PRO-AI in Healthcare: Participatory Protocol for Drafting Guidelines. A Proposal for a Tool of Responsive Regulation *

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1. Introducing Guidelines as a Tool of Responsive Regulation

Guidelines play a crucial role in the normative environment surrounding artificial intelligence (AI) in healthcare.[1] As soft law instruments, they do not carry formal binding authority,[2] yet their flexibility allows them to be particularly responsive to organizational and societal needs. Precisely because of this flexibility, guidelines can more effectively adapt to the evolving ethical, professional, and technological landscape than legislative solutions.[3] They are thus increasingly relied upon as tools to orient complex decision-making and to translate normative principles, such as transparency, responsibility, and equality, into practice.[4]

This approach resonates with the theory of responsive law, first introduced by Philip Selznick, who defined it as a system of law that is capable of reaching beyond formal regularity and procedural fairness to substantive justice. That achievement, in turn, requires institutions that are competent as well as legitimate".[5] Responsive law, as later developed by Nonet and Selznick, starts from the assumption that if a legal order is to lend "affirmative authority to purpose […] the focus of legal analysis must be the social patterns and institutional arrangements that frustrate the achievement of legal ends, not the

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[1] K. MURPHY, E. DI RUGGIERO, R. UPSHUR, *et al.*, *Artificial intelligence for good health: a scoping review of the ethics literature*, in *BMC Med Ethics*, 22, 1, 2021, 1-17.

[2] On the ambiguous yet increasingly pervasive nature and normative force of soft law, see R. BIN, *A discrezione del giudice*, Milano, 2014, 38-39. Bin describes soft law as part of a "twilight world" ("mondo crepuscolare"), situated between quasi-contractual self-regulation typical of private law, and delegated norm-setting mechanisms aimed at integrating formal legislation. In this regulatory ecosystem, acts such as guidelines, best practices, codes of conduct, and self-regulatory instruments issued by private, hybrid, or public entities govern professional ethics, consumer rights, and intra-organizational conduct, often generating interpretive uncertainty for courts. Judges frequently confront questions such as: can a best practice serve as a legal basis for a financial interest? Should a code of conduct be read as a normative source or a private agreement? Does following professional guidelines shield one from civil or criminal liability? For further analysis, see V. DESANTIS, *L'avanzata del soft-law e l'arretramento della partecipazione democratica. Spunti e riflessioni sulle tendenze della normazione*, in *Nuove Autonomie*, 1, 2025, 428 ff.

[3] R. HAGEMANN, J. HUDDLESTON SKEES, A. THIERER, *Soft law for hard problems: The governance of emerging technologies in an uncertain future,* in *Colorado Technology Law Journal*, 17, 2018, 37 ff. A review of current legal frameworks in M. FASAN, *Regulating the use of artificial intelligence in the doctor-patient relationship? A primer on supranational and national legal frameworks*, in *BioLaw Journal – Rivista di Biodiritto*, 1, 2025, 193-211. See on this focus the conclusive remarks by V. DESANTIS, *Linee guida, intelligenza artificiale e medicina: riflessioni sintetiche*.

[4] See S. LARSSON, *On the governance of artificial intelligence through ethics guidelines*, in *Asian Journal of Law and Society*, 7, 3, 2020, 437-451.

[5] P. SELZNICK, *The Moral Commonwealth*, Berkeley, 1994, 336.

aggrieved individual *per se*",[6] Thinking of law as responsive, rather than autonomous or repressive, means understanding claims of right as opportunities for uncovering disorder or malfunction: "legal energies should be devoted to diagnosing institutional problems and redesigning institutional arrangements"[7].

Responsive law, therefore, is inherently adaptive: it embraces social pressure as a source of institutional learning, and it promotes community participation in lawmaking as a condition for democratic legitimacy and systemic efficacy. In this sense "new modes of supervision, new ways of increasing the visibility of decisions, new organizational units, new structures of authority, new incentives"[8] shall be the characteristic remedies of responsive law. Rather than focusing solely on enforcing existing legal rules, responsive law promotes cooperation between the community, government and institutions to achieve common goals, recognizing that collaborative efforts are critical to addressing complex challenges.[9]

In sum,

> "Responsive institutions preserve their essential integrity while taking into account new forces in their environment. Responsiveness strengthens the ways in which openness and integrity can support each other, even in the face of conflicts between them. Responsive institutions consider social pressures as sources of knowledge and opportunities for self-improvement. Responsive law is synonymous with a type of law that is adaptive to the dynamics of culture and civilization, which is not fixed".[10]

Building on this concept, Ayres and Braithwaite introduced the theory of responsive regulation, incorporating principles such as flexibility, purposive competence, participatory citizenship, and negotiation.[11] Their work highlights how regulation, rather than law narrowly conceived, provides the right level of abstraction and adaptability to govern emerging technologies like AI.

