Australian Government

Repatriation Medical Authority

Repatriation Medical Authority Guidelines for Researchers

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Contents

This document sets out the current standards for processes and procedures used by researchers when undertaking investigations for the purposes of assisting the consideration of sound medical-scientific evidence (SMSE) by the Repatriation Medical Authority (RMA). It is endorsed by the RMA and reviewed regularly.

Writing briefing papers

1. The assistance provided to the Authority by the medical researchers is focussed on identifying and evaluating the sound medical-scientific evidence (SMSE) relevant to the disease or injury under consideration. The suite of decision support papers includes:

    a) The main briefing paper summarising the SMSE relevant to the disease or injury under consideration;

    b) A comparison table (a working document, comprising the suggested revisions to a Statement of Principles (SoP) with the content of the current SoP and suggestions for change and reasons for changes; or suggested factors and definitions for a new SoP); and

    c) Setting out the phrasing of the contents of the proposed SoPs.

Note: The Authority acknowledges that the quantity and quality of Sound Medical-Scientific Evidence (SMSE) available to the RMA for the Statements of Principles varies and is based on investigating causation of disease or injury and not usually for compensatory purposes. However the interpretation of the available evidence is made with a beneficial standard of proof in keeping with the intention of the MRCA legislation.

Main briefing paper

2. The purpose of the main briefing paper is to provide the information needed to make a decision as to whether there is evidence to support the inclusion of a factor for that condition, and if so at what standard. There may also be issues of dose and latency to decide.

3. The following standard subheadings are utilised in the main briefing paper:

Current Statements of Principles

4. The number/date of the current SoPs is stated, with a list of current factors. It is not necessary to copy the full wording of the factors in the current SoPs. The differences between the reasonable hypothesis (RH) and balance of probabilities (BoP) SoPs are highlighted in a table.

Background

5. This section summarises the reason for carrying out the investigation.

Submissions/correspondence

6. The researcher lists all submissions. This includes letters, requests for investigation and submissions. If the investigation is being undertaken because of a request from an eligible person or organisation, it is included in the section entitled "background", and any subsequent correspondence or submissions are summarised here.

7. Submissions may include an amount of material which is not peer-reviewed or not relevant. The researcher examines the material provided and obtains full articles that might be relevant or informative.

Literature search

8. See section on searching.

Definition of disease or injury

9. The current definition and ICD (International Classification of Disease) codes are listed. Relevant definitions are provided from authoritative sources and adapted as necessary. The suggested definition is written in the comparison table rather than in the main briefing paper. ICD codes are included in the suggested definition if they correspond closely to the word definition. If there is poor correspondence between the ICD codes and the word definition, then their inclusion may cause confusion and it is preferable to omit them. If there is uncertainty about the use of ICD codes this can be discussed at the RMA meeting.

Introduction

10. The purpose of the introduction is to provide a brief overview of the main facts about the condition. Some more detail may be required if it impacts on relevant decisions. For example, the definition may not be clear cut, or there may be factors that might be relevant to only some forms of the condition (for example, a certain histological subtype of a cancer).

11. Resources which are useful for giving good background information include *Harrison's Principles of Internal Medicine*, *UpToDate* and the *Oxford Textbook of Psychiatry*. There are various textbooks relevant to particular specialty areas in the RMA. A Google search is often useful. For definitions, useful references include *Dorland's Medical Dictionary*, DSM-5 and the ICD codebook.

Factors

12. If there is a current factor for a particular exposure, the wording of the factor and any associated definition should be included.

13. Where relevant and useful, there should be an indication or "sign-posting" of the major issues and the conclusions pertaining to each factor at the beginning of the presentation of evidence (without repeating all the evidence) in the Summary of Important Issues section.

14. In this section the papers that have been identified as relevant from your search are analysed separately, then the information from all the studies is synthesised in the summary. The papers should be discussed in order of study type, from the highest quality to the lowest quality:

- Meta-analyses, systematic reviews
- Cohort studies (prospective studies first)
- Case-control studies
- Cross-sectional studies
- Case series, case reports.

15. General (non-systematic) reviews are of varying quality, but may be included before the other studies if they help to give an overview of the evidence or highlight important issues.

16. In the interests of efficiency, in the first instance, information should be obtained from systematic reviews, meta-analyses, International Agency for Research on Cancer (IARC) monographs, Health and Medicine Division reports, Veterans and Agent Orange updates, UpToDate or other relevant reviews, where such information exists and provided that it is of good quality and from a reputable source. Further information may be necessary if such reviews are not recent, or if more detailed information about dose, latency or cessation periods is needed to formulate a factor. Information from case-control studies or cross-sectional studies may not be needed if there are a reasonable number of good quality cohort studies.

17. Some systematic reviews are very recent and comprehensive, and in that case there is no need to separately analyse the papers that were included in the review. However, there may be a need to separately obtain papers that have been published more recently, or to obtain papers that are particularly influential or informative.

18. There are sometimes studies which don't fit the above categories. Where the study design is distinctive, a separate heading may be used (e.g. record linkage studies, case-cohort studies, nested case-control studies, case-time-control studies, genetic studies). In some cases, review of a a paper may indicate that the authors have categorised the study incorrectly. In these circumstances, the study should be placed in the category considered most appropriate, with the rationale for the categorisation documented.

19. Randomised controlled trials (RCTs) are seldom available in the field of causation, but can add to the coherence of an argument for or against causation. For example, if RCTs of vitamin D supplementation do not consistently increase bone mineral density, it can go against an argument for a causal association between vitamin D and osteoporosis (bearing in mind mechanism of action, adequacy of dosage and adherence to treatment).

