

# Medical devices in Africa: ethical aspects and universality of norms

This survey aims to identify ethical aspects and norms related to Medical Devices (MD) used by the Beninese government, and the perspective of some Beninese experts of the field. For this reason, the survey will be extended to local biomedical engineers/technicians (BMETs). In order to try to understand, among other things, what the perception of women in the field of biomedical engineering is, considering the traditional gender biases.

This is a multidisciplinary study, which will also focus on the ethical aspects (Ethical Committees, Deontological Codes) for the use of technology in hospitals.

In conclusion, a part of this questionnaire will be focused on the rural population's perception of medical devices, trying to evaluate whether there is reticence about health technologies.

This survey consists of 7 sections, namely Introduction, Personal information, Hospitals ethical situation, Medical Device Regulations, Gender biases, Maintenance of medical devices, Perception of medical devices.

You may be a member of the government or an employee of the hospital (e.g., a nurse, a medical doctor, a BMET) or any person who is familiar with the hospital or expert in MDs. The answers will be anonymized and used in a research study of the Applied Biomedical Signal Processing and Intelligent eHealth Lab

(<https://warwick.ac.uk/fac/sci/eng/research/grouplist/biomedicaleng/abspie>) at the University of Warwick, led by Dr Leandro Pecchia.

Your answers will not be disclosed and your participation to this study will remain confidential.

## Consent

1. Pictures and videos of the interviewee, the medical locations and/or the medical devices may be taken before/during/after the interviews. They will be stored securely and may be used during seminars and as additional materials in journal publications. I hereby authorize the acquisition and treatment of such pictures and videos, as above mentioned.

*Mark only one oval.*

Yes

No

Other: \_\_\_\_\_

2. I hereby authorize, according to the EU regulation 679/2016, the treatment of the transmitted personal data.

*Mark only one oval.*

- Accept
- Do not accept

### Personal Information

This section asks some general questions about your personal information.

3. Date

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*Example: 7 January 2019*

4. District and Country
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5. Age

*Mark only one oval.*

- <20
- 21-30
- 31-40
- 41-50
- 51-60
- 61-70

6. Sex

*Mark only one oval.*

- Male
- Female
- Prefer not to say

7. The highest grade or level of school/education that you have

*Mark only one oval.*

- Less than primary school
- Primary school
- Secondary school
- High school or equivalent
- College or University

8. Job

*Mark only one oval.*

- Minister
- Doctor
- Nurse
- Biomedical engineer/technician
- Other: \_\_\_\_\_

9. How long (years) have you stayed in this job?

*Mark only one oval.*

- 1-3
- 4-6
- 7-9
- 10 or more

### Hospital ethical situation

This section aim to obtain information about ethics in hospitals

10. Hospital/Institution name

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11. Classification of the Hospital

*Mark only one oval.*

- Public
- Private
- Religious (specify order)

12. Setting type

*Mark only one oval.*

- Rural/District Hospital
- Regional/ Provincial Hospital
- National/University Hospital

13. How many patients you are able to treat (beds)?

*Mark only one oval.*

- <50
- 50<X<100
- >100
- Do not know
- We do not have patients
- Other: \_\_\_\_\_

14. How many doctors are available in your facility?

*Mark only one oval.*

- 1-5
- 5-10
- 10-15
- 15-20
- 20-30
- 30-50
- Do not know
- we do not have doctors
- Other: \_\_\_\_\_

15. How many of them are women?

*Mark only one oval.*

- 0-10%
- 10-30%
- 30-50%
- >50%
- Do not know
- We do not have doctors
- Other: \_\_\_\_\_

16. How many nurses are available in your facility?

*Mark only one oval.*

- 0-5
- 5-10
- 10-20
- 20-30
- >30
- Do not know
- We do not have nurses
- Other: \_\_\_\_\_

17. How many of them are women?

*Mark only one oval.*

- 0-10%
- 10-20%
- 20-30%
- 30-50%
- >50%
- We do not have nurses
- Other: \_\_\_\_\_

18. How many biomedical engineers/technicians are available in your facility?

\_\_\_\_\_

19. How many of them are women?

\_\_\_\_\_

20. In this Hospital-Institution is there an Ethical Committee?

*Mark only one oval.*

- Yes
- No
- Other: \_\_\_\_\_

21. In the hospital where you work, do you ask patients to sign a document before a surgery (i.e., informed consent)?

*Mark only one oval.*

- Yes
- No
- Other: \_\_\_\_\_

22. If the patient is not able to understand the treatment they will undergo, do you provide for the consultation of someone who clarifies all aspects of the treatment?

*Mark only one oval.*

- Doctors do that
- Nurses do that
- Other: \_\_\_\_\_

23. Has it ever happened that a patient sued the hospital or a doctor for misconduct in the communication of the therapy/surgery?

