

Opportunities for IVD companies in the developing world

Andreas Knaack
Director of Biomedical Instruments and Devices

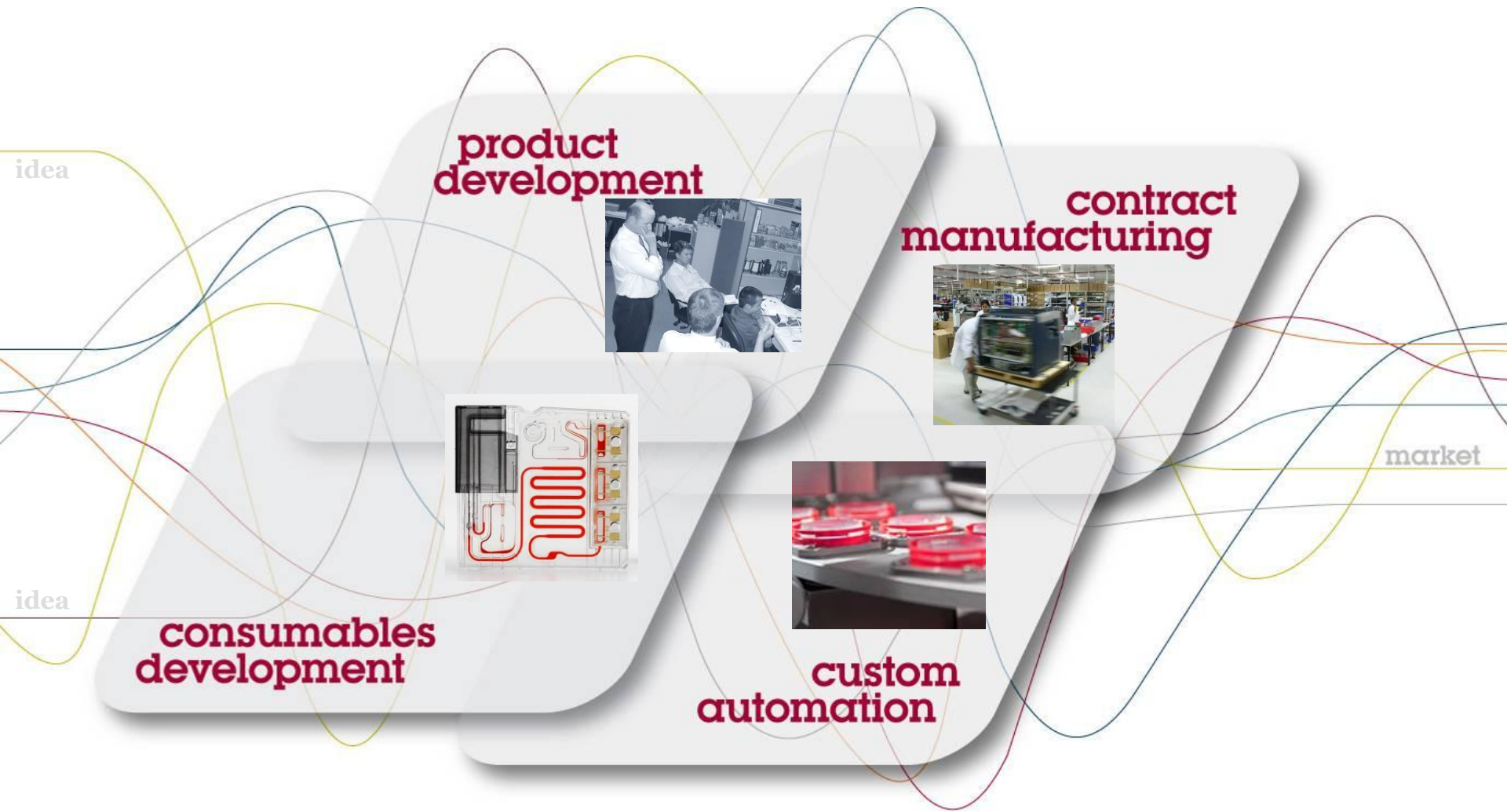


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Contents

- 1. Introduction**
2. Overview of developing nations
3. Key areas of need
4. Some specific considerations
5. Strategies of entry
6. The result of inaction

We develop and manufacture automated systems

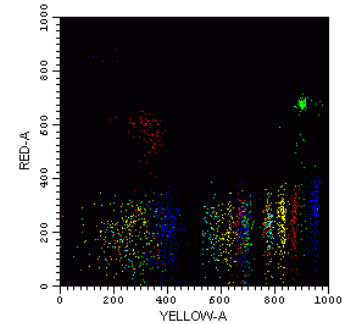
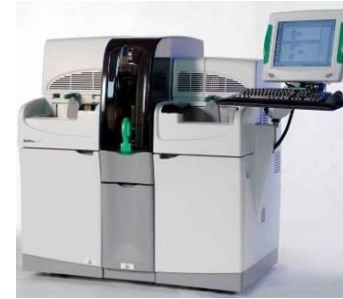


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We work with clients throughout the world



IVD portfolio examples

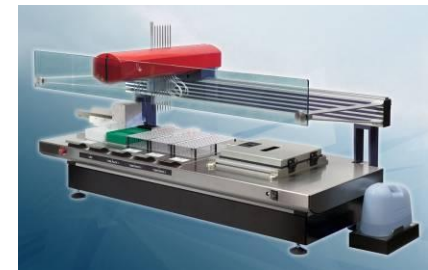
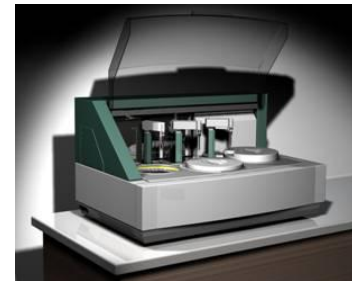


bioMérieux PREVI™ Isola

bioMérieux easyMAG™

Bio-Rad immunoassay

Genera Biosystems



Streck hematology

Abbott hematology

Bayer clinical chemistry

Quadrascpec Inspira™



Radiometer POCT

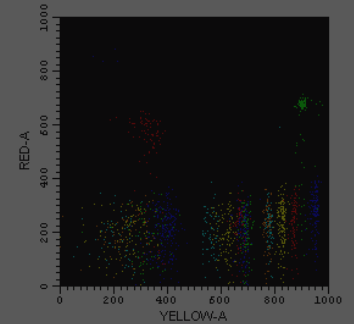
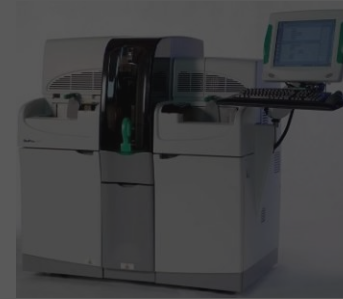
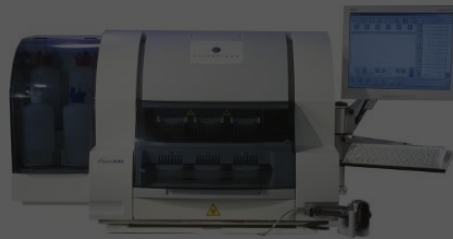
TearLab POCT