As Bennett Moses has noted, focusing on "regulation" instead of "law" offers important advantages when discussing how technology is governed. Regulation is at once "broader and narrower than law:" it includes guidelines and standards that fall outside classical legal definitions and encompasses decentered and informal mechanisms of control.[12] In the context of AI, this regulatory lens allows for more adequate responses to technological innovation, enabling less formal and more agile forms of rule-making that are particularly well-suited to dynamic fields like digital health.

In light of these theoretical foundations, this article presents a participatory qualitative protocol for stakeholder engagement in the drafting of healthcare AI guidelines. Based on the concept of responsive law and responsive regulation, the protocol aims to ensure that ethical, clinical, and legal concerns are addressed in a way that is collaborative, contextualized, and professionally

[6] P. NONET, P. SELZNICK, *Law and society in transition: Toward responsive law*, New York, 1978 (2nd ed. 2017), 106 ff.

[7] *Ibidem*.

[8] *Ibidem*.

[9] T. SUKMANA, Z.S. ASHARI, Y. DARMAWAN, *Responsive Law and Progressive Law: Examining the Legal Ideas of Philip Nonet, Philip Selznick, and Sadjipto Raharjo*, in *Peradaban Journal of Law and Society*, 2, 2023, 92-106.

[10] *Ibidem*.

[11] I. AYRES, J. BRAITHWAITE, *Responsive Regulation: Transcending the Deregulation Debate*, New York, 1992, 5.

[12] L. BENNETT MOSES, *How to think about law, regulation and technology: Problems with 'technology' as a regulatory target*, in *Law, Innovation and Technology*, 5, 2013, 4: "[Regulation] is capable of capturing 'soft law' that may be ignored by traditional definitions of 'law' as well as more distributed means of control".

grounded. As a matter of fact, there is a growing consensus, reflected in initiatives like the FUTURE-AI consortium, the Partnership on AI, and the Montréal Declaration on Responsible AI, that transparent, participatory, and qualitatively informed processes are essential to ensure that AI guidelines are responsive to real-world challenges, ethically and legally grounded, as well as actionable.

2. The Relevance of Participatory Approaches to Guidelines for AI and Healthcare

Developing guidelines through participatory qualitative processes is increasingly recognized as a best practice across fields such as AI-driven healthcare, digital health innovation, and broader health governance. A growing body of both peer-reviewed research and grey literature supports methodologies that involve purposive expert sampling, qualitative feedback collection, and stakeholder integration.

A 2020 research protocol[13] by Petkovic emphasizes that stakeholder engagement is now widely "accepted as a foundational element of trustworthy guideline" development. Institutions such as the World Health Organization (WHO) and the UK National Institute for Health and Care Excellence (NICE) explicitly recommend involving those affected by guidelines in their design and revision. The authors highlight both practical and normative justifications for engagement: including end-users (clinicians, patients, and policymakers) improves a guideline's relevance, transparency, and uptake since stakeholders "can also ensure that equity and human rights issues are taken into consideration and support the adoption of its recommendations into policy and practice", while also fulfilling what they describe as a "moral imperative": the people's right to be involved in decisions that may affect them. Importantly, they caution that "a lack of connection between guideline developers and those who use them often leads to controversy and uncertainty," whereas engaging guideline users can improve the uptake of recommendations. On this base, the same Authors developed in 2025 the GIN-McMaster Guideline Development Checklist (GDC) Extension for Engagement is a structured protocol designed to support the inclusion of diverse interest-holders throughout the health guideline development process. Its main goal is to improve the usefulness and acceptability of health guidelines, which play a key role in shaping clinical and public health practice. The checklist was developed through a three-phase mixed-methods study. First, ten key interest-holder groups were identified, such as patients, providers, and policymakers, and 26 co-leads were recruited to represent them. The process included systematic reviews on engagement methods, a survey with 195 responses, and 43 key informant interviews. The final checklist was developed through a consensus process involving the co-leads.[14]

