Update processes for guidelines –

Systematic review protocol

August 2021

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About HRB-CICER

In 2016, the Department of Health requested that the Health Research Board (HRB) fund an evidence synthesis service called HRB-CICER (Collaboration in Ireland for Clinical Effectiveness Reviews) to support the activities of the Ministerial appointed National Clinical Effectiveness Committee (NCEC). Following a competitive process, the Health Information and Quality Authority (HIQA) was awarded the contract for the five-year period from 2017 to 2022. The HRB-CICER team comprises a dedicated multidisciplinary research team supported by staff from the Health Technology Assessment team in HIQA and the HRB Centre for Primary Care Research at the Royal College of Surgeons in Ireland (RCSI), as well as national and international clinical and methodological experts.

With regard to clinical guidelines, the role of the HRB-CICER team is to independently review evidence and provide scientific support for the development, by guideline development groups (GDGs), of National Clinical Guidelines for the NCEC. The HRB-CICER team undertakes systematic reviews of the clinical effectiveness and cost-effectiveness of interventions included in the guidelines as well as estimating the budget impact of implementing the guidelines. The HRB-CICER team also works closely with the GDGs provides tailored training sessions; assists in the development of clinical questions and search strategies; performs systematic reviews of international clinical guidelines and supports the assessment of their suitability for adaption to Ireland; and supports the development of evidence-based recommendations informed by the evidence produced by HRB-CICER within the National Clinical Guidelines.

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List of abbreviations that appear in this report

AHRQ	Agency for Healthcare Research and Quality
bpac^{nz}	The Best Practice Advocacy Centre New Zealand
CADTH	Canadian Agency for Drugs and Technologies in Health
CIMO	Context, intervention, mechanism, outcome
EUnetHTA	European Network for Health Technology Assessment
GDG	Guideline development group
GIN	Guidelines International Network
HRB-CICER	Health Research Board – Collaboration in Ireland for Clinical Effectiveness Reviews
HTA	Health Technology Assessment
HSE	Health Service Executive
IOM	Institute of Medicine
KCE	Belgian Health Care Knowledge Centre
NCEC	National Clinical Effectiveness Committee
NCG	National Clinical Guideline
NHMRC	Australian National Health and Medical Research Council
NICE	National Institute for Health and Care Excellence
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
SIGN	Scottish Intercollegiate Guidelines Network
THL	Finnish Institute for Health and Welfare
WHO	World Health Organization

1 Background

1.1 Description of National Clinical Guideline development in Ireland

National Clinical Guidelines (NCGs) are systematically developed statements, based on a thorough evaluation of the evidence, to assist practitioner and service users' decisions about appropriate healthcare for specific clinical circumstances across the entire clinical system. The National Clinical Effectiveness Committee (NCEC) was established in September 2010, and works to prioritise and quality assure NCGs so as to recommend them to the Minister for Health to become part of a suite of NCGs.[1] The NCGs are then implemented in the public healthcare system by the Health Service Executive (HSE) and available to all healthcare providers. The NCEC has a mandate to provide methods guidance for the development of NCGs.[2] As such, the NCEC has published several guidance documents to support guideline developers in this process. Examples include, the *Implementation Guide and Toolkit for National Clinical Guidelines*[3] and *How to develop a National Clinical Guideline: A manual for guideline developers*.[4]

Clinical guideline development is resource intensive and time-consuming. As such, the NCEC has developed prioritisation criteria to assist them in identifying the guidelines most significantly in need of development. These prioritisation criteria are:

- Patient safety issue
- Burden of clinical topic
- Evidence analysis
- Economic impact
- Variability in practice
- Potential for addressing health issues
- Clinical guideline implementation.[4]