Micronics POCT

**Gates Foundation
POCT**

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IVD portfolio examples

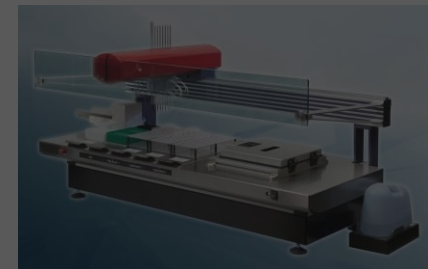
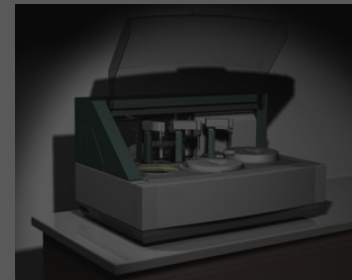
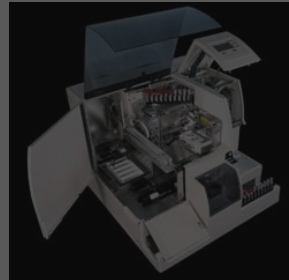


bioMérieux PREVI™ Isola

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**Gates Foundation
POCT**

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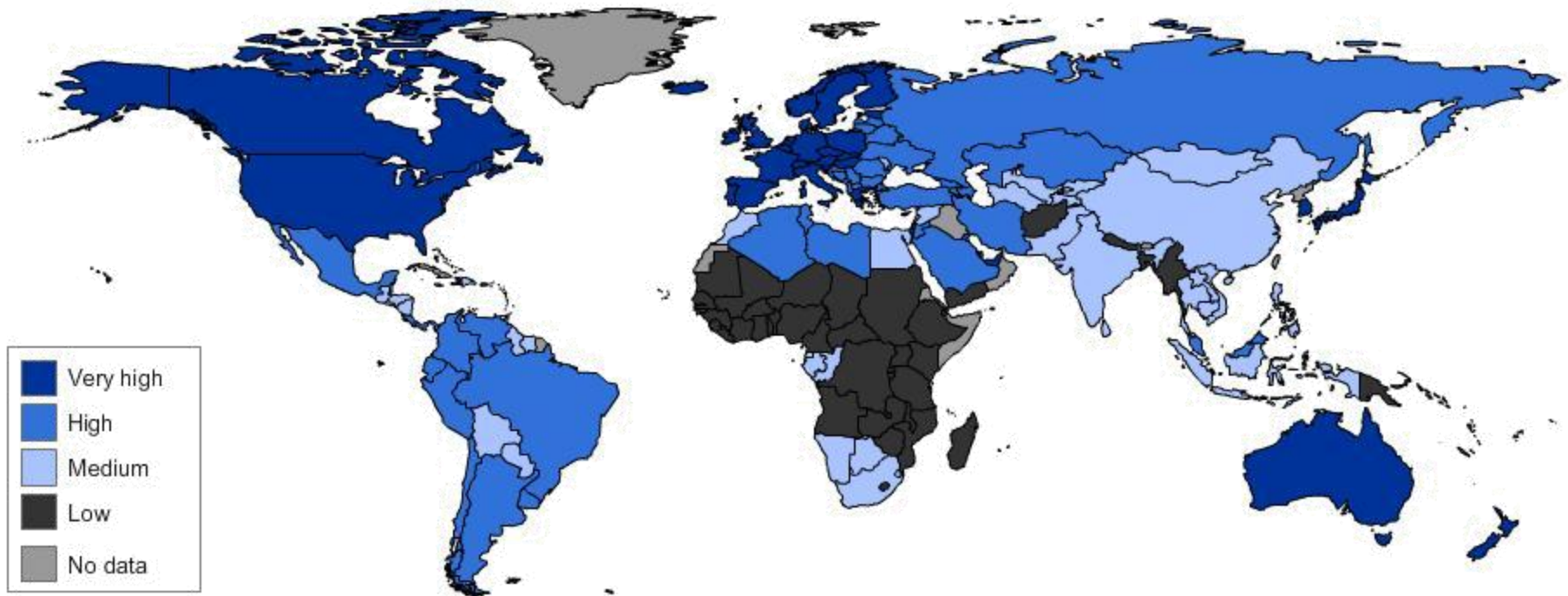
In this presentation

- **The moral obligation**
- **The commercial imperative**
- **Strategic pathways**

Contents

1. Introduction
- 2. Overview of developing nations**
3. Key areas of need
4. Some specific considerations
5. Strategies of entry
6. The result of inaction
7. Conclusion

