Principles for marking and redacting confidential information in technology appraisals and highly specialised technologies evaluations

24/04/2023

1. Who sees which documents and when?

Table 1.1 Unredacted documents and files

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| Document or file | Who | When  |
| Unredacted company and non-company submission documents.This includes all documents in response to clarification, technical engagement (when included in the process) and addenda.These company submission documents are included in the committee papers. | * NICE staff
* External assessment group (EAG)
* Committee members without conflicts of interest and who have signed a confidentiality agreement
* Patient and clinical experts who have been formally selected and signed a confidentiality agreement
* NHS commissioning experts attending the committee meeting
 | * NICE staff and EAG: at submission to NICE
* Committee members: 1 to 2 weeks before the committee meeting
* Patient, clinical and NHS commissioning experts: 1 to 2 weeks before the committee meeting, or at technical engagement (when included in the process)
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| Methodological appendices to company submission B. | * NICE staff
* EAG (the EAG adheres to the company’s confidential marking if it refers to data from these appendices in its report)
* Committee members without conflicts of interest and who have signed a confidentiality agreement
 | At submission to NICEThese are sent to committee members as separate documents to the committee papers |
| Unredacted company model (and updated versions including EAG scenarios). | * NICE staff
* EAG
* Committee members without conflicts of interest and who have signed a confidentiality agreement
 | At submission to NICE.This is sent to committee members as a separate file to the committee papers |

Table 1.2 Redacted documents and files

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| Document or file | Who | When |
| Model (on request, stakeholders receive conditions of use).Committee papers. For the first committee meeting, these include:* Company submission B
* Non-company stakeholder submissions
* Clarification responses from company
* EAG report (with any updates after factual accuracy and confidentiality marking check by company)
* Company’s factual accuracy check of EAG report
* If applicable, technical engagement responses and EAG critique of these responses
* Addenda submitted over the course of the evaluation
* Committee slides

Committee papers. For the second committee meeting, these include:* Company draft guidance response
* Consultee draft guidance response
* EAG draft guidance response critique
* Committee slides
 | All stakeholders | If technical engagement is included in the process stakeholders will see the company submission and EAG report at this point. The model may be requested at technical engagement if it happens, or after the committee meeting when draft guidance is producedIf there is no technical engagement, stakeholders will see Committee papers: * from 2 weeks after the committee meeting when draft guidance is produced, or
* about 4 to 5 weeks after the committee meeting if final draft guidance is produced.
 |
| Committee papers (as above) | Public  | Published on NICE website 1 week after release to stakeholders. |

1. What is redactable and non-redactable?

Table 2.1 Which categories of data and other information in the submission are redactable and non-redactable

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| Category | Redactable | Rationale |
| Methods used to conduct a study or to analyse data from a study | No | Methods information is required to understand how model inputs are derived. |
| Clinical data that is available in the public domain | No | Information that is publicly available is not considered confidential.  |
| Clinical data not yet in the public domain but either:* awaiting publication, including in a journal or
* will be released into the public domain by regulatory authorities
 | No | To avoid redaction of data that will subsequently be available and when publishing in committee papers will not jeopardise publication elsewhere. The International Committee of Medical Journal Editors (ICMJE) recommendations on overlapping publications state that it ‘does not consider results or data contained in assessment reports published by health technology assessment agencies, medical regulators, medical device regulators, or other regulatory agencies to be duplicate publication’. |
| Clinical data that has not been made publicly available and for which there is no plan for the data to become publicly available | Yes, except for minimum reporting requirements.Data collected within NHS clinical practice as part of a managed access agreement cannot be considered confidential unless it meets other criteria, for example it allows for subject identification. | In recognition that there will be unpublished clinical data that will be confidential. However, to allow transparent reporting of decision making, NICE has outlined minimum reporting requirements for data which is likely to be fundamental to committee decision making (see table 3.1). Clinical data should be treated as clinical data without a publication plan if:* there is clinical data awaiting first public presentation at a congress that is scheduled to take place after documentation from NICE would be released to the public, and
* this data is not awaiting publication in a journal or within marketing authorisation documentation.
 |
| Data from real-world evidence studies that has not been made publicly available and for which there is no plan for the data to become publicly available. | Yes (if collected by company then minimum summary information should be provided).The confidentiality requirements of third-party sources of data will be adhered to. | See the above rationale for clinical data that has not been made publicly available and for which there is no publication plan. |
| Company’s indirect comparison that has not been made publicly available and for which there is no plan for the data to become publicly available | Yes, except for minimum summary information. | It is recognised that indirect comparisons may be specific to the decision problem for NICE evaluations. Assessing the benefit of a technology compared with its comparators and the uncertainty around these comparisons is fundamental to committee decision making. NICE has outlined the minimum reporting requirements for indirect comparisons outcomes to allow transparent reporting of committee decision making (see table 3.1). |
| Critical appraisal of clinical studies and indirect comparisons (for example, of the validity of methodology and assessment of bias and uncertainty) | No | Critical appraisal is not considered to be confidential information and will not be redacted. This applies to critical appraisals carried out by both the company and the EAG. |
| Data derived from clinical opinion | No | Clinical opinion may vary and it is vital to have transparent discussion. This includes the outcome of expert elicitation. |
| Assumptions which are not based on empirical data | No | The committee’s discussion on validity of assumptions needs to be described transparently. |
| Data which is commercially sensitive or allows back-calculation of data which is commercially sensitive | Yes | Please see guidance on how this may be applied in table 3.1. |

1. Data and information which is fundamental to committee decision making and the minimum reporting requirements

A committee considers the generalisability, uncertainty around and plausibility of parameters included in the economic model in its decision making. Committees also consider the plausibility of modelled outcomes and cost-effectiveness estimates to make the recommendations.

