

Quality of Decision-Making Orientation Scheme (QoDoS©): A Study to Evaluate the Quality of Decision-Making within the Zambia Medicines Regulatory Authority (ZAMRA)

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Introduction

A consistent and transparent approach is an important element of quality decision-making in the review and approval of medicines. This is achieved through the use of a standard and well-defined framework. Most National Medicines Regulatory Authorities (NMRAs) have designed frameworks, these are often unvalidated or inconsistently applied.

Aim of the study

To assess the Zambia Medicines regulatory authorities compliance with quality decision-making practices in the regular regulatory review process, including those applied by the Medicines and veterinary committees

Objectives of the study

- Evaluate the quality of the decision-making process of individual members and their perception of ZAMRA's decision-making process using QoDoS
- Assess the QoDoS instrument in terms of its benefits for routine assessment of quality of decision-making, its acceptability by ZAMRA as well as, if appropriate, its sensitivity to detect changes in practice.
- Suggest ways of improving the lowest scoring practices and how these may be implemented into the decision-making framework to ensure consistency.

QoDoS instrument

	Not at all	Sometimes	Frequently	Often	Always	Not applicable
Part i: Organisational - level influences						
A. Decision-Making Approach						
1. My organisation evaluates the impact of the decisions it makes						
2. My organisation's decision making is transparent						
3. My organisation's decision making is consistent						
4. My organisation uses a structured approach in its decision making						
5. My organisation's decision making is influenced by external stakeholder's demands						
6. My organisation assigns qualitative values to its decision-making criteria						
7. My organisation assigns quantitative values to its decision-making criteria						
8. My organisation is open to using better alternatives in its decision making						
9. My organisation encourages innovative decision making						
10. My organisation considers uncertainties in relation to its decision making						
11. My organisation provides training in the science of decision making						
12. My organisation re-examines its decision making as new information becomes available						
B. Decision-making culture						
13. My organisation has suffered a negative outcome due to slow decision making						
14. My organisation's culture has resulted in its inability to make a decision						
15. My organisation's decision making is influenced by organisational politics						
16. My organisation's decision making results in making the same mistake as in the past						
17. My organisation's decision making is influenced by the vested interest of individuals (e.g. conflict of interest)						
18. My organisation underestimates problems which adversely impact its own decisions						
19. My organisation continues with projects/products which should be terminated at an earlier stage						
20. My organisation's decision making is influenced by similar organisations or competitors						
21. My organisation's decision making is influenced by incentives or penalty payments						
22. My organisation effectively communicates the decisions it makes						
23. My organisation provides clear and unambiguous instructions for decision making						
Part ii: Individual - level influences						
A. Decision-making competence						
24. My decision making is knowledge based						
25. My decision making is consistent						
26. I consider uncertainty and unknowns in my decision-making approach						
27. I generate a Strengths-Weaknesses-Opportunities-Threats (SWOT) analysis in my decision making						
28. I present contingencies or achievable options as part of my decision making						
29. My decision making is transparent						
30. I understand the context of the decision I am being asked to make						
31. I understand the importance of the decisions I make						
32. I use a structured approach in my decision making						
33. I assign qualitative values to its decision making criteria						
34. I assign quantitative values to its decision making criteria						
35. I receive training in the science of decision making						
36. I use intuition or "gut-feeling" in my decision making						
37. My professional experience is important when having to make challenging decisions						
B. Decision-making style						
38. Emotion is part of my decision making						
39. I have experienced "paralysis by analysis" caused by my slow decision making						
40. I have experienced a negative outcome by a decision not being made						
41. In my decision making, I make the same mistakes as in the past						
42. Recent or dramatic events greatly impact my decision making						
43. My procrastination has resulted in a negative outcome						
44. My decision making could be improved by assigning relative importance to decision criteria						
45. I underestimate problems which adversely impact my decision making						
46. I continue with projects/products which should be terminated at an early stage						
47. I feel that I could make better quality decisions						