UNDP Human Development Index 2010



Source: <http://hdr.undp.org/en/data/map/>

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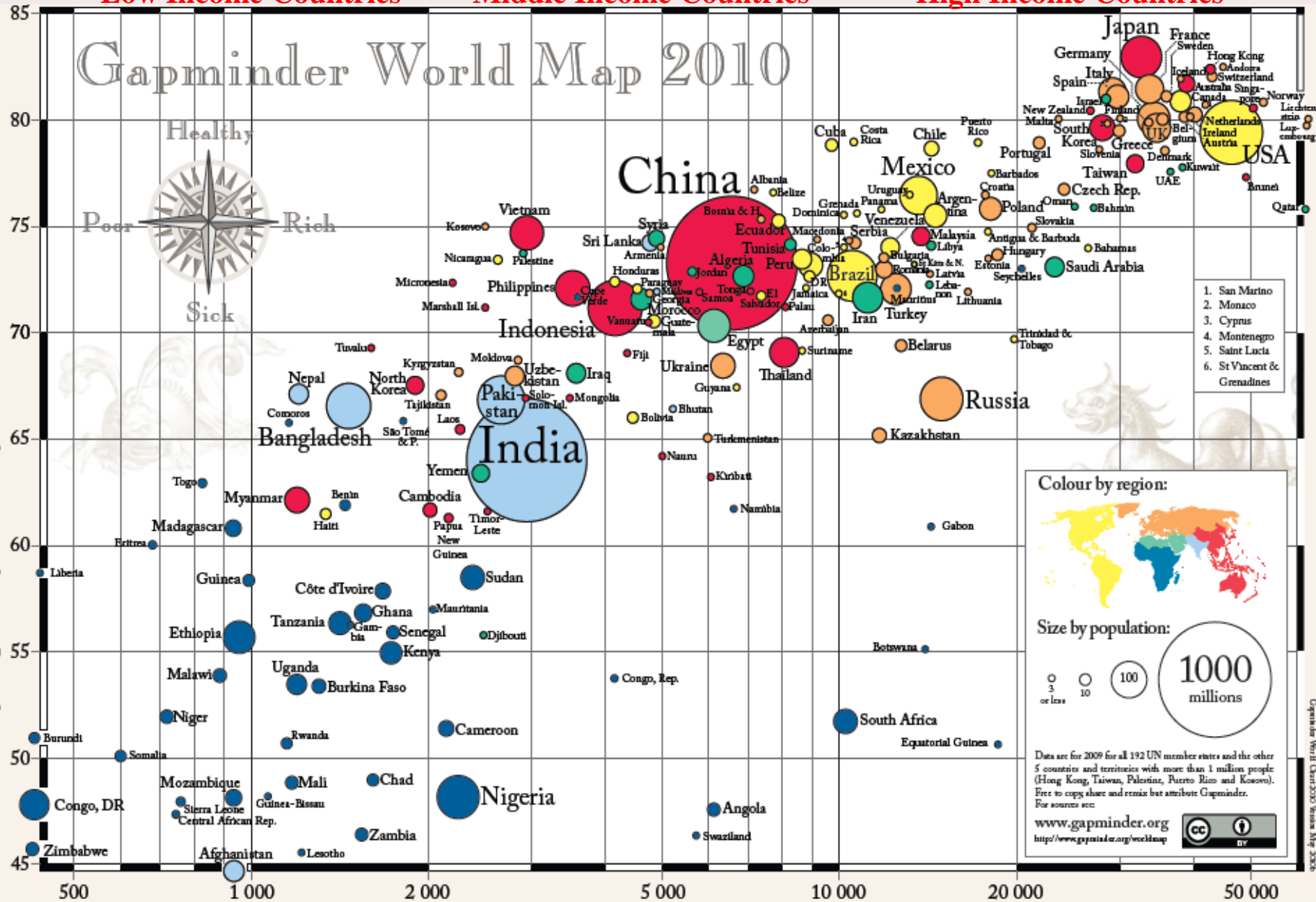
Low Income Countries

Middle Income Countries

High Income Countries

Gapminder World Map 2010

Health Life expectancy at birth (years)

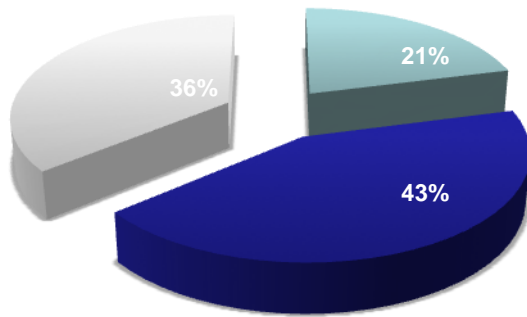


Money GDP per person in US dollars (purchasing power adjusted) (log scale)

www.gapminder.org

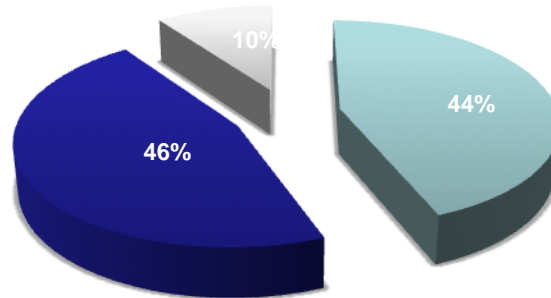
Gapminder World Map 2010 Terms Map 2010

Death distribution by age and income – children in developing nations remain at high risk



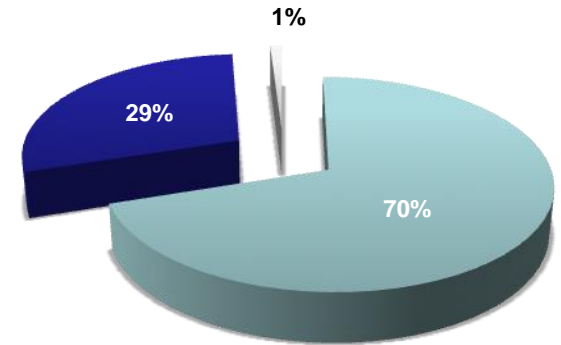
Low income Countries

21% Deaths among people over 70
43% Deaths among people 15 - 69
36% Deaths among people 0- 14



Middle income Countries

44% Deaths among people over 70
46% Deaths among people 15 – 69
10% Deaths among people 0- 14



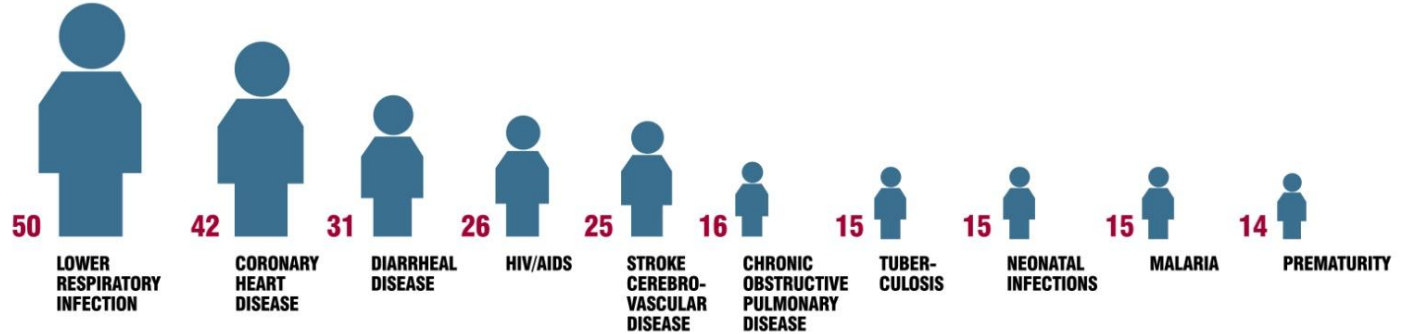
High income Countries

70% Deaths among people over 70
29% Deaths among people 15 – 69
1% Deaths among people 0- 14

