



# MEDICATION SAFETY IN RESOURCE LIMITED SETTINGS

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Global Launch

Global Patient Safety Challenge on Medication Safety  
2nd Global Ministerial Summit on Patient Safety 2017

29<sup>th</sup> -30th March

Bonn, Germany

**Professor Priyadarshani Galappatthy**

MBBS(Col),MD(SL),MRCP(UK),DipMedTox(Cardiff),FCCP,FRCP(Lond),

Consultant Physician and Professor in Pharmacology Head,  
Department of Pharmacology and Pharmacy Faculty of  
Medicine University of Colombo Sri Lanka.

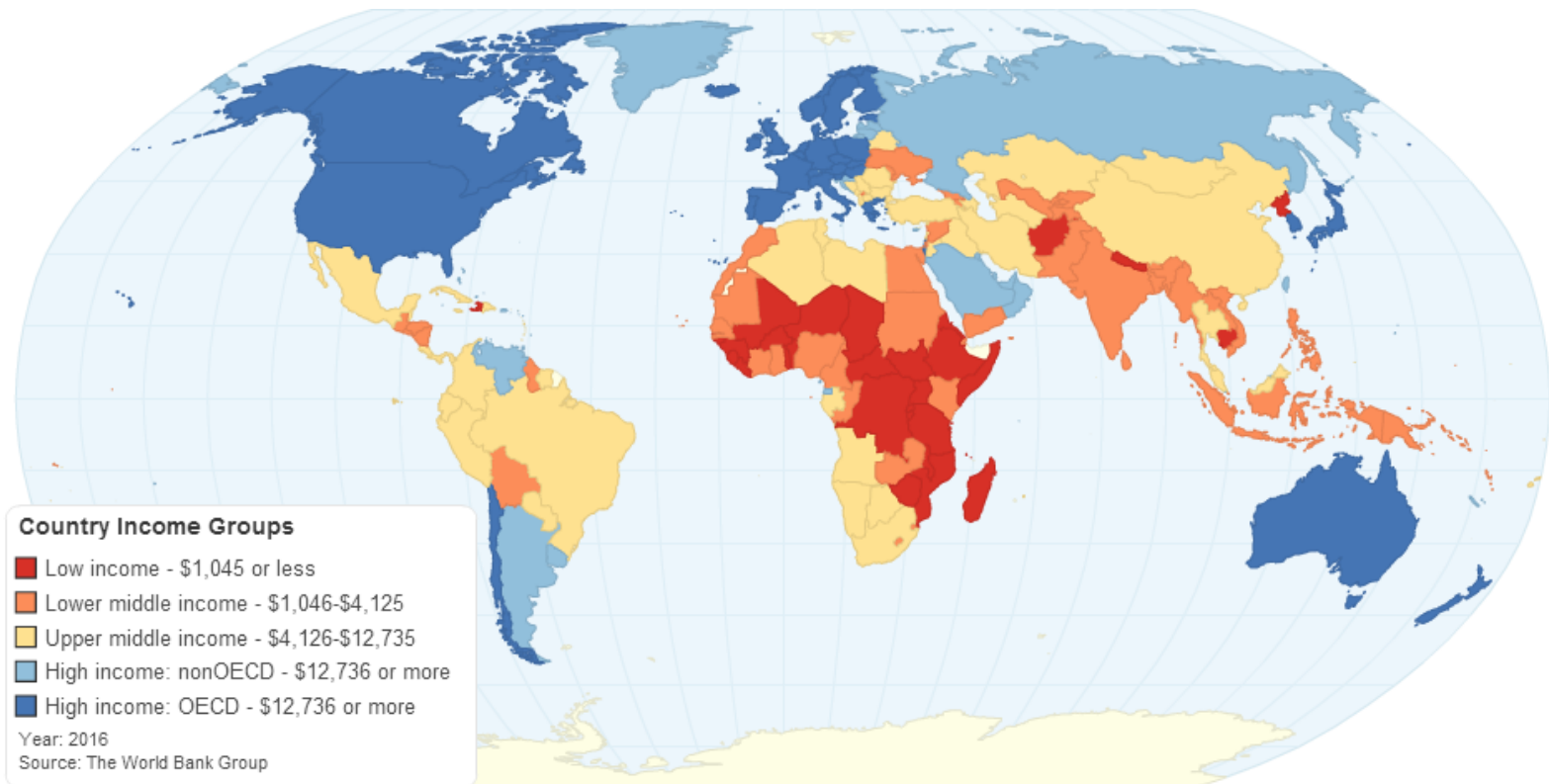


# Outline

- **Data from Resource Limited Settings (RLS) on 4 areas**
  - Systems and Practices
  - Healthcare professionals
  - Medicines
  - Patients
- **Focusing on**
  - Problems identified
  - Possible interventions
- **Summary of Key issues and possible solutions**