20. Case reports can provide evidence for causation when a combination of the criteria below are met.
    - a close temporal link between exposure and effect
    - reversibility
    - recurrence of symptoms or pathology on repeat exposure
    - absence of likely alternative explanations
    - multiple case reports (usually at least three, though one or two reports may be enough if they are convincing using the other criteria)
    - a likely mechanism for the effect is known (biological plausibility)

- a dose-response effect

21. Information in textbooks needs to be treated with caution, as it is often out of date by the time it is published, and broad lists of factors may be perpetuated without reference to the original research, or without consideration of the quality of the source.

22. PhD, Masters and Honours' theses are sometimes submitted by applicants. These documents are subject to a peer review process and published by universities, therefore the Authority considers them to be SMSE. The usual requirement for critical evaluation of the quality of the evidence applies. However, researchers are not required to search for and obtain these types of theses when conducting investigations.

23. Nearly all SoPs have a factor for "inability to obtain appropriate clinical management". However, this factor is not automatic. The management of the condition needs to be briefly documented, and consideration given as to whether such management would prevent worsening of the condition, or delay death from the condition.

24. Consider whether or not or any of the factors should be differentiated by gender. Different doses for males and females should be specified where there is sufficient evidence to do so.

25. In general, the RMA considers that exposures which can cause a condition may also permanently worsen that condition or increase the rate of progression beyond that normally expected. Some exceptions are cancers and infectious diseases, in which some causes logically only relate to the onset of the condition. Before any exposure can be included as a worsening factor, it is necessary to be satisfied that the exposure is able to be related to service after the onset of that condition (as per *s 370C of the Military Rehabilitation and Compensation Act 2004*). For example, a chronic disease could not logically worsen an infectious disease of acute onset because it would have to occur after the onset of the infectious disease.

26. Medicine factors require special consideration in situations where there is uncertainty about inclusion of a medicine as a possible or probable cause of the disease under investigation. At its April 2018 meeting, the RMA agreed that in those situations specific criteria should be applied. Details of these criteria can be found in Appendix 3 – Paragraph 11. *Medicine factors and lists*.

Summary and conclusions

27. The amount of information in this section will depend on the number of studies available, and whether or not the conclusions are obvious. Where there are a number of studies and the outcome is not immediately evident, an assessment of the evidence in terms of the Bradford Hill criteria is usually the most useful method of summarising and weighing the material before you.

28. For example, the summary should describe the number of cohort studies identified, including the number reporting significant positive findings and the number reporting null findings. The same approach should then be applied to case-control studies and any other relevant study designs.

29. Commentary should be provided on the strength of the effect in positive studies, including any concerns relating to bias or confounding. Where relevant, consideration should also be given to whether studies showing lack of effect were underpowered.

30. The summary should identify studies that measured a dose-response effect and state how many reported evidence of such an effect. A brief description of the proposed biological mechanisms, or the lack of knowledge thereof should also be included.

31. The summary should conclude with an assessment of the overall level of evidence, including the assignment of an evidence grade (e.g., the evidence for that particular association supports a judgement of a convincing/suggestive/possible causal association, or the evidence is too limited/inadequate/insufficient to suggest a causal association)..

32. At each review, carefully consider whether or not factors should be retained in either the RH or BoP SoPs. New evidence may alter the balance of the total body of SMSE, such that it may not reach the threshold for an RH or BoP factor. Conversely, the evidence may have strengthened. In the absence of new information, the available SMSE should still be evaluated afresh against the grading system.

Referencing

33. All material should be referenced. The standard referencing style in the body of briefing paper is numerical footnoting. In the summary and conclusions, use author/date citations to support statements made (no need to footnote again). In general the full article is obtained, but if only the abstract is used in an investigation (e.g., foreign language articles) then the reference must state "abstract only".

34. Articles may be obtained online or requested through the administrative staff. Requests may be submitted using a printout of a search, a printout of an abstract, or an emailed list of requested articles. Each request should include the researcher’s name, the name of the condition, and the date of the request. Where only the abstract is required, this should be clearly indicated on the request.

35. Allow 4 weeks to receive the requested articles. To maintain a flow of work it is advisable to start searching for articles for a new investigation while completing a current investigation. In some circumstances, articles may be required urgently. When this occurs, discuss the matter with the Principal Medical Officer (PMO) or administrative staff. Such a circumstance might include follow up of a request from the RMA at a meeting for more information, or the need to finalise a briefing paper in time for the meeting.

36. The reference to any material obtained from the internet must be entered by the administrative staff into the RMA Database and the relevant HPE Content Manager container, including the date the information was accessed. A PDF version of any article or internet page downloded directly must be provided to the administrative staff.

37. A bibliography for each investigation should be compiled and added to the finalised briefing paper. This is most easily accomplished by transforming the footnotes. Ensure that the reference style in the footnotes matches the standard reference style. The bibliography is included in the briefing paper and saved in the appropriate investigation container so that the administrative staff can check the references against the database.

Comparison Table

38. A working document referred to as the comparison table is used during the Authority's consideration of an investigation. The document succinctly records the implications and recommendations arising from the main briefing paper and associated tables. This document is also

used to record the grading of the evidence, to summarise the reasons for changes, to highlight issues for discussion, and to document directions given at RMA meetings.

39. For reviews of existing conditions, the comparison table lists the current condition definition, current factors and current factor definitions in the left hand column, and the proposed definition, factors and factor definitions in the middle column. The right hand column provides the grade. The comparison table also lists all factors for which the evidence was examined but no risk factors were proposed, as well as any factors which are being removed on the basis of new evidence.

40. The wording of the proposed factor should provide doses/timeframes for each standard of proof, where such parameters are relevant. Proposed factors and definitions are discussed with the supervising professor before the RMA meeting (see Interactions with Professors).

41. For a new condition, the left hand column lists only the contended factor (e.g., smoking) and the middle column is used to list the proposed factors and definitions as usual.

42. Issues and reasons are recorded above the SoP definition and factors - issues in left hand column and reasons in the right hand column.