10 Quality decision-making practices

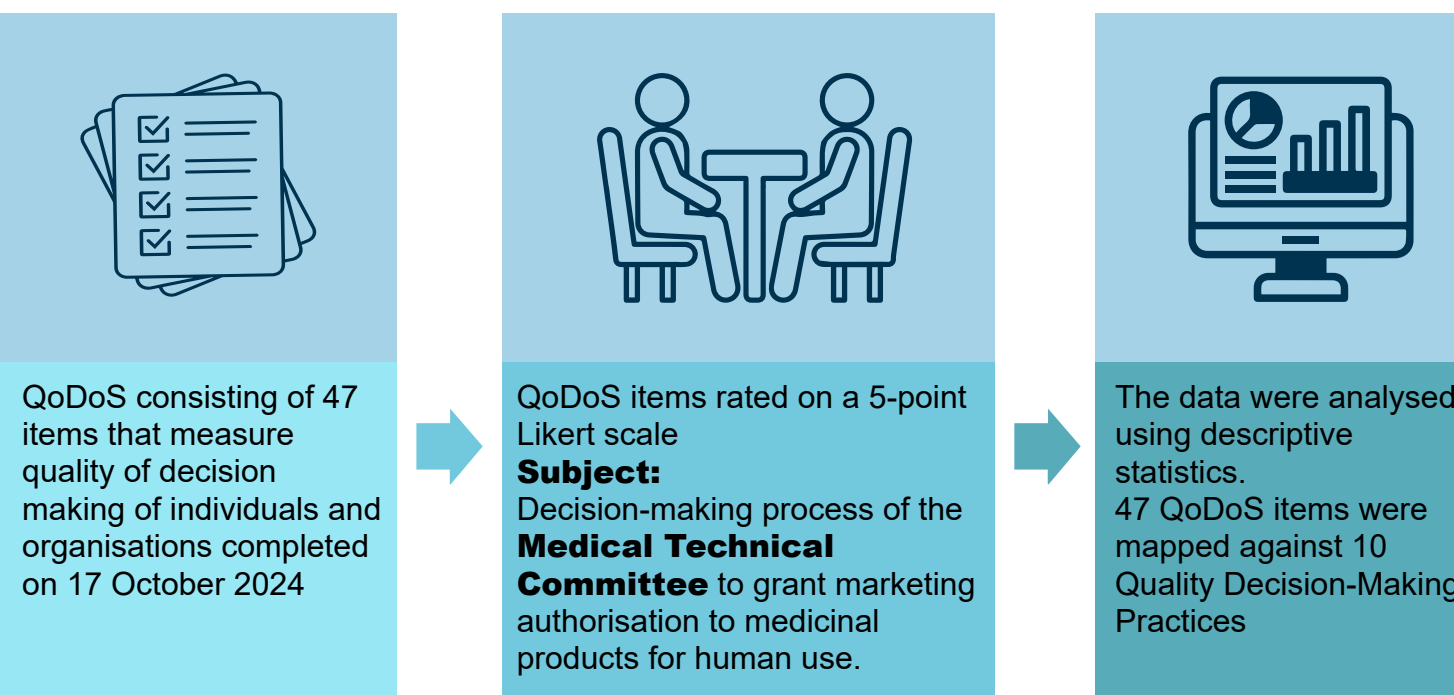
Quality is difficult to define, but we can define the practices that make up a quality decision-making process

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| <p>Establish who, why and how decisions are made</p> <ol style="list-style-type: none"> 1. Have a systematic, structured approach to aid decision making (consistent, predictable and timely) 2. Assign clear roles and responsibilities (decision makers, advisors, contributors) 3. Assign values and relative importance to decision criteria | <p>Ensure decision quality, relevance and importance</p> <ol style="list-style-type: none"> 4. Evaluate both internal and external influences/biases 6. Consider uncertainty 7. Re-evaluate as new information becomes available |
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10 Quality Decision-Making Practices

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|---|--|
| <p>Ensure decision transparency and communication</p> <ol style="list-style-type: none"> 9. Ensure transparency and provide record trail 10. Effectively communicate the basis of the decision | <p>Consider decision alternatives and impact</p> <ol style="list-style-type: none"> 5. Examine alternative solutions 8. Perform impact analysis of the decision |
|---|--|

