PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Protocol: a systematic review and meta-analysis of the effectiveness of community-based health services by nurse practitioners
AUTHORS	Kanda, Mikiko; Ota, Erika; Fukuda, Hiromi; Miyauchi, Shinji; Gilmour, Stuart; Kono, Yuko; Nakagama, Erika; Murashima, Sachiyo; Shibuya, Kenji

VERSION 1 - REVIEW

REVIEWER	Denise Bryant-Lukosius School of Nursing and Dept of Oncology McMaster University, Canada
REVIEW RETURNED	30-Jan-2015

GENERAL COMMENTS	Overall, the major limitation of this protocol is that conceptually key issues relevant to the evaluation of NP roles and NP roles in community settings have not been considered. The study objective could be more focused and clear. The objective is to investigate if there are statistically significant patient outcomes between NP and MD care. It is not clear how this objective relates to evaluating NP effectiveness in relation to equivalent, improved or worse outcomes. Evaluating effectiveness would be an objective more in keeping with a systematic review. For NP roles that are introduced as MD replacements, determining equivalence in outcomes would be sufficient (e.g., at a minimum NP care leads to similar outcomes to physicians), while in complementary models studies would be designed to assess for improved outcomes. Further, NP practice in community settings could be more clearly defined on page 8. Does this include roles in primary health care and public health? Rationale for MD care as the comparison group is not established. For example, standard care may be an appropriate comparison to NPs introduced to replace or complement existing models of care that do not include a physician (which often may be the case in community settings). Finally, rationale for the selection of primary and secondary outcomes is not clear. The objective indicates a focus on patient outcomes and yet health utilization outcomes such as hospitalization, ED visits, LOS and cost are included. It may be an issue related to English translation, however the use of the words assessment, inspection, prescription and consultation do not adequately define NP role activities as understood from an international perspective. For example, how does assessment differ from inspection? Inspection is an uncommon word used to describe NP practice. Other relevant role responsibilities such as diagnosis are not included in the description.

	Some methodological details are missing: 1) It is not clear why inclusion is by high income country OR NP master's education. These are very different criteria. 2) I agree that limiting studies to master's prepared NPs is an important inclusion criteria. How will eligibility of studies be determined based on countries that require NPs to hold a master's degree? Master's degree requirements may have been implemented at different time periods within and across countries and may have occurred after studies have been completed. It will be determining the educational preparation of NPs at the time the study was conducted that will be important. How will you confirm this? 3) What criteria or what factors do you anticipate will be relevant to determining if studies are eligible for a meta-analysis? 4) Will GRADE be used to assess the quality of individual outcomes? If not why? 5) The methods could also be strengthened considering specific factors that are relevant to NPs and the validity and generalizability of study results such as the number of NPs delivering the intervention in each study, and NP experience and additional training.

REVIEWER	Esther Sangster-Gormley University of Victoria Canada
REVIEW RETURNED	05-Feb-2015

GENERAL COMMENTS	I look forward to the results of the review. My concern is the authors will not locate adequate references to conduct the review.

VERSION 1 – AUTHOR RESPONSE

Reviewer Name Denise Bryant-Lukosius
Overall, the major limitation of this protocol is that conceptually key issues relevant to the evaluation of NP roles and NP roles in community settings have not been considered.
The study objective could be more focused and clear. The objective is to investigate if there are statistically significant patient outcomes between NP and MD care. It is not clear how this objective relates to evaluating NP effectiveness in relation to equivalent, improved or worse outcomes. Evaluating effectiveness would be an objective more in keeping with a systematic review. For NP roles that are introduced as MD replacements, determining equivalence in outcomes would be sufficient (e.g., at a minimum NP care leads to similar outcomes to physicians), while in complementary models studies would be designed to assess for improved outcomes.

We appreciate your comment, which will make the focus of this review more clear. This study will focus on NP activities as a replacement for MD activities in a community setting, so we only need to test for equivalence of outcomes. We have modified the objectives and related parts of the manuscript in order not to cause confusion, as follows.
Page 3, first paragraph:
this systematic review aims to assess the equivalence of NP services to standard care provided by MDs and to determine whether their practice is an effective alternative to that of MDs in community settings.
Page 7, last paragraph:
To investigate whether services delivered by NPs substitution for MDs result in statistically equivalent patient and health system utilization outcomes to standard care provided by MDs in a community setting.

Page 16, last paragraph:
Information on which NP activities are effective as a substitute for standard care provided by MDs in terms of patient and health system utilization outcomes will further drive efforts to develop an effective NP utilization strategies.

Further, NP practice in community settings could be more clearly defined on page 8. Does this include roles in primary health care and public health? Rationale for MD care as the comparison group is not established. For example, standard care may be an appropriate comparison to NPs introduced to replace or complement existing models of care that do not include a physician (which often may be the case in community settings).

NP practice in community settings in the Type of intervention section on page 8, last paragraph, based on an international perspective [1], as follows:
The types of interventions included will be as follows: As a first point of contact for patients or clients, perform assessments, order diagnostic and laboratory tests; offer diagnoses, prescribe medications and treatments; implement procedures; take responsibility for case management; follow-up and monitoring of patient health and medical plan adherence; counselling and education for preventing non-communicable disease (NCDs); ensuring continuity of care and hospital re-admission; disease symptom management. All interventions are provided by NPs in a community setting.

Finally, rationale for the selection of primary and secondary outcomes is not clear. The objective indicates a focus on patient outcomes and yet health utilization outcomes such as hospitalization, ED visits, LOS and cost are included.

