

Investment and Innovation in Medical Devices: *Feasibility of local production and commercialization*

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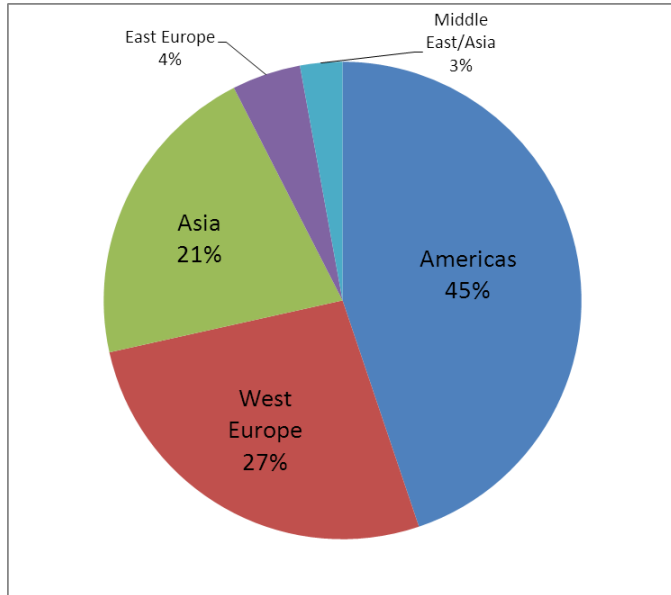


Scoping study on local production of medical devices

- Overview of the medical device production in low-resource settings.
 - Global medical devices market, Innovation of medical devices, Research and development for medical devices, Technology transfer and intellectual property, Governance and regulation, etc.
- Country case studies
 - Brazil | Americas Region
 - China | Western Pacific Region
 - Ethiopia | Africa Region
 - India | South-East Asia Region
 - Jordan | Eastern Mediterranean Region

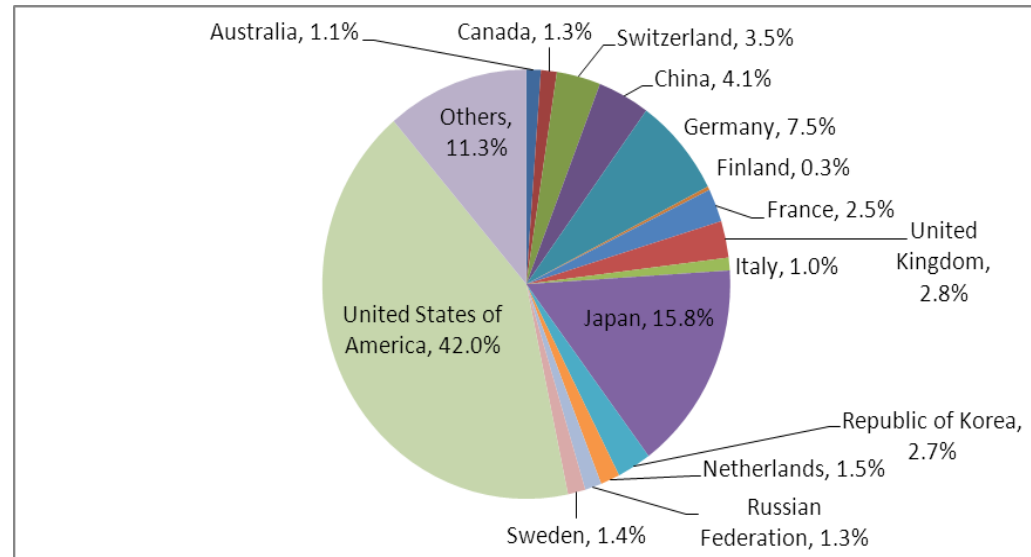


Medical devices market and patent application



World medical markets by sector, 2010

** Based on The World Medical Markets Fact Book 2011, which provides estimates based on the 66 countries for which sufficient data are available.*



- Patent applications in the field of medical technology by country, 2005-2009
- Source: World intellectual property organization (WIPO). World Intellectual Property Indicators 2011



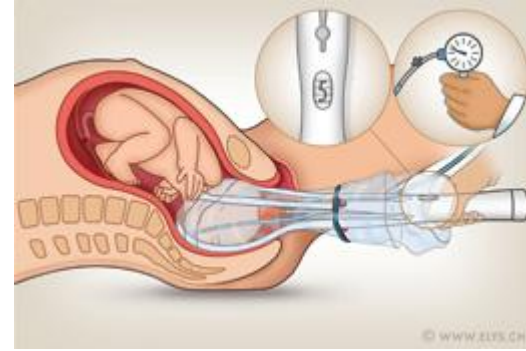
10 success stories

Neonatal intensive care equipment	Devices offered through the Breath of Life Programme in eight countries in South and South-East Asia.
LifeStraw	A point-of-use water filtration device.
Mechanical heart valve	Award-winning valves produced in India and exported to neighbouring countries.
Jaipur Foot	Leg and knee prosthetics made of locally sourced materials. The prosthetics are offered without cost to amputees.
Intraocular lenses	Lenses developed at less than one eighth of the price of comparable imports.
Telemedicine unit	Programmes in South Africa to offer services to remote populations.
Non-pneumatic anti-shock garments	Device controls the impact of post-partum haemorrhage.
Odon device	Assisted vaginal delivery device.
Solar Ear	A solar powered hearing aid.
Electrocardiograph	Affordable devices designed and developed by academic researchers and PhD students.





Jaipur foot, rubber and wood



Odon device to help birthing



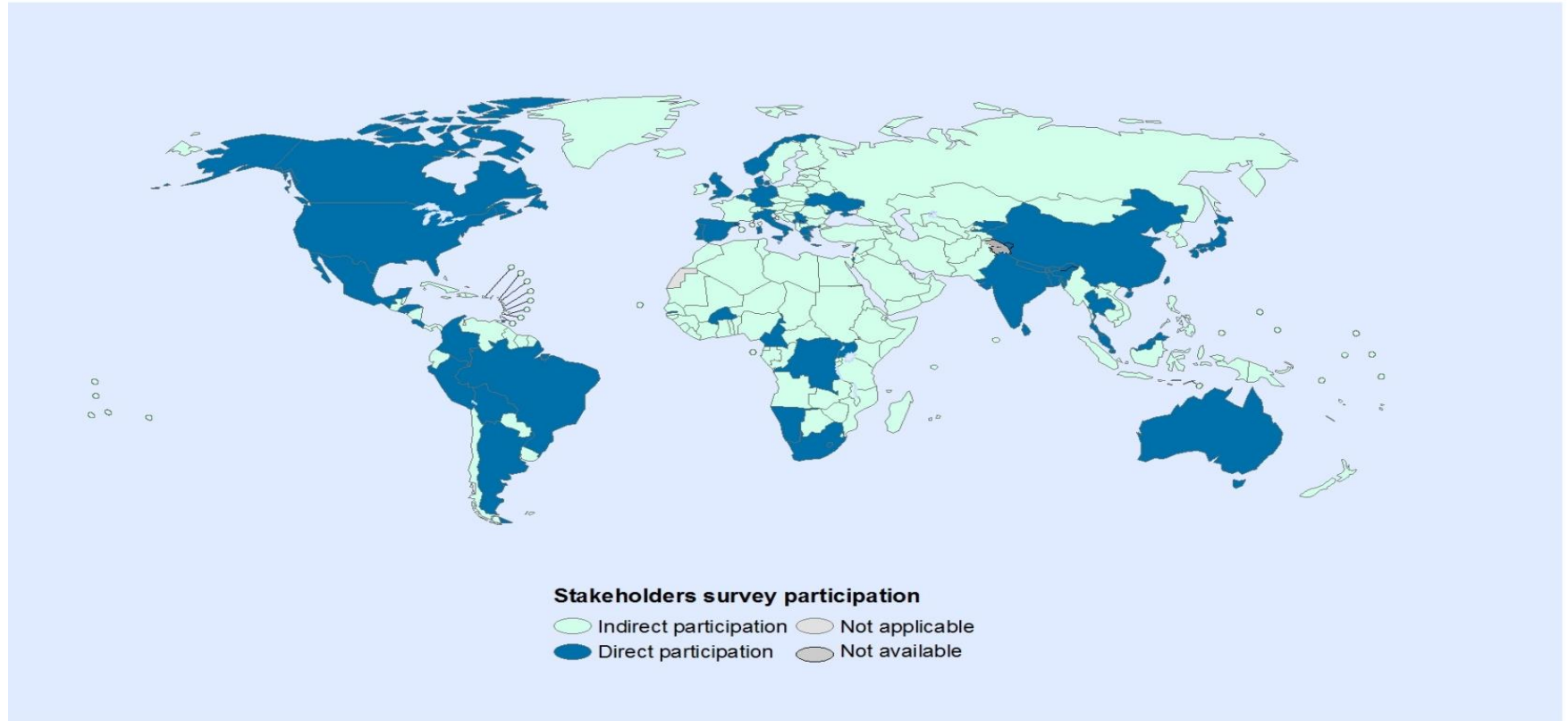
Solar ear, deaf people develop solar chargers



