborators here and all sign in next column][17]	Dr Mary Morrell	**26/08/14**

[1]Title, full name, current post, department, institution, contact postal address, email address, telephone (including country and area code)
[2]Title, full name, department, institution, email address
[3]Max 20 words
[4]Project summary in simple English. Max 200 word
[5]Provide rationale for study
[6]Concise; specific and directional hypotheses
[7]Participants; research design; study schematic; procedures; statistical analyses; identification of main outcome measure; justification of sample size
[8] Graphs as likely to be presented in manuscript depicting theoretical relationships but correct units and physiologically plausible absolute values; explanatory text to justify relationships (based on previous literature)
[9]Target journal(s)
[10]Timeline from research proposal to submission of, manuscript to target journal (including conference presentations and 1st draft of introduction/methods/results/discussion sections)
[11]Total time participants will spend on study; 12Risk to participants and how risks will be mitigated
[12]Staff required to run project successfully
[13]Make, model, where equipment will be sourced from, rough estimate of power requirements
[14]Plastics, paper, disposable accessories for equipment, etc
[15]Rough estimates of: sample transport (if required); equipment total weights; laboratory requirements (space, environmental conditions, services (water, electric, light, waste disposal)
[16]Direct expenditure related to project and explanation of how these costs will be met. Do <u>not</u> include expedition fees or logistics, or indirect salaries
[17]Principal Investigator and Collaborators must provide consent to submit proposal. This can be done with either physical or electronic signatures on the research proposal, or alternatively each researcher may email j.h.macdonald@bangor.ac.uk the following text: "I [INSERT NAME] approve the full research proposal entitled [INSERT TITLE]"

- Formatting
  - Please type information into table above and expand table as necessary
  - Min 12 point, min 1.5 line spacing, 2cm margins, times new roman, reference format as per Journal of Applied Physiology guidelines, include page numbers and principal investigator surname in a footer on every page; scientific proposal section should not exceed six pages of A4 plus references; research requirements should not exceed four pages of A4

- Submission
  - Email one pdf file to j.h.macdonald@bangor.ac.uk
  - Closing date: 01.11.13, 1200, Greenwich Mean Time
  - Please also ensure all researchers have read, completed and submitted form 3: researcher application form
  - Please also ensure the principle investigator has read, completed and submitted form 4: principal investigator contract.
  - Suggest at least four reviewers
    - Must have no known conflict of interest
    - Provide title, full name, position, department, institution, email address and phone number (including country and area code)
  - You will receive confirmation of submission within five working days
- Queries
  - Contact MEDEX Manaslu 2015 Research Lead
    - Jamie Macdonald PhD, Extremes Research Group, Bangor University
    - Email: j.h.macdonald@bangor.ac.uk
    - Tel: +44 1248 383272

References

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5 – Biff, P. 2010. Physiology and Pathophysiology With Ascent to Altitude. American Journal of the Medical Sciences. 340(1):69-77
6 – Bartsch, P & Swenson, E. 2013. Acute High-Altitude Illness. NEJM. 368;24
7 – Basnyat B and Litch JA (1997). Medical problems of porters and trekkers in the Nepal Himalaya. Wilderness Environ Med 8:78-81.
8 – Basnyat B, Cumbo TA, and Edelman R (2000). Acute medical problems in the Himalayas outside the setting of altitude sickness. High Alt Med Biol 1:167–74.
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