

CONTRIBUTIONS OF AUTHORS

Erika Ota (EO) and Windy Wariki (WW) designed, set up, and drafted the protocol. Narumi Hori (NH), Rintaro Mori (RM), and Kenji Shibuya (KS) revised the article and KS supervised development of the protocol. All authors read and approved the final protocol. NH is a content specialist, who has been working in the field of HIV/AIDS education. RM has experiences in systematic reviews in NICE guidelines and Cochrane reviews in the field of Pregnancy and Childbirth. KS is an expert of global health field including both high- and low-income settings.

DECLARATIONS OF INTEREST

We declare that we have no conflict of interest.

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参考資料 2

Risk of bias assessment tool

The Cochrane Collaboration’s tool for assessing risk of bias

Domain	Description	Review authors’ judgement
Sequence generation	Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.	Was the allocation sequence adequately generated?
Allocation concealment	Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment.	Was allocation adequately concealed?
Blinding of participants, personnel and outcome assessors <i>Assessments should be made for each main outcome (or class of outcomes)</i>	Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.	Was knowledge of the allocated intervention adequately prevented during the study?
Incomplete outcome data <i>Assessments should be made for each main outcome (or class of outcomes)</i>	Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by the review authors.	Were incomplete outcome data adequately addressed?
Selective outcome reporting	State how the possibility of selective outcome reporting was examined by the review authors, and what was found.	Are reports of the study free of suggestion of selective outcome reporting?
Other sources of bias	State any important concerns about bias not addressed in the other domains in the tool. If particular questions/entries were pre-specified in the review’s protocol, responses should be provided for each question/entry.	Was the study apparently free of other problems that could put it at a high risk of bias?

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Possible approach for *summary assessments* outcome (across domains) within and across studies

Risk of bias	Interpretation	Within a study	Across studies
Low risk of bias	Plausible bias unlikely to seriously alter the results.	Low risk of bias for all key domains.	Most information is from studies at low risk of bias.
Unclear risk of bias	Plausible bias that raises some doubt about the results	Unclear risk of bias for one or more key domains.	Most information is from studies at low or unclear risk of bias.
High risk of bias	Plausible bias that seriously weakens confidence in the results.	High risk of bias for one or more key domains.	The proportion of information from studies at high risk of bias is sufficient to affect the interpretation of the results.

Criteria for judging risk of bias in the ‘Risk of bias’ assessment tool

SEQUENCE GENERATION Was the allocation sequence adequately generated? [Short form: <i>Adequate sequence generation?</i>]	
Criteria for a judgement of ‘YES’ (i.e. low risk of bias).	<p>The investigators describe a random component in the sequence generation process such as:</p> <ul style="list-style-type: none"> ▪ Referring to a random number table; Using a computer random number generator; Coin tossing; Shuffling cards or envelopes; Throwing dice; Drawing of lots; Minimization*. <p>*Minimization may be implemented without a random element, and this is considered to be equivalent to being random.</p>
Criteria for the judgement of ‘NO’ (i.e. high risk of bias).	<p>The investigators describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example:</p> <ul style="list-style-type: none"> ▪ Sequence generated by odd or even date of birth; ▪ Sequence generated by some rule based on date (or day) of admission; ▪ Sequence generated by some rule based on hospital or clinic record number. <p>Other non-random approaches happen much less frequently than the systematic approaches mentioned above and tend to be obvious. They usually involve judgement or some method of non-random categorization of participants, for example:</p> <ul style="list-style-type: none"> ▪ Allocation by judgement of the clinician; ▪ Allocation by preference of the participant; ▪ Allocation based on the results of a laboratory test or a series of tests; ▪ Allocation by availability of the intervention.
Criteria for the judgement of ‘UNCLEAR’ (uncertain risk of bias).	Insufficient information about the sequence generation process to permit judgement of ‘Yes’ or ‘No’.
ALLOCATION CONCEALMENT Was allocation adequately concealed? [Short form: <i>Allocation concealment?</i>]	
Criteria for a judgement of ‘YES’ (i.e. low risk of bias).	<p>Participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation:</p> <ul style="list-style-type: none"> ▪ Central allocation (including telephone, web-based, and pharmacy-controlled, randomization); ▪ Sequentially numbered drug containers of identical appearance; ▪ Sequentially numbered, opaque, sealed envelopes.
Criteria for the judgement of ‘NO’ (i.e. high risk of bias).	<p>Participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on:</p> <ul style="list-style-type: none"> ▪ Using an open random allocation schedule (e.g. a list of random numbers); ▪ Assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or non-opaque or not sequentially numbered); ▪ Alternation or rotation; ▪ Date of birth; ▪ Case record number; ▪ Any other explicitly unconcealed procedure.