Phototherapy equipment in Vietnam



2012 Survey about access of medical devices

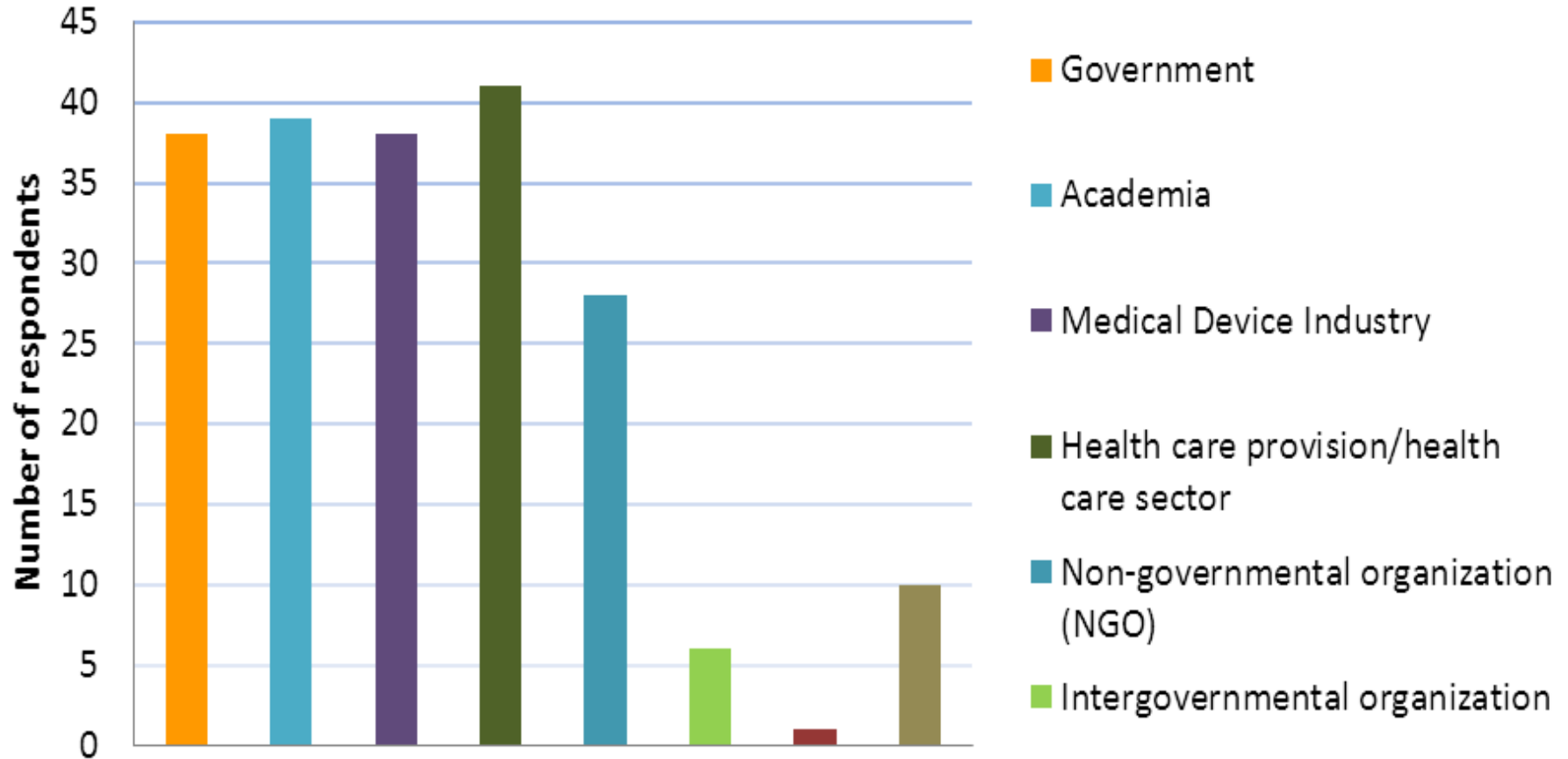


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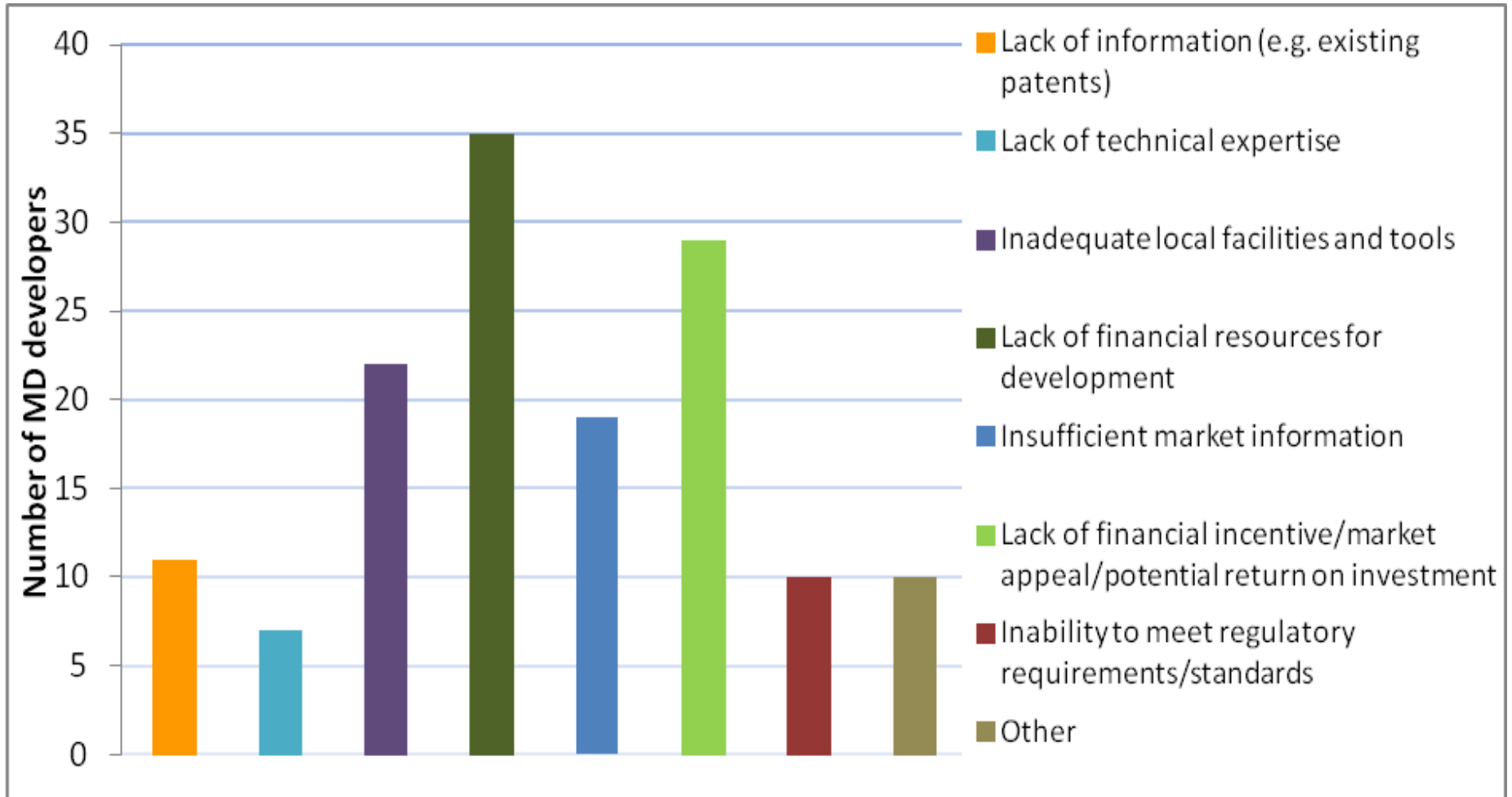
Participants with backgrounds and expertise in 46 different countries.