43. In the third column of the table the grade of evidence is recorded next to the proposed factor, after discussion with and approval by the lead Professor. Grades are assigned by the researcher's after a critical appraisal and assessment of the available evidence pertaining to each contended risk factor. They serve as a guide to Authority members in determining whether factors should be included in the RH instrument, both instruments or neither instrument. The grades, and the basis for each grade, can be found in the "RMA Practices and Procedures" document or on the RMA website.

Consistency of factor wording and doses

44. To ensure consistency across SoPs, factors and definitions should be written in the same style and format as that of previous similar factors and definitions, unless the evidence requires that the factor be updated or differentiated.

45. Documents describing standard factors and standard definitions are kept up to date following the outcomes of each RMA meeting.

46. The documents include tables of SoPs with common factors, such as smoking, mefloquine, dioxin and radiation.

47. It is also important to search previous SoPs for similar factors, paying particular attention to the wording of more recent SoPs. SoPs can be searched by two methods: a factor search on the RMA website, or a word or phrase search in the HPE Content Manager.

48. Some commonly used factors and definitions have been the subject of discussion at RMA meetings and a standard form of words has been endorsed. These factors are listed in Appendix 3 of these guidelines and should be used unless the evidence suggests otherwise.

49. Advice was provided at the December 2016 meeting concerning the use of notes. Notes have legal standing and are to be used when a part of a definition or factor provides useful but non-essential information.

50. When referring to eponymous conditions in factors, the possessive apostrophe 's' should be omitted, unless there are SoPs which use the possessive form. For example, there is a SoP for "Parkinson's disease", so factors should continue to be spelt this way rather than changing to "Parkinson disease".

51. The two standards of proof allow for different doses in RH and BoP, but the amount and quality of available evidence may affect the ability to differentiate between the suggested factors. Where there is detailed information concerning the relationship between the exposure dose and the condition, it may be possible to accurately determine a dose consistent with the reasonable hypothesis standard, i.e., which is associated with a small but measurable increase in risk. When such information is absent, the lowest dose in the range can be applied to the reasonable hypothesis standard. For risk factors with less information, a reliable distinction between the doses for the two standards is harder to make based on empirical evidence and it may not be possible to make a differentiation between the doses suggested in the RH and BoP standards.

Searching

Databases

52. The databases most commonly used are *PubMed*, *Ovid Medline* and *PsycInfo*. The latter two are available via the DVA intranet. ToxNet is a public website which may be useful when researching toxic substances. Another public website, *PubChem* provides chemical synonyms and has sections on "Toxicity" and "Associated Diseases and Disorders" which are cross-referenced with articles in PubMed.

Standard database searches

53. The standard Medline search for doing an initial "sweep" of the literature is "condition/ epidemiology, aetiology, chemically induced". It is often useful to limit the initial search to systematic reviews and meta-analyses, as a way of scoping the information.

54. For a new condition generally do a ten year search. For reviews of existing conditions generally do a search from the year before the existing SoPs were determined, to the present. For both new conditions and reviews, research may indicate that older articles are important and require consideration.

55. After the initial search, additional specific searches for the condition and each factor of interest are conducted.

56. Check the HPE Content Manager articles container for the condition being researched for any recent, relevant articles that may have been added since the last investigation (key papers may have been saved there for later review).

57. Printouts of search results do not need to be retained, but the search strategy should be clearly described, especially if it varies from the standard method.

Checklist of common factors

58. There are a number of factors which are of particular interest to veteran and military groups. These should be routinely considered, depending on the type of condition being investigated. They include: firefighting, per- and poly-fluoroalkyl substances (PFAS), moral injury, burn pits, and low level blast exposure.

59. Any mefloquine, passive smoking, benzene, radiation or dioxin-related factors should be brought to the attention of the administrative staff in case they need to be tagged so that they will be identified on a factor search on the RMA website. For example, a search for the term mefloquine will not identify factors for "quinoline derivatives" unless these factors are tagged.

Standard reference texts

60. Some standard references that should be checked if they are relevant to the condition are listed below. Most are available in the RMA library or on the internet.

- IARC Monographs on causes of cancer;
- ATSDR (Agency for Toxic Substances and Disease Registry) toxicological profiles for toxic substances;
- The latest update of the US VAO (Veterans and Agent Orange) review of the literature concerning the health effects of exposure to dioxin-contaminated herbicides and dioxin;
- UNSCEAR (United Nations Scientific Committee on the Effects of Atomic Radiation) for the health effects of ionising radiation;
- The Australian Study of Health Outcomes in Aircraft Maintenance Workers (SHOAMP) for solvents;
- The US Institute of Medicine's Gulf War and Health series of literature reviews of the health effects of fuels, infectious diseases, stress, depleted uranium, pyridostigmine bromide, sarin, vaccines, traumatic brain injury and other Gulf War related exposures;
- The World Cancer Research Fund/American Institute of Cancer Research and IARC Handbooks of Cancer Prevention for cancer risks related to diet, obesity and physical activity;
- The US Surgeon General's reports on the health consequences of exposure to tobacco smoke and environmental tobacco smoke.
- The Diagnostic and Statistical Manual of Mental Disorders, currently in its 5th edition revised version (DSM-5-TR), is the official handbook published by the American Psychiatric Association (APA) to define, classify, and diagnose mental health disorders.
- The Australian Medicines Handbook (AMH), an independent, evidence-based national resource for healthcare practitioners, providing curated information on therapeutic medicines in Australia.

Interactions and correspondence

Interactions with Professors

61. An Authority member is designated the "lead Professor" for each investigation. The lead professor-researcher arrangement enables the detailed review and epidemiological analysis of the SMSE with respect to the disease or injury in question to proceed in a timely and effective manner.

