Developing a Proactive Quality Assurance/Quality Improvement (QA/QI) Program

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Problem Statement

When addressing compliance issues or concerns, organizations tend to take a reactive approach (responding case-by-case) rather than a proactive approach (addressing a concern before it's a problem/issue) due to limited resources (staff, goals, time, funds) and a myriad of other organizational priorities. The challenge of a reactive or “band-aid” approach is that the underlying issue(s) are often not addressed or go unnoticed until a serious issue arises. A successful QA/QI program adopts and maintains a proactive approach towards compliance issues and concerns.

Program

This poster guides readers through:
1) An assessment of their organization’s current approach to QA/QI
2) Developing a proactive QA/QI program
3) Common pitfalls that can revert back to a reactive program
4) Helpful tips to maintain a proactive program

The Value of Adopting a Proactive Program

- Improves the odds of early identification and management of compliance issues and concerns
- Allows for better planning and scheduling of QA/QI reviews and addressing current issues and concerns
- Fosters an environment that encourages early reporting of compliance concerns or issues
- Ideally leads to less noncompliance through recognition of potential compliance concerns and better management of noncompliance issues.

Assessing An Organization’s Current Approach to QA/QI

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<tr>
<th>Question</th>
<th>True</th>
<th>False</th>
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<td>Noncompliance concerns and issues are regularly identified and reported to the IRB by the PI/study team AND during QA/QI reviews.</td>
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<td>Noncompliance issues, concerns or reviews always have an educational component built in or are requested of the study team and/or PI (i.e., a Corrective and Preventative Action Plan; CAPA).</td>
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<td>QA/QI reviews are scheduled and conducted on a regular and ongoing basis regardless if additional or other important tasks are also priority.</td>
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If the answer is “False” to any of the above questions, the organization’s current QA/QI program may be reactive as opposed to proactive.

Developing a Proactive Program

Implementing an effective proactive QA/QI program relies heavily on early and frequent education and communication. A proactive program emerges from an environment that is fostered to encourage the early recognition and reporting of noncompliance concerns or issues before they become serious or continuing noncompliance.

1. Use any/all opportunities as educational opportunities (e.g., meetings with a Principal Investigator (PI)/study team about a topic should include a copy of the relevant policy, including the team on a list of educational sessions offered by the IRB, asking if there are other concerns the QA/QI person can clarify, listening to feedback and providing feedback to the IRB, etc.)
2. Establish clear policies and procedures and offer tools/templates when possible. Develop flowcharts clearly delineating policies and processes so that they are transparent and easy to follow. Solicit feedback of the above from study staff and PI’s from recent compliance cases.
3. Keep QA/QI reviews moving forward towards closure to allow adequate time to conduct educational sessions and address new incoming compliance issues and concerns.
4. At on-site reviews, provide a brief information sheet of upcoming educational sessions, common audit findings, Frequently Asked Questions (FAQ’s), the names of key office contacts names, the location of policies, etc.
5. At the start of any QA/QI review, briefly meet with the PI and study team to put QA/QI members’ faces to names and establish an atmosphere of help and assistance.
6. Develop or improve upon a Frequently Asked Questions (FAQ) webpage to include questions and answers that the IRB and QA/QI members frequently receive.
7. Use a recent noncompliance case as a springboard to contact the relevant Department Dean/Chair to ask for his/her support of a brief presentation at an upcoming departmental meeting to discuss noncompliance issues.
8. When noncompliance is identified, hold a targeted educational session with the PI and study team to specifically review the issues and answer questions.
9. Post de-identified and generalized educational presentations from #6 & #7 on your webpage.
10. Frequently review the availability of realistic resources (e.g., QA/QI staff time, rolling in IRB staff, funds (if available), any electronic medium to get important or frequently misunderstood information out such as in the footer of e-mails or e-mail bounce-back messages, etc.)

PITFALL: Several compliance concerns come in at the same time. Slipping into “panic” mode.

PITFALL: One QA/QI review “spiders” into several or the size of the review has been greatly or unexpectedly underestimated.

PITFALL: Getting “stuck” on one review for too long.

PITFALL: Losing focus.

HELPFUL TIP # 1: Triage incoming issues or concerns by the level of severity; most serious concerns and issues first.

HELPFUL TIP # 2: Do not lose sight of the scope and time assigned for the QA/QI review. Remember the specific concern that brought you to the QA/QI review. Do not get swayed from the purpose of the review. A follow-up review can be conducted at another time when the workflow has eased.

HELPFUL TIP # 3: Pull in qualified IRB personnel or IRB members to assist in conducting QA/QI reviews.

HELPFUL TIP # 4: Set aside weekly planning time to map out short-term goals (“on the burner”) and long term goals (“back burner”).

HELPFUL TIP # 5: Maintain a board or tracking spreadsheet to keep big ticket items in your sight to ensure movement forward each week.