Once prioritised, development of the guideline is an iterative process and it commences with the establishment of the guideline development group (GDG). All stakeholders, that is, any entity or group with an interest in development of the guideline, should be represented on the GDG.[4] Having founded the GDG, the next step in the process is establishment of the evidence base. This is achieved through formulation of the guideline questions, a review of existing international clinical guidelines (to determine if they can be adapted, adopted or contextualised for use in the Irish setting) and a literature review to identify, synthesise and appraise the evidence.[4] Having established the evidence base, recommendations are made

based on that evidence, an implementation plan is developed and a budget impact analysis conducted. Once drafted by the GDG, the guideline is sent for external review by wider national stakeholders and international experts before it is submitted to the NCEC for quality assurance. Thereafter, the guideline is recommended by the NCEC to the Chief Medical Officer for consideration for approval and if successful, onwards for Ministerial approval. Alternatively, the NCEC may require that the guideline be amended and resubmitted for quality assurance.[4]

1.2 Description of updating National Clinical Guidelines in Ireland

As a consequence of the growth in the volume of the scientific literature, clinical guidelines require updating to ensure validly of the recommendations contained within.[5] In Ireland, the NCEC recognises three types of update, namely, full, partial (that is, modular) and rapid.[4] A full update is when the content, questions and recommendations within a guideline are completely updated. Typically, this occurs after a predefined time period has lapsed; in Ireland the time period recommended is every three years. For example, in 2019 the Irish Maternity Early Warning System guideline[6] was fully updated and in 2020 the Irish National Early Warning System guideline[7] was fully updated. A partial (or modular) update is an alternative to a full update. This occurs when, following consideration of all section within a guideline, only certain sections require updating; no guideline has been partially updated to date.[4]

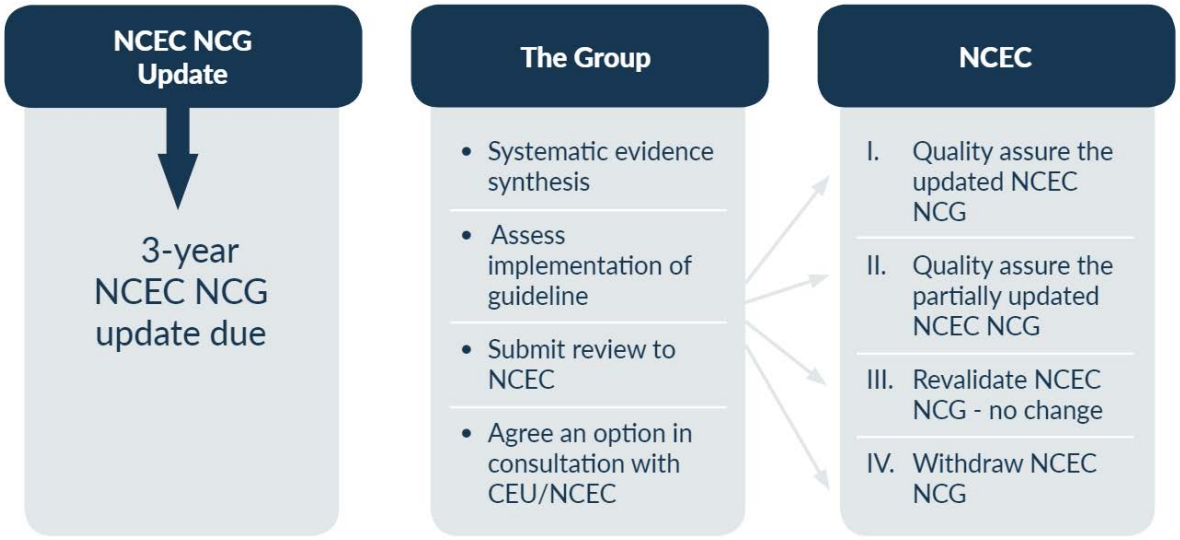
A rapid update occurs when new evidence emerges that could change a recommendation within a clinical guideline, such as following the publication of new studies, expert opinions or medicine alerts. For example, in 2016 the Irish Paediatric Early Warning System guideline[8] was rapidly updated. The updates included, the addition of the term “child/children” to the glossary, an update to the audit outcomes, renumbering of the recommendations, changes to the wording of recommendations to provide clearer guidance and the addition of references to resources.