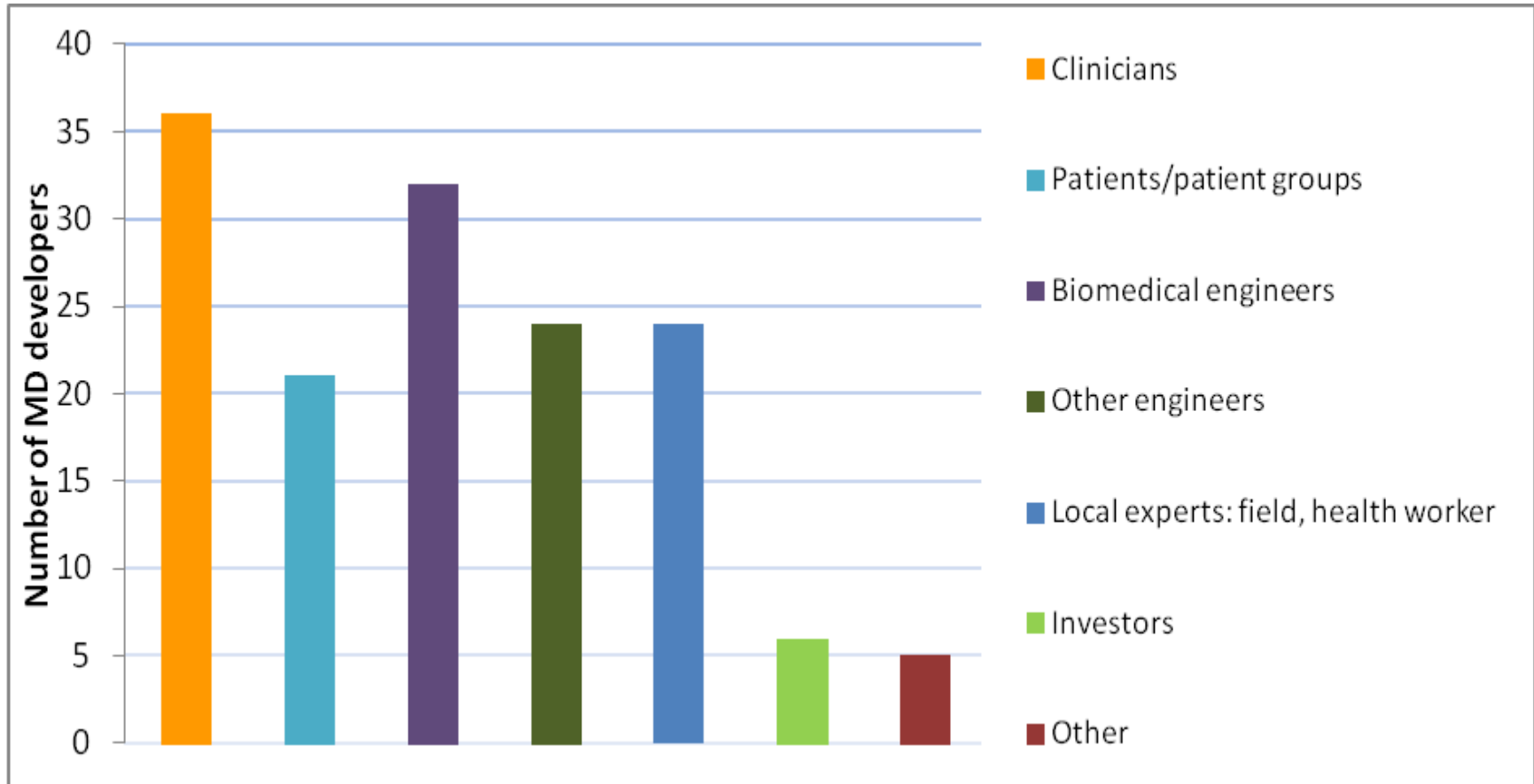
Respondents' sectors of work



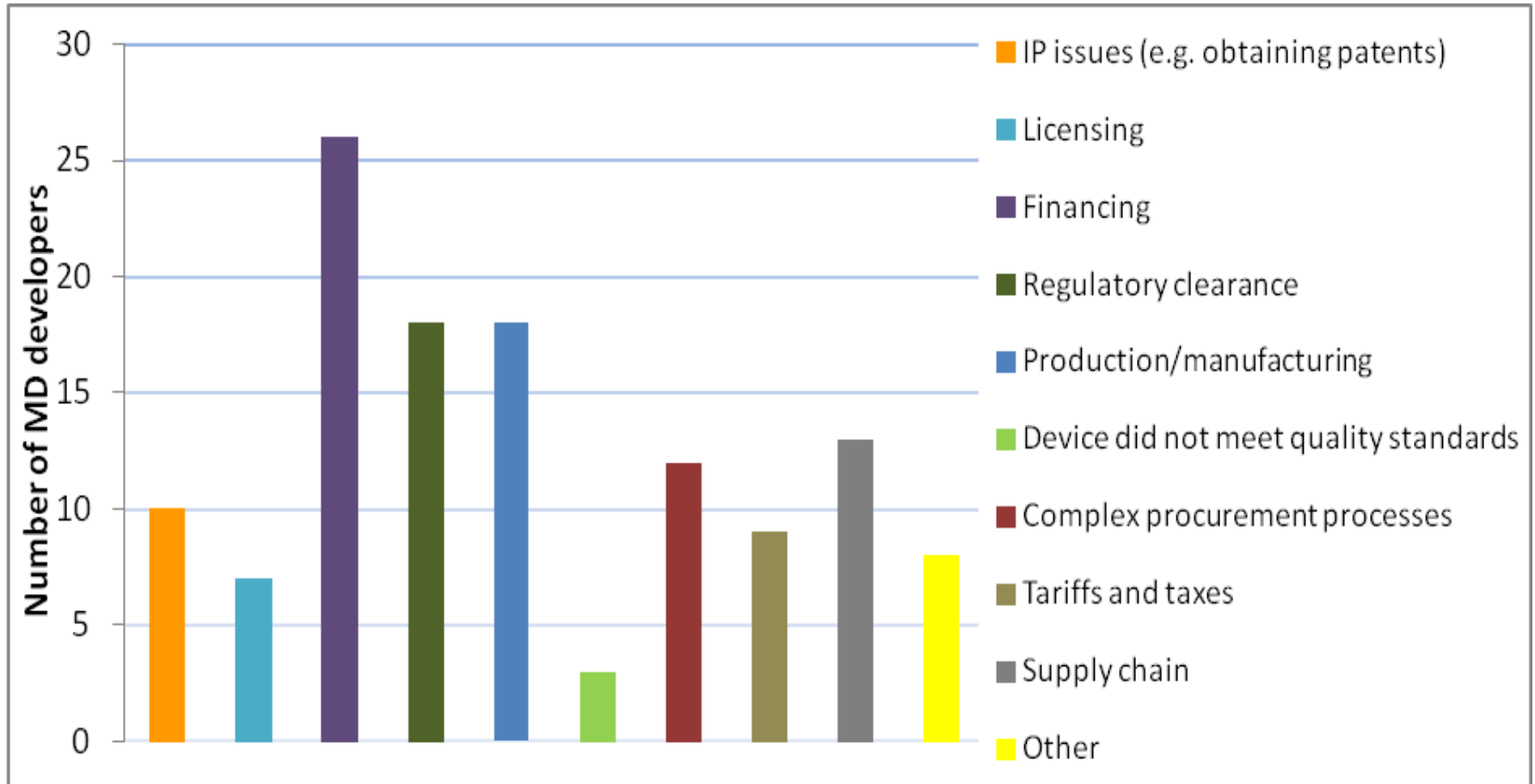
Barriers faced during product development