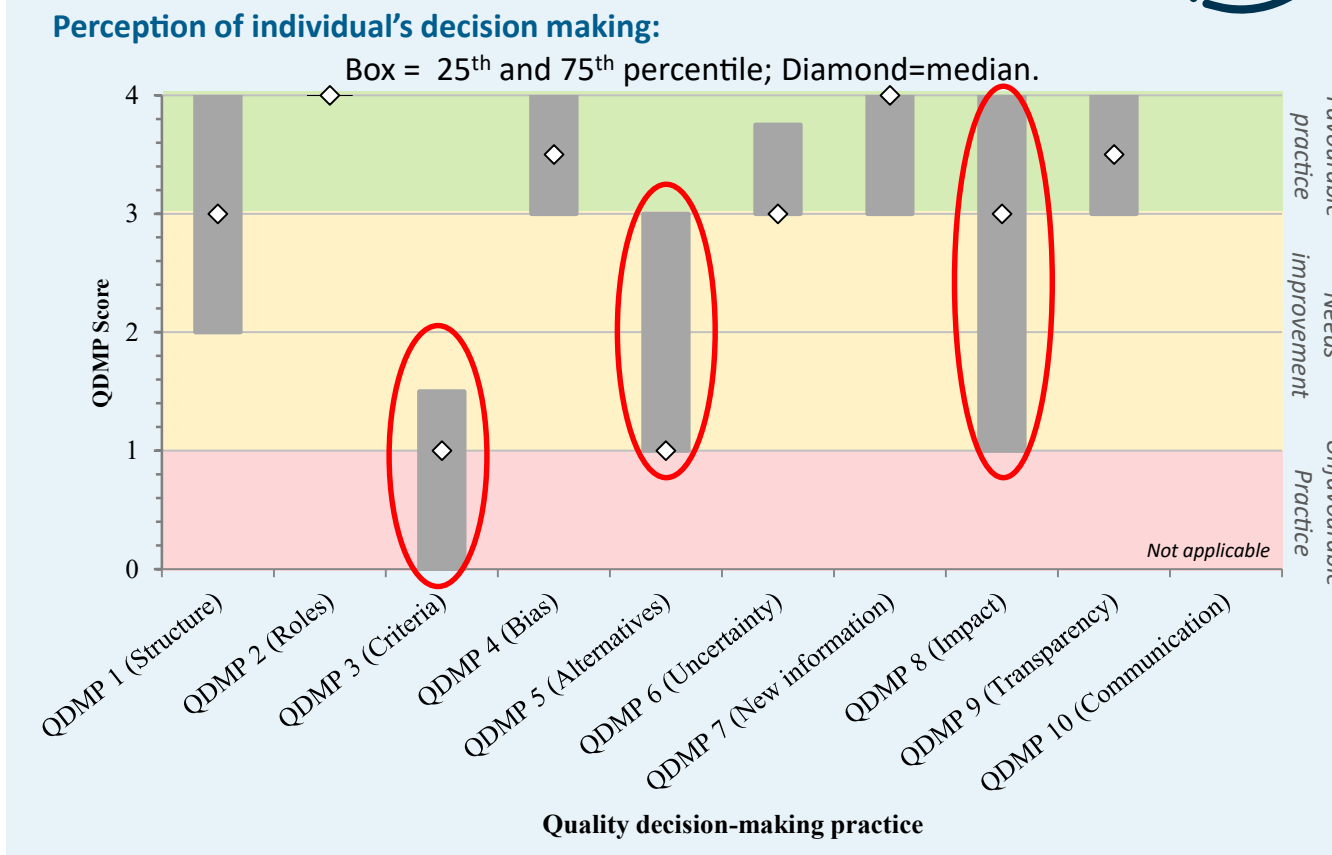
Methodology



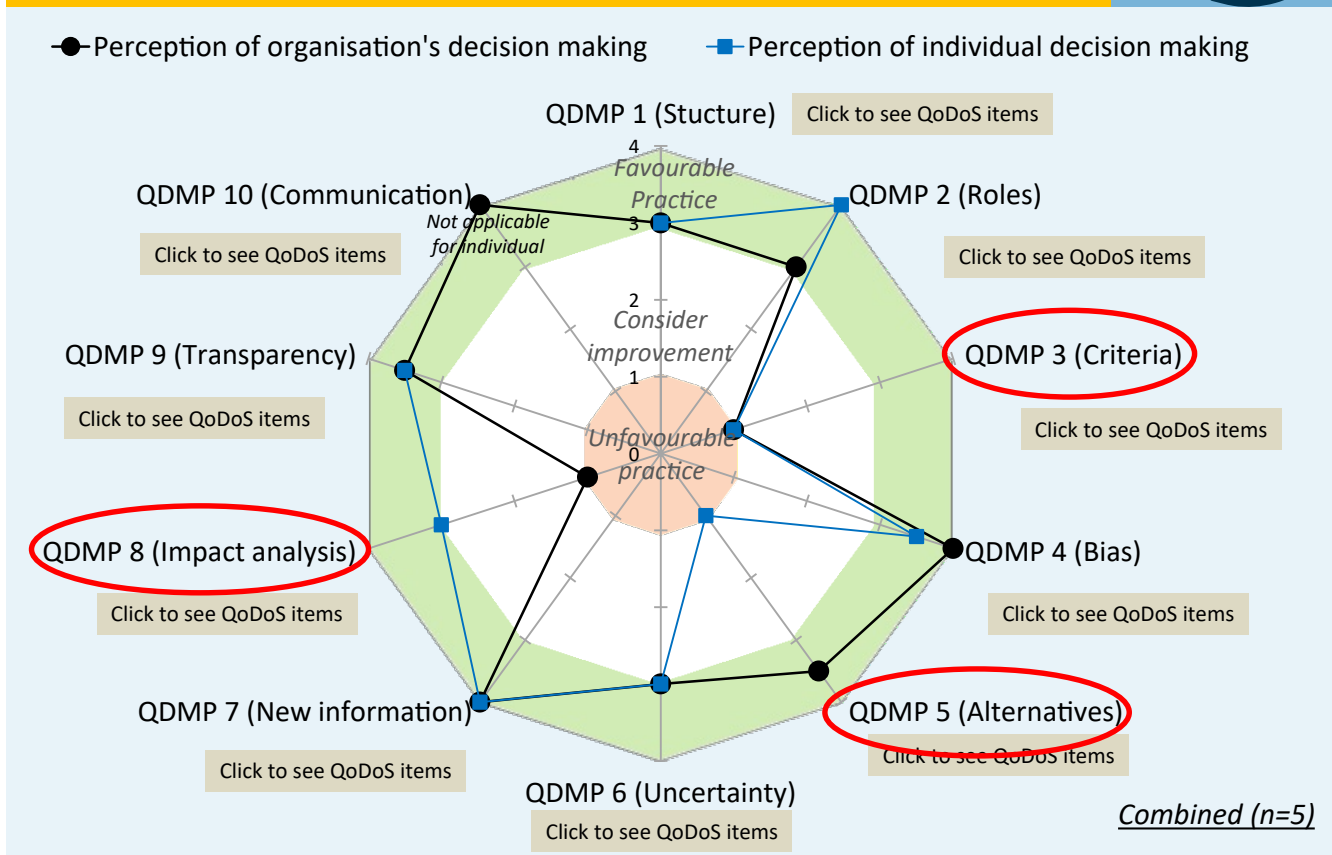
QoDoS questions mapped to the 10 QDMPs

10 Quality decision making practices QDMPs	24 QoDoS individual items	23 QoDoS organizational items
10 Quality decision making practices		
1. Have a systematic, structured approach to aid decisionmaking (consistent, predictable and timely)	24, 25, 27, 30, 32, 35, 36, 39, 40, 43	3, 4, 11, 13, 14
2. Assign clear roles and responsibilities (decision makers, advisors, contributors)	37	15, 23
3. Assign values and relative importance to decision criteria	33, 34, 44	6, 7
4. Evaluate both internal and external influences/biases	38, 42	5, 17, 20, 21
5. Examine alternative solutions	28	8, 9
6. Consider uncertainty	26, 45	10, 18
7. Re-evaluate as new information becomes available	46	12, 19
8. Perform impact analysis of the decision	31, 47	1
9. Ensure transparency and provide a record trail	29, 41	2, 16
10. Effectively communicate the basis of the decision		22