The NCEC guideline developers’ manual highlights that consideration of the following criteria can help determine the validity of an existing guideline, and the type of update required:

1. Have interventions (whether diagnostic or treatment) been superseded or replaced by other interventions?
2. Has new evidence altered the relationship between benefits and harms?
3. Have outcomes not considered at the time of the original guideline become important or have outcomes then considered important now become unimportant?
4. Is there evidence that current performance is optimal, and the guideline is no longer needed?[9]

Having decided upon the type of update indicated, and having reviewed any new and or emerging evidence, the GDG, will undertake an assessment as to whether the guideline is to be revised and updated, partially updated with changes to specific recommendations, retained unchanged or withdrawn.[4] This will be considered as part of the guideline update submission to the NCEC. Figure 1.1 provides a summary of the process of updating national clinical guidelines.

Figure 1.1 Process of updating NCEC National Clinical Guidelines



Source: How to develop a National Clinical Guideline, Department of Health (Ireland), 2019.[4]

Like the guideline development process, updating clinical guidelines is an iterative process that is both resource intensive and time-consuming. Moreover, it is acknowledged that deciding to update a clinical guideline depends on factors other than pre-defined time periods, such as the volume of new research published on the topic and the resources available to update a guideline.[10] As a result, policy makers and other stakeholders are advocating for a move away from updating guidelines based on a pre-defined time-period (that is, three years as specified by the NCEC) and moving towards updating guidelines based on prioritisation criteria, to ensure appropriate investment of resources.[10]

1.3 Purpose of this systematic review

Evolution of the scientific literature brings new and updated methodologies. This has been especially evident throughout the COVID-19 pandemic where the emphasis was on development and implementation of strategies to manage the rapidly evolving evidence base in response to a public health emergency. The purpose of this systematic review is to describe the most recent guideline update processes, including up-to-date prioritisation methods, used by international or national groups who provide methods guidance for developing and updating clinical guidelines. This will support the NCEC in consideration of amendments to

the current update processes.

2 Review question

What are the most recent guideline update processes, including up-to-date prioritisation methods, used by international or national groups who provide methods guidance for developing and updating clinical guidelines?

3 Methods

This protocol outlines the proposed approach to achieve the stated purpose. The review will adhere to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) criteria.[11]

3.1 Search methods for identification of studies

Due to changes in process and methodologies in guideline development in the last 10 years, the overall search span for this review will be the last 10-years (2011-2021). The primary data source for this review will be methodological handbooks which detail update processes, including prioritisation methods, used by international or national groups who provide methods guidance for developing and updating clinical guidelines. Through scoping searches, HRB-CICER has identified a published systematic review of methodological handbooks that provide guidance for updating clinical practice guidelines.[12] This systematic review by Vernooij et al.[12] was published in 2014 and will be considered an index document, whereby for methodological handbooks, data from 2011-2012 will be taken from Vernooij et al.[12] and data from 2013-2021 will be gathered through a new search of organisations' websites and grey literature (see section 3.1.1 and 3.1.2).

The secondary data source will be peer-reviewed articles which detail the development of, and or implementation of guideline update processes. For peer-reviewed articles, data from 2011-2021 will be gathered through a database search (see section 3.1.3). While peer-reviewed articles will not be the primary data source for this systematic review, they may serve as "sign-posts" to the handbooks and may also provide qualitative data relating to the usability of the handbooks and update processes.

In 2017, Martinez-Garcia et al.[10] published a systematic review of prioritisation processes for updating guidelines, which focused on peer-reviewed articles rather than methodological handbooks. Data specific to prioritisation methods from 2011-2015 will be taken from

Martinez-Garcia et al.,[10] and data from 2016-2021 will be gathered from the new database search (see section 3.1.3).

3.1.1 Organisations

The organisations listed in Table 3.1 will be searched for relevant methodological handbooks. The organisations were chosen based on identification of the organisation from previous systematic reviews on this topic and guidance being available in English.