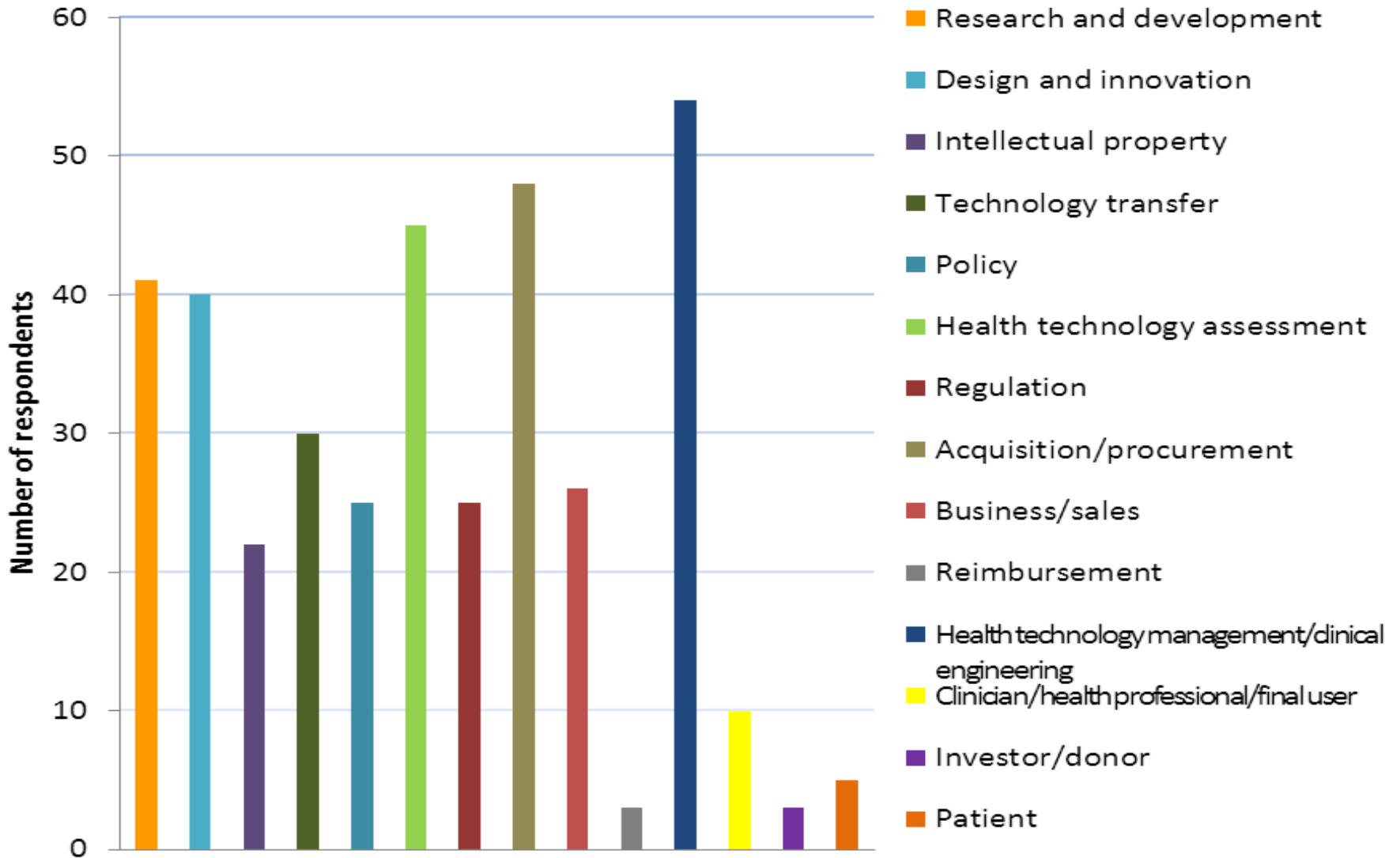
Stakeholders participating in development process



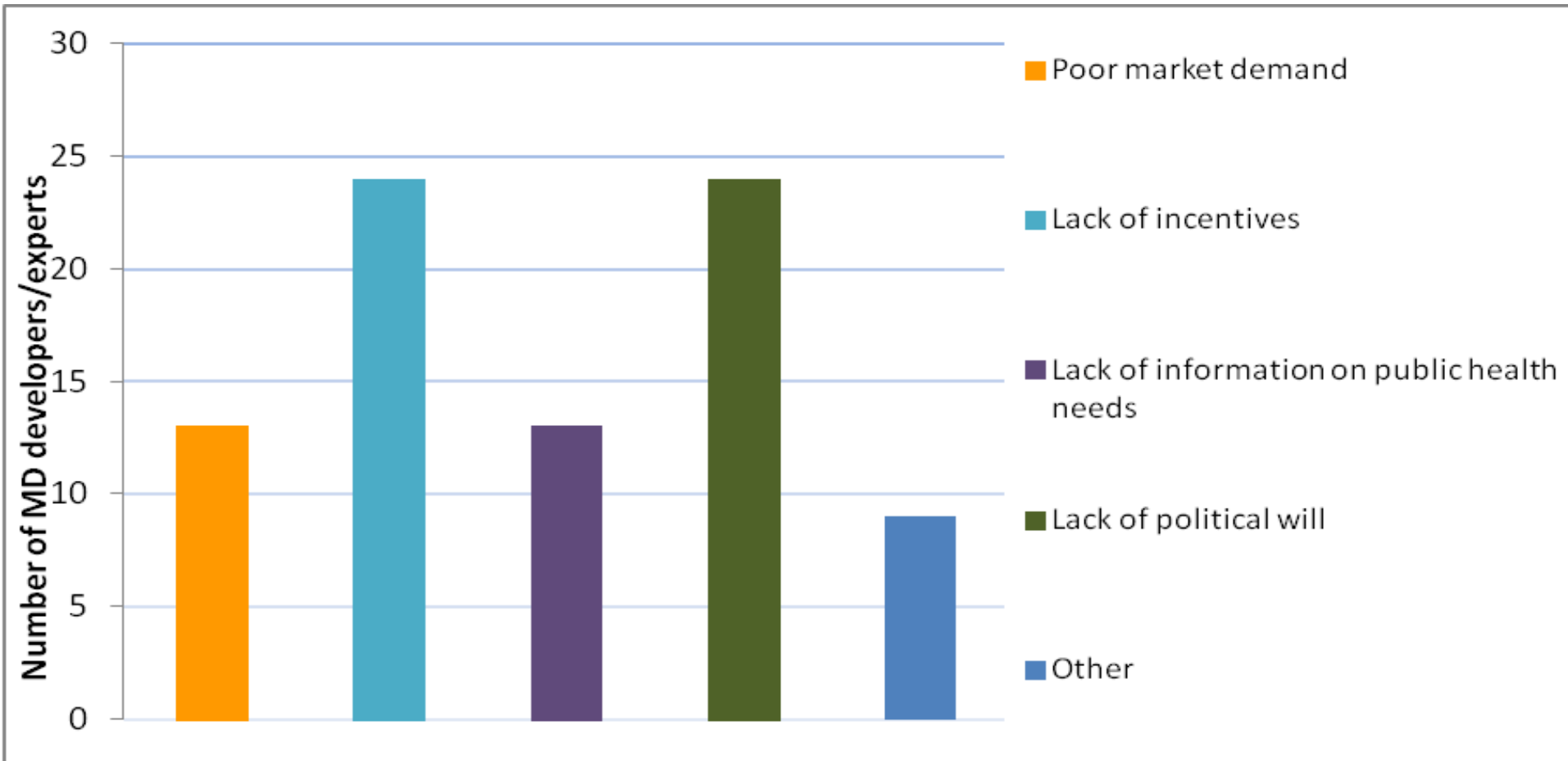
Barriers faced in commercializing/selling medical devices