Preparation for initial planning discussion

62. If the condition has a current SoP the researcher should prepare for the initial discussion by:

- reviewing the previous comparison tables and the previous briefing paper;
- conducting a standard database search of the condition to identify any contentious issues that may have arisen since the previous investigation; and
- reviewing any correspondence or submissions that have been received about the condition to see if any issues raised require attention

63. If the condition is non-SoP the researcher should conduct initial standard database searches and review standard texts to gain an understanding of the condition and any potential contentious issues.

64. The researcher should consider developments in the literature which may bear on nomenclature, status as a SoP condition, relationship to other SoPs and whether the RMA has varied current factors in other SoPs in a relevant manner. The RMA may have already flagged these issues in its decision to investigate.

Scoping document and discussions

65. In conjunction with the PMO and the legal team, a scoping document about the proposed investigation should be prepared. The scoping document should be in the form of a draft comparison table and should include the established factors, the likely contentious issues and the new issues arising in the literature which may require greater focus.

66. Once the scope is settled, additional discussions with the PMO and legal team may occur in the course of the investigation as required. In particular during the investigation the nature of the issues requiring investigation and the focus of the investigation may change. *First Draft – Final Papers*

67. There should be a discussion of the two briefing papers, the main briefing paper and the comparison paper, at the first draft stage with the lead Professor together with the PMO. The documents are updated following the discussion with the lead Professor.

68. Prior to that discussion, the comparison table with proposed factors and proposed definitions will be discussed with the PMO and the legal team.

Interactions with outside sources

69. Occasionally the RMA may consider that external expert advice is necessary to clarify a technical issue, or to seek current clinical opinion. The information request should be filed, as should any responses. A summary of the advice should be recorded in the main briefing paper.

Meeting and post-meeting procedures

Presentation of briefing papers at RMA meetings

70. The researcher and supervising Professor give a brief introduction which could include the following: reason for the investigation, plus any defining features of the condition that need to be highlighted (e.g., particular problems with the quality of the evidence, or issues with defining the condition or a major change in thinking about the nature or causes of the condition).

71. The researcher goes through the comparison table, starting with the definition, current factors, new factors, then factors that were investigated but not proposed. There is no need to discuss in detail the factors that are not changing. There is no need to read out the factor or go through the evidence in detail unless it is something that requires clarification.

72. Factors "investigated but not proposed" are listed at the end of the table. It is not a requirement to go through each factor, but any contentious factors should be highlighted (e.g., factors which were reviewed as part of a request).

Briefing papers

73. Briefing papers are sent to the Deputy Registrar on the Monday, two weeks before the RMA meeting is scheduled to allow time for the material to be distributed and considered by all of the Authority members and stakeholders.

74. At the meeting the relevant researcher is responsible for recording the decisions that have been taken with regard to a particular condition. The decisions are documented in the comparison table in a different coloured font, using the subheading "month meeting" to indicate the words that were agreed to, whether or not the factors are in RH only, RH and BoP or neither, and whether or not the factor is for both onset and worsening. If there are any changes to the factor or definition, then the whole factor and definition should be copied below the proposed factor. This makes clear the exact wording that has been approved. Where a change to a proposed factor is significant or important, the reason should be documented in the table.

75. Normally the comparison table will only need to record one decision. If a factor is changed at multiple meetings, use a different coloured font to record the change for each meeting.

76. The final row of the post-meeting comparison table should state which factors or sub-parts of factors have been removed. If a factor has been removed but subsumed by another factor, then this should be stated. The post-meeting comparison table is sent to the Deputy Registrar for drafting the SoPs for that condition, which will appear at the next meeting. The Deputy Registrar drafts the SoPs which are tabled at the meetings for second mention and approval by the Authority. These drafts are based on the updated comparison table. The responsible Medical Researcher will be asked to check and affirm that the draft is accurate in terms of words, doses, punctuation, differences between RH and BoP and use of onset and worsening factors.

77. Following the meeting, the briefing paper and comparison table, should be updated and finalised and sent to the Deputy Registrar well before the meeting at which the draft SoPs are considered (ideally within a week of the meeting at which they were considered). If the grading of a factor has been changed at the direction of the RMA, the change should be reflected in the briefing papers. If a