Deaths across the globe: an overview

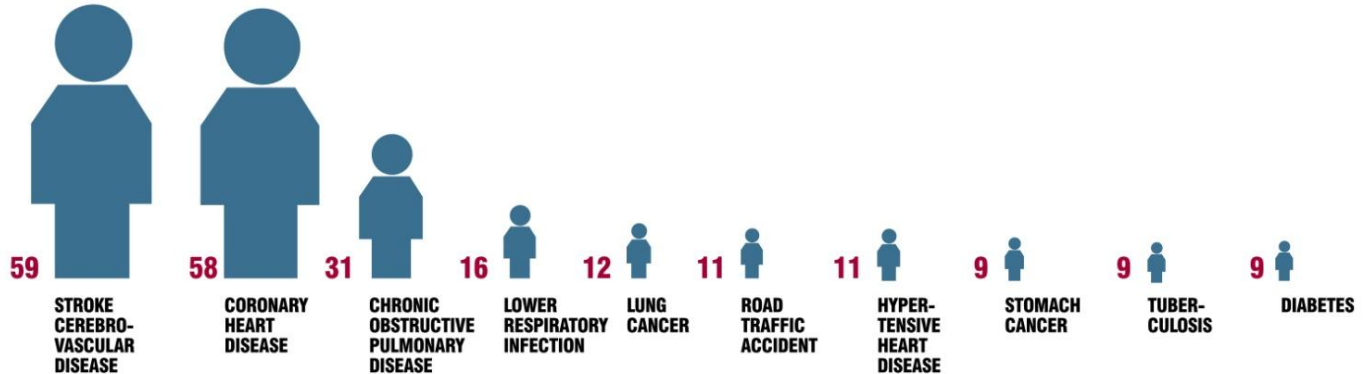
LOW INCOME COUNTRIES

447
of 1000



MIDDLE INCOME COUNTRIES

415
of 1000



HIGH INCOME COUNTRIES

138
of 1000



Source: <http://www.who.int/mediacentre/factsheets/fs310/en/index.html>

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Differences in the developing world

Q: What are the main differences between rich and poor countries with respect to causes of death?

High-income countries

- > 66% of all people live beyond the age of 70
- predominantly die of **chronic diseases**: cardiovascular disease, chronic obstructive lung disease, **cancers**, **diabetes** or **dementia**
- **lung infection** remains the only leading infectious cause of death

Middle-income countries

- >50% of all people live to the age of 70
- chronic diseases are the major killers, just as they are in high-income countries
- additionally **TB** and road traffic accidents also are leading causes of death

Low-income countries

- < 25% of all people reach the age of 70
- dominant causes are **infectious diseases**: lung infections, diarrheal diseases, HIV/AIDS, tuberculosis, and malaria

Key point

In low income countries children under 14 account for 36% of all deaths

In high income nations it is just 1%

Contents

1. Introduction
2. Overview of developing nations
- 3. Key areas of need**
4. Some specific considerations
5. Strategies of entry
6. The result of inaction
7. Conclusion

UN millennium goal number 6

- Millennium Development Goals under review at the UNITED NATIONS SUMMIT 20-22 September 2010, New York High-level Plenary Meeting of the General Assembly
- Goal number 6 pledges to combat
 - HIV/AIDS
 - Malaria
 - TB
 - Measles
 - Polio and other diseases

The Global Fund

- Founded January, 2002 as a unique public-private partnership in global health
- To respond to AIDS, tuberculosis and malaria
- Channels two-thirds of all international financing provided to fight TB and malaria, and a fifth of international financing against AIDS

Source: http://www.un.org/millenniumgoals/pdf/MDG_FS_6_EN.pdf

Bill & Melinda Gates Foundation

- “Our Global Health Program harnesses advances in science and technology to save lives in poor countries”
- Priority focus on infectious diseases:
 - Enteric and diarrheal diseases
 - HIV/AIDS
 - Malaria
 - Pneumonia
 - Tuberculosis