Similarly, the 2024 report from the Partnership on AI,[15] a U.S.-based multi-stakeholder nonprofit, calls for inclusive design processes as critical for the development of ethical AI systems. It urges developers to "adopt inclusive research

[13] J. PETKOVIC *et al.*, *Protocol for the development of guidance for stakeholder engagement in health and healthcare guideline development and implementation*, in *Systematic Reviews*, 9, 2020, 1-11.

[14] J. PETKOVIC *et al.*, *The GIN-McMaster Guideline Development Checklist extension for engagement*, in *Journal of Clinical Epidemiology*, 181, 2025.

[15] T. KHAN, T. PARK, *AI Needs Inclusive Stakeholder Engagement Now More Than Ever*, in *Partnership on AI – Blog*, 2024, available at: https://partnershiponai.org/ai-needs-inclusive-stakeholder-engagement-now-more-than-ever/.

and design principles such as engaging diverse stakeholders to identify and mitigate biases" embedded in AI technologies. Particularly, the report emphasizes that early and sustained engagement with a broad range of actors, especially those from marginalized communities, helps to foresee and address risks and societal harms before they materialize. Stakeholder engagement, it argues, "opens up opportunities to foresee and manage risks… fosters awareness of social context, [and] drives development towards outcomes that are meaningful and relevant to a broad array of users".

These principles are also reflected in the work of the FUTURE-AI consortium[16] which offers a concrete example of participatory, cross-disciplinary guideline-making. Bringing together over 100 experts, including clinicians, computer scientists, ethicists, and social researchers, from more than 50 countries, the group conducted an "iterative, participatory process" combining literature reviews, a modified Delphi survey, and consensus-building workshops. Their goal was to define a common framework for "trustworthy AI" in healthcare. The final guidelines are organized around core values such as fairness, traceability, and explainability. The initiative's leaders underscore that the diversity and breadth of stakeholder input is precisely what makes the framework robust and globally relevant:

"Bringing so many international and multi-disciplinary perspectives together… is part of what makes this work unique. We hope such broad consensus will shed light on the greater good AI can bring… and help avoid problems before they ever impact patients." "To have a real impact at scale, such guidelines for responsible and trustworthy AI must be obtained through wide consensus involving international and interdisciplinary experts".

In another example, Mahl and colleagues conducted a Delphi study to develop ethical and operational principles for the use of AI in public health.[17] They employed purposive expert sampling to convene a panel of specialists in digital health, community engagement, and risk communication. Participants were drawn from 27 countries and included both academic scholars and field practitioners. By deliberately assembling diverse perspectives and conducting multiple rounds of feedback and iteration, the researchers fostered progressive convergence toward shared principles. The Delphi method, a structured, iterative process used to gather and refine expert opinions through multiple rounds of anonymous surveys or questionnaires, was particularly well-suited to this goal. The method is designed to build consensus among a panel of experts by systematically collecting feedback, synthesizing responses, and providing controlled feedback between rounds. According to the study, "two categories of experts were identified" and efforts were made to ensure diversity in discipline, sector, and geography.

Finally, the Montréal Declaration for a Responsible Development of AI[18] exemplifies a publicly engaged, bottom-up approach to guideline creation. Developed over a year-long participatory process, the initiative included 15 deliberative workshops involving more than 500 citizens, experts, and stakeholders. This process of co-construction was aimed at identifying shared values

[16] K. LEKADIR *et al., FUTURE-AI: international consensus guideline for trustworthy and deployable artificial intelligence*, in *BMJ*, 388, 2025: e081554.

[17] D. MAHL *et al.*, *Responsible artificial intelligence in public health: a Delphi study on risk communication, community engagement and infodemic management*, in *BMJ Global Health*, 10, 5, 2025: e018545.

