

RESEARCH QUESTIONNAIRE

PROJECT TITLE: "Quality Management System Knowledge and Implementation Attitude Evaluation in Medical Diagnostic Laboratories in Lagos State, Nigeria"

INTRODUCTION: Proper patient management requires good laboratory practice; this on the other hand will only be possible by adequate knowledge and implementation of quality management system. The purpose of this study is to assess knowledge, awareness and implementation challenges facing the medical laboratory management and staff about quality management implementation to underscore the strength and weaknesses of facilities and reveal the training gaps to the policy makers and regulatory bodies. Please feel free to participate in the study and whatever response you give will be treated with utmost confidentiality; however, you may also wish to decline. This study is not Council related.

Kindly indicate (tick) as deemed appropriate

1. What kind of medical laboratory do you operate? (a) Government clinical diagnostic lab ☐ (b) Faith based ☐ (c) Private laboratory ☐ (d) Government public health ☐ (e) Research class ☐.
2. What is your level of involvement? (a) Med. Lab. Scientist ☐ (b) Support staff ☐ (c) Lab. manager ☐ (d) Med. Lab Scientist/Director/Manager ☐.
3. What is the approximate number of samples analyzed daily in lab? (a) <10 ☐ (b) 10 – 20 ☐ (c) $20 \leq 50$ ☐ (d) >50 ☐.
4. What category of laboratory do you operate? (a) National reference ☐ (b) Zonal public health ☐ (c) Primary healthcare ☐ (d) Private (e) Secondary/tertiary facility ☐.
5. What is the current status of your medical laboratory with regard to the MLSCN (regulatory body)? (a) Registered ☐ (b) Accredited ☐ (c) a & b ☐ (d) None of the above ☐.
6. Is your facility ISO 15189 accredited? (a) Yes ☐ (b) No ☐; if No, please skip No 7.
7. If yes, to what star level were you facility graded? (a) 0 ☐ (b) 1–3 star ☐ (c) 4 star ☐ (d) 5 star ☐ (e) Do not know ☐ (f) Never audited ☐.
8. How many specialties do you cover in your facility? (a) All ☐ (b) Haem/BGS ☐ (c) Clinical chemistry ☐ (d) Microbiology ☐ (e) Other combinations specify.....
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9. Your facility has qualified scientist in all specialties? (a) Yes ☐ (b) No ☐.
10. If no, do you think your facility may require referral arrangement? (a) Strongly agree ☐ (b) Agree ☐ (c) Disagree ☐ (d) Strongly disagree ☐.
11. The sole essence of QMS is to ensure timely, accurate, reliable and interpretable result (a) Strongly agree ☐ (b) Agree ☐ (c) Disagree ☐ (d) Strongly disagree ☐.
12. Is your lab registered or certified by any relevant regulatory body? (a) Yes ☐ (b) No ☐.
13. Quality Management implementation is extremely essential in clinical diagnostic labs? (a) Strongly agree ☐ (b) Agree ☐ (c) Disagree ☐ (d) Strongly disagree ☐.
14. Does your facility practice QMS? (a) Yes ☐ (b) No ☐.
15. Do you have quality manual? Yes ☐ No ☐ I don't know ☐.