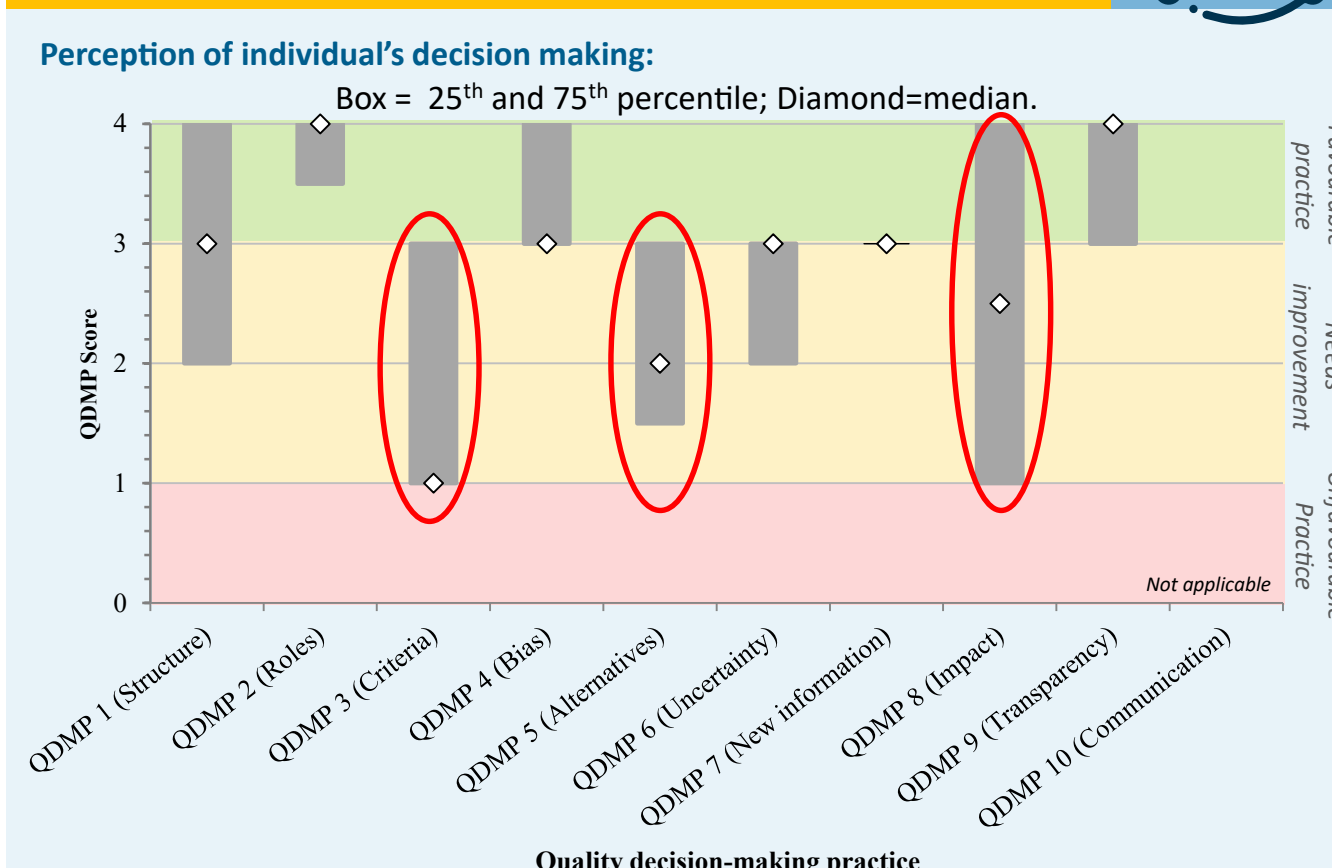
Median and Variance Combined Responses of the Medical Technical Committee: QoDoS Individual items mapped to the 10 Quality Decision-Making Practices