# LMIC in the world – 5.5 billion population (133 countries)

- **LMIC – Per capita (GNI) < \$12,735**



# The global burden of unsafe medical care: analytic modelling of observational studies

Jha AK, et al. *BMJ Qual Saf* 2013;**22**:809–815. doi:10.1136/bmjqs-2012-001748

**Table 3** Annual number of cases for selected adverse events

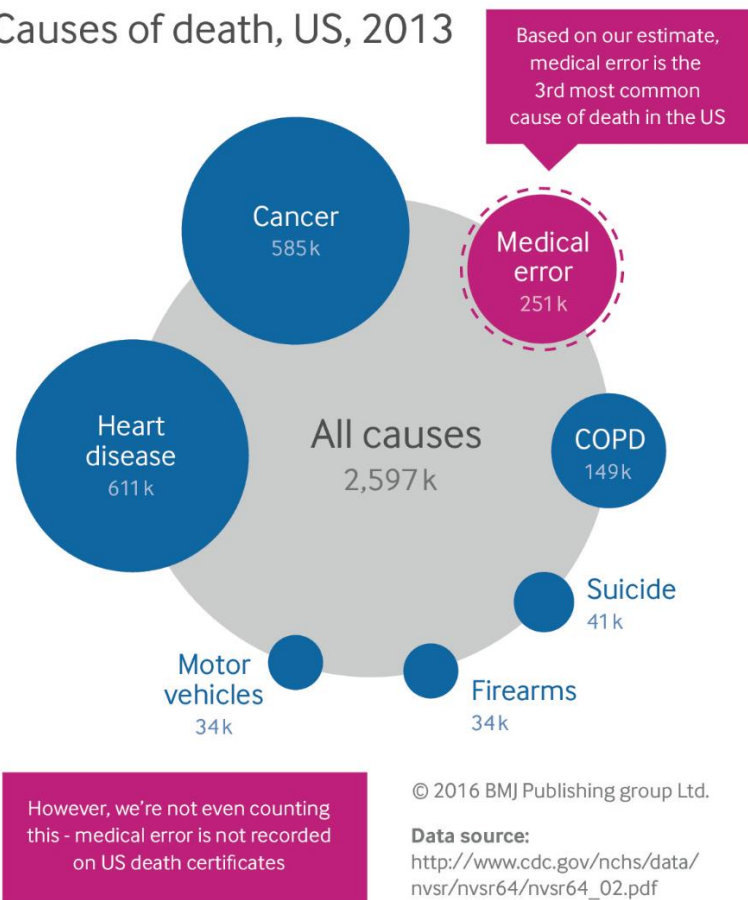
	High-income countries	Low-income and middle-income countries
Catheter-related UTI	1.4 M (0.8 M to 2.0 M)	4.1 M (0.5 M to 9.2 M)
Adverse drug events	5.8 M (2.7 M to 9.5 M)	6.0 M (0.6 M to 13.9 M)
Falls in the hospital	1.3 M (0.3 M to 2.5 M)	3.3 M (1.7 M to 5.7 M)
Catheter-related blood stream infection	0.5 M (0.1 M to 0.8 M)	0.9 M (0.4 M to 1.6 M)
Nosocomial pneumonia	1.0 M (0.7 M to 1.4 M)	0.9 M (0.3 M to 1.7 M)
Decubitus ulcers	2.9 M (0.7 M to 6.2 M)	4.9 M (1.1 M to 12.1 M)
Venous thromboembolisms	3.9 M (1.9 M to 6.3 M)	6.0 M (1.2 M to 12.8 M)
Total	16.8 M	25.9 M

