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Preliminary results of a review of regulatory environments relevant to BP devices in HEARTS countries

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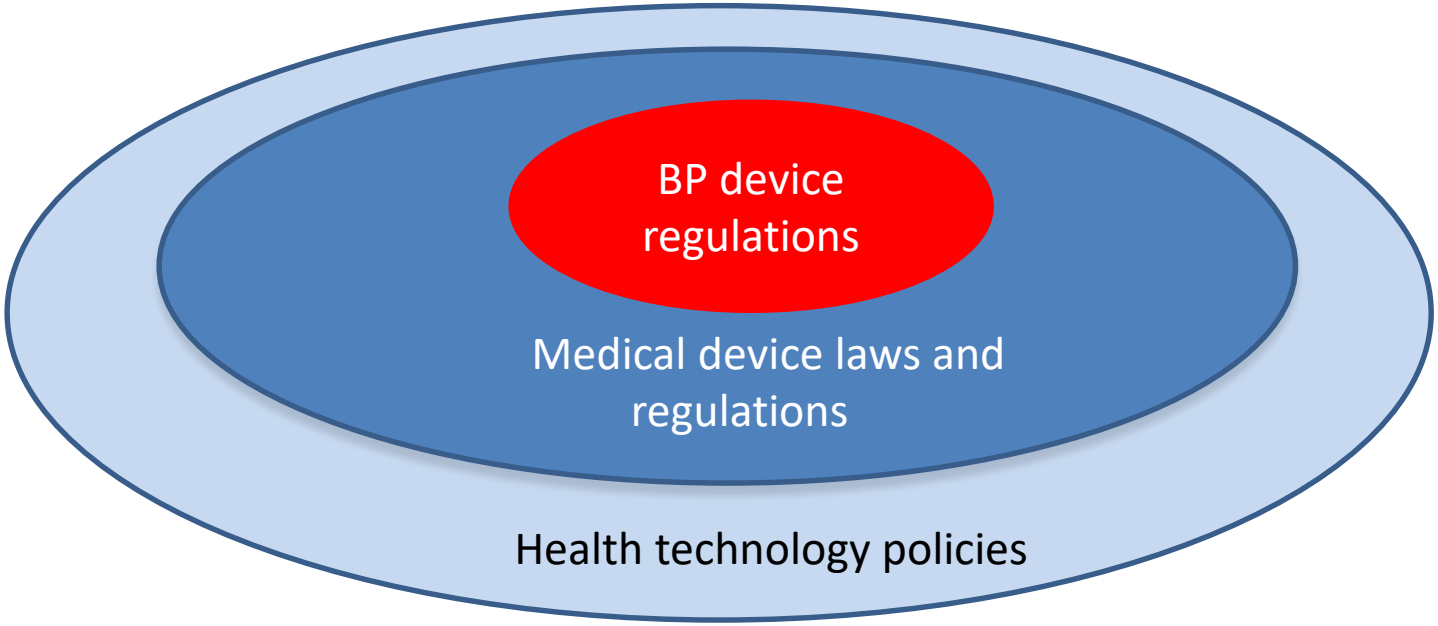
"Health technology is one of the weakest components of the national health system, and the absence of **suitable health technology policies** is at the root of the problem."

WHO. Development of medical device policies. 2011.



Review: objective, sections and response

A multi-pronged approach to regulatory frameworks is needed to ensure universal access to validated BP devices.

Objectives: Mapping of regulations relevant to accuracy of electronic BP devices in HEARTS countries. Exploring available information on procurement modality and availability at PHC.

Sections:

- Existence of laws/regulations
- Aspects of regulations:
  - Validation (standards)
  - Pre-market approval and post-market surveillance
  - E-commerce
  - Marketing
  - Labelling
  - Cuffs
  - Acquisition for use in PHC
- Monitoring, enforcement
- Acquisition modality

Response:

13 countries

Regulatory frameworks – current situation 1

Countries	Any BP regulation?			Refers to clinical validation?				Regulates e-commerce and promotion?	
	Med. devices law/decree?	BP devices provision?	BP devices regulation?	Mandatory accuracy validation?	Independent study?	Results published?	Requisite for approval?	Regulation of e-commerce?	Regulation of promotion?
Argentina	YES	NO	YES	NO	NO	NO	NO	YES	YES
Barbados	NO	NO	NO	NO	NO	NO	NO	NO	NO
Brazil	YES	NO	YES	NO	NO	NO	NO	YES	NO
Chile	YES	NO	NO	NO	NO	NO	NO	NO	NO
Colombia	YES	NO	NO	NO	NO	NO	NO	NO	YES
Cuba	Regulation	YES	YES	YES	YES	YES	YES	YES	YES
Dominican Republic	YES	NO	NO	NO	NO	NO	NO	NO	NO
Ecuador	YES	NO	NO	NO	NO	NO	NO	NO	NO
Mexico	?	NO	NO	NO	NO	NO	NO	NO	YES
Panama	YES	NO	YES	NO	NO	NO	NO	NO	NO
Peru	YES	NO		NO	NO	NO	NO	NO	NO
Saint Lucia	Act	YES	YES?	NO	NO	NO	NO	NO?	YES
Trinidad & Tobago	NO	NO	NO	NO	NO	NO	NO	NO	NO

