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BACKGROUND

Sustainability in the healthcare industry has become paramount as technology advances and the financial, environmental, and social benefits become more well known. In 1993, the Medical Device Directive (MDD) was developed, which allowed safe reuse and reprocessing of single-use medical devices, by creating standards and regulations for device manufacturers. However, this type of policy does not exist worldwide. India lacks policy and regulation over safe reuse and reprocessing of medical devices.

PURPOSE

The purpose of this study is to compare the policies of the United Kingdom (UK) and India regarding reusable medical devices and explore the environmental and financial outcomes of implementing a more sustainable approach to medical devices in India.

RESEARCH QUESTIONS

1. How do policies influencing reuse of medical devices in India and the UK differ?
2. How does the environmental impact and expenditures related to reuse of medical devices differ between India and the UK?
3. How would implementation of a more sustainable approach to medical devices impact the environment and expenditures in India?
4. What recommendations can be made to inform policy makers regarding reusable medical devices in India?

METHODS

A comparative policy analysis was conducted using the Integrated Acceptance and Sustainability Assessment Model (IASAM) to explore differences between existing policies regarding reusable medical device in India and the UK. International precedents were applied to develop projections estimating the environmental and financial impact of implementing a sustainable approach in India.

REFERENCES

1. Aizstrauta, D. Ginters, E., & Eroles, M.A. (2015). Applying theory of diffusion of innovations to evaluate technology acceptance and sustainability. *Procedia Computer Science*, 43, 69- 77

THEORETICAL MODEL

Two components of the Integrated Acceptance and Sustainability Assessment Model (IASAM) were applied (acceptance and management) to evaluate policies regarding reusable medical devices in India and the United Kingdom.

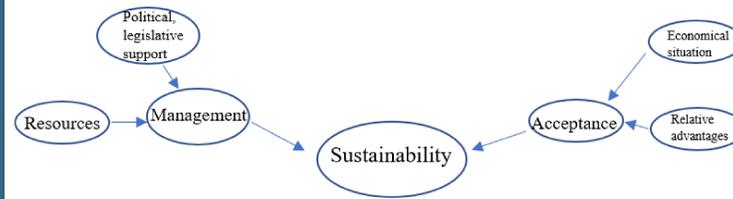


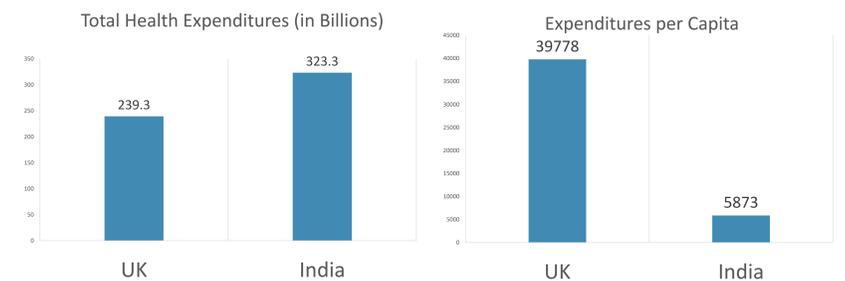
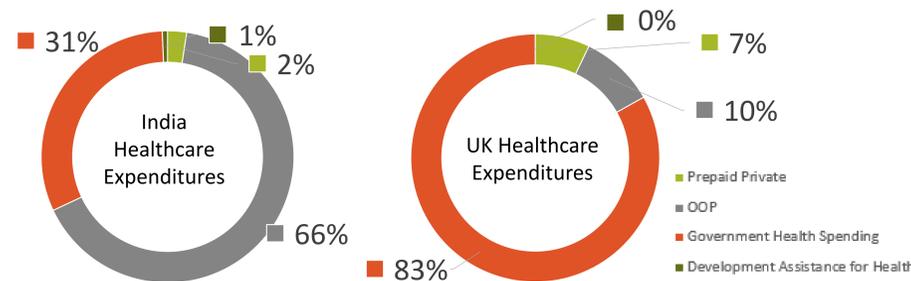
Figure 1: Adapted IASAM Framework for the Comparison of Sustainability Between Policies¹

RESULTS

Comparisons of the UK and India based on the components of the IASAM Framework

		UK	India
Political, Legislative Support	Levels of governance	One governing authority: Parliament	Levels of governance: National, State, District & Block
	Agencies devoted to policy regulation and enforcement	Many separate agencies dedicated to policy enforcement	One agency devoted to regulation of medical devices
Resources & Product Quality	One agency in charge of product quality	✓	✓
	Labeling system for approved reprocessed devices	✓	✗
Relative Advantages	Legislation in place allowing control over reprocessing	✓	✗
	Restriction over packaging and manufacturing waste	✓	✗
Economical Situation	Effect on jobs	Employment increase between 11-23%	Predicted: Increase by 20%
	Device Pricing	50% cheaper	Predicted: 60-70% less

RESULTS



- The UK and India were found to have similar healthcare system components (government role, insurance opportunities and coverage) based on all relevant dimensions of the framework.
- The major difference was that the UK regulates policies at the governmental level, while India regulates the reprocessing at the hospital level.
- India was found to have a greater healthcare expenditure compared to the UK, but the expenditures per capita were much lower for India.
- India has increased in their CO₂ emissions from manufacturing, the indicator used to measure environmental impact, while the UK had reduced their emissions since 1993, the implementation of the MDD.

RECOMMENDATIONS

- Adapt MDD and other global policies existing regarding medical device reprocessing
- Integrate labeling system of MDD and standard process for remanufacturers to follow when reprocessing
- Allow hospitals to be accountable for reprocessing
 - Create organization or committee for each hospital to oversee processes
- Create standardized lowered prices for reprocessed devices
- Increase government spending to mimic the UK healthcare system and increase per capita expenditure
- Insurance coverage over reprocessed medical device

PROPOSED IMPACT

- Increase in generation of jobs by 20%
- 60-70% reduction in device prices resulting in 382 crore turnover (\$61.12 million cost savings) for India
 - 20% reduction in waste generated
 - 10% reduction in CO₂ emissions

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