Source: <http://www.gatesfoundation.org/global-health/Pages/overview.aspx>

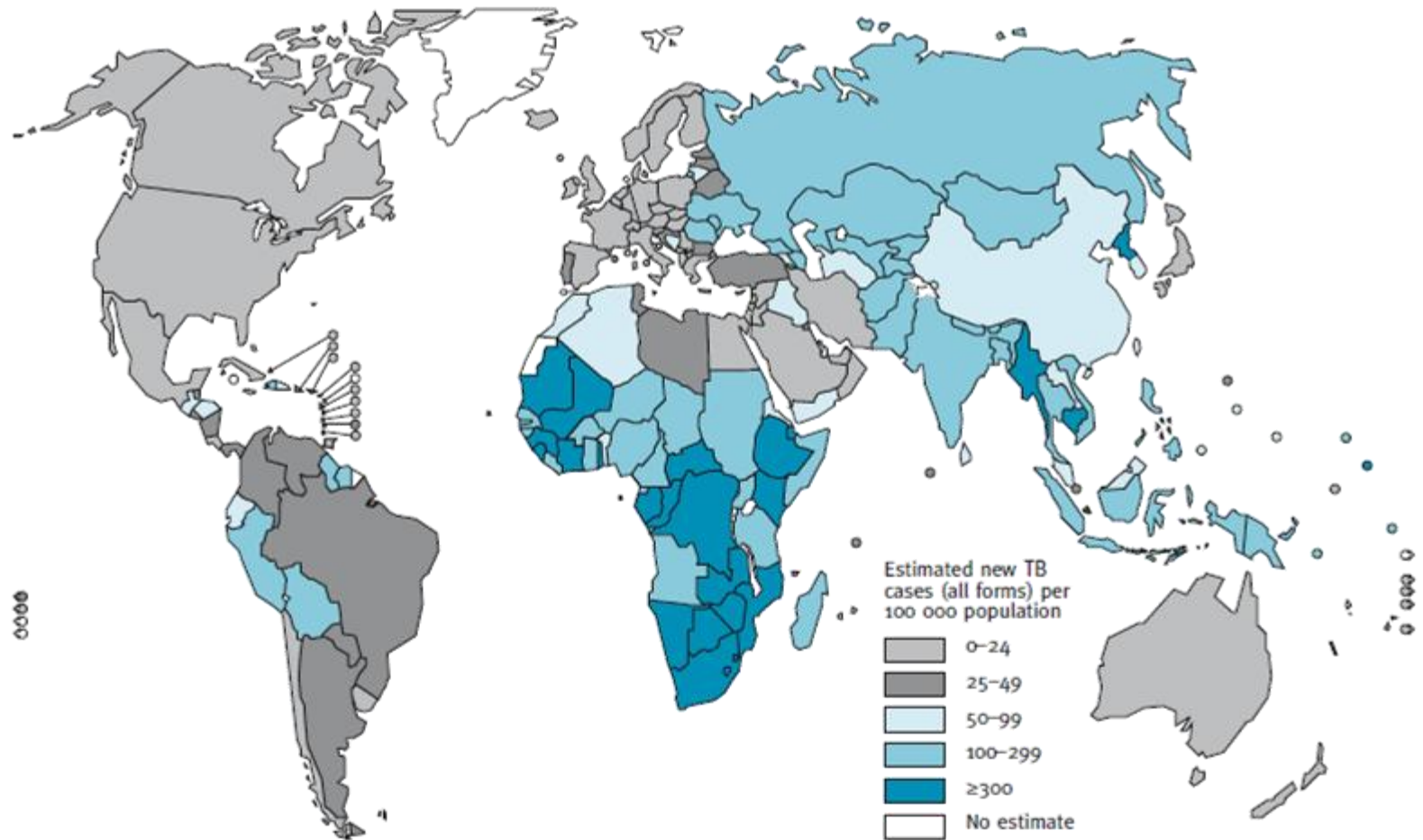
Key point

The world is converging on addressing the top infectious diseases, starting with...

- **TB**
- **HIV**
- **Malaria**

TB worldwide

Estimated TB incidence rates, by country, 2009



Source: WHO Report 2010 Global Tuberculosis Control

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TB facts

- **Annual cases of TB**
 - 9.4 million new TB cases in 2009
 - a third of all new cases are in **India** and **China**
- **Population at risk**
 - one third of the world's total population is infected with TB
 - one in every 10 of these develop active TB in their lifetime
- **Annual deaths from TB**
 - 1.7 million died from TB in 2009
 - someone dies of TB every 18 seconds

Source: http://www.who.int/features/factfiles/tb_facts/en/index1.html

TB diagnostics

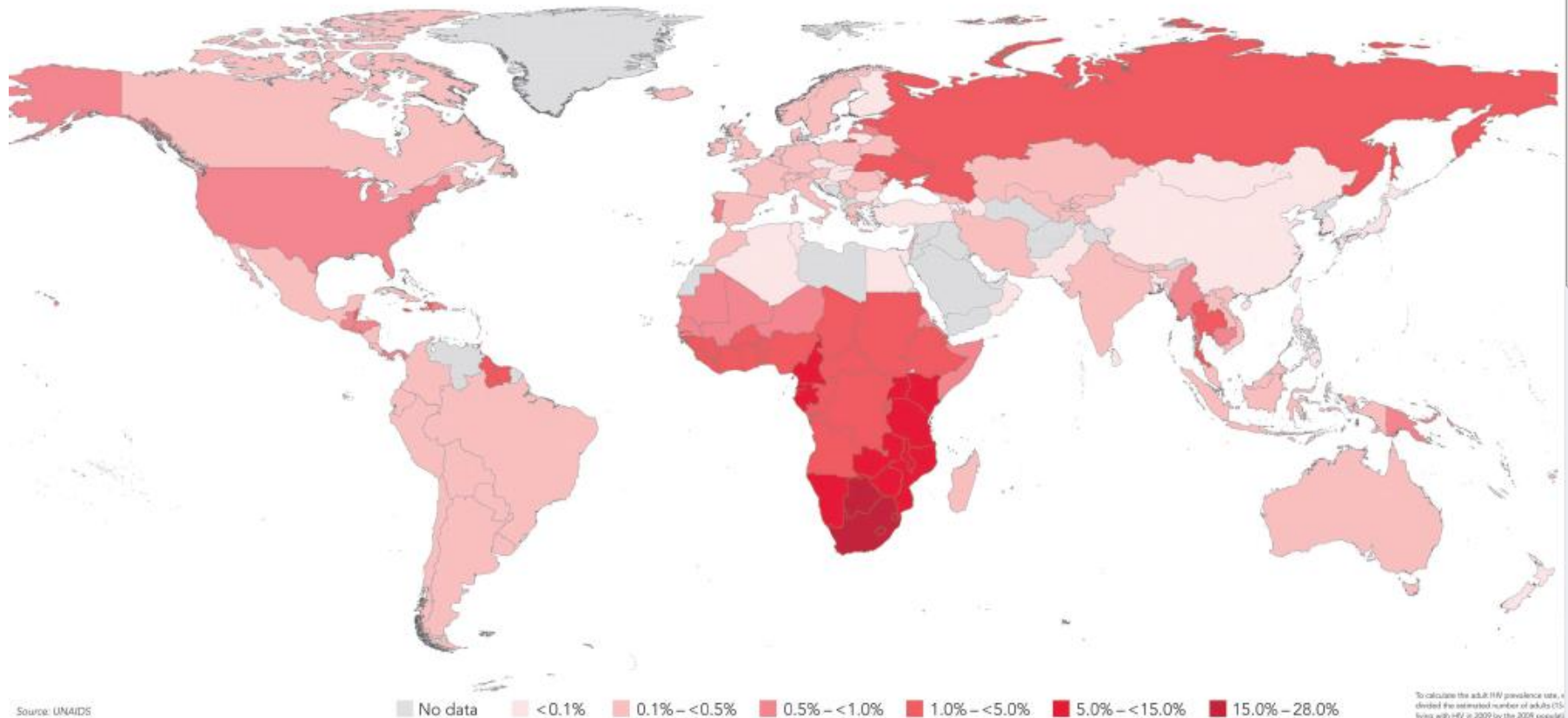
- **Standard diagnosis is via sputum smear and Mantoux Test**
 - require skilled operators and stable lab conditions
- **Enzyme linked immunoassays and molecular diagnostics exist**
 - potential to reduce turn around time
 - lower operator dependence
 - cost currently hinders wider adoption

Source: <http://www.rph.wa.gov.au/malaria/diagnosis.html>

HIV worldwide

2010: A global view of HIV infection

33.3 million people [31.4–35.3 million] living with HIV, 2009



Source: http://www.unaids.org/documents/20101123_2010_HIV_Prevalence_Map_em.pdf

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HIV facts

- **Annual Cases of HIV**
 - 2.7 million were newly infected with HIV in 2008
- **Population at risk**
 - 33.3 million live with HIV/AIDS
 - majority are in low- and middle-income countries
 - more than 2 million children are living with HIV/AIDS
 - 1,200 children are newly infected with HIV each day
- **Annual deaths from HIV**
 - 2 million people die every year from HIV/AIDS
(HIV/AIDS has claimed more than 27 million lives)

Source: <http://www.who.int/features/factfiles/hiv/facts/en/index2.html>

HIV diagnostics

- ELISA Tests
- CD4 Cell Count
- HIV viral load testing
- A variety of simple / rapid tests exist some of which work with finger prick blood samples