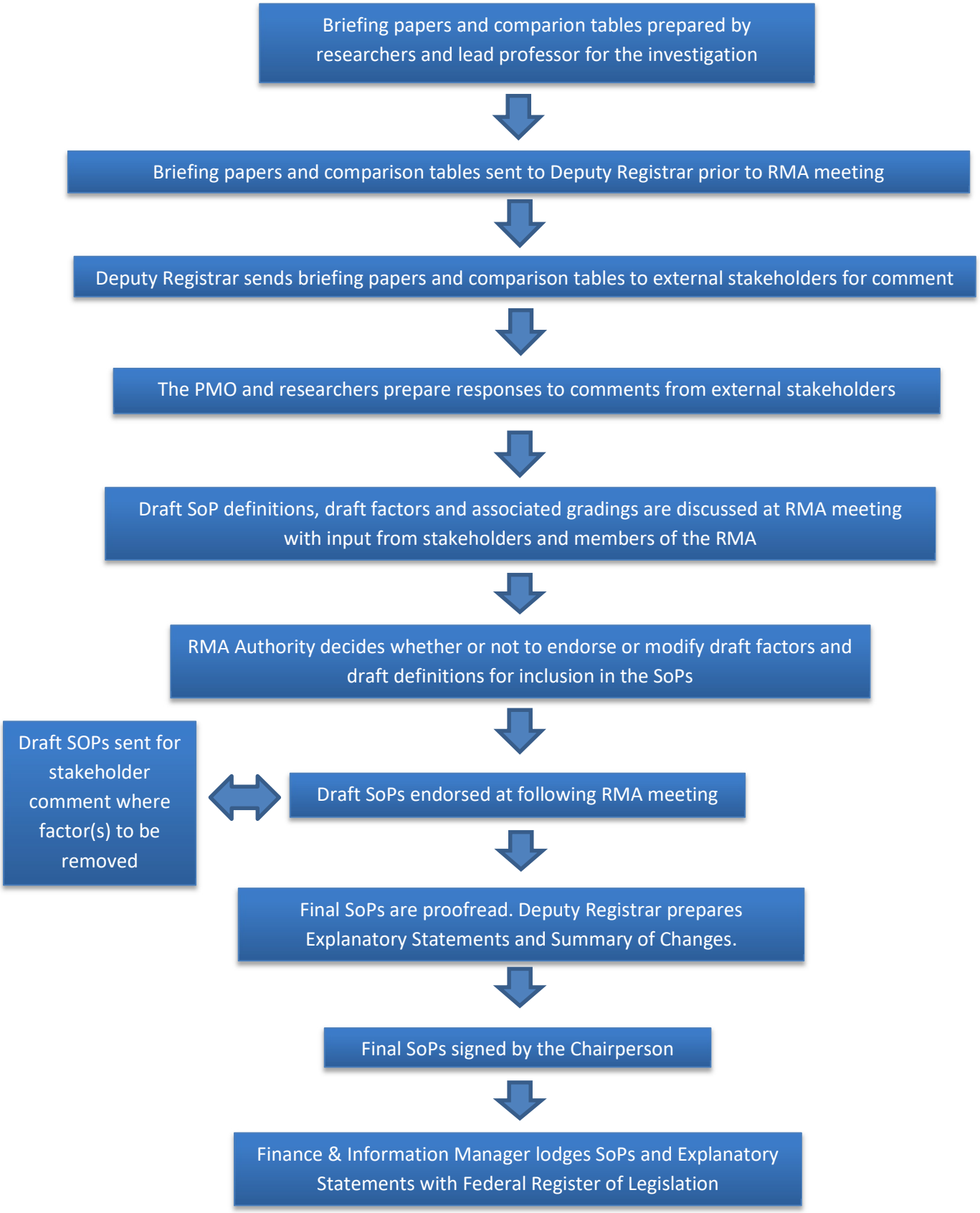
draft SoP has gone out for stakeholder consultation due to the removal of an existing factor, it is the Medical Researcher's responsibility to ensure that the briefing papers and the amended comparison table are updated and provided to the Deputy Registrar well before the meeting at which the SoPs will be determined.

78. A separate bibliography should be prepared and stored in the appropriate HPE Content Manager container for that investigation. The administrative staff use the bibliography to check that all articles have been entered into the database before preparing a reference list for that condition.

79. Final versions of the papers are provided to the Authority members for review and consideration at the meeting at which the SoPs are determined. For the purposes of reviews by the SMRC, the main briefing paper and the comparison table comprise the information that was available to the RMA.

80. In preparing all documentation, researchers should be mindful that any document may potentially be subject to public scrutiny or may be the subject of legal consideration. It is important that the writing is of a high standard and that attention is paid to professional-looking formatting in the finalised documents, including correction of errors, removal of template prompts and unnecessary spaces, updating of footers, and inclusion of the bibliography. If an additional briefing paper has been developed and presented subsequent to the main briefing paper, it must be incorporated into one finalised briefing paper.

Appendix 1 Flowchart for SoP processing procedures



Appendix 2 Glossary/Abbreviations

BoP	balance of probabilities
CI	confidence interval
DVA	Department of Veterans' Affairs
ESO	Ex-Service Organisation
IARC	International Agency for Research on Cancer
ICD	International Classification of Diseases
OR	odds ratio
RH	reasonable hypothesis
RMA	Repatriation Medical Authority
RR	relative risk
SMRC	Specialist Medical Review Council
SMSE	sound medical-scientific evidence
SoP	Statement of Principles

Appendix 3 Standard wording for specified factors and definitions

Some commonly used factors and definitions have been the subject of discussion at RMA meetings and a standard form of words has been endorsed. These include:

1. Infectious disease SoPs and factors concerning infectious disease
2. Standard radiation factors
3. Genetic risk factors and genetic disorder SoPs
4. Smoking factors in SoPs
5. Obesity factors
6. Immunosuppression factors
7. Wording of transplantation factors and associated definitions in cancer SoPs
8. Chronic kidney disease and chronic renal failure
9. Dietary factors
10. Harmonisation of ingredient names
11. Medicine factors and lists
12. Periods of one month
13. Generic exposure factors

1) Infectious disease SoPs and factors concerning infectious disease

A standard approach for infectious disease SoPs was agreed at the February 2020 RMA meeting as listed below. The following recommendations are to be implemented for infectious diseases SoPs whenever a new SoP is created, or an existing SoP is revised. The recommendations do not apply to diseases which are defined as having an infectious aetiology but for which there is not a requirement in the definition to specify a particular organism, such as osteomyelitis.

There should be good documentation in the underlying Briefing Paper of the evidence and reasoning to support the inclusion of an additional clinical onset factor. The clinical worsening factors should be checked to ensure that they are not already covered by the generic inability to obtain appropriate clinical management factor.

1. The title of an infectious disease SoP should always include the term infection. For example, hepatitis A would become hepatitis A infection. An exception to this rule may occur when the infection is widely known by a commonly used name, such as malaria.
2. The definition of diseases specific to an organism should use one of two types of wording, in which x is the name of the organism:
    a) Means an infection caused by x; or
    b) Means an illness caused by infection with x, followed by the symptoms and signs which characterise the illness.
3. Factors in infectious disease SoPs are one of four categories:
    (i) an exposure factor;
    (ii) a proxy for exposure;

(iii) additional clinical onset factor;
(iv) clinical worsening.

Infectious disease factors included in SoPs should generally follow the standard wording "having infection with", although there will be variations in latency/cessation periods, or if the factor refers to a particular circumstance or specified list. Examples are given below.