16. Does your facility have written job description / schedule for all the staff? (a) Yes [] (b) No [] (c) I don't know
17. Is it likely that your facility may not have adequate staff for all your processes? (a) Strongly agree [] (b) Agree [] (c) Disagree [] (d) Strongly disagree
18. Do you have SOPs for your processes? (a) Yes [] (b) No [] (c) I don't know [].
19. How often do you review your SOPs? (a) Annually/biannually [] (b) Quarterly [] (c) Monthly [] (d) I don't know []
20. Have you had any formal training on QMS? (a) Yes [] (b) No [] (c) I don't know [].
21. Proper training for all levels of staff in the lab is very necessary for QMS implementation (a) Strongly agree [] (b) Agree [] (c) Disagree [] (d) Strongly disagree []
22. Does your facility participate in EQA by Med. Lab. Science Council of Nigeria? (a) Yes [] (b) No [] (c) I don't know []
23. If yes for no 22 above, do you conduct preventive/corrective action on failed EQA? (a) Yes [] (b) No [] (c) I don't know
24. Have you had any training on logistics and cold chain management? (a) Yes [] (b) No [] (c) I don't know []
25. Do you carry out periodic audit of your lab QMS processes? (a) Yes [] (b) No [] (c) I don't know
26. Do you conduct management review of your processes? (a) Yes [] (b) No [] (c) I don't know []
27. Internal Quality Control (IQC) is essential and integral part of QMS? (a) Strongly agree [] (b) Agree [] (c) Disagree [] (d) Strongly disagree []
28. Do you report your results in S.I units? (a) Yes [] (b) No [] (d) I don't know []
29. Do you periodically maintain your equipment and document the processes? (a) Yes [] (b) No [] (c) I don't know []
30. Do you dispose your waste in accordance with waste disposal guideline? (a) Yes [] (b) No [] (c) I don't know
31. If yes for no 30 above, into how many compartments does your facility segregate waste? (a) 2 [] (b) 3 [] (c) 4-5 [] (d) Universal disposal []
32. Is there a system for competency assessment of staff in your lab? (a) Yes [] (b) No [] (c) I don't know
33. Effective quality indicators are essential and indeed indispensable in operative QMS implementation (a) Strongly agree [] (b) Agree [] (c) Disagree [] (d) Strongly disagree []
34. Do you have regular staff meetings in your establishment? (a) Yes [] (b) No [] (c) I don't know []
35. Do you have a good lab work plan? (a) Yes [] (b) No [] (c) I don't know []

36. Does your lab request patients' request/suggestions? (a) Yes [] (b) No [] (c) I don't know []
37. Do you have sample tally sheet filled daily? (a) Yes [] (b) No [] (c) I don't know []
38. How often do you carry out routine test with the reference test? (a) Very often [] (b) Often [] (c) Sparingly [] (d) Never []
39. Do you carry out repeating sample assay in view of the cost? (a) Yes [] (b) No [] (c) I don't know []
40. How often do you carry out inter lab test trials for quality checks? (a) Frequently [] (b) Rarely [] (c) Never []
41. How often does staff in your establishment undertake refresher courses? (a) Frequently [] (b) Rarely [] (c) Never []
42. Your facility may have operated for how long? (a) <5years [] (b) 5 – 10 years [] (c) >10years []
43. Has any of your laboratory staff had any laboratory accident before? (a) Yes [] (b) No [] (d) I don't know []
44. If yes, please state the type of accident (a) Needle prick [] (b) Sample splash [] (c) Fall [] (d) Electric shock [] (e) Others, please specify.....(answer may be multiple)
45. Have you ever carried out risk assessment of your laboratory before? (a) Yes [] (b) No [] (c) I don't know []
46. Do you have check list (criteria) for risk assessment in your facility? (a) Yes [] (b) No [] (c) I don't know []
47. What is/are your facility's budget proposal consideration(s) based on? (a) [] Past pattern [] (b) Present trends [] (c) Future plans [] (d) all of the above
48. Do you arrange your reagent on first expiry first out principle? (a) Yes [] (b) No [] (c) I don't know []
49. One of the most appropriate methods of pre-analytical quality indicator monitoring is? (a) Doctor's history taking from the patient [] (b) Specimens rejection/acceptance rate [] (c) Interviewing the patients on arrival [] (d) None of the above []
50. The processes in QMS could best be described by one of the following respectively (a) Post-analytical, pre-analytical and analytical [] (b) Pre-analytical, analytical and post-analytical [] (c) Analytical, pre-analytical and post-analytical [] (d) None of the above []