Regulatory frameworks – current situation 2

Countries	Regulates labelling?				Regulates cuff size?			Regulates acquisition?	
	Any regulation of labelling?	… devices have been validated?	… independent validation?	… placing of informatio n?	Any regulation of cuff size?	Several cuff sizes?	Mention of arm circumf for size?	… for use national facilities?	… requires validation data?
Argentina	YES	NO	NO	NO	YES	YES	YES	YES	NO
Barbados	NO	NO	NO	NO	NO	NO	NO	NO	NO
Brazil	YES	?	?	?	YES	?	YES	NO	NO
Chile	NO	NO	NO	NO	NO	NO	NO	NO	NO
Colombia	YES	NO	NO	NO	NO	NO	NO	NO	NO
Cuba	YES	YES	YES	YES	NO	NO	NO	YES	YES
Dominican Republic	NO	NO	NO	NO	NO	NO	NO	NO	NO
Ecuador	NO	NO	NO	NO	NO	NO	NO	YES	YES
Mexico	YES	NO	NO	NO	NO	NO	NO	YES	NO
Panama	NO	NO	NO	NO	NO	NO	NO	YES	NO
Peru	NO	NO	NO	NO	NO	NO	NO	NO	NO
Saint Lucia	NO	NO	NO	NO	NO	NO	NO	NO	NO
Trinidad & Tobago	NO	NO	NO	NO	NO	NO	NO	NO	NO

Regulatory frameworks – current situation 3

Countries	What is used in PHC?		Data? Compliance?				
	Modality: centralized?	Data available on models used in PHC?	Data repository on models sold in the country?	How many validated?	Agency that monitors compliance?	Surveillance of online sales?	Agency that ensures compliance?
Argentina	CENTR, COUNTY, INST	NO	NO		YES	NO	YES
Barbados	CENTR	?	NO		NO	YES	?
Brazil	CENTR	NO	YES		YES	NO	YES
Chile	COUNTY, H REGION, INST.	NO	?		NO	NO	NO
Colombia	CENTR	NO	YES	?	NO	NO	YES
Cuba	CENTR	NO	YES	?	YES	YES	YES
Dominican Republic	CENTR	YES	NO		YES	NO	NO
Ecuador	INSTITUTION	YES	YES	?	YES	NO	YES
Mexico	CENTR	NO	NO		YES	YES	YES
Panama	CENTR	NO	NO		NO	NO	NO
Peru	H REGION, INST.	YES	YES	?	YES	NO	NO
Saint Lucia	CENTR	YES	?		YES	NO	YES
Trinidad & Tobago	H REGION	In progress	NO		NO	NO	?

Summary (n = 13)

Question	YES
Medical devices law?	9
Regulation of BP devices?	5
… mandatory validation?	1
… by independent group?	1
… published?	1
… requirement for pre-market approval?	1
… includes e-commerce?	3
… marketing?	5
--- cuff size?	2
… acquisition?	5
--- requires validation?	2
Data on models used in PHC?	4
Data on models sold in country?	5

Challenges

- Lack of awareness of importance of validation.
- Lack of knowledge of validation studies methodology, accredited labs.
- Difficulties in knowing which devices are validated.
- Lack of data on devices being used in health care facilities.
- Multitude of medical devices, burdened agencies.
- Local approval linked to approval by international entities (unspecified) or other countries' agencies.
- Challenges in monitoring internet promotion and e-commerce.
- Decentralized/fragmented acquisition.
- Higher cost of validated devices?
- Industry tactics and pressure.

The most important strategy for promoting the medical device industry was "clarifying the application of regulations" (easing regulations).

Lee M. Strategies for Promoting the Medical Device Industry in Korea: An Analytical Hierarchy Process Analysis. Int J Environ Res Public Health. 2018 Dec; 15(12): 2659.

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IN THE AMERICAS

				
	Medidor de pressão arterial G-Tech BSP11 (Este produto)	Medidor de pressão arterial G-Tech BP3AF1 Ver produto	Medidor de pressão arterial G-Tech RW450 Ver produto	Medidor de pressão arterial Techline BP-2208 Ver produto
Opiniões	★★★★½ (333)	★★★★½ (193)	★★★★½ (733)	★★★★½ (30)
Tipos de medições	Pressão sistólica, Pressão diastólica, Frequência cardíaca	Pressão sistólica, Pressão diastólica, Frequência cardíaca	Pressão sistólica, Pressão diastólica, Frequência cardíaca	Pressão sistólica, Pressão diastólica, Frequência cardíaca
Tipos de alimentação	Pilhas	Pilhas	Pilhas	Pilhas
Tamanho da pilha	AAA	AAA	AAA	AAA
Tipo de enchimiento	Automático	Automático	Automático	Automático
Quantidade de usuários	–	–	2	2

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Produto recomendado

Ótimo produto. Fez a medição mais corretamente do que o modelo de pulso, conferido com um estetoscópio. Vem com o selo do inmetro. Fácil de operar e de boa qualidade dado o preço do produto. A única ressalva fica por conta da braçadeira. Pessoas que tenham o braço um pouco mais largo que a média, precisará adquirir outro tamanho de braçadeira. Eu peso 71 kg e o tamanho foi correto. Porém, meu amigo que pesa 120 kg não conseguiu utilizá-lo.

★ ★ ★ ★ ★

Robusto e preciso.

O aparelho possui precisão e robustez. Por ser de medição no braço, não é tão prático quanto o que se utiliza no pulso, mas em compensação, possui maior precisão. Recomendo a todos, mas se você busca um aparelho para levar a todos os lugares, este não atenderá sua necessidade.

2 1

Wish list

- Regulations that include clinical validation as a requisite for pre-market approval.
- Ensure validation of imported devices.
- Development of standard procurement/acquisition procedures.
- Regulation that includes monitoring.
- Collaboration of MoH and agencies for validation of devices.
- Only validated devices should be used in medical facilities.
- Technical support for clinical validation of devices.

- Inclusion of BP devices in the Strategic Fund.

How to get there?

- Awareness (advocacy)
- Knowledge (capacity strengthening)
- Action (regulations development, implementation, monitoring and enforcement)