Standard infection factor:

having infection with y virus before [within the z days/weeks/months before] clinical onset/worsening;

Example:

having infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) within the 3 months before clinical onset;

Examples of varied wording of infectious disease factors included in SoPs:

having an infection of the gastric mucosa at the time of clinical onset or clinical worsening by one of the following organisms:
(a) *Anisakis simplex* (causing anisakiasis);
(b) cytomegalovirus;
(c) herpes simplex virus;
(d) fungi (such as *Candida* spp or Mucormycetes);
(e) *Helicobacter heilmannii*;
(f) *Mycobacterium tuberculosis*;
(g) *Strongyloides stercoralis* (causing strongyloidiasis);
(h) *Treponema pallidum* (causing syphilis);

having an infection in the X months before clinical onset or clinical worsening with any of the following conditions:
(a) gastrointestinal infection;
(b) influenza;
(c) pneumonia;
(d) septicaemia;
(e) severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection;
(f) upper respiratory tract infection;
(g) urinary tract infection;

2) Standard radiation factors

Standing rules for radiation factors were agreed upon by the RMA in 2011 and modified at the October 2016 meeting in respect of therapeutic radiation factors. Revisions to the definition of cumulative equivalent dose were accepted at the August 2017 meeting. There is a set of rules for radiation factors in cancer SoPs and another set of rules for radiation factors in non-cancer SoPs.

Cancer SoPs

Solid cancer factor
having received a cumulative equivalent dose of at least 0.1 [BoP 0.5] sievert of ionising radiation to the [affected organ/region] at least 5 years [BoP 10 years] before clinical onset;

Note: ***cumulative equivalent dose*** is defined in the Schedule 1 – Dictionary.

cumulative equivalent dose means the total dose of ionising radiation received by the particular organ or tissue from external exposure, internal exposure or both, apart from normal background radiation exposure in Australia, calculated in accordance with the methodology set out in *Guide to calculation of 'cumulative equivalent dose' for the purpose of applying ionising radiation factors contained in Statements of Principles determined under Chapter 9A of the Military Rehabilitation and Compensation Act 1986, Australian Radiation Protection and Nuclear Safety Agency,* as in force on 2 August 2017.

Note 1: Examples of circumstances that might lead to exposure to ionising radiation include being present during or subsequent to the testing or use of nuclear weapons, undergoing diagnostic or therapeutic medical procedures involving ionising radiation, and being a member of an aircrew, leading to increased levels of exposure to cosmic radiation.

Note 2: For the purpose of dose reconstruction, dose is calculated as an average over the mass of a specific tissue or organ. If a tissue is exposed to multiple sources of ionising radiation, the various dose estimates for each type of radiation must be combined.

Leukaemia factor
having received a cumulative equivalent dose of at least 0.01 [BoP 0.05] sievert of ionising radiation to the bone marrow at least 1 year [BoP 2 years] before clinical onset;

Note: ***cumulative equivalent dose*** is defined in the Schedule 1 – Dictionary.

Non-cancer SoPs

Circulatory disease (two factors, one quantitative and one qualitative)
having received a cumulative equivalent dose of at least 0.5 sievert [1 sievert BoP] of ionising radiation to the affected organ [latency] before clinical onset/worsening;

Note: ***cumulative equivalent dose*** is defined in the Schedule 1 – Dictionary.

undergoing a course of therapeutic radiation for cancer, where the affected organ was in the field of radiation, [latency] before clinical onset/worsening;

Non-circulatory disease (only a qualitative factor, unless there is evidence for a quantitative factor as well)
undergoing a course of therapeutic radiation for cancer, where the affected organ was in the field of radiation, [latency] before clinical onset/worsening;

Generally no latency period is required, on the grounds that effects could be prompt if an organ was directly exposed to high doses. However, if the mechanism was by fibrosis then a latency period of 1 to 2 years might be appropriate. Depending on the evidence for a particular condition, a longer latency period might be warranted.

3) Genetic risk factors and genetic disorder SoPs

It was agreed at the April 2011 meeting that genetic risk factors would be included if they met the tests listed below. It was further agreed at the December 2012 meeting that the below criteria would also apply to determining SoPs for genetic disorders.

(i) the condition would not preclude entry to service; and

(ii) the condition could be worsened by some service-related factor; or

(iii) the condition could be worsened by inability to obtain appropriate clinical management.

4) Smoking factors in SoPs

When determining doses for new smoking factors, refer to doses in other factors in the table to ensure that dose relativities are consistent with other conditions with similar relative risks.

A consistent approach is taken to the assessment of cessation periods for smoking factors. Studies which assess cessation will report the number of years it takes for the relative risk to return to null, compared to never smokers. Where there is more than one study, there may be a category which is common to most studies. There is usually some uncertainty about number of years because of the size of the categories (which can range from 5 to 20 years).

In general:

(i) the cessation period for the BoP standard should reflect the majority of the evidence; and

(ii) the cessation period for the RH standard can be relaxed by five years in most cases (possibly ten years in some cases), to allow for uncertainty in the data.

The standard smoking factor in all SoPs should include the dose, and where the evidence is available, should also include a latency period and a cessation period. The dose may be expressed in pack-years or the equivalent thereof in other tobacco products. Additional wording may be added with regard to whether the person is a current smoker.

Examples of smoking factors and associated definitions are given below.

Example of standard smoking factor with dose expressed as pack-years:

having smoked at least X pack-years before clinical onset or clinical worsening, and where smoking has ceased, clinical onset or clinical worsening occurred within X years of cessation;

Note: ***one pack-year*** is defined in the Schedule 1 - Dictionary.

one pack-year means the amount of tobacco consumed in smoking 20 cigarettes per day for a period of 1 year, or an equivalent amount of tobacco products.

Note 1: An equivalent amount of tobacco products is 7,300 grams of smoking tobacco by weight, either in cigarettes, pipe tobacco or cigars, or a combination of same. For pipe tobacco, cigars or combinations of multiple tobacco types, 1 gram of tobacco is considered to be equal to one cigarette.