M, Million

# Medical error—the third leading cause of death in the US

Medical error is not included on death certificates or in rankings of cause of death. **Martin Makary** and **Michael Daniel** assess its contribution to mortality and call for better reporting

Causes of death, US, 2013



BMJ 2016;353:i2139 doi: 10.1136/bmj.i2139 (Published 3 May 2016)

- **180 000 iatrogenic deaths per year**
- **51% - 78% are preventable**

Fig 1 Most common causes of death in the United States, 2013<sup>2</sup>

# Systems and practices in RLS

Data from countries in Africa, Asia and South America

## Key messages

- **Serious lack of studies from RLS**
- **Poor safety culture**
- **Lack of reporting systems, learning and prevention**
- **Staff shortages, heavy workload for HCP**
- **Establishing safe patient practices needed**
  - *Medication errors in South East Asian countries : a systematic review. PLOS One 2015*
  - *A systematic review on medication errors I International J of Drug Development and Research 2015*
  - *Patient safety and quality of care in developing countries in South East Asia. International J for Quality in Healthcare 2015*
  - *Medication errors in Middle eastern countries. Eur J of Clinical Pharmacology 2013*
  - *Measures of patient safety in developing and emerging countries:A review literature A revu Quality and safety in healthcare 2010*

# Pharmacovigilance Activities in 55 Low- and Middle-Income Countries

## A Questionnaire-Based Analysis

Drug Saf 2010; 33 (8): 689-703  
0114-6916/10/0008-0689/\$49.95/0

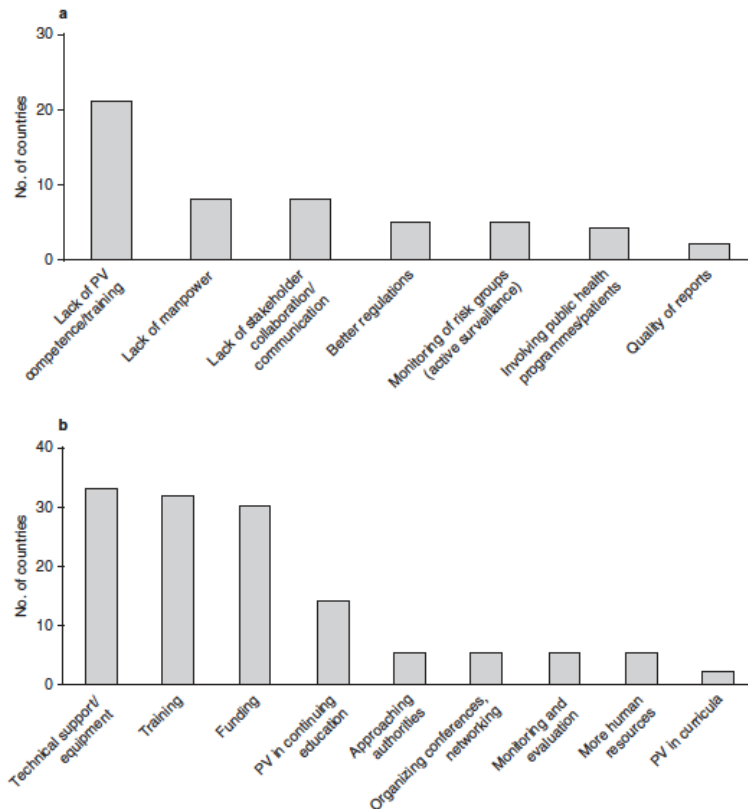


Fig. 6. (a) Challenges to pharmacovigilance (PV) and (b) type of assistance needed.