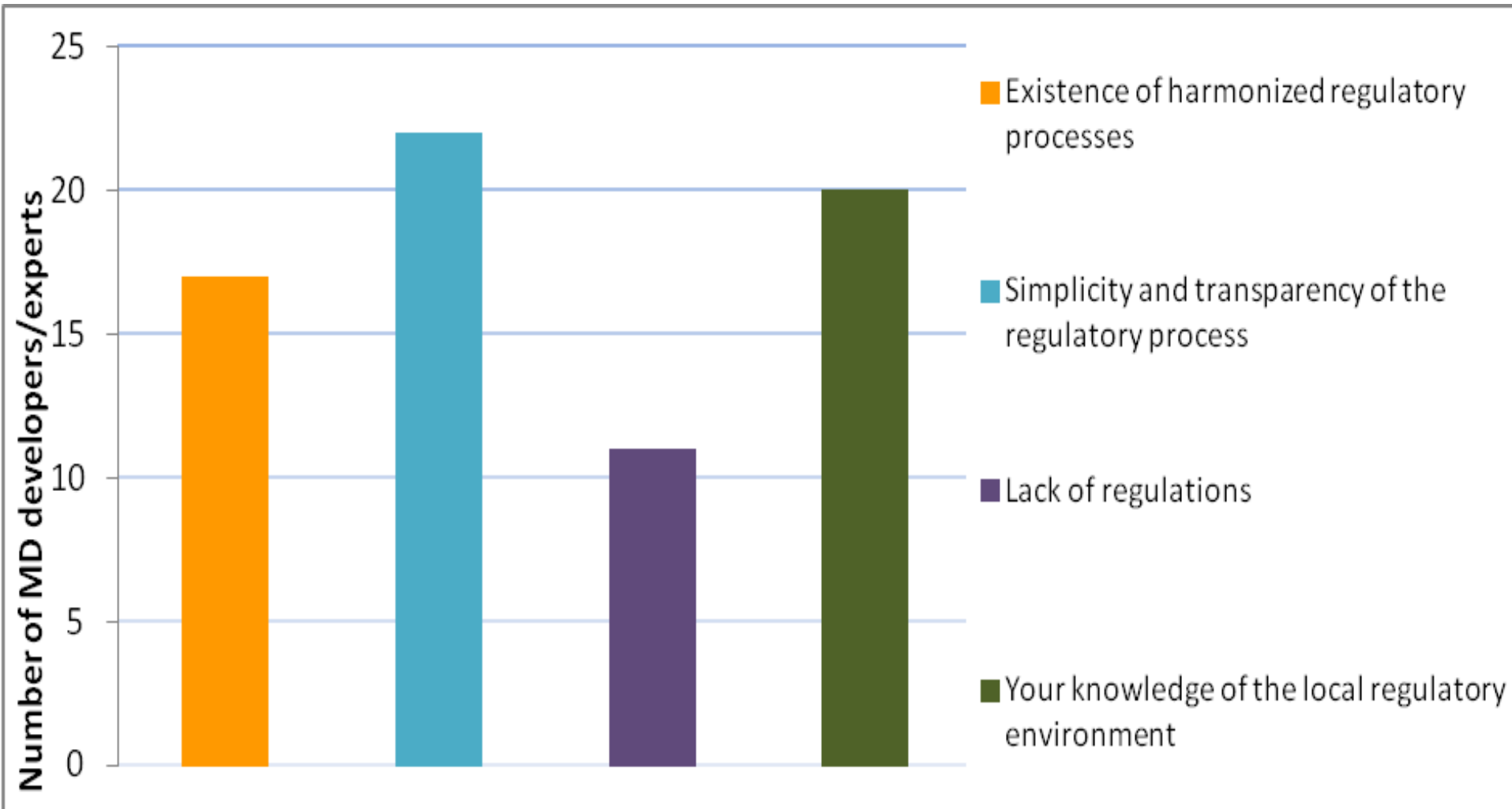
Survey respondents' fields of expertise



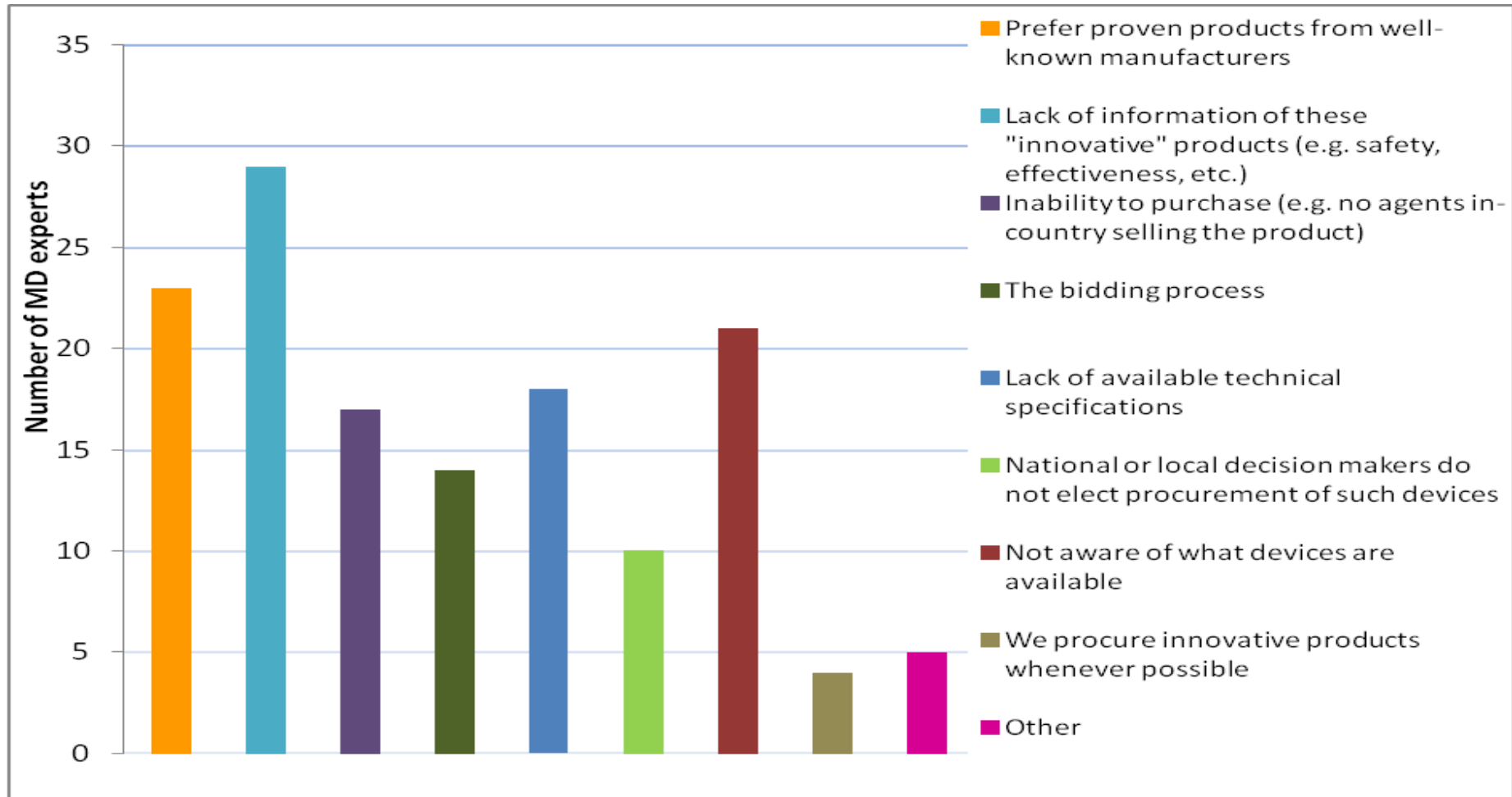
Main limitations of collaborations/partnerships in succeeding to increase access to medical devices