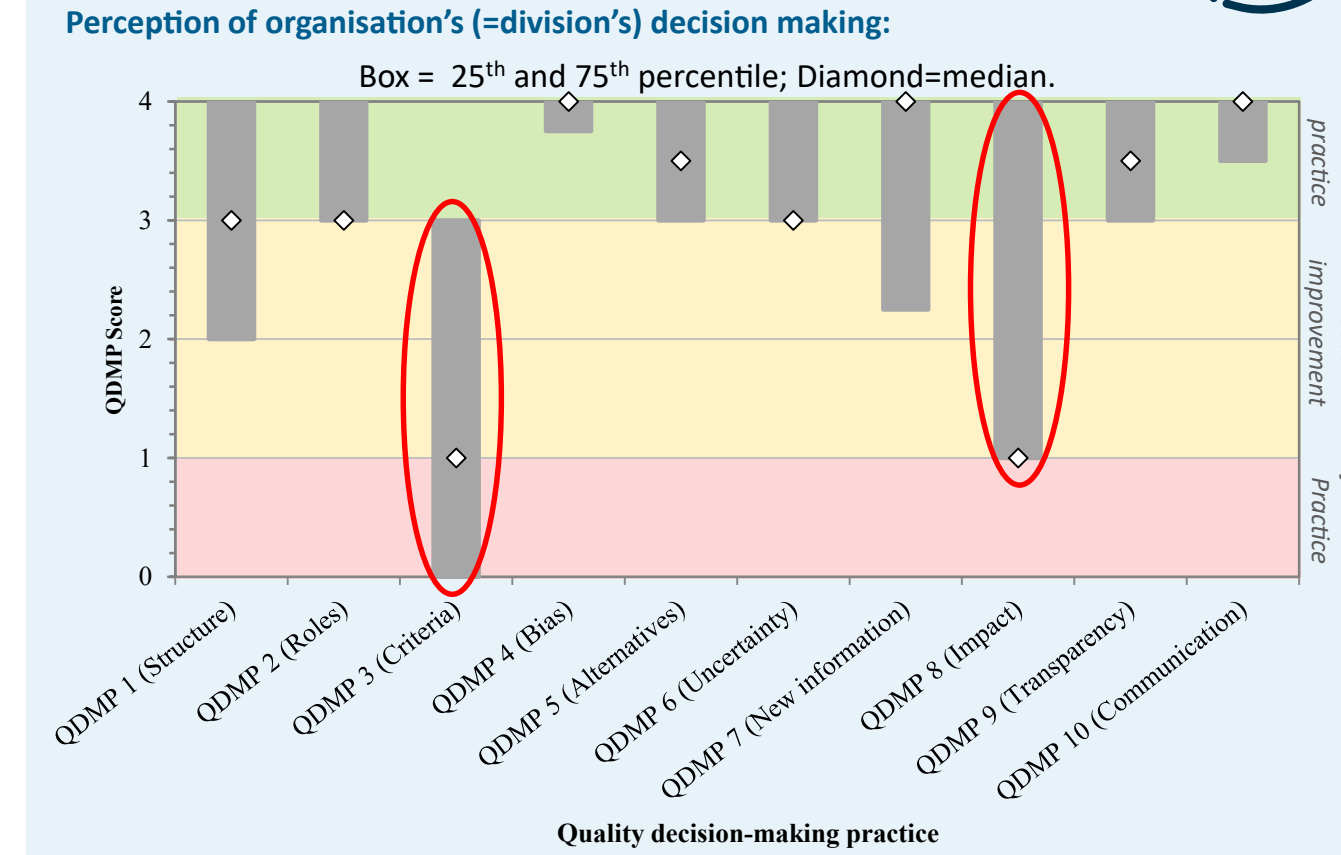
Median Combined Responses of the Medical Technical Committee: Organisational vs. Individual QoDoS Items Mapped to the 10 Quality Decision-Making Practices