Table 3.1 Organisations that will be searched for relevant methodological handbooks

Organisation name	Organisation URL
Agency for Healthcare Research and Quality (AHRQ), USA	https://www.ahrq.gov/
Australian National Health and Medical Research Council (NHMRC), Australia	https://www.nhmrc.gov.au/
Belgian Health Care Knowledge Centre (KCE), Belgium	https://kce.fgov.be/en
Canadian Agency for Drugs and Technologies in Health (CADTH), Canada	https://www.cadth.ca/
European Network for Health Technology Assessment (EUnetHTA)	https://www.eunethta.eu/
Finnish Institute for Health and Welfare (THL), Finland	https://thl.fi/fi/
Guidelines International Network (GIN)	https://g-i-n.net/
Institute of Medicine (IOM), USA	https://nam.edu/about-the-nam/
McMaster GRADE centre, Canada	https://cebgrade.mcmaster.ca/
National Institute for Health and Care Excellence (NICE), UK	https://www.nice.org.uk/
Ravijuhend, Estonia	https://www.ravijuhend.ee/
Scottish Intercollegiate Guidelines Network (SIGN), Scotland	https://www.sign.ac.uk/
National Board of Health and Welfare, Sweden	https://www.socialstyrelsen.se/en/regulations-and-guidelines/national-guidelines/
Public Health Agency of Sweden (PHAS), Sweden	https://www.folkhalsomyndigheten.se/the-public-health-agency-of-sweden/
The Best Practice Advocacy Centre New Zealand, (bpac^{nz}), New Zealand	https://bpac.org.nz/guidelines/
World Health Organization (WHO)	https://www.who.int/

When guideline manuals are not found online, or where any data gaps are identified, these will be addressed by contacting organisations (via email) to gather information relating to guideline update processes (including prioritisation methods). Other relevant organisations identified during the searching process will also be included in those searched.

3.1.2 Grey literature

Other sources of grey literature will be searched for relevant methodological handbooks. These are listed in Table 3.2.

Table 3.2 Grey literature that will be searched for relevant methodological handbooks

Grey literature source	URL
Google (first 10 pages of results)	www.google.com
Open Grey	http://www.opengrey.eu/
Reference chasing	NA

3.1.3 Databases

The following databases will be searched for peer-reviewed articles using the search strategy defined in Appendix 1:

- Medline (EBSCO)
- Embase
- The Cochrane Methodology Register.

3.2 Criteria for considering publications for this review

This systematic review protocol has been developed to answer the review question:

What are the most recent guideline update processes, including up-to-date prioritisation methods, used by international or national groups who provide methods guidance for developing and updating clinical guidelines?

The review question was formulated in line with the CIMO (Context, Intervention, Mechanism, Outcome) framework,[13] as presented in Table 3.3. The CIMO framework describes "the problematic Context, for which the design proposition suggests a certain Intervention type, to produce, through specified generative Mechanisms, the intended Outcome(s)."[13] The context describes the environment within which change occurs, the intervention is what influences a change, the mechanism is triggered by the intervention and this produces the outcome.[13]

Table 3.3 Context, Intervention, Mechanism, Outcome

Context	▪ Clinical guidelines require updating to maintain relevancy.
Intervention	▪ International or national groups provide methods guidance (in published handbooks and/or peer-reviewed articles) for developing and updating clinical guidelines, as well as prioritising clinical guidelines for updating.
Mechanism	▪ Clinical guidelines considered for updating (includes full, modular, rapid updates). ▪ Tools or guidance available to support prioritisation.
Outcome	▪ Description of update (or retirement) process (including roles and responsibilities at each stage) o types of update that exist o criteria used to determine if update necessary o process for retiring a guideline o criteria to prioritise which guideline is updated first o criteria to prioritise which clinical questions within a guideline are updated o evidence synthesis methodologies used to update clinical questions o dissemination of updated guideline o resources required to undertake update o differences between review process for updated guideline verses original guideline o differences between approval and endorsement process for updated guideline versus original guideline ▪ Evaluation of the process o usability and or critique of the updating methodology o timeliness, that is, specific processes that enable a more efficient and timely update.

The types of publications eligible for inclusion will be:

- methodological handbooks that provide updating guidance, including prioritisation methods, for clinical practice guidelines
- peer-reviewed articles that describe or have implemented updating guidance, including prioritisation methods.

Due to changes in process and methodologies in guideline development in the last 10 years, only publications from 2011 onwards will be considered for inclusion; publications published before 2011 will have been included in the index documents,[10, 12] as described in section 3.1 but will not be included in this review.