[18] Montréal Declaration for a Responsible Development of Artificial Intelligence, 2018, available at: https://montrealdeclaration-responsibleai.com/the-declaration/.

and principles to guide the ethical development of AI. The resulting declaration articulates ten core values, such as autonomy, justice, well-being, and privacy, and is praised for its "strong democratic legitimacy" grounded in the input of both citizens and domain experts. This example demonstrates the ethical and political advantages of designing AI guidelines that are deeply rooted in community values and public reasoning.

It is then possible from this brief review to distinguish three principal models of participatory processes. One is a "public co-construction model" emerging in cases where participatory workshops with citizens and experts alike foster community guidelines with strong democratic legitimacy, as in the case of the Montréal Declaration. Another is "cross-disciplinary global consensus", as seen in large-scale international collaborations that bring together diverse professional communities to jointly shape guidelines grounded in shared principles of fairness, transparency, and explainability, as in the case of FUTURE-AI[19]. Finally, a "iterative experts engagement", where a small team of ethical, legal and policy experts develop a draft that is progressively refined through structured input from domain professionals, an approach exemplified by expert-iterative frameworks in public health, as in the case of the GIN-McMaster protocol. PRO-AI belongs to this last model[20].

3. The PRO-AI Protocol: A Proposal for Responsive Guidelines

This protocol proposes a structured, participatory process for the qualitative integration of stakeholder feedback in the development of AI and healthcare guidelines, ensuring that the final document reflects professional realities, ethical standards, and clinical/technical feasibility, according six step: 1) experts' selection; 2) distribution; 3) qualitative survey and comment collection; 4) feedback coding and themes; 5) feedback synthesis and integration; 6) internal and external validation.

3.1. Experts' selection

Experts and stakeholders should be chosen using purposive sampling to ensure a rich variety of perspectives. Purposive sampling "selects respondents most likely to yield appropriate and useful information" and explicitly aims to include specific kinds of experts who hold different, important views[21]. Importantly, inclusion and

[19] A further case of "cross-diciplinary global consensus" it can be considered the OECD Artificial intelligence and health workforce: perspectives from medical associations on AI in health (2024) described in this Issue by M. DAVERIO, *Linee guida con (e non solo per) i medici: le priorità emerse dalla recente survey OCSE – Artificial intelligence and health workforce: perspectives from medical associations on AI in* health, 2024.

[20] The GIN-McMaster Guideline Development Checklist Extension for Engagement (GDC Extension) can also be classified under the expert-iterative model, alongside the PRO-AI protocol. Both share core features such as structured methodologies, targeted stakeholder engagement, and a multi-step iterative refinement process aimed at producing context-sensitive, implementable guidance. However, while PRO-AI focuses specifically on AI in healthcare and adopts a closed distribution model prioritizing clinical and technical feasibility, as we will explain in section 3, the GDC Extension was developed through a broader engagement study and serves as a meta-guidance tool for enhancing stakeholder participation across various guideline development contexts. Its aim is to inform chairs, methodologists, and oversight committees in tailoring engagement strategies to diverse interest-holder groups, including patients and the public. Despite these differences, both tools exemplify developed frameworks rooted in expert consensus and iterative validation.

[21] S. KELLY, *Qualitative interviewing techniques and styles*, in I. BOURGEAULT, R. DINGWALL, R. DE VRIES (eds),

diversity criteria must guide selection. For example, the Partnership on AI Guidelines stress seeking feedback from diverse communities, including AI developers, socially marginalized groups and public agencies, to ensure all viewpoints are incorporated[22]. Specifically, in healthcare, participants shall be selected through a purposive sampling strategy to ensure diversity in expertise, practice context (e.g., hospital, university, healthcare institutions), and gender representation. Selection prioritizes professionals with documented experience in digital health innovation, ethical assessment of technology, or frontline interaction with AI tools.

3.2. Distribution of draft

A preliminary version of the guidelines is disseminated to the selected group of healthcare experts and institutions. These include clinicians across diverse specialties, bioethicists, hospital administrators, and representatives of professional medical associations. A different practice in guidelines protocol is to post the draft publicly and invite registered stakeholders to comment. For example, the UK National Institute for Health and Care Excellence usually shares the draft version of guideline on its website and notifies all registered stakeholder organization asking them to submit comments by a deadline[23]. The WHO similarly conducts open online consultations. A recent WHO ethics guidance invited broad stakeholder input via a public call, with instructions to submit feedback through an online form.[24] Unlike these practices, which post drafts publicly and invite feedback from registered stakeholders, this protocol adopts a closed distribution model. Feedback is solicited only from a selected group of participants, rather than an open or broad audience, prioritizing contextualized, actionable input over general commentary as targeted engagement of experienced stakeholders fosters recommendations that are realistic and aligned with practice contexts.[25]