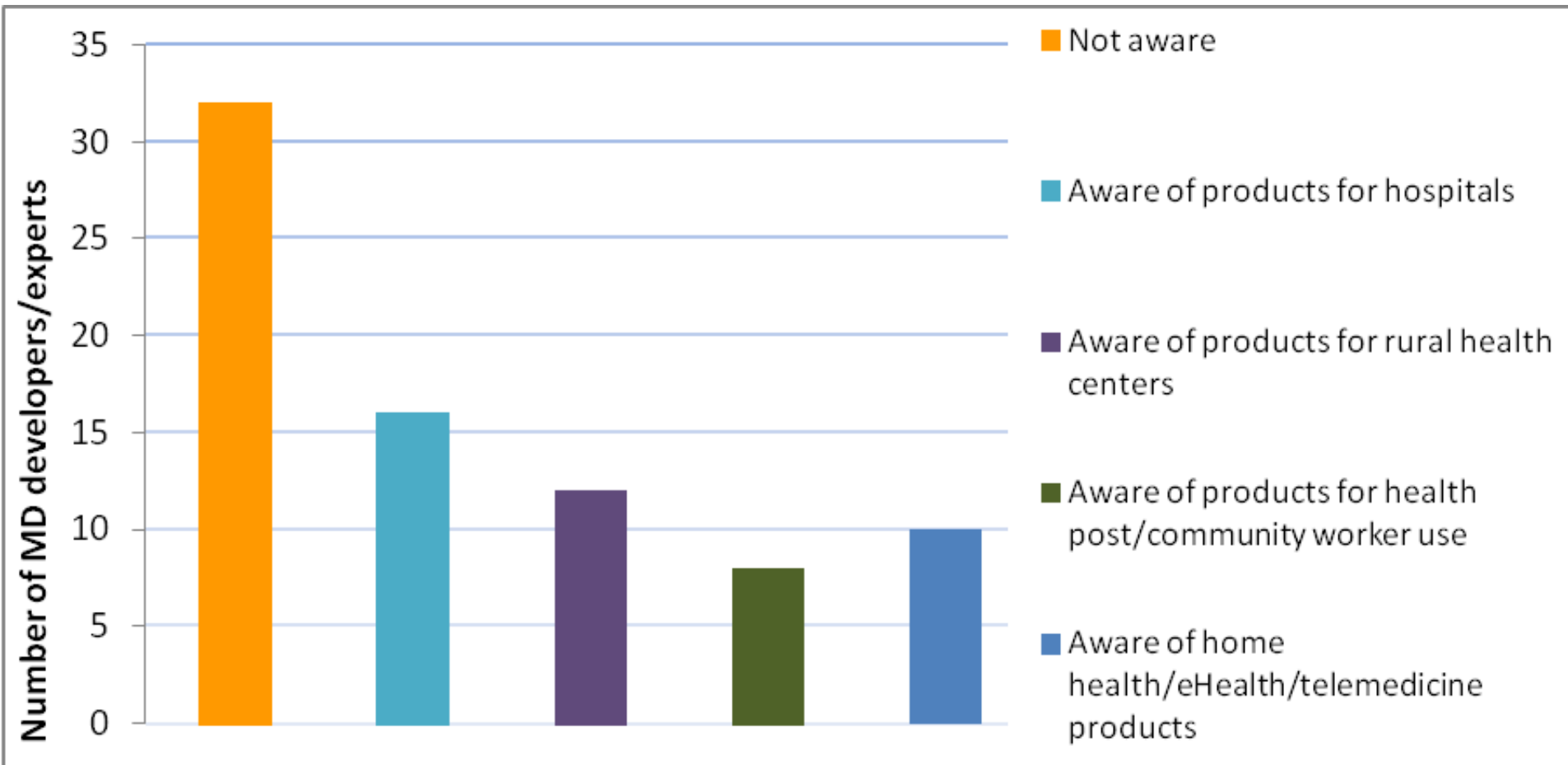
Regulation-related market determinants in selection of target market



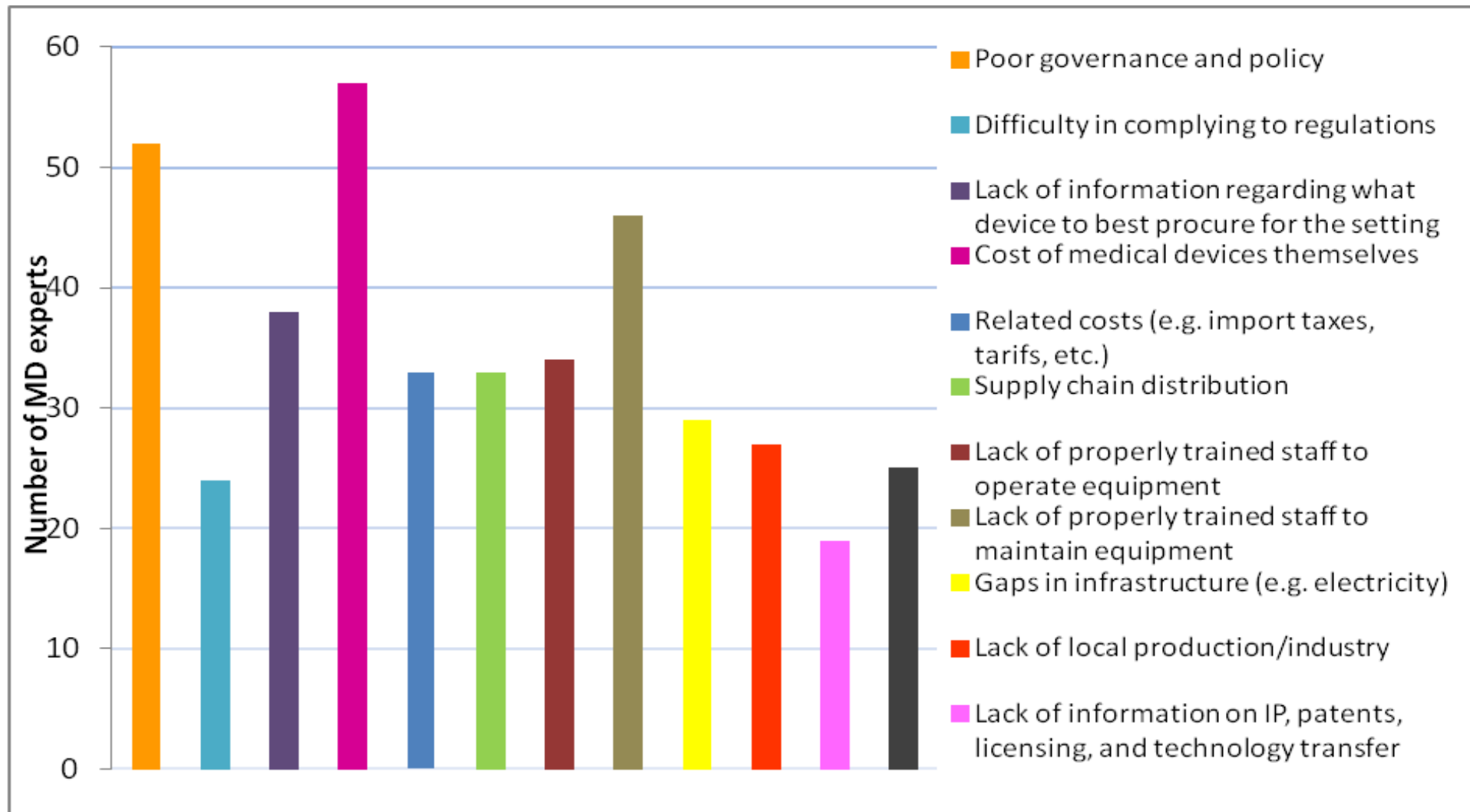
Factors preventing procurement of innovative technologies specifically designed for developing world



Are clinical engineers aware of local innovations to solve needs in low-resource settings?



Main barriers to access to medical devices in low-resource settings



Feasibility Tool

- Based on the
 - Survey findings,
 - Literature review, and
 - WHO Guidance
- Aim is to measure the possibility for a device to produced and successfully commercialized in Low or Mid-Income Country.

“To what extend is medical device X suitable for successful local production in low-resource region Y?”



