Guide for quality assurance and governance of NCAPOP algorithms and analytical models

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1. Scope

The intention of this guide is to give NCAPOP providers a starting point from which to assess their own **quality assurance (QA) and governance processes in relation to algorithms and analytical models that have an impact on patient care**. NCAPOP providers must assure themselves, HQIP and relevant stakeholders that their own internal quality assurances processes are high quality, have integrity and are robust.

The title of the guide refers to 'algorithms and analytical models', but the principles within this guide will likely apply to any type of analytical/statistical/coding work which has the potential to have a direct or indirect impact on patient care. It is more important to consider the need for QA and governance of this type of work according to the potential impact rather than based on the categorisation of the work.

Please note that the development and implementation of risk tools, algorithms and models designed as clinical decision aids for direct care may require accreditation with the MHRA and so would require discussion and agreement with HQIP prior to development.

What is out of scope for this guide is the technologies, methodologies and statistical techniques that underpin the work. These need to be considered separately by NCAPOP providers and with appropriate expertise.

2. Background

HQIP conducted a survey in December 2023 to establish a clear picture of the use of risk prediction across the NCAPOP. The survey found that:

- Only a few providers are using risk predicting tools.
- Many providers are using case-mix risk adjustment models.
- Beyond the scope of the survey on risk prediction, there are many other types of analytical/coding work.

All of the above have the potential to impact patient care directly or indirectly.

A Methodology Advisory Group (MAG) session was set-up to share best practice and lessons learnt, and with the aim of co-creating this guide to make it useful to NCAPOP projects.

As a starting point for this guide, existing public sector recommendations on best practice were used including:

- Review of quality assurance of Government analytical models (Macpherson 2013) and
- Quality assurance of models: a guide for audit committees (NAO 2023)

3. Guide

HQIP developed this guidance in collaboration with providers at the MAG virtual meeting.

For brevity, we're using the acronym MPIP (models potentially impacting patients), to cover any algorithm/modelling/analytical/statistical/coding work that has a direct or indirect impact on patient care.

For each consideration below, providers should determine in advance whether they have a consistent approach for the governance and QA of MPIPs, or a context-specific approach (e.g. based on risk level, with more rigorous expectations where there is higher risk).

There are some fundamental principles which providers need to consider throughout all aspects of their approach: risk identification, assessment, escalation and mitigation; the need to include a clinical perspective in understanding the implications of a risk; root-cause-analysis to get to the contributing factors; and the need for continuous quality improvement (the approach can be refined on an ongoing basis).

3.1 Consideration 1:

The governance required:

1. There should be a single Senior Responsible Owner (SRO) for each MPIP through its lifecycle. Consider who would be best placed in this role. For example, it might be a methodologist or a clinical lead. Requirements:
    a. One key lead with responsibility
    b. Methodology expertise to ask correct questions
    c. Need to ensure individual / or support of individual that has confidence and is of appropriate seniority in order to escalate issues as needed
2. SRO roles and responsibilities include:
    a. A named SRO for the MPIP in the team
    b. A clear set of expectations for the SRO; these should be written in an internal policy
    c. Sufficient expertise to understand the MPIP and sufficient seniority to challenge the team if they are not fully assured that QA has been thorough
    d. Clarity on the actions required if the SRO is not assured by the governance and due diligence processes the MPIP has been through when designing or refreshing it
    e. Oversight of the quality assurance and sign-off processes the MPIP needs to go through and where audit trails are recorded
    f. Owning a documented process for when the SRO role will be activated e.g. what types of MPIPs require this oversight role and how will the decision be documented
    g. Setting the escalation approach (e.g. if an issue is detected in the MPIP during the QA, who is involved and what are the anticipated timelines for dealing with the error correction)
3. Risk and issues registers:
    a. Clear operational definitions must be used to adequately describe the risk on the risk register

b. Risks and issues should be documented on the host organisation's Board risk and issues registers
c. Risks and issues should also be documented on the HQIP Contract Review Meeting risk and issues registers and should follow the HQIP escalation guidance in the Provider Technical Manual
d. Risks and issues must be correctly ascribed (e.g. 'risk': found before release and put right by putting appropriate mitigations in place; 'issue': QA and due diligence processes failed and the event actually happened)
e. The audience should be considered when documenting risks and issues (what information the host organisation Board needs to know might be different from what HQIP need to know)
f. A risk assessment framework should be used appropriately
g. Learning from incidents should be fed back into management processes including risk assessment

4. Raising concerns and board level oversight:
    a. Anyone working on the MPIP should be able to (and feel confident to) raise concerns (with clear channels or points of contact); background work should be conducted to ensure the escalation process is fully understood by all relevant staff
    b. Decision-making on which groups (such as Steering Groups or Clinical Reference Groups) need to be involved in this governance process, to what level of detail and at what point(s). Consideration should be given to how these groups will have the necessary expertise to understand the process (an expert member or advisor may be needed)
    c. Consider in organisational policy/process whether there will be general oversight from, or assurances given to, any other senior staff (such as CEO), e.g. an annual update providing assurance that good quality governance and QA is in operation across all MPIPs (perhaps signed by SRO)
    d. Consider whether external organisations, stakeholders and partners would ever need to be notified and if so, in what circumstances
5. HQIP need to be assured of the governance associated with the MPIP (this may depend on risk register categorisation). This is about working in partnership and using the contract review meeting mechanism to explore risks and issues, adopting a higher level of scrutiny as needed
6. Consider how the governance processes will be communicated externally to key stakeholders and publicly. For any communications, there should be preparation and input from key stakeholders. Consideration should be given to whether communication with the MHRA is required