3.3 Exclusion criteria

The following exclusion criteria will be applied:

- Disease-specific publications (handbooks and or peer-reviewed publications which describe, or have implemented, guidance for updating disease-specific guidelines).
- Editorials/commentaries/opinion pieces.
- Abstracts only.
- Animal studies.
- Non-English language publications.

3.4 Selection of eligible publications

Methodological handbooks will be identified through searching the websites of eligible organisations (see Table 3.1) and through screening the methodological handbooks included in the index document.[12] This will be done by one reviewer and relevant handbooks will be imported into Endnote (Version X8). Imported handbooks will be reviewed by a second reviewer to confirm their eligibility.

All citations identified from the collective search strategy (see Appendix 1), and through screening the peer-reviewed articles included in the index document,[10] will be exported to EndNote (Version X8) for reference management, where duplicates will be identified and removed. Using Covidence (www.covidence.org), two reviewers will independently review the titles and abstracts of the remaining citations to identify those for full-text review. The full texts will be obtained and independently evaluated by two reviewers applying the defined inclusion and exclusion criteria. Where disagreements occur, discussions will be held to reach consensus and where necessary, a third reviewer will be involved. Citations excluded during the full-text review stage will be documented alongside the reasoning for their exclusion and included in the PRISMA flow diagram.

3.5 Data extraction and management

Data will be extracted from methodological handbooks by one reviewer and checked for accuracy and omissions by a second. Where disagreements occur, discussions will be held to reach consensus and where necessary, a third reviewer will be involved. Data extraction will be conducted in Microsoft Word, using a data extraction form (Appendix 2). The data extraction form will be piloted first and refined as necessary.

Peer-reviewed articles will not be the primary data source for this systematic review; the primary data source is most likely to be the methodological handbooks. However, in addition to signposting to methodological handbooks, and providing supplemental data relating to update and prioritisation processes, peer-reviewed articles may also provide usability and process evaluation data (relating to the associated handbook); these data will be extracted (see Appendix 2).

3.6 Quality appraisal

Methodological handbooks will be quality appraised independently by two reviewers and any disagreements will be resolved by deliberation, or if necessary, a third reviewer. In the absence of an appropriate quality appraisal tool, quality will be assessed using the GIN-McMaster Guideline Development Checklist, which is a checklist of items to consider during the development of guidelines. Specifically, we will use the six criteria relating to updating guidelines.[14] These six criteria are:

1. Set a policy, procedure and timeline for routinely monitoring and reviewing whether the guideline needs to be updated.
2. Decide who will be responsible for routinely monitoring the literature and assessing whether new significant evidence is available.
3. Set the conditions that will determine when a partial or a full update of the guideline is required.
4. Make arrangements for guideline group membership and participation after completion of the guideline.
5. Plan the funding and logistics for updating the guideline in the future.
6. Document the plan and proposed methods for updating the guideline to ensure they are followed.[14]

Methodological quality of peer-reviewed articles will be independently assessed by two reviewers. Depending on study design an appropriate version of the Newcastle-Ottawa Scale[15] or the Appraisal tool for Cross-Sectional studies (AXIS)[16] will be used. The tools will be piloted first on a small number of included studies, and modifications made if needed, before standardising for the remaining studies. Any disagreements will be resolved by deliberation or, if necessary, a third reviewer.

3.7 Data synthesis

As the main data to be extracted for this review is descriptive in nature a narrative synthesis will be undertaken.

3.8 Timeline

It is estimated that this review will require four months to complete following agreement of the protocol. These timelines are based on preliminary scoping searches of the literature and dependent upon available resources. The timelines are presented in Appendix 3.