Criteria for the judgement of 'UNCLEAR' (uncertain risk of bias).	Insufficient information to permit judgement of 'Yes' or 'No'. This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgement – for example if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque and sealed.
BLINDING OF PARTICIPANTS, PERSONNEL AND OUTCOME ASSESSORS	
Was knowledge of the allocated interventions adequately prevented during the study? [Short form: <i>Blinding?</i>]	
Criteria for a judgement of 'YES' (i.e. low risk of bias).	Any one of the following: <ul style="list-style-type: none"> ▪ No blinding, but the review authors judge that the outcome and the outcome measurement are not likely to be influenced by lack of blinding; ▪ Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken; ▪ Either participants or some key study personnel were not blinded, but outcome assessment was blinded and the non-blinding of others unlikely to introduce bias.
Criteria for the judgement of 'NO' (i.e. high risk of bias).	Any one of the following: <ul style="list-style-type: none"> ▪ No blinding or incomplete blinding, and the outcome or outcome measurement is likely to be influenced by lack of blinding; ▪ Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken; ▪ Either participants or some key study personnel were not blinded, and the non-blinding of others likely to introduce bias.
Criteria for the judgement of 'UNCLEAR' (uncertain risk of bias).	Any one of the following: <ul style="list-style-type: none"> ▪ Insufficient information to permit judgement of 'Yes' or 'No'; ▪ The study did not address this outcome.
INCOMPLETE OUTCOME DATA	
Were incomplete outcome data adequately addressed? [Short form: <i>Incomplete outcome data addressed?</i>]	
Criteria for a judgement of 'YES' (i.e. low risk of bias).	Any one of the following: <ul style="list-style-type: none"> ▪ No missing outcome data; ▪ Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias); ▪ Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups; ▪ For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate; ▪ For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size; ▪ Missing data have been imputed using appropriate methods.
Criteria for the judgement of 'NO' (i.e. high risk of bias).	Any one of the following: <ul style="list-style-type: none"> ▪ Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups; ▪ For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate; ▪ For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size; ▪ 'As-treated' analysis done with substantial departure of the intervention received from that assigned at randomization; ▪ Potentially inappropriate application of simple imputation.

Criteria for the judgement of 'UNCLEAR' (uncertain risk of bias).	Any one of the following: <ul style="list-style-type: none"> ▪ Insufficient reporting of attrition/exclusions to permit judgement of 'Yes' or 'No' (e.g. number randomized not stated, no reasons for missing data provided); ▪ The study did not address this outcome.
SELECTIVE OUTCOME REPORTING	
Are reports of the study free of suggestion of selective outcome reporting? [Short form: <i>Free of selective reporting?</i>]	
Criteria for a judgement of 'YES' (i.e. low risk of bias).	Any of the following: <ul style="list-style-type: none"> ▪ The study protocol is available and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way; ▪ The study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon).
Criteria for the judgement of 'NO' (i.e. high risk of bias).	Any one of the following: <ul style="list-style-type: none"> ▪ Not all of the study's pre-specified primary outcomes have been reported; ▪ One or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not pre-specified; ▪ One or more reported primary outcomes were not pre-specified (unless clear justification for their reporting is provided, such as an unexpected adverse effect); ▪ One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis; ▪ The study report fails to include results for a key outcome that would be expected to have been reported for such a study.
Criteria for the judgement of 'UNCLEAR' (uncertain risk of bias).	Insufficient information to permit judgement of 'Yes' or 'No'. It is likely that the majority of studies will fall into this category.
OTHER POTENTIAL THREATS TO VALIDITY	
Was the study apparently free of other problems that could put it at a risk of bias? [Short form: <i>Free of other bias?</i>]	
Criteria for a judgement of 'YES' (i.e. low risk of bias).	The study appears to be free of other sources of bias.
Criteria for the judgement of 'NO' (i.e. high risk of bias).	There is at least one important risk of bias. For example, the study: <ul style="list-style-type: none"> ▪ Had a potential source of bias related to the specific study design used; or ▪ Stopped early due to some data-dependent process (including a formal-stopping rule); or ▪ Had extreme baseline imbalance; or ▪ Has been claimed to have been fraudulent; or ▪ Had some other problem.
Criteria for the judgement of 'UNCLEAR' (uncertain risk of bias).	There may be a risk of bias, but there is either: <ul style="list-style-type: none"> ▪ Insufficient information to assess whether an important risk of bias exists; or ▪ Insufficient rationale or evidence that an identified problem will introduce bias.

参考資料 3

ニューキャッスルオタワスケール

**NEWCASTLE - OTTAWA QUALITY ASSESSMENT SCALE
CASE CONTROL STUDIES**

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Exposure categories. A maximum of two stars can be given for Comparability.