Note 2: Pack-years are calculated by dividing the number of cigarettes smoked per day by 20 and multiplying this number by the number of years the person has smoked. For example, smoking 10 cigarettes per day for 10 years is equal to 5 pack-years, and smoking 40 cigarettes per day for 10 years is equal to 20 pack-years.

Example including dose expressed as cigarettes per day:

smoking at least X cigarettes per day, or the equivalent thereof in other tobacco products, for at least the X months before clinical onset or clinical worsening;

Note: One gram of tobacco is considered to be equivalent to one cigarette.

Example including second-hand smoke:

being exposed to second-hand tobacco smoke produced by others in an enclosed space:
(a) for at least X hours before clinical onset; and

(b) where exposure commenced at least X years before clinical onset; and
(c) if exposure has ceased before clinical onset, then that onset occurred within X years of cessation;

Example including cannabis products:
having smoked cannabis products:
(a) in an amount of at least X joint-years before clinical onset; and
(b) commencing at least X years before clinical onset; and
(c) if smoking has ceased before clinical onset, then that onset occurred within X years of cessation;
Note: ***one joint-year*** is defined in the Schedule 1 - Dictionary.

one joint-year means the amount of cannabis consumed in smoking one joint per day for a period of 1 year.

5) Obesity factors

It was agreed at the April 2025 meeting 'being obese' or 'being overweight' be changed to BMI since the obesity and overweight threshold can vary between study populations (i.e., Western versus Asian population groups).

having a Body Mass Index (BMI) of 25 or greater for at least X years in the X years immediately preceding clinical onset;

Note: Body Mass Index (BMI) is calculated as W/H^2 where:
(a) W is the person's weight in kilograms; and
(b) H is the person's height in metres.

having a Body Mass Index (BMI) of 30 or greater for at least X years in the X years immediately preceding clinical onset;

Note: Body Mass Index (BMI) is calculated as W/H^2 where:
(a) W is the person's weight in kilograms; and
(b) H is the person's height in metres.

6) Immunosuppression factors

The following factors and definitions were adopted at the October 2025 meeting.

having a substantially compromised immune system at the time of clinical onset or clinical worsening due to any of the following:

(a) chronic renal failure as indicated by:
(i) a glomerular filtration rate of less than 15 mL/min/1.73 m^2 for a period of at least 3 months; or
(ii) undergoing chronic dialysis for renal failure;
(b) haematological or solid organ malignancy;
(c) infection with human immunodeficiency virus;
(d) severe malnutrition (protein-calorie malnutrition associated with a Body Mass Index (BMI) of less than or equal to 18.5 kg/m^2);
(e) solid organ, stem cell or bone marrow transplantation;

(f) taking one of the following immunosuppressive medicines:
(i) corticosteroids other than inhaled or topical corticosteroids;
(ii) medicines used to prevent transplant rejection;
(iii) tumour necrosis factor-α inhibitors;
(iv) chemotherapeutic agents used for the treatment of cancer;

Note: Body Mass Index (BMI) is calculated as W/H^2 where:
(a) W is the person's weight in kilograms; and
(b) H is the person's height in metres.

taking an immunosuppressive medicine in the X years immediately preceding clinical onset or clinical worsening/at the time of clinical onset or clinical worsening;

Note: Examples of immunosuppressive medicines include corticosteroids other than inhaled or topical corticosteroids, medicines used to prevent transplant rejection, tumour necrosis factor-α inhibitors and chemotherapeutic agents used for the treatment of cancer.

7) Wording of transplantation factors

The following factor was adopted at the October 2023 meeting.

having a solid organ transplant (excluding corneal transplant), stem cell transplant or bone marrow transplant before clinical onset;

8) Chronic kidney disease and chronic renal failure

The RMA agreed to adopt standard factors and definitions in future SoPs at its February 2016 meeting. The factor and definition of chronic kidney disease will progressively replace current factors for chronic renal disease. The factor and definition of chronic renal failure will progressively replace current factors for end-stage renal disease.

In 2024, the factor and definition concerning chronic kidney disease and chronic renal failure was revised.

Chronic kidney disease
having chronic kidney disease before clinical onset as indicated by one of the following:

(a) a glomerular filtration rate of less than X mL/min/1.73 m^2 for at least 3 months; or
(b) albuminuria with an albumin to creatinine ratio of at least 3 milligrams/millimole for at least 3 months;
(c) kidney damage, as evidenced by renal biopsy, imaging studies, urinary sediment abnormalities or other markers of abnormal renal function;
(d) having had a kidney transplant.

Chronic renal failure
having chronic renal failure at the time of clinical onset or clinical worsening as indicated by:
(a) a glomerular filtration rate of less than 15 mL/min/1.73 m^2 for a period of at least 3 months; or
(b) undergoing chronic dialysis for renal failure.

9) Dietary factors

The adoption of standard wording for dietary factors was agreed at the February 2016 meeting.

For protective factors:
inability to consume an average of at least x grams per day of any combination of fruit and vegetables, for at least 5 consecutive years within the 20 years before clinical onset;

For risk factors:
consuming an average of at least x grams per day of processed meat product, for at least 5 consecutive years within the 20 years before clinical onset;

10) Harmonisation of ingredient names

From April 2016 the Therapeutics Goods Administration (TGA) will be updating some medicine ingredient names used in Australia to align with names used internationally. The RMA is adopting the same policy for medicine factors, to be applied progressively to SoPs from April 2016. A list of affected ingredients is available on the TGA website at https://www.tga.gov.au/updating-medicine-ingredient-names-list-affected-ingredients

11) Medicine factors and lists

At the April 2018 meeting, it was agreed that in situations where there is uncertainty about inclusion of a medicine as a possible or probable cause of the disease under investigation, the following criteria will be applied.