Data which is fundamental to committee decision making and is typically discussed in the committee meetings is shown in table 3.1. If this data is unpublished and not awaiting publication, please adhere to the reporting requirements outlined in table 3.1 to allow transparent reporting of committee decision making. In general, this means not redacting the data listed under ‘standard reporting requirements’. However, if there are reasons why this data is commercially sensitive (for example, the data would allow demonstrable back-calculation of confidential pricing), please provide the minimum reporting listed under ‘minimum reporting requirements’. In these instances, the company should give a clear rationale explaining how the data could be used and why it would be a commercial risk to the company if it is not redacted. This rationale should consider when the document containing the information will be released by NICE (see section 1 on who sees which documents and when).

Table 3.1 Standard reporting and minimum reporting requirements for clinical data and information

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| --- | --- |
| Standard reporting requirements These should not be redacted when possible | Minimum reporting requirementsThese should be used when there is a demonstrated risk to the company of releasing data specified in the standard reporting column. When these minimum reporting requirements list a descriptive summary of the data, this should be presented in addition to the data which is highlighted as confidential |
| Baseline and patient characteristics of whole trial population informing the company’s decision problem. | This data for the whole trial population should be reported in full because it is expected to be published within marketing authorisation documentation. |
| Baseline and patient characteristics of all subgroups included in the company’s decision problem. This includes:* subgroups outlined in the final scope issued by NICE for whom the company have presented data
* data for the population covered by the marketing authorisation, if the trial population is broader than that covered by the marketing authorisation
* the subgroup for whom the company are positioning the technology if this population is narrower than that covered by the marketing authorisation.
 | For the subgroups, a description of any imbalances between treatment arms or differences between the subgroups and whole trial population should be provided. |
| Primary outcomes (including for subgroups in the company’s decision problem, if relevant) at the data cut included in the model. | Primary outcomes at the data cut which inform the regulatory submission should be reported because they are published within marketing authorisation documentation. |
| Relative treatment effect and measure of precision such as 95% confidence interval. | If data from a later data cut than what informed the marketing authorisation is used in the model and is marked as confidential, then the unredacted data cut informing the marketing authorisation should also be presented alongside the later data cut.Commentary should be provided on similarities or differences between the point estimates and confidence intervals from publicly available versus confidential data cuts.For subgroup data that will not be reported within marketing authorisation documentation, an accompanying description of the direction of treatment effect and how the point estimate and measure of precision compare with the data for the whole population should be provided alongside the confidential information.  |
| Kaplan–Meier data (including extrapolations), if relevant.  | If Kaplan–Meier data from a later data cut than what informed the marketing authorisation is used in the model and is marked as confidential, then the unredacted data cut informing the marketing authorisation should also be presented alongside the later data cut.For overall survival extrapolation, the proportions of people alive at a range of time intervals over the time horizon should be provided to enable discussion of plausibility of this modelled outcome. |
| Secondary outcomes at the data cut that inform the modelling. | Follow the principles for the primary outcomes.  |
| Adverse events including death. | The equivalent data to that reported in marketing authorisation documentation is expected. |
| Indirect treatment comparison:* an overview of the methodological approach, including any matching of data or adjustments
* number of patients included in studies
* patient characteristics from included studies
* commentary on potential heterogeneity or sources of bias
* outcomes (for example, comparative efficacy) with measure of precision such as 95% credible interval, if relevant.
 | All methodology and critical appraisal should be reported. If there is a demonstrated reason why numerical outcomes are confidential then an accompanying statement of direction of treatment effect and commentary on the measure of precision should be provided. For example, the width of the credible intervals and if the credible intervals cross parity.For adjusted outcomes, an accompanying description of how these outcomes differ from unadjusted outcomes should be provided. |
| Utility values (by health state, intervention utility increments or decrements, and disutility for adverse events) which are used in the model. | Quality of life data collected in the trial may be redactable. UK-specific utility values (have used UK tariffs) that are used in the model cannot be redacted.  |
| Severity estimates:* absolute quality-adjusted life-year (QALY) shortfall and estimates of total QALYs underpinning this estimate
* proportional QALY shortfall and estimates of total QALYs underpinning this estimate.
 | These cannot be redacted because they inform the application of a QALY modifier and are fundamental to committee decision making. |
| Undiscounted incremental QALYs (for highly specialised technologies). | These cannot be redacted because they inform the application of a QALY modifier and are fundamental to committee decision making.  |
| Incremental cost-effectiveness ratios (ICERs). | ICERs may be marked as confidential if:* there is a comparator patient access scheme (PAS), in which case the ICER (with comparator list prices) is not the decision-making ICER and will not be presented publicly in committee meetings
* it is anticipated that there will be a new or increased company PAS over the course of an evaluation and publishing the pre- and post-PAS amendment would allow back-calculation of the PAS.
* redacting ICERs allows other numerical data which is fundamental to committee decision making to not be marked as confidential.

If ICERs are redacted incremental QALYs should be unredacted.Please note NICE documentation will include a statement about whether the ICER is above or below a decision-making threshold. |
| Net health benefit. | If showing a net health benefit would allow back-calculation of a PAS then, as a minimum, an accompanying statement on whether the net health benefit is positive or negative should be reported. |
| Incremental costs (in cost-comparison analyses). | In cost comparisons the incremental costs may be redacted if reporting them would allow back-calculation of a PAS. An accompanying statement about whether the analyses show that the new technology is cost-saving or cost-incurring compared with its comparator should be provided. |