3.2 Consideration 2:

The level and type internal QA required:

1. There should be:
    a. Version control logs

    b. File name conventions
    c. Peer checking
    d. Checks on potential human transcription errors
    e. Analytical assurance plans/logs (approved by SRO)
    f. Checks for rounding errors
    g. Checks for disclosure risk relating to small numbers
    h. Use of simulated datasets to check MPIP produce correct results
2. Each time a change is required to the MPIP, QA and due diligence should be applied
3. The project must assure itself and HQIP that there is sufficient expertise to carry out the QA tasks
4. Consider how frequently data cleaning might need to take place
5. Consider whether using a mixture of software (e.g. R/Stata/SPSS) might provide helpful comparison (can flag problems if there are major discrepancies)
6. If there are known to be gaps in the role-specific expertise required for the QA due to sickness or vacancies, then a contingency plan must be documented to ensure the role-specific tasks have taken place. In the absence of this the MPIP cannot be released for use
7. There should be processes in place to rapidly deal with reported errors that take into account the seriousness of the problem. Some errors are more significant than others, and therefore may need different processes
8. A culture which prioritises QA, and where all staff feel enabled to raise potential risks and issues, needs to be embedded; this could perhaps be measured using anonymous staff surveys
9. If there are time constraints with the QA process, these should be escalated and raised in the risk register, with adequate mitigation put in place. The SRO should sign-off the mitigation plans

3.3 Consideration 3:

The level and type of external QA required:

1. Consideration should be given to carrying out some/all of the following:
    a. Independent analytical assurance (this might include somebody external to the team but within the same host organisation; paid-for external consultation; or reciprocal peer review across NCAPOP projects in different organsiations)
    b. External testing / user acceptance testing (usually this would be with intended users and might include: use of test patients and checks for extreme values and ‘fringe cases’)
    c. Wider piloting following initial testing
2. With regard to 1a above, analysts/statisticians may want to consider creating an informal network with colleagues working on NCAPOP projects in other organsiations, with the aim of helping each other via peer review and sharing best practice and lessons learnt

3. In addition to user acceptance testing and piloting, there should be opportunities for ongoing review and feedback by users/participants, e.g. participant review of results, with encouragement of reporting of potential errors by any user, even if not an official tester/piloter
4. There should be checks to ensure that there is no difference between what the project team can see and what external people can see (e.g. ensuring that any functionality is not potentially different when using different types of login accounts, web browsers or operating systems)
5. If relying on an externally published MPIP: processes should be put in place for testing the application in the context of the NCAPOP project and the team should set up a means for being notified about any updates to the external MPIP to ensure old versions are not in use
6. It should be clear to external testers how to report findings back; who will receive this information and how will it be used to inform not only any specific issues identified but also any possible wider issues that might need checking (e.g. if X has been identified it might mean Y and Z also need to be checked). A touchpoint meeting might be required to go over feedback in detail and to ensure it is fully understood. This would ideally include the clinical lead/team, so that there is a clinical appreciation of external findings, e.g. if there were fringe cases for which the MPIP did not work well
7. If external QA reveals something that should have been picked up by internal QA, the internal QA process should be thoroughly reviewed

3.4 Consideration 4:

How to get assurance for the work of sub-contractors:

1. There should be standard operating procedures in place between the NCAPOP provider and their sub-contractor(s). These need to be reviewed with specific attention to MPIP work, and should include all relevant requirements from Considerations 1-3 above. Ideally these should be established before a sub-contract is signed.
2. Sub-contractors should be involved in early discussions (e.g. around risks) even if their role doesn't come until later in the process
3. It is also important to have ongoing regular meetings, usually at least quarterly, but with consideration given to whether these should be more frequent at peak times of work.
4. Consideration should be given to having some/all of the following:
    a. seeking formal assurance of sub-contractors' QA processes (e.g. via contract review meetings and/or document to complete) with clarity on when this will occur (e.g. specific checks after any changes and a general check annually)
    b. NCAPOP provider conducting own QA on sub-contractor's work
    c. combined QA processes
5. There should be a clear process for how errors will be dealt with if identified, and in particular if a 'stop moment' should be applied

6. Sub-contractors must feel enabled to raise potential issues even for parts of work they have not completed themselves
7. Budget considerations need to be taken into account when determining all of the above (i.e. how to ensure the sub-contractor can deliver against these requirements within their existing budgets)
8. Formal documentation (shared and agreed with subcontractors) of all of the above points should prove helpful

4. Conclusion

HQIP is grateful to all providers who participated in helping to compile and co-create this guidance document. Most especially, HQIP is keen to share lessons learnt and disseminate good practice guidance for NCAPOP providers. There are implications for consideration across the NCAPOP portfolio but also the wider NHSE landscape and other programmes within NHSE.

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