1. Introduction

- A medical device is an instrument that is used to diagnose/prevent/treat disease, without any chemical action on the body.
- India has the second largest population in the world and a health care sector divided into government & private sectors.
- We aimed to explore maintenance and repair of existing medical devices across the two sectors in a province in India (2014).
- Maintenance of medical devices in India is contracted out to companies from which the Maintenance of Medical Devices in the Health Care Sector of India

3.1 LACK OF BIOMEDICAL ENGINEERS

Biomedical engineers: Individuals with specialist expertise in medical devices in-house repair
- Government Hospitals: Significant lack of Biomedical Engineers
- Private Hospitals: Only a few employed and without proper training and qualifications

3.2 PROCEDURAL DELAY

- Government Hospitals:
  - Lack of direct responsibility: Individuals not delegated device responsibility causing delay in fault identification, fault reporting
  - Procedural Delay: Process of reporting device fault is unnecessarily lengthy, involves too many personnel, prone to communication failure.
  
  - Private Hospitals: Motivated by business acumen, individuals cultivate urgency in device repair

3.3 COMPANY RESPONSE

- Government Hospitals:
  - Delayed Payments: Companies receive delayed payments from government sector due to procedural delay.
  - Brand Loyalty: Companies provide better service to private hospitals due to brand loyalty

4. Discussion

- Effect on lower socioeconomic class: Device breakdown delays management of patients in government hospitals impacting primarily the lower socioeconomic class.
- Wastage of Resources: In government hospitals, purchase of new devices is preferred to repair of existing ones due to maintenance delay leading to substantial wastage of repairable devices.
- Lack of Regulation of companies: Discrepancy in company service provision between sectors highlights lack of regulation of companies & widens gap between healthcare sectors.
- Limitations of study: Observer Bias: Participants guarded in protecting professional image, Researcher bias: Unable to carry out focus groups – lack of triangulation, Language barriers

6. Conclusion

- Problems embedded at each stage of the maintenance process, predominantly affecting the government sector causing major delay.
- Delay impacts on clinician work, widens socioeconomic divide, and leads to resource wastage.
- Increased accountability of device manufacturers and employment of Biomedical Engineers is recommended.

5. Recommendation

- Employ Specialists: Biomedical Engineers
  - Utilise expertise for fault repair, device selection/procurement

- Designate Responsibility
  - Make individuals directly accountable
  - Allow department to directly communicate with companies

- Standardization of service provision
  - Set up regulatory boards to ensure standardization of company service provision

References

- Kazunari Asanuma. Definition of the Terms ‘Medical Device’ and ‘In Vitro Diagnostic (IVD) Medical Device’. GHTF 2012

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