Basic criteria (first 3 plus 4 or 5) for limited association (RH)

(1) Plausible/reasonable temporal association- onset precedes effect within reasonable time frame for that particular medicinedisease association; and
(2) Dechallenge - recovery occurs on medicine cessation; and
(3) At least two independent reports (where no additional criteria are met); and
(4) Other aetiologies possible but not likely (e.g., other diseases or other medicines; or
(5) Plausible biological mechanism.

Additional criteria (one or more) for suggestive or convincing association (RH and BoP)

(6) Rechallenge - response recurs on repeat administration (may be to the same medicine or the same class of medicine).
(7) Recovery on administration of an antagonist (e.g., anticholinergics after organophosphate poisoning).
(8) Proven biological mechanism in that patient (e.g., medicine dependent antibodies, positive hypersensitivity testing).
(9) A significant association is demonstrated in adequately powered epidemiological studies or randomised controlled trials.
(10) Other aetiologies excluded or highly unlikely.

(11) Characteristics of the patient are linked to the metabolism of the medicine (e.g., presence of a relevant genetic polymorphism, renal or liver impairment).
(12) Dose-response effect (not always present, there may be a threshold for toxicity or an idiosyncratic reaction).
(13) Commonality of reports across different reviews (unless there is an indication of perpetuation of single case reports or the reviews are based on loose criteria).
(14) A large number (usually at least 10) of independent reports.
(15) The medicine is not common and the effect is not common (so that the association is less likely to be coincidental).
(16) Length of time the medicine has been on the market - all but rare adverse effects are likely to be known for older medicines, previously unreported effects may plausibly occur for newer medicines once they are marketed to a wider population.
(17) The medicine is in the same class as a medicine which has a probable association.

At the October 2024 meeting, it was agreed that medicines should be listed separately in medicines lists, unless there is evidence that the entire class of medicines is causally associated with the condition under investigation. Generally, three examples of common medicines used within a class may be included following the class name.

All medicine factors should start with "taking a medicine", along with the relevant time frames, with no requirement to mention 'class of medicines' if these are included in the list. Where medicine lists, either classes or individual medicines, are short (≤ 15), the medicines are listed within the factor. Where medicine lists are long (> 15), the medicines are included in a specified list of medicines.

There is a standard generic medicine factor for idiosyncratic medicine reactions, although there are variations depending on the particular condition. Examples are given below.

≤ 15 medicines
taking any of the following medicines for at least X weeks, in the X months immediately preceding clinical onset or clinical worsening;
(a) clopidogrel;
(b) glucocorticoid, excluding topical or inhaled;
(c) deferasirox;
(d) nicorandil;
(e) paracetamol of more than 2 grams daily;
(f) selective serotonin re-uptake inhibitors;

> 15 medicines
taking a medicine from the specified list for at least X weeks, in the X months immediately preceding clinical onset or clinical worsening;
Note: ***medicine from the specified list*** is defined in the Schedule 1 – Dictionary.

medicine from the specified list means:
(a) clopidogrel;
(b) glucocorticoid, excluding topical or inhaled;
(c) deferasirox;

(d) nicorandil;
(e) paracetamol of more than 2 grams daily;
(f) selective serotonin re-uptake inhibitors;
(g) etc.

Generic medicine factor
taking a medicine which is associated with:
(a) the development of *SoPname* including laboratory markers during medicine therapy; and
(b) the cessation of *SoPname* including laboratory markers within X days/weeks/months of discontinuing medicine therapy; and
where treatment with the medicine continued for at least the 3 days before clinical onset or clinical worsening;

Malignant disease

Medicine factors can be complex as there are many variables that can be included, particularly for malignant conditions. Factors concerning taking a medicine for a malignant condition may include:

1. dose (related to duration of taking the medicine or the pharmaceutical dose);
2. proximity to the onset of the condition; and
3. latency;

if the relevant data can be obtained from the sound medical-scientific literature. Medicine taking may be continuous or cumulative. The wording of the factor will depend on the evidence that is available.

12) Periods of one month

A standard way to express periods of one month was agreed at the June 2015 meeting. Where duration of exposure is concerned, the factor should be expressed as 4 weeks. Where the exposure must have occurred within a certain time period, the factor should be expressed as 30 days. Examples are given below:

living or working in a hostile or life-threatening environment for a period of at least 4 weeks before the clinical onset of posttraumatic stress disorder;

having a cerebrovascular accident involving the brainstem within the 30 days before the clinical onset of trigeminal neuropathy;

13) Generic exposure factors

With the refinement of the smoking factors in 2021, the wording of factors for other exposures (e.g., chemical agents) should be expressed and formatted in the same way where there is evidence for dose, and latency with or without cessation. Examples are given below:

being exposed to benzene in any of the following circumstances on at least X days within a continuous period of X years before the clinical onset, and where the first exposure occurred at least X years before clinical onset or clinical worsening;
(a) having cutaneous contact with liquids containing benzene greater than 1% by volume;
(b) ingesting liquids containing benzene greater than 1% by volume;
(c) inhaling benzene vapour where such exposure occurs at an ambient 8 hour time-weighted average benzene concentration (averaging of different exposure levels to benzene during an average exposure period equivalent to 8 hours) exceeding five parts per million;

inhaling respirable crystalline silica dust for a cumulative period of at least 2,000 hours before clinical onset or clinical worsening;

Note: Examples of when exposure to respirable crystalline silica dust can occur include when material containing crystalline silica is being produced, excavated, drilled, cut or ground, or used in construction, manufacturing, cleaning or blasting.

Document Control

Document	Version	Effective Date	Approved By
RMA Guidelines for Researchers	1.0	June 2026	Authority

Revision History

Version	Date	Description
1.0	June 2026	Formal version control introduced. This version reflects the document as it existed on the date version control was implemented.

Note: Version control was introduced in June 2026. Amendments made prior to this date were not formally recorded in a version history. The document current at the date of implementation was designated Version 1.0.