Sections and subsections of the feasibility tool

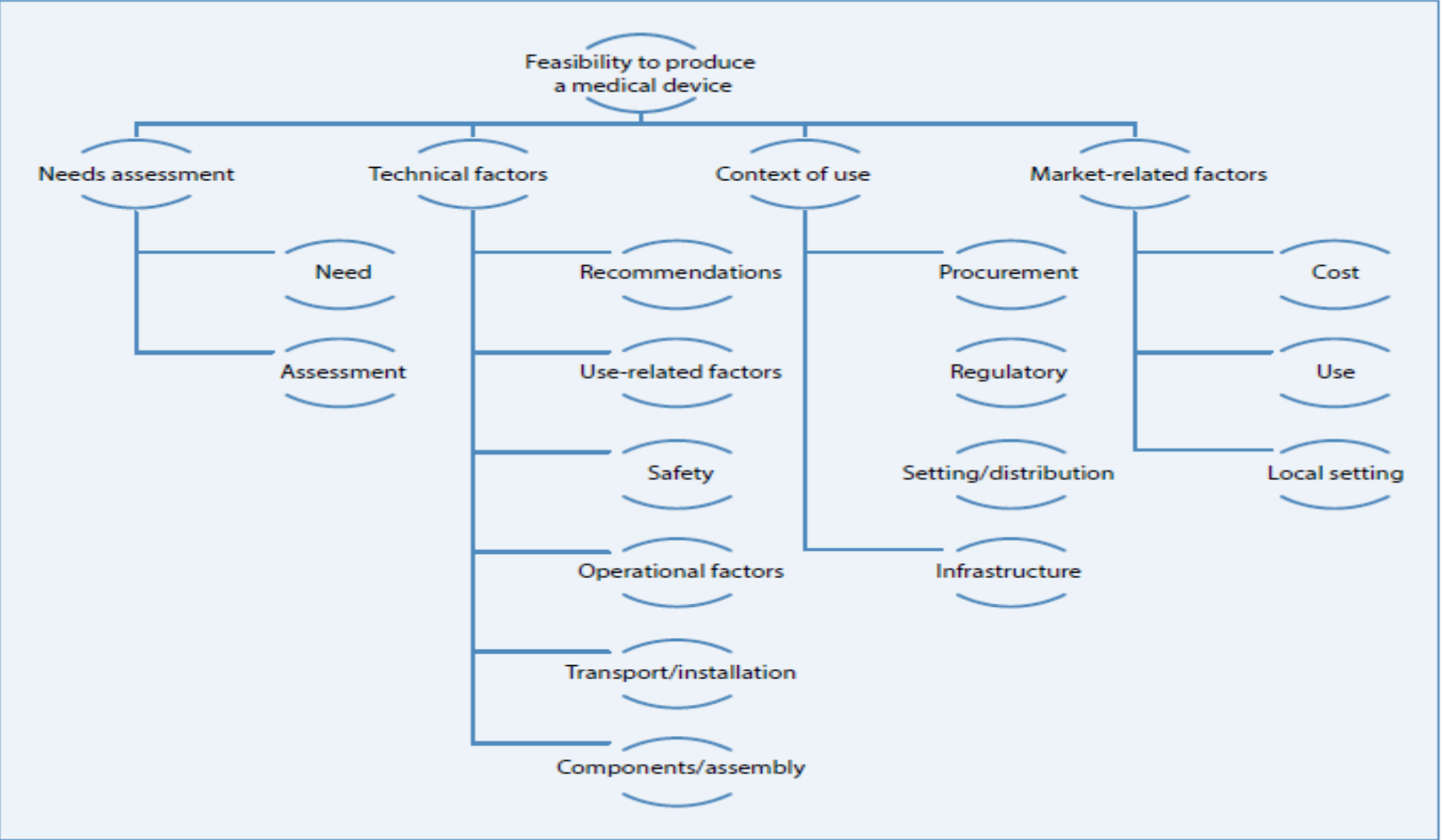


Table 1: Needs Assessment

- **Need**

- a) Is the device required to solve a pressing local health problem/priority disease in your country?
- b) Is the device used in
 - prevention?
 - diagnostics?
 - treatment?
 - rehabilitation?
 - support for other devices?
- c) Is the device essential in clinical procedures?
- d) Is the device an essential support technology for another device that is already available on the respective market?
- e) Is the device filling a gap in the region because no similar device is available yet?



Table 1: Needs Assessment

• Assessment

- a) Is the device superior to similar devices available in region Y?
- superior effectiveness
 - enhanced ease of use and/or maintenance
 - reduced training requirements
 - labour saving
 - improved safety level for patients
 - improved safety level for user or environment
 - improved safety level for manufacturing
 - increased social/cultural acceptability
 - reduced resource requirements (*such as independent of electricity or clean water supply*)
 - technical superiority
 - improved accessibility
 - better long-term value versus up-front costs
 - better affordability
 - better durability



Table 1: Needs Assessment

- **Assessment in place Y,**

- b) Is the device **adapted for use in the low-resource** setting it needs to be employed in?*
- Are there physicians and/or nurses and/or technicians available who will handle the device?
- Do these users have the expertise needed to handle the device correctly?
- Is availability of electricity, water, gas and/or other necessary resources ensured?
- Is resistance against dust/temperature changes/heat/other adverse conditions as found in the hospital/region ensured?
- Do the local safety standards meet the safety requirements for use and maintenance?*
- Does the local infrastructure allow easy distribution of the device?* (1="yes, delivery systems in place", 0="no, people in need difficult to reach")
- Does the local infrastructure allow easy installation of the device?*

* For each question answered with "no", the follow-up question is: "Can this situation be easily remedied?" In that case, the answer gains 1 point respectively.

Table 2: Device-related factors

• Components/Assembly

- a) Is the device manufactured
 - WITHOUT integration of complex electronic technology?
 - WITHOUT integration of complex biological technology?
 - WITHOUT integration of complex chemical components?
 - WITHOUT integration of complex mechanical components?
- b) Are the components made using material locally available?
- c) Are the components simple to produce?
 - can be produced without heavy machinery
 - can be produced without complex manufacturing process
 - can be produced without high precision measurements
 - can be easily imported



Table 2: Device-related factors

• Components/Assembly

d) Can the device be produced using a production line already in place for other devices?

(3 = “yes, with the same human resources and machinery”,

2=“yes, machinery in place, but different human resources needed”,

1=“yes, human resources in place, but different machinery needed”,

0=“no, needs special fabrication process that is not available locally”)

d) Is the assembling of the device simple?

- can be assembled without heavy machinery
- can be assembled without high level expertise
- can be assembled without high precision measurements
- can be assembled without complex infrastructure
- can be assembled by trained aid



Table 2: Device-related factors

• Operational factors

a) Is maintenance of the device simple?

- *(please rate between 0 and 3: e.g. 3 = “no maintenance needed”, 2=“maintenance can be done by nurse/local technician”, 1=“needs daily calibration by expert”, 0 = “requires maintenance by manufacturer”)*

b) Can maintenance of the device be done without complex training?

- *(Please rate between 0 and 3: 3=“no training needed”, 2=“introduction less than 1 hour”, 1=“training up to 1 day”, 0=“training more than a day”)*

c) Can the device be used on its own?

- can be employed without cold chain
- can be employed without regular safety checks
- can be employed without any other additional requirements



Table 2: Device-related factors

• Operational factors

d) Is the device independent of consumables?

- *(Please rate between 0 and 3: 3="no consumables", 2="very few and low-cost consumables", 1="few or low-cost consumables", 0="many and/or expensive consumables")*

e) Is the device independent of spare parts?

- *(Please rate between 0 and 3: 3="no spare parts", 2="very few and low-cost spare parts", 1="few or low-cost spare parts", 0="many and/or expensive spare parts")*

f) Is the device independent of energy sources?

- *(e.g. 3="no energy required", 2="manual energy source", 1="solar, battery, gas, fuel,...", 0="high voltage/stable electricity")*



Table 2: Device-related factors

• Use-related factors

- a) Can the device be used safely and effectively without complex training?
 - *(Please rate between 0 and 3: 3="no training needed", 2="introduction less than 1 hour", 1="training up to 1 day", 0="training more than a day")*
- b) Can the device be used in multiple health care settings?
 - in home care
 - by a community health care worker
 - in a mobile unit
 - in ambulatory care
 - within a telemedicine system
 - in a health post
 - in a health center
 - in a district hospital
 - in a regional hospital (4 or more specialties)
 - in a specialized hospital (III level university/ research hospital)
 - Is the device reusable? *(1="yes", 0="no")*
- c) Is the device suitable for use in low-resource settings?
 - works without any type of electricity? *(1="yes", 0="no")*
 - works without any additional resources (gas, water,...)? *(1="yes", 0="no")*
 - can be transported to regions where there are no roads? *(1="yes", 0="no")*
 - is it rugged and resistant? *(1="yes", 0="no")*



Table 2: Device-related factors

- **Safety**

- a) Is the risk level for the patient/user/health care worker/environment low?
 - works WITHOUT radiation
 - works WITHOUT sharps
 - works WITHOUT mercury
 - works WITHOUT gas
 - works WITHOUT risk of contamination
 - works WITHOUT implantable parts
 - remains less than 30 days in the body
- b) Is the risk level during manufacturing low?
 - works WITHOUT turning parts in machinery
 - only low voltage needed
 - general safety is ensured without special safety standards
 - works WITHOUT toxic fumes or similar



Table 2: Device-related factors

• Safety

c) Is the risk level during installation low?