Source: <http://www.rph.wa.gov.au/malaria/diagnosis.html>

Malaria worldwide



Source: <http://www.rollbackmalaria.org/keyfacts.html>

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Malaria facts

- **Annual Cases of Malaria**
 - *Globally*: 247 million (2008)
 - *Africa*: 212 million *Asia*: 21 million
- **Population at risk**
 - 3.3 billion (*half of the world population*)
- **Annual deaths from malaria**
 - *Globally*: 781,000 (2009)
 - 85% of deaths are in children under 5
 - Every 30 seconds a child dies from malaria

Malaria diagnostics

- Standard diagnosis is via blood smear which requires skilled operator and minimum lab conditions
- Rapid Tests have increased in use from 200,000pa in 2005 to 30 million in 2009
- Molecular diagnostics exist which offer the potential to reduce turn around time and operator dependence but cost currently hinders wider adoption

Source: <http://www.rph.wa.gov.au/malaria/diagnosis.html>

Key point

According to the

“Global Malaria Action Plan”

**approximately 1.5 billion
diagnostic tests are needed
globally on an annual basis**

Source: http://www.rollbackmalaria.org/gmap/GMAP_Advocacy-ENG-web.pdf page12

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Contents

1. Introduction
2. Overview of developing nations
3. Key areas of need
- 4. Some specific considerations**
5. Strategies of entry
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Developing the right product

Products and
technology
developed for this
environment ...

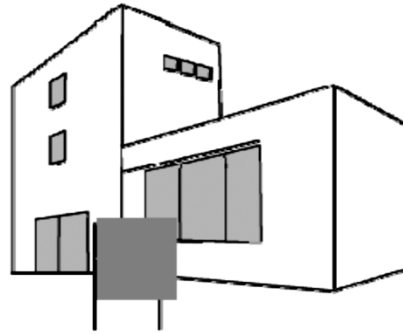


Understand your market

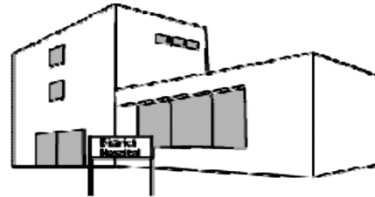
May not
function well
here ...



A wide variety of conditions



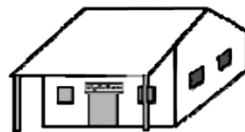
Referral Hospital



District Hospital



Health centres



Health Post/Clinic



Community/Home

Source:

Haileyesus Getahun, Stop TB Department, WHO Geneva, Switzerland
Workshop to accelerate the implementation of the Three Is for HIV/TB and earlier
Initiation of ART in Southern Africa, March 14-18, 2011, Johannesburg, South Africa.

Contents

1. Introduction
2. Overview of developing nations
3. Key areas of need
4. Some specific considerations
- 5. Strategies of entry**
6. The result of inaction
7. Conclusion

Examples of different strategies for entry

- bioMérieux
- BD
- Cepheid
- Micronics

Foundation Mérieux

- Developing a network of reference biological laboratories
- Mali, Cambodia, Laos, Haiti, Madagascar, China
- bioMérieux is the IVD partner for Fondation Mérieux

International Operations



Becton Dickinson – NGO and Discounting

- BD is working with the **William J. Clinton** Foundation to expand the accessibility of advanced CD4 cell-counting technology for monitoring HIV/AIDS
- BD is also partnered with Foundation for Innovative New Diagnostics (FIND) to work on TB diagnostics
- Access is improved through deeply discounted pricing up to **75 percent** – for some developing nations
- BD also provides training and equipment servicing

Source: http://www.bd.com/citizenship/soc_responsibility/dev_world.asp

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Cepheid – NGO and Discounting

- WHO says Cepheid rapid test will transform TB care (2010)
- Cepheid to offer a **75 percent** price discount to 116 low and middle-income countries
- The Xpert MTB/RIF is a "while-you-wait" test for use outside conventional laboratories by general health workers
- Capable of identifying Multi Drug Resistant strains of TB in under 2 hours

Source: <http://www.reuters.com/article/2010/12/08/us-tuberculosis-test-idUSTRE6B71RF20101208>

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Cepheid – WHO recommendations on MDR TB diagnostics 2010

- Xpert MTB/RIF should be used as the **initial diagnostic** test in individuals suspected of having MDR-TB or HIV associated TB

Source:
Haileyesus Getahun, Stop TB Department, WHO Geneva, Switzerland
Workshop to accelerate the implementation of the Three Is for HIV/TB and earlier
Initiation of ART in Southern Africa, March 14-18, 2011, Johannesburg, South Africa.

WHO prequalification

- The WHO procurement service for diagnostics was established in 1990 to facilitate access to high quality HIV test kits at a reasonable cost
- The service has expanded to include diagnostics for:
 - HIV/AIDS
 - Malaria
 - Hepatitis B
 - Hepatitis C
 - basic laboratory consumables
 - lab equipment