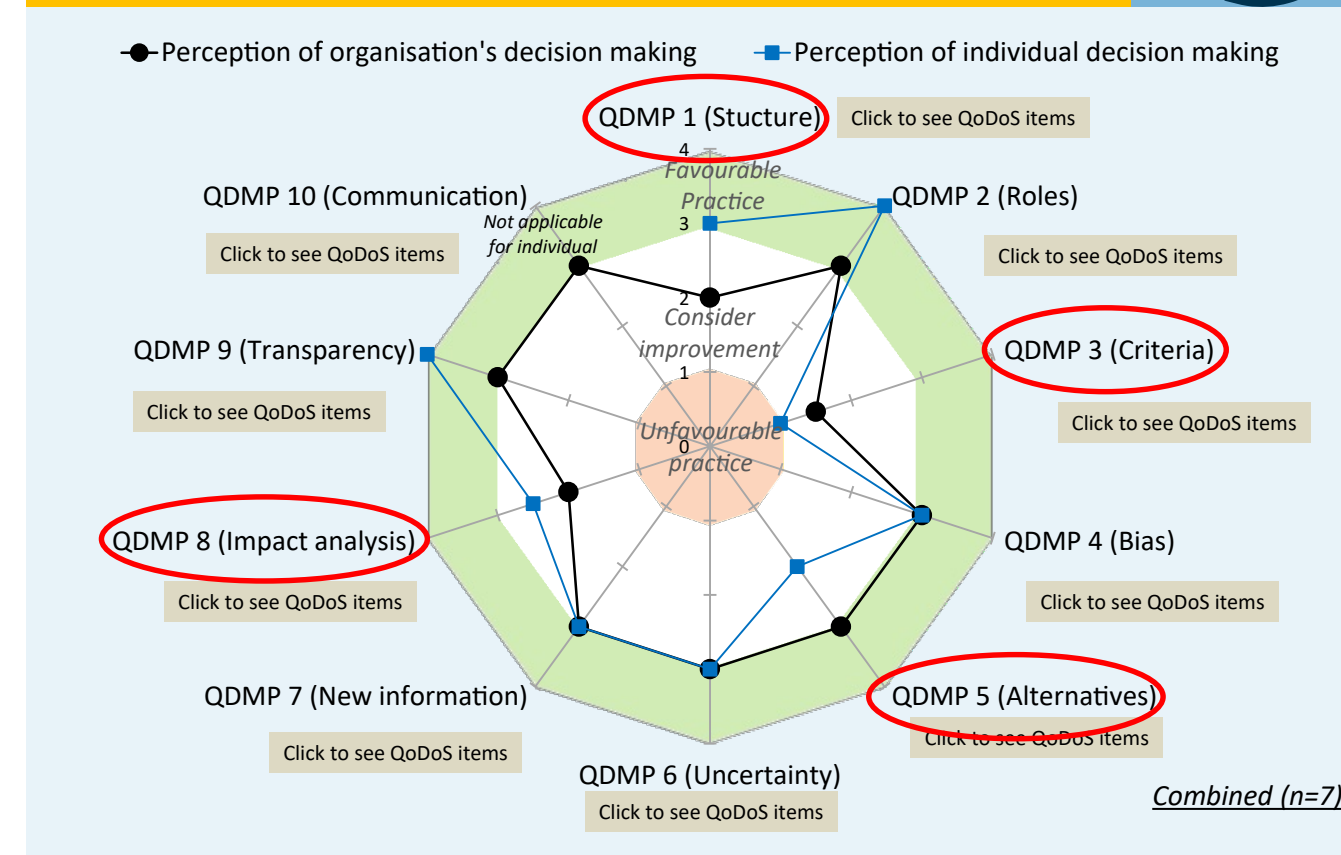
Median and Variance Combined Responses of the Veterinary Technical Committee: QoDoS Individual items mapped to the 10 Quality Decision-Making Practices