- *(Please rate between 0 and 3. e.g. 3="yes, no health risk", 2="yes, but heavy components and/or electricity connection and/or ...", 0="no, installation workers need special safety training")*

d) Is the device usable in an environmentally friendly way?

- works WITHOUT water pollution
- works WITHOUT air pollution
- needs only sustainable amounts of resources (water/gas/...)

e) Has risk assessment been performed on the device?

f) Does the device comply with any international standards?



Table 2: Device-related factors

- **Transport/Installation/Disposal**

a) Is the device

- light weight?
- Resistant against vibration?
- sturdy, resistant against blows?
- easy to carry by one person?
- transported in a single package?

b) Is the device transportable and storable without special conditions?

- temperature independent? (1="yes", 0="no")
- pressure independent? (1="yes", 0="no")
- humidity independent? (1="yes", 0="no")
- dust-resistant? (1="yes", 0="no")

c) Is the installation of the device easy?

- can be done without special training? (1="yes", 0="no")
- can be explained by pictorial manuals? (1="yes", 0="no")

d) Is disposal of the device easy?

- is disposal of device and consumables and spare parts risk free for workers and environment? (1="yes", 0="no")
- can it be done without special machinery? (1="yes", 0="no")



Table 2: Device-related factors

- **Recommendations**

- a) Is the device type mentioned as essential in any guideline of WHO, UNICEF, or UNFPA?
- b) Is the device endorsed or prequalified by a UN organization?
- c) Is the device endorsed by one or several NGO?
- d) Has the device won any prestigious awards (for innovation or for low-resource settings)?
- e) Is the device on a donor list as e.g. Oxfam, US AID, MSF?



Table 3: Device-in-local-region/Context-of-use

• Regulatory

a) Is the device classified as low-risk?

(according to GHTF classifications in <http://www.gh tf.org/documents/sg1/SG1-N15-2006-Classification-FINAL.pdf>) (1="yes", 0="no")

a) Can the device be produced and sold without regulatory approval in the country? (1="yes", 0="no")

b) Can the device be manufactured, sold and used

- in accordance with the human laws in the country? (1="yes", 0="no")
- in accordance with the labor laws in the country? (1="yes", 0="no")
- in accordance with the environment laws in the country? (1="yes", 0="no")



Table 3: Device-in-local-region/Context-of-use

- **Procurement**

- a) Do public and/or private health sectors have fair and open procurement processes?
- b) Are locally produced medical devices accepted by health care workers/decision makers in terms of confidence in quality?
- c) Has the device been approved for procurement/reimbursement in the country?
- d) Does the device comply with technical specifications for medical devices issued by the country?



Table 3: Device-in-local-region/Context-of-use

• Infrastructure *

- a) Is the level of required skill for manufacturing coherent with the engineering setting in the country/region?
 - *(Please rate between 0 and 3, e.g.: 3="definitely yes, no additional training needed", 2="some local engineers/technicians in place, education of additional workers easy to do", 1="too few local experts in place, substantial additional education needed", 0="not at all, no local experts in place, education very complex".)*
- b) Is the level of required skill for use coherent with the health care setting in the country/region?
 - *(Please rate between 0 and 3, e.g.: 3="definitely yes, no additional training needed", 2="some local experts in place, training of additional experts easy to do", 1="too few local experts in place, substantial additional training needed", 0="not at all, no local experts in place, training very complex".)*

** For each question answered with "no", the follow-up question is: "Can this situation be easily remedied?" In that case, the answer gains 1 point respectively.*



Table 3: Device-in-local-region/Context-of-use

• Infrastructure *

- c) Is the level of required skill for maintenance coherent with the health care setting in the country/region?
- *(Please rate between 0 and 3, e.g.: 3="definitely yes, no additional training needed", 2="some local experts in place, training of additional experts easy to do", 1="too few local experts in place, substantial additional training needed", 0="not at all, no local experts in place, training very complex".)*
- d) Is the local infrastructure suitable for manufacturing the device?
- machinery available or easy to import? (1="yes", 0="no")
 - tools available or easy to import? (1="yes", 0="no")
 - required resources (electricity/water/...) in place? (1="yes", 0="no")

** For each question answered with "no", the follow-up question is: "Can this situation be easily remedied?" In that case, the answer gains 1 point respectively.*



Table 3: Device-in-local-region/Context-of-use

• Setting/Distribution *

- a) Has the device been tested successfully in the setting it should be used in?
 - *(Please rate between 0 and 3, e.g. 3 = “successfully tested in exact same setting” or “already in use in similar setting”; 0 = “not tested in low-resource setting at all”)*
- b) Are the necessary consumables available?
 - *(Please rate between 0 and 3: 3=“no consumables needed”, 2=“local consumables”, 1=“consumables imported but generally available”, 0=“no”)*
- c) Are the necessary spare parts available?
 - *(Please rate between 0 and 3: 3=“no spare parts needed”, 2=“local” spare parts, 1=“spare parts imported but generally available”, 0=“no”)*
- d) Can the device be packaged locally using local human resources?
- e) Can the device be labelled locally using local human resources?
- f) Is the device easy to distribute in the region

** For each question answered with “no”, the follow-up question is: “Can this situation be easily remedied?” In that case, the answer gains 1 point respectively.*



Table 4: Market-related factors

- **Local setting**

- a) Do physicians/health care workers/decision-makers recognize the need of the device and request its deployment?

- *Please rate from 0 (not at all) to 3 (definitely yes).*

- b) Does the country have a transparent legal and regulatory framework in place covering aspects like finance, investment, IP, and business set up encouragement strategies?

- *(Please rate from 0 (not at all) to 3 (definitely yes). Please take into account influence of IP to further develop, manufacture or commercialize the product.)*



Table 4: Market-related factors

• Cost

- a) Is the device affordable and cost-effective for the intended user-group (patient, funder, govt.)/payer (if payer is not the user)?
 - *Please rate from 0 (not at all) to 3 (definitely yes). Please take into account acquisition costs and service costs.*
- b) Can the device be produced locally at lower costs than currently imported ones?
- c) Are the consumables/spare parts/accessories locally available within an acceptable and pre-determined time frame?
- d) Are the cost of consumables/spare parts/accessories affordable for the intended user-group (patient, funder, govt.)/payer (if payer is not the user)?
 - *Please rate from 0 (not at all) to 3 (definitely yes).*



Table 4: Market-related factors

• Cost

- e) Are the costs of operation (i.e. service and engineering maintenance) affordable for the intended user-group (patient, funder, govt.)/payer (if payer is not the user)?
- *Please rate from 0 (not at all) to 3 (definitely yes).*
- f) Does the device have the potential to be deployed in a large number of regions/countries with the same needs?
- *(1="yes", 0="no")*
- g) Is the cost of import of consumable / spare-parts / accessories affordable for *(if no import necessary, put "1" to all)*:
- *tariffs? (1="yes", 0="no")*
 - *fees? (1="yes", 0="no")*
 - *"high" taxes? (1="yes", 0="no")*



Application of the tool to a set of new medical device inventions

• Technologies

- Mechanical heart valve (India)
- Telemedicine unit (South Africa)
- Wound suction device (India)
- NASG project (Nigeria)
- CPaP ventilator (Viet Nam)
- Bubble CPaP (Malawi)
- Computerized ECG (Bangladesh)

• Weighing ratios

Section	Ratio	Max Score
Needs Assessment	0.657	66
Technical Factors	0.234	23
Context of Use	0.082	8
Market	0.027	3



Thank You