Source: http://www.who.int/diagnostics_laboratory/procurement/en/

Micronics – PanNat a product designed for developing nations

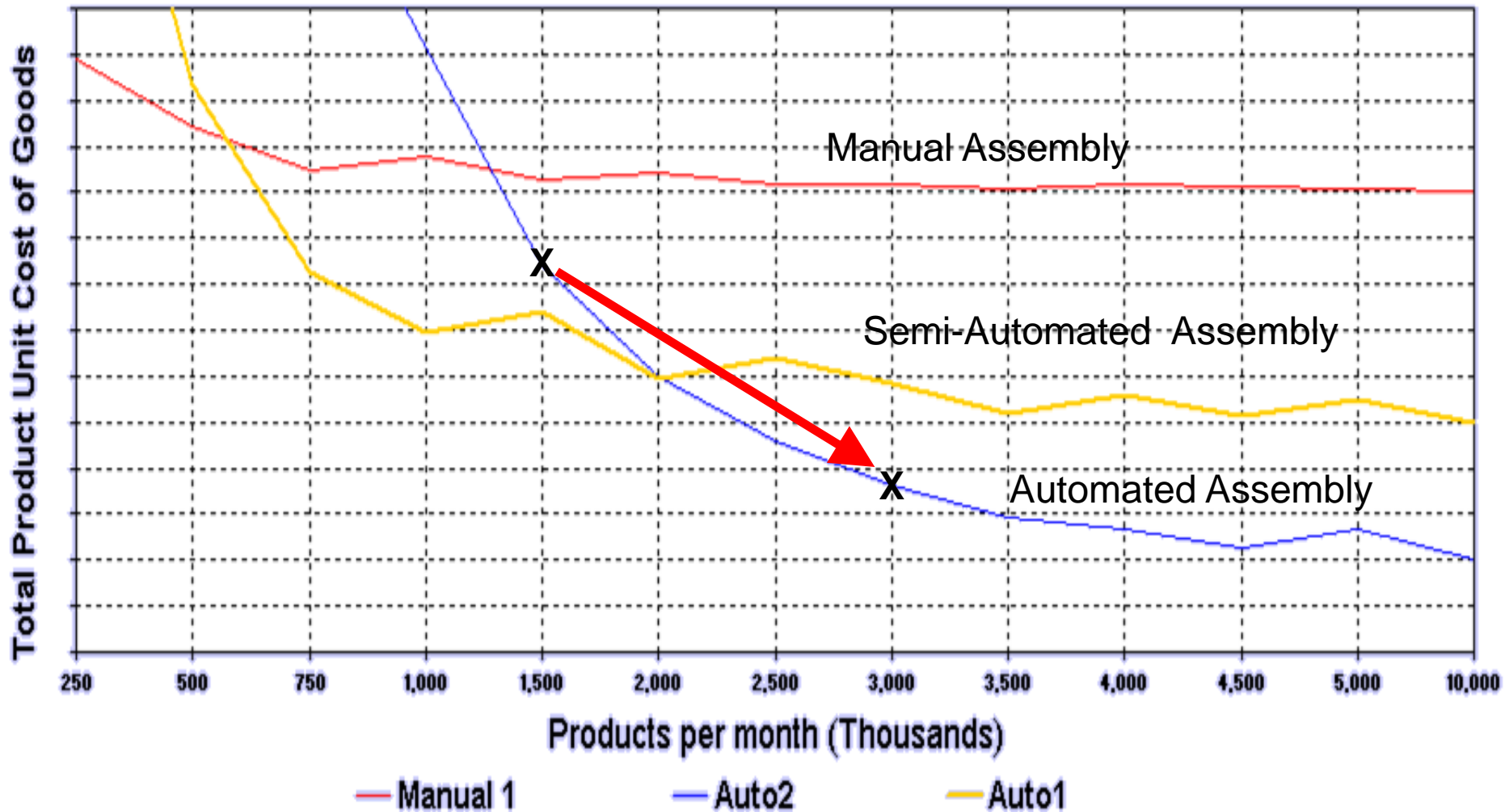


- No Sample Prep
- Result in as little as 30 mins
- Battery Powered
- Cartridge per Test
- Nucleic Acid Amplification Platform

PanNat Assays in development

- **PanNAT Malaria Assay:** Detects all species that cause Malaria; differentiates *P. falciparum* from fingerstick whole blood sample
- **PanNAT STEC (Shiga Toxin-producing *E. coli*) Assay:** Detects Shiga toxin I and II, differentiates *E. coli* O157:H7 serotype directly from diarrheal stool sample

Deep discounting to access the economy of scale



Contents

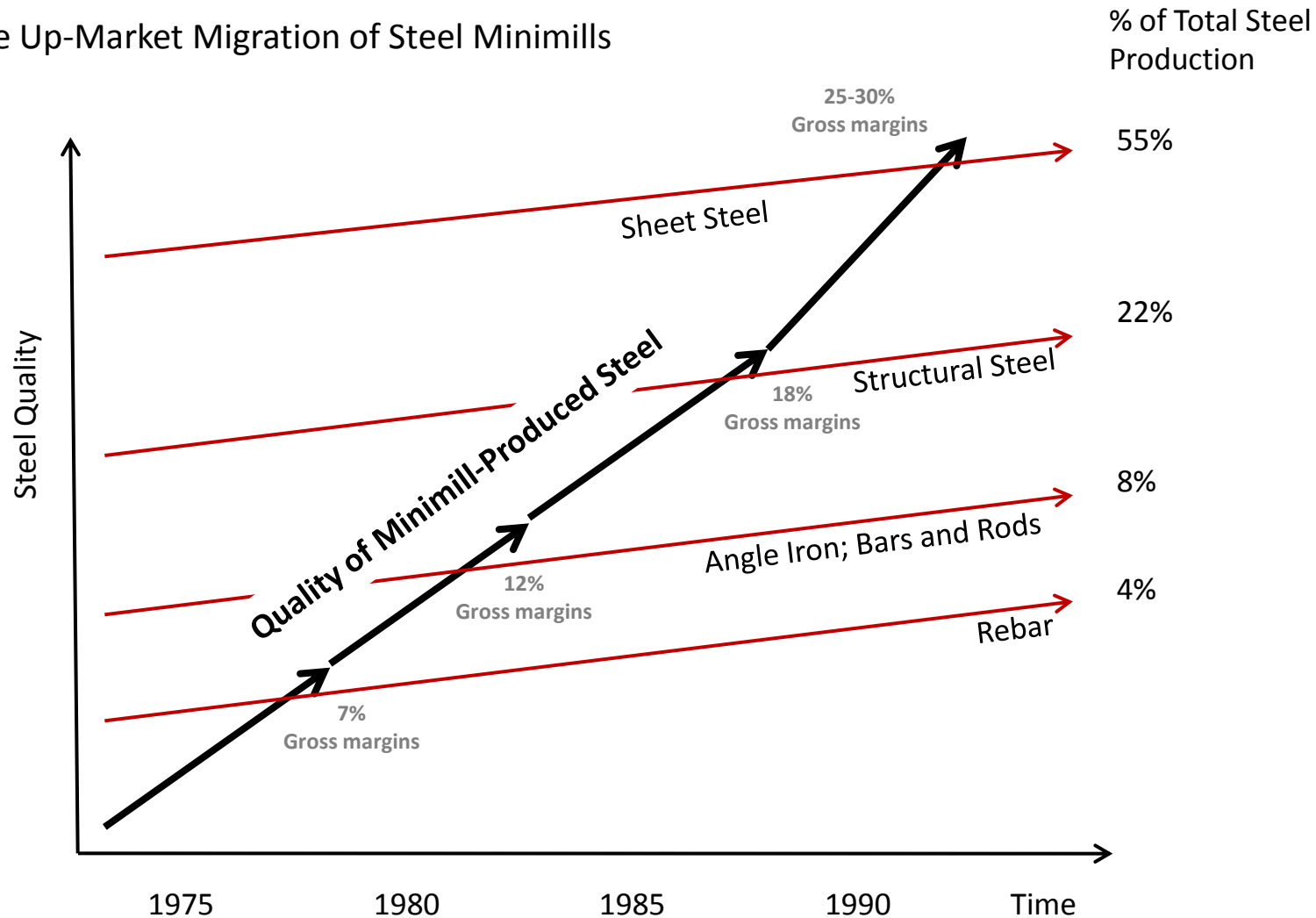
1. Introduction
2. Overview of developing nations
3. Key areas of need
4. Some specific considerations
5. Strategies of entry
- 6. The result of inaction**

A Mini Mill story in IVD?