3.3. Qualitative survey and comments collection

Stakeholder input is gathered either through structured surveys or open comment opportunities or both. In particular, the experts are asked to reflect on the feasibility, clarity, and relevance of each section of the guidelines, as well as to identify potential gaps or risks. Narratives and free-text responses or commentary shall be allowed and incentivized so that qualitative feedback is captured alongside any quantitative input.

The Sage Handbook of Qualitative Methods in Health Research, Thousand Oaks, 2010, 317. See also: S. CAMPBELL *et al.*, *Purposive sampling: complex or simple? Research case examples*, in *Journal of Research in Nursing*, 25, 653.

[22] T. PARK, *Stakeholder Engagement for Responsible AI: Introducing PAI's Guidelines for Participatory and Inclusive AI*, in *Partnership on AI - Blog*, 2024, available at: https://partnershiponai.org/stakeholder-engagement-for-responsible-ai-introducing-pais-guidelines-for-participatory-and-inclusive-ai.

[23] UK National Institute for Health and Care Excellence, Developing NICE guidelines: the manual of NICE process and methods, 31 October 2014, Last updated: 29 May 2024, available at: https://www.nice.org.uk/process/pmg20/chapter/the-validation-process-for-draft-guidelines-and-dealing-with-stakeholder-comments.

[24] World Health Organization, Online public consultation on the draft WHO guidance on the ethics of health research priority setting, 6 November 2024, available at: https://www.who.int/news-room/articles-detail/online-public-consultation-on-the-draft-who-guidance-on-the-ethics-of-health-research-priority-setting.

[25] H.J. SCHÜNEMANN, *et al.*, *Guidelines 2.0: Systematic development of a comprehensive checklist for a successful guideline enterprise*, in *Canadian Medical Association Journal*, 182, 13, 2017, E839–E842.

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3.4. Themes and feedback coding

All stakeholder feedback will be analyzed using systematic qualitative methods, primarily thematic analysis complemented by elements of content analysis. First, the drafters will review and code the responses and commentaries. Each piece of feedback will be read in full by the team to ensure important points are not missed. Using an open coding technique,[26] the researchers will annotate segments of text (e.g. phrases or sentences) with codes that capture their meaning or concern (for example, codes might include "feasability", "clarity" "technical mistakes" "irrelevance" etc.).[27] A code of feedback is a standardized label used to categorize the type or focus of a stakeholder's comment on the draft guidelines. Each code represents a specific kind of concern, suggestion, or validation, such as lack of clarity, ethical issues, feasibility problems, or missing content. Applying these codes helps the analysis team group similar types of feedback, identify recurring themes, and ensure systematic, transparent integration of stakeholder input. Multiple codes can be assigned to a single comment if it raises more than one issue. The team will then refine these codes, clustering them into themes that correspond to the main concerns that the guidelines are called to answer (e.g. "discrimination"; "transparency", "liability") This thematic analysis will allow identification of recurrent patterns in the feedback, such as common concerns about how AI might affect doctor-patient interactions, or suggestions to clarify certain ethical responsibilities in the guidelines.[28]

3.5. Synthesis of feedback and integration

Once the feedback is coded and themes are established, the team will produce a summary of the feedback. Key questions guiding this stage include: Which guideline sections or principles attracted the most concern or confusion? What aspects of the draft do stakeholders find most valuable or critical? Are there any gaps in the guidelines that multiple participants independently identified? The results will be synthesized into a set of actionable insights. For instance, if a significant number of physicians express that a guideline statement is too vague or not feasible in practice, this will be noted as an issue to address. If experts highlight an area not covered by the draft (e.g., a risk of AI not previously considered), that gap will be flagged for inclusion. The diversity of the expert feedback will also be considered, and any divergent viewpoints or minority opinions will be documented so that the guideline developers can decide how to handle them (for example, by adding clarifying notes or alternative recommendations for certain contexts). To facilitate this process, the matrix of integration in Table 1 and 2 should be used.