*Mark only one oval.*

- yes, often
- yes, sometimes
- yes, rarely
- no, never



24. According to the local culture, whose is the decision to undergo a treatment / intervention / trial?

*Tick all that apply.*

- Of the patient  
 Of the family members  
 Of the head of the family  
 Of the husband / father

25. According to the laws of the Republic of Benin, is staff required to comply with a Code of Conduct (Deontologic)?

*Mark only one oval.*

- Yes of course, we have a National Conduct Code  
 Yes, each hospital has its own code  
 Not mandatory  
 No, there is no Code of Conduct  
 Other: \_\_\_\_\_

26. Is a Code of Ethics complied with by health personnel?

*Mark only one oval.*

- Yes, we have a State Code of Ethics  
 Yes, we have a Code of Ethics of the hospital  
 Not mandatory  
 No

27. How much does the ethical behavior of a doctor / nurse depend on their religion / culture / personal ethics ?

*Mark only one oval.*

- None
- A little
- Enough
- Very much

28. In your opinion, how good do you consider the role of ethics in the Beninese national healthcare system?

*Mark only one oval.*

	1	2	3	4	5	
very poor	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	very good

### Medical Devices Regulations

This section aim to clarify the Regulations adopted by Republic of Benin about Medical Devices

29. Are local Medical Device Regulations complied with in Benin?

*Mark only one oval.*

- Yes
- No

30. If you answered no, to which regulation on medical devices does Benin refer to?

*Mark only one oval.*

- American
- European
- Asian
- Do not know
- Other: \_\_\_\_\_

31. Does Benin have its own medical devices regulation?

*Mark only one oval.*

- yes
- not
- Do not know

32. In this hospital, do you respect any guideline or regulations on medical devices?  
if so, which?

\_\_\_\_\_

33. Do Beninese biomedical engineers/technicians perceive European medical device regulations as inadequate to the context?

*Mark only one oval.*

- yes
- not
- other

34. Have they ever proposed regulatory changes?

*Mark only one oval.*

yes

No

35. Do Beninese politicians consider the European regulations on medical devices inadequate for their country?

*Mark only one oval.*

Yes

No

Other: \_\_\_\_\_

36. Have they ever proposed regulatory internal changes for their own country?

*Mark only one oval.*

yes

No

Other: \_\_\_\_\_

37. Have they ever proposed regulatory changes to Europe?

*Mark only one oval.*

no, it is not necessary

no, but it will be necessary

yes

other

38. Is there a Biomedical Engineering department in the Ministry of Health of Benin?

*Mark only one oval.*

- Yes
- No
- Other: \_\_\_\_\_

39. Is there a department of biomedical engineering or clinical engineering or health technology management in this hospital?

*Mark only one oval.*

- Yes
- No
- Other: \_\_\_\_\_

## Gender biases

40. What is the relation between women and science in this country?

\_\_\_\_\_

41. How is a woman involved in biomedical engineering perceived in this country?

*Mark only one oval.*

- much admired
- appreciated
- normally, as a man
- not very understood
- not very well

42. What is the percentage of female biomedical engineers in this country?

*Mark only one oval.*

- 0-25%
- 25-50%
- 50-75%
- 75-100%

43. What is the percentage of female biomedical engineers in this hospital?

*Mark only one oval.*

- 0-25%
- 25-50%
- 50-75%
- 75-100%

44. Who mainly takes care of a medical device maintenance in a hospital?

*Mark only one oval.*

- Male engineers/technicians
- Female engineers/technicians
- Both
- Other: \_\_\_\_\_

45. In this hospital, who is in charge of medical device maintenance?

\_\_\_\_\_

46. Do you believe that, given the role of the Beninese woman, traditionally linked to home and family maintenance, even medical devices maintenance is considered a "woman's business"?

*Mark only one oval.*

- Yes, surely
- Yes, could be
- Maybe
- No, absolutely
- other

### Maintenance of medical devices

47. How important is medical device maintenance, in your opinion?

*Mark only one oval.*

- Really Important
- Important
- Not so relevant
- Absolutely not relevant

48. In your opinion, on a scale from 1 (Not degrading) to 5 (Very degrading), how degrading can a job based solely on maintenance be perceived?

*Mark only one oval.*

	1	2	3	4	5	
Yes, surely	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	No, absolutely

49. What do you think if the state took actions aimed at fostering the role of women in biomedical engineering?

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50. What is the biggest problem of medical device maintenance in Benin?

Mark only one oval.

- local technicians not trained
- different language of the instructions
- no supply chain
- different setting from the MD country of origin
- Other: \_\_\_\_\_

Perception of medical devices

This section aim to underline the perception of technology from different respondents

51. How good do you consider medical devices in Benin?

Mark only one oval.

	1	2	3	4	5	
very poor	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	very good

52. How good do you consider medical devices in this hospital?

Mark only one oval.

	1	2	3	4	5	
very poor	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	very good

53. How are medical devices perceived by the rural population?

\_\_\_\_\_



54. Do you think that the local population has some reticence about the use of technology and prefers the traditional form of care?
- 

55. Who should introduce the rural population to the use of health technologies?

*Mark only one oval.*

- ethical committee members
- doctors
- nurses
- other