Thank you for this comment. We agree with this point. We modified the objectives from a focus only on patient outcomes to both patient and health system utilization outcomes, including hospitalization, ED visits, LOS and cost, as follows.
Page 3, last paragraph:
We will assess patient and health system utilization outcomes of interventions comparing treatment and care provided by NPs in community settings with that provided by MDs.
Page 7, last paragraph:
To investigate whether services delivered by NPs substitution for MDs result in statistically equivalent patient and health system utilization outcomes to standard care provided by MDs in a community setting.
Page 16, last paragraph:
Information on which NP activities are effective as a substitute for standard care provided by MDs in terms of patient and health system utilization outcomes will further drive efforts to develop an effective NP utilization strategies.

It may be an issue related to English translation, however the use of the words assessment, inspection, prescription and consultation do not adequately define NP role activities as understood from an international perspective. For example, how does assessment differ from inspection? Inspection is an uncommon word used to describe NP practice. Other relevant role responsibilities such as diagnosis are not included in the description.

This systematic review aims to cover all possible NP activities in a community setting, but we did not clarify this adequately. We have added a detailed explanation of NP roles in a community setting on page 8 (see our response to the previous comment), and have changed the text elsewhere in the manuscript to reflect a more comprehensive expression of the NP's role. We also added the following explanation at page 5, last paragraph:
For instance, in a community setting where NPs are the first point of contact, such as at a nursing home, geriatric health care facility, home-visit nursing agency, in the home or at the clinic, the NP

performs assessments and diagnoses, orders diagnostic and laboratory tests, prescribes medication and offers treatments with a high level of autonomy and independence. Also taking responsibility for case management, the NP monitors patient health and medical plan adherence, offers counselling and education for non-communicable disease (NCD) prevention, ensures continuity of care and manages hospital re-admission, The NP is also responsible for disease symptom management and is expected to show advanced consultation, collaboration, education, research and leadership skills.

Some methodological details are missing:
1) It is not clear why inclusion is by high income country OR NP master's education. These are very different criteria.

We agree with this point and have corrected our study criteria to combine these two using an AND condition, rather than an OR condition. See also our response to point 2) below. We have modified the text on page 11, paragraph 5 to say:
5. High-income countries based on World Bank criteria in 2013
6. Countries that require NP to hold a master's degree at the time of the study period. If education qualifications are not clearly mentioned, detailed information will be obtained by contacting authors of the article or by reference to established qualification standards for the country in question where the study clearly specifies that NPs are defined with reference to national accreditation boards.

2) I agree that limiting studies to master's prepared NPs is an important inclusion criteria. How will eligibility of studies be determined based on countries that require NPs to hold a master's degree? Master's degree requirements may have been implemented at different time periods within and across countries and may have occurred after studies have been completed. It will be determining the educational preparation of NPs at the time the study was conducted that will be important. How will you confirm this?

Thank you for your comment. We will include studies if the NP program is clearly identified as a master's degree course and exclude if it is clearly shown not to be a master's degree course (e.g. special training course). Where no information on educational type is provided, we will contact the authors.

3) What criteria or what factors do you anticipate will be relevant to determining if studies are eligible for a meta-analysis?

We expect to determine eligibility for meta-analysis based on the following inclusion criteria, described in the methods section (page 13, first paragraph):
Studies will be included in meta-analysis if they are of the same type of such as RCTs or cluster RCTs and have the same population, intervention, comparison and outcomes.

4) Will GRADE be used to assess the quality of individual outcomes? If not why?

GRADE will be used to assess the quality of individual outcomes. Text on page 15 was modified to explain this as follows:
Finally we will assess the quality of the following individual outcomes and produce summaries using the GRADE approach
1. Hospitalization
2. Patient mortality
3. Biological data
4. Cost
5. Patient satisfaction
6. Self-reported perceived health

Data will be imported from RevMan 2014 to the GRADE profiler to produce “summary of findings” tables. These tables will include a summary of the intervention effect and a quality of individual outcomes using the GRADE approach. The quality of the body of evidence for each outcome will be assessed based on five factors: study limitations, consistency of effect, imprecision, indirectness and publication bias.

5) The methods could also be strengthened considering specific factors that are relevant to NPs and the validity and generalizability of study results such as the number of NPs delivering the intervention in each study, and NP experience and additional training.

Thank you for your suggestion. We agree with this point. We will conduct subgroup analyses by number of NPs and years of experience, dichotomized based on common categories obtained from previous studies. We changed the text on the bottom of page 15 and top of page 16 to include the following:
5. The number of NPs delivering the intervention: less than 10 versus 10 and over
6. The years of NP experience: less than 10 years versus 10 and over

Reviewer Name Esther Sangster-Gormley
I look forward to the results of the review. My concern is the authors will not locate adequate references to conduct the review.

Thank you for your comments.

1. International Council of Nurses. Nurse Practitioner/Advanced Practice Nurse: Definition and Characteristics. Nursing Matters 2004; Available from: http://www.icn.ch/images/stories/documents/publications/fact_sheets/1b_FS-NP_APN.pdf
2. Higgins, J.P. and S. Green, Cochrane handbook for systematic reviews of interventions. Vol. 5. 2008: Wiley Online Library

VERSION 2 – REVIEW

REVIEWER	Denise Bryant-Lukosius School of Nursing and Dept of Oncology McMaster University Canada
REVIEW RETURNED	31-Mar-2015

GENERAL COMMENTS	Good effort to address feedback. Minor edits only. Check the margins in the abstract. Check the objective on page 7, it appears the word compared is missing e.g., ...compared to standard care provided by MDs in a community setting.