Selection

- 1) Is the case definition adequate?
 - a) yes, with independent validation ✳
 - b) yes, eg record linkage or based on self reports
 - c) no description
- 2) Representativeness of the cases
 - a) consecutive or obviously representative series of cases ✳
 - b) potential for selection biases or not stated
- 3) Selection of Controls
 - a) community controls ✳
 - b) hospital controls
 - c) no description
- 4) Definition of Controls
 - a) no history of disease (endpoint) ✳
 - b) no description of source

Comparability

- 1) Comparability of cases and controls on the basis of the design or analysis
 - a) study controls for _____ (Select the most important factor.) ✳
 - b) study controls for any additional factor ✳ (This criteria could be modified to indicate specific control for a second important factor.)

Exposure

- 1) Ascertainment of exposure
 - a) secure record (eg surgical records) ✳
 - b) structured interview where blind to case/control status ✳
 - c) interview not blinded to case/control status
 - d) written self report or medical record only
 - e) no description
- 2) Same method of ascertainment for cases and controls
 - a) yes ✳
 - b) no
- 3) Non-Response rate
 - a) same rate for both groups ✳
 - b) non respondents described
 - c) rate different and no designation

**NEWCASTLE - OTTAWA QUALITY ASSESSMENT SCALE
COHORT STUDIES**

Note: A study can be awarded a maximum of one star for each numbered item within the Selection and Outcome categories. A maximum of two stars can be given for Comparability

Selection

- 1) Representativeness of the exposed cohort
 - a) truly representative of the average _____ (describe) in the community ✱
 - b) somewhat representative of the average _____ in the community ✱
 - c) selected group of users eg nurses, volunteers
 - d) no description of the derivation of the cohort
- 2) Selection of the non exposed cohort
 - a) drawn from the same community as the exposed cohort ✱
 - b) drawn from a different source
 - c) no description of the derivation of the non exposed cohort
- 3) Ascertainment of exposure
 - a) secure record (eg surgical records) ✱
 - b) structured interview ✱
 - c) written self report
 - d) no description
- 4) Demonstration that outcome of interest was not present at start of study
 - a) yes ✱
 - b) no

Comparability

- 1) Comparability of cohorts on the basis of the design or analysis
 - a) study controls for _____ (select the most important factor) ✱
 - b) study controls for any additional factor ✱ (This criteria could be modified to indicate specific control for a second important factor.)

Outcome

- 1) Assessment of outcome
 - a) independent blind assessment ✱
 - b) record linkage ✱
 - c) self report
 - d) no description
- 2) Was follow-up long enough for outcomes to occur
 - a) yes (select an adequate follow up period for outcome of interest) ✱
 - b) no
- 3) Adequacy of follow up of cohorts
 - a) complete follow up - all subjects accounted for ✱
 - b) subjects lost to follow up unlikely to introduce bias - small number lost - > ____ % (select an adequate %) follow up, or description provided of those lost) ✱
 - c) follow up rate < ____ % (select an adequate %) and no description of those lost
 - d) no statement

參考資料 4

Health risk assessment WHO



Health risk assessment

from the nuclear accident
after the 2011 Great East Japan
Earthquake and Tsunami

based on a preliminary dose estimation



World Health
Organization

Health risk assessment

from the nuclear accident
after the 2011 Great East Japan
Earthquake and Tsunami

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Executive summary

Introduction

The earthquake and tsunami in Japan on 11 March 2011 led to releases of radioactive material into the environment from the Tokyo Electric Power Company's Fukushima Dai-ichi nuclear power plant.

A major release of radioactivity to the environment is always of concern, owing to potential acute and long-term health effects. Evidence from historic events confirms that any major uncontrolled release of radiation should be cause for immediate response and scientific assessment of potential health effects.

When such an event occurs, the World Health Organization's mandate, as described in the Joint Radiation Emergency Management Plan of the International Organizations, is to assess and respond to public health risks.

The primary purpose of this health risk assessment of the Fukushima Daiichi nuclear accident is to estimate its potential public health impact so that future health needs can be anticipated and public health actions can be taken. This assessment is based on a preliminary estimate of radiation doses, as described in a WHO report published in May 2012.

Methods

This health risk assessment was conducted by independent international experts who were selected by WHO for their expertise and experience in radiation risk modelling, epidemiology, dosimetry, radiation effects and public health. All experts completed a declaration of interests form. The group met in December 2011 and March 2012. At both meetings, observers were in attendance from the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), the International Labour Organization, and the Government of Japan. The observers participated in discussions and sharing of data but were not involved in the decision-making process.

The risk assessment was made using four steps:

- The specific radiation sources, such as different radionuclides and pathways of exposure, were identified (hazard identification).
- The types of harmful effects that could result were identified based on scientific knowledge about the relationships between radiation dose and biological effects (dose-response relationships).
- Based on the preliminary dose assessment, lifetime organ doses were estimated for the general population within geographical locations ranging from the most affected areas of Fukushima prefecture to the rest of the world. Based on available data on