3.6. Validation

After incorporating changes, the revised sections will undergo an internal validation. The drafters

[26] See M.S. LINNEBERG, S. KORSGAARD, *Coding Qualitative Data: A synthesis guiding the novice*, in *Qualitative Research Journal*, 19, 3, 2019, 259–270.

[27] See V. BRAUN, V. CLARKE, *Using thematic analysis in psychology*, in *Qualitative Research in Psychology*, 3, 2, 77–101; L.S. NOWELL, J.M. NORRIS, D.E. WHITE, N.J. MOULES, *Thematic analysis: Striving to meet the trustworthiness criteria*, in *International Journal of Qualitative Methods*, 16, 1, 1–13.

[28] See H.F. HSIEH, S.E. SHANNON, *Three approaches to qualitative content analysis*, in *Qualitative Health Research*, 15, 9, 2005, 1277-1288; M. VAISMORADI, H. TURUNEN, T. BONDAS, *Content analysis and thematic analysis: Implications for conducting a qualitative descriptive study*, in *Nursing & Health Sciences*, 15, 3, 2013, 398-405.

will review the modifications to ensure they accurately reflect the feedback and do not introduce any contradictions or new issues. Particular attention will be paid to balancing different stakeholder perspectives. For example, if physicians and institutional policy makers had slightly different concerns, the text will be adjusted to address both, possibly by adding context or flexibility to the recommendations. While a formal "member check" (respondent validation) is not planned as a mandatory step (due to possible resource and time considerations), the team will consider circulating the revised portions of the guidelines back to a small subset of the original participants for an informal validation. If any of the original stakeholders are available and willing to provide quick feedback on the revisions, their input will be used to make final refinements.[29]

4. Conclusive remarks

The protocol's process can be embedded in diverse organizations, from hospital ethics committees to governmental regulatory agencies by adding its engagement steps to existing review or standards-setting procedures. Because clinical and technical guidelines are routinely issued by providers, professional bodies and regulators, those institutions can use this protocol to co-create guidelines with patients, clinicians, engineers and other experts. Such inclusive development is known to make the guidance more acceptable and easier to implement. The method is agnostic to content, so it works for clinical practice guidelines, technical standards, ethical codes. It can integrate a broad set of stakeholders (patients, caregivers, providers, public representatives, researchers, policymakers, and more) ensuring that each guideline process gathers the relevant voices. In any domain, this kind of broad participation helps produce recommendations that are trusted and aligned with diverse needs. Inclusive, participatory processes do more than check a box: they legitimize the outcome. As argued, fair decision-making requires treating all stakeholders as "moral equals" with a right to endorse policies.[30] Given the urgent need for trustworthy AI governance this protocol offers a concrete, repeatable model. It is ethically grounded, anchored in a practice-aware and evidence-based framework, drawing on real-world expertise. By embedding experts' voices, it helps ensure that medical AI guidelines are not only evidence-based but also broadly accepted and scientifically legitimate.

[29] See L. BIRT, *Member Checking: A Tool to Enhance Trustworthiness or Merely a Nod to Validation?*, in *Qualitative Health Research*, 26, 2016, 1802-1811.

[30] M. JANSEN, R. ROB BALTUSSEN, K. BÆRØE, *Stakeholder participation for legitimate priority setting: a checklist*, in *International Journal of Health Policy and Management*, 7, 11, 2018, 973.

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Theme *Which theme addressed by the guidelines has been targeted by the expert?*	**Sentence/Part** *Which sentence or part of the guidelines has been targeted by the expert?*	**Code of feedback** *What kind of issue or comment the expert raised?*	**Feedback** Synthesis of the feedback	**Integration** *How has it been integrated?*

Table 1 - The integration matrix.

Theme *Which theme addressed by the guidelines has been targeted by the expert?*	**Sentence /Part** *Which sentence or part of the guidelines has been targeted by the expert?*	**Code of feedback** *What kind of issue or comment the expert raised?*	**Feedback** *Synthesis of the feedback*	**Integration** *How has it been integrated?*
Risk of manual deskilling for healthcare workers.	"AI should support decisions…"	Feasibility	"This is not feasible without intensive training for staff"	Added clarification and training recommendation.

Table 2 - Example of feedback integration.