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Appendix 1: Search strategy

Database: Medline (EBSCO) **Run: Tuesday, July 27, 2021 8:45:21 AM**			
#	**Query**	**Limiters/Expanders**	**Results**
S1	TI ((updat* or up-to-date or up to date) N8 (guideline* OR guidance OR priorit*)) OR AB ((updat* or up-to-date or up to date) N8 (guideline* OR guidance OR priorit*))	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	12,099
S2	TI (methodolog* OR handbook*) OR AB (methodolog* OR handbook*)	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	350,978
S3	(MH "Guidelines as Topic+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	168,963
S4	(MH "Evidence-Based Medicine+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	75,074
S5	S2 OR S3 OR S4	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	572,842
S6	S1 AND S5	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	4,913
S7	PT guideline OR practice guideline	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	159,011
S8	S6 NOT S7	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	1,127
S9	S6 NOT S7	Limiters - Date of Publication - 20110101-20211231	833
S10	S6 NOT S7	Limiters - Date of Publication - 20110101-20211231 Expanders - Apply equivalent subjects Narrow by Language - English	765
Database: Embase 1974 to 2021 July 26 **Date run: Tuesday, July 27, 2021 10:40AM**			
#	**Query**	**Results**	
1	((updat* or up-to-date or up to date) adj8 (guideline* or	17,644	

	guidance or priorit*)).ab,ti.	
2	(methodolog* or handbook*).ab,ti.	507,558
3	*evidence based practice/	10,010
4	2 or 3	516,891
5	1 and 4	1,258
6	limit 5 to yr="2011 -Current"	1,014
7	limit 6 to (conference abstract or conference paper or "conference review")	300
8	6 not 7	714
9	limit 8 to English language	639
Database: The Cochrane Library **Date Run: Tuesday, July 27, 2021 9:56AM**		
#	**Query**	**Results**
1	(updat* NEAR/8 (guideline* or guidance or priorit*)):ab (Word variations have been searched)	444
2	MeSH descriptor: [Guidelines as Topic] explode all trees	1,928
3	MeSH descriptor: [Practice Guidelines as Topic] explode all trees	1,640
4	MeSH descriptor: [Evidence-Based Medicine] explode all trees	906
5	(methodolog* or handbook*):ab (Word variations have been searched)	22,038
6	#3 OR #4 OR #5	24,384
7	#1 AND #6 with Cochrane Library publication date Between Jan 2011 and Jan 2021, in Cochrane Reviews, Cochrane Protocols, Special Collections	10

Appendix 2: Data extraction templates

Data extraction for updating methods guidance

Guideline identification	
Organisation	
Year	
Country	
URL	
Title of the publication	
Description of the update/retirement process	
What types of update exist?	
What criteria are used to determine if an update is necessary, and if it is necessary, the type of update is indicated? Include whose role/responsibility it is to do this.	
If a guideline is to be retired, what is the process for this and where is it stored? Whose role/responsibility it is to sign-off retired guideline?	
Of the guidelines scheduled to be updated, are there any criteria used to prioritise which guideline to update first? If yes, please describe. Include whose role/responsibility it is to do this.	
Once a guideline has been prioritised for updating, are all clinical questions within that guideline updated? If not, what criteria are used to prioritise clinical questions within a guideline that has been prioritised for updating? Include whose role/responsibility it is to do this.	
What evidence synthesis methodologies are used to update the clinical questions prioritised for updating? Include whose role/responsibility it is to do this.	
When the guideline has been updated, how is the update disseminated? Include whose role/responsibility it is to do this.	
What resources are required to undertake update and who decides this?	
Is the process of reviewing the updated guideline different to that of the original guideline? If so, how is this process different?	
Is the process of approving and endorsing the updated guideline different to that of the original guideline? If so, how is this process different?	
Notes	
Reviewer notes	
Associated peer-reviewed article(s)	

Data extraction template for process evaluations

Publication identification	Publication description	Process evaluation (as reported by authors)	Reviewer notes	Associated handbook(s)
Authors (year): Organisation: Country: DOI:	Design: Objective:	Usability/critique: Timeliness:		

Appendix 3: Project timeline

Project Task	Resources	Duration (weeks)	Aug 2021 (week ending)				Sep 2021 (week ending)				Oct 2021 (week ending)					Nov 2021 (week ending)				Dec 2021 (week ending)			
			6	13	20	27	3	10	17	24	1	8	15	22	29	5	12	19	26	3	10	17	24
Grey literature searching	1	1																					
Database search	1	1																					
Screen titles and abstracts	2	1																					
Full text review	2	1																					
Data extraction	2	5																					
Write-up of full report	1	4																					
Final report (review)	2	2																					

Proposed start date: 24 August 2021

Estimated duration: 15 weeks

Estimated end date: 3 December 2021