- Mini Mills appeared in the mid-1960s producing low quality steel at low cost
- Initially production targeted low quality, low margin steel products
- Not perceived as a threat by Integrated Steel Mills who were focused on high quality, high margin products
- Mini Mills successfully dominated this low quality, “low margin” sector

The Mini Mill story – impact of disruptive technologies

The Up-Market Migration of Steel Minimills



Source: Clayton Christensen "The Innovator's Solution" HBR Press 2003

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A Mini Mill story in IVD?

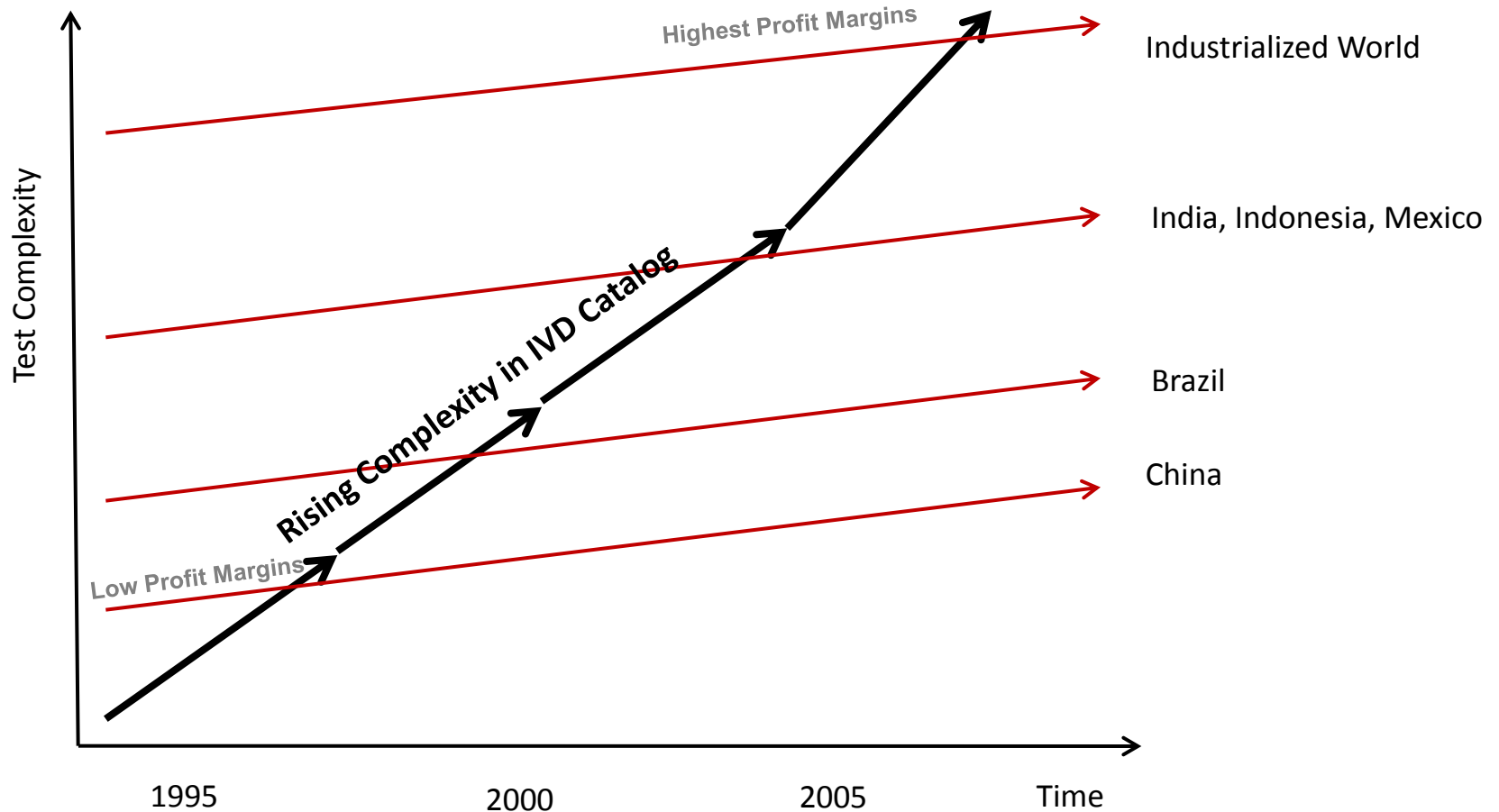
Mindray

- Founded 1991 to deliver competitively priced medical devices
- Distribution & service network 31 branch offices in China, and subsidiaries in 16 countries ...
- NYSE listing 2006
- R&D located in Shenzhen, Beijing, Nanjing, Seattle, New Jersey and Stockholm. ...
- Launched 56 new products in the last 7 years

Source: <http://www.mindray.com/na/aboutus/aboutus01.html>

The Mini Mill story in IVD

The market migration of Mindray



Source: Clayton Christensen "The Innovator's Solution" HBR Press 2003

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Measures of engagement

- **Exhibitors country of origin at Africa Health 9 - 11 May 2011**

Johannesburg Expo Centre, Nasrec, South Africa

- Austria 1
- Belgium 2
- Canada 1
- **China 56**
- Cyprus 1
- Egypt 1
- Finland 1
- **France 17**
- **Germany 49**
- Hong Kong 1
- Hungary 2
- **India 22**
- Iran 3
- Italy 10
- Japan 1
- Lebanon 1
- Netherlands 2
- Norway 1
- Pakistan 2
- Poland 2
- Portugal 1
- Russia 1
- South Africa 38
- **South Korea 15**
- Spain 1
- **Switzerland 2**
- Taiwan 11
- Turkey 1
- Uganda 1
- United Arab Emirates 12
- **United Kingdom 5**
- **United States 8**
- Vietnam 1

Are opportunities
being missed ?

Contents

1. Introduction
2. Overview of developing nations
3. Key areas of need
4. Some specific considerations
5. Strategies of entry
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- 7. Key take home messages**

Key take home messages

- **Moral obligation CAN be aligned to the commercial imperatives**
- **For IVD companies, engagement in developing nations is key to long term survival**

Key take home messages

Time to create your own mini mill story ...

(before someone else does) !