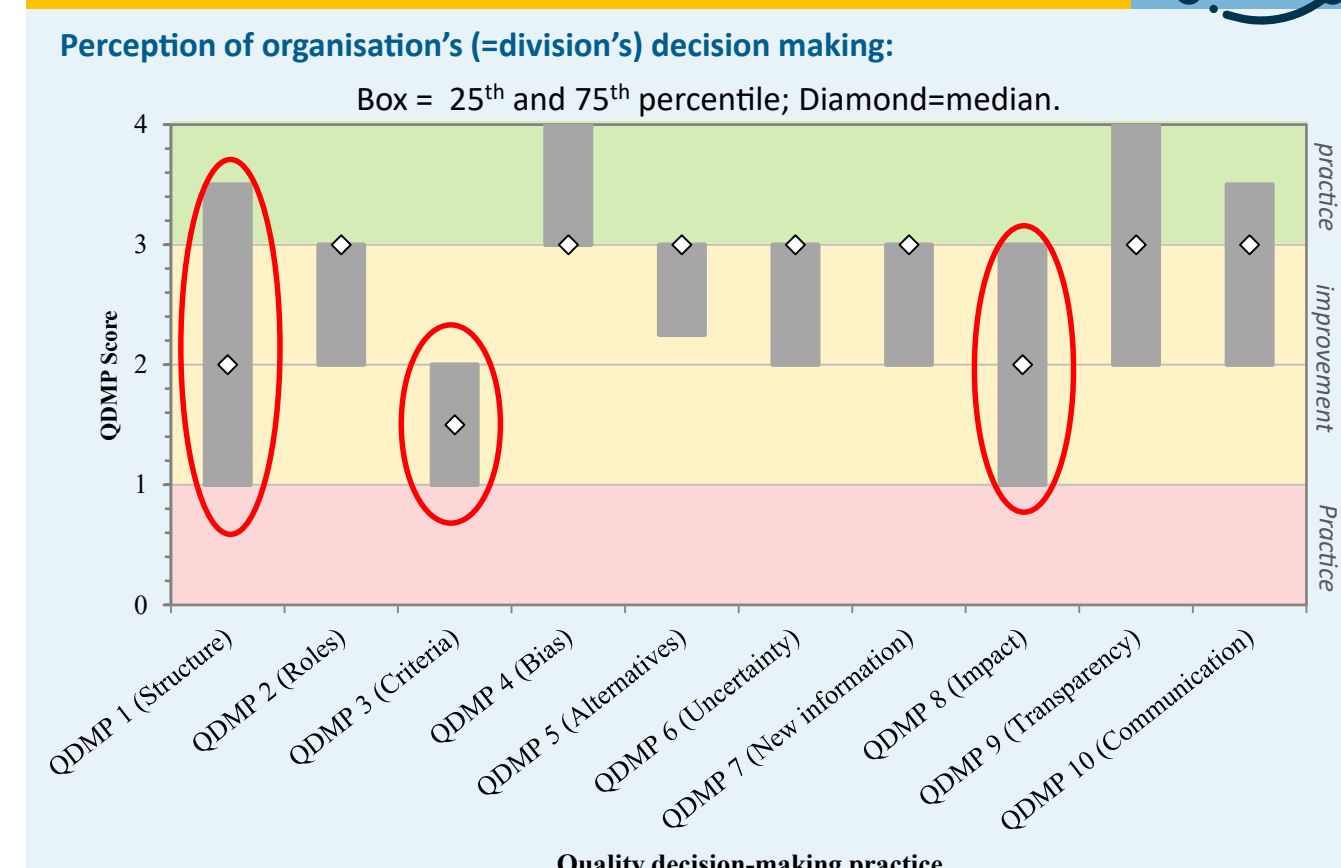
Median and Variance Combined Responses of the Medical Technical Committee: QoDoS Organisational items mapped to the 10 Quality Decision-Making Practices



Median Combined Responses of the Veterinary Technical Committee: Organisational vs. Individual QoDoS Items Mapped to the 10 Quality Decision-Making Practices



Median and Variance Combined Responses of the Veterinary Technical Committee: QoDoS Organisational items mapped to the 10 Quality Decision-Making Practices



Summary

- Favourable Individual responses included Structure, Roles & responsibilities, Account of Biases, Uncertainty, New information, Impact, Transparency and communication.
- Areas for improvement included Criteria & Alternatives reviewed, and Impact monitored.
- Organisation included Account of structure, Roles & responsibilities, Biases, Alternatives, Uncertainty, Transparency and communication.
- Areas for improvement for organisation included Criteria and Impact analysis.

Recommendations of the study

- The following are the recommendations from the study. The Authority should:
 - Conduct decision making training for the technical committee members so that they are aware of the 10 QDMPs and implement them in those areas that need improvement in the decision-making process.
 - Clearly define a framework for the decision-making processes.
 - Have formal assessments in place to periodically measure the quality of the decision-making process in the review of medicines.
 - Improve in the practices that scored poorly which include impact analysis for both the individual and organisational perspective.