## Challenges

- Lack of competence on PV
- Lack of manpower
- Lack of stakeholder collaboration

## Assistance needed

- Technical support
- Training
- Funding

# Pharmacovigilance in resource-limited countries

*Expert Rev. Clin. Pharmacol.* 8(4), 449–460 (2015)

Sten Olsson, Shanthi N Pal & Alex Dodoo

- Many LMIC have joined the WHO's global PV network.
- Very few have fully functional systems.
- More access to medicines in RLS - medication safety is a concern
- Burden of medicine-related harm and preventability ?
- Legislation and regulatory framework needed

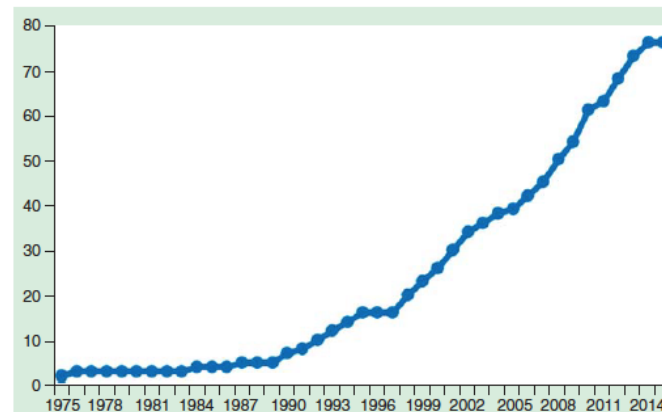


Figure 1. Number of LMIC countries becoming members of the WHO International Drug Monitoring Program over time.



# Healthcare professionals in RLS

## Issues in prescribing

- Prescriptions legible with effort - 65 % , illegibility - 9 %.
- Potential drug interactions – in 53%
- Unapproved and error-prone abbreviations use – 69%
- Generic prescribing – 36% in private sector
  - *Rathish D et al Drug utilization, prescription errors and potential drug-drug interactions: an experience in rural Sri Lanka. BMC Pharmacology and Toxicology. 2016 Jun 25;17(1):27.*
  - *Samaranayake NR, The Pattern of Abbreviation Use in Prescriptions: A Way Forward in Eliminating Error-Prone Abbreviations and Standardisation of Prescriptions. Current drug safety. 2014 Mar 1;9(1):34-42.*

## Sentinel events

- Calcium prescribed as CaCO<sub>3</sub> - Interpreted as LiCO<sub>3</sub>
- Child prescribed IV ampicillin was administered IV aminophylline

# Drug dispensing indicators

- Drugs adequately labeled - 3- 24%
- Average dispensing time - 0.8- 1.2 minutes
  - *Menik HL. A survey: Precepts and practices in drug use indicators at Government Healthcare Facilities: A Hospital-based prospective analysis. Journal of Pharmacy and Bioallied Sciences. 2011 Jan 1;3(1):165*

## A Sentinel event

- Patient prescribed prednisolone 30mg for asthma was dispensed glibenclamide 30 mg
  - Became severely hypoglycaemic and unconscious
- Both were white colored small tablets (LASA medicines)

# Clinical Pharmacy services in RLS

- Clinical Pharmacy services are non existent in most RLS
- Comparative Interventional studies in RLS
  - Reduce drug related problems (DRP)
  - Prevalence of DRP 80-92%
  - clinical pharmacists identified 83-86% DRP
  - 73% suggestions accepted and implemented
    - *Shanika LG et al . Acceptance and attitudes of healthcare staff towards the introduction of clinical pharmacy service: a descriptive cross-sectional study from a tertiary care hospital in Sri Lanka. BMC Health Services Research. 2017 Jan 18;17(1):46.*
    - *The Need for clinical Pharmacy services in Sri Lanka: A study based on prevalence of drug related problems in two hospitals in Sri Lanka. International Journal of scientific and research publications 2014*
    - *The role of Pharmacists in developing countries: Current scenario in Pakistan 2009*

# Medicines in RLS

## Counterfeit medicines

- Up to 15% of sold drugs
- In Africa and Asia may be > 50%
- FDA estimates -10% of global market
- Sentinel events
  - 1/3-1/2 Artesunate tablets in SEA had no active drugs.
  - China closed 1,300 factories after 192,000 died in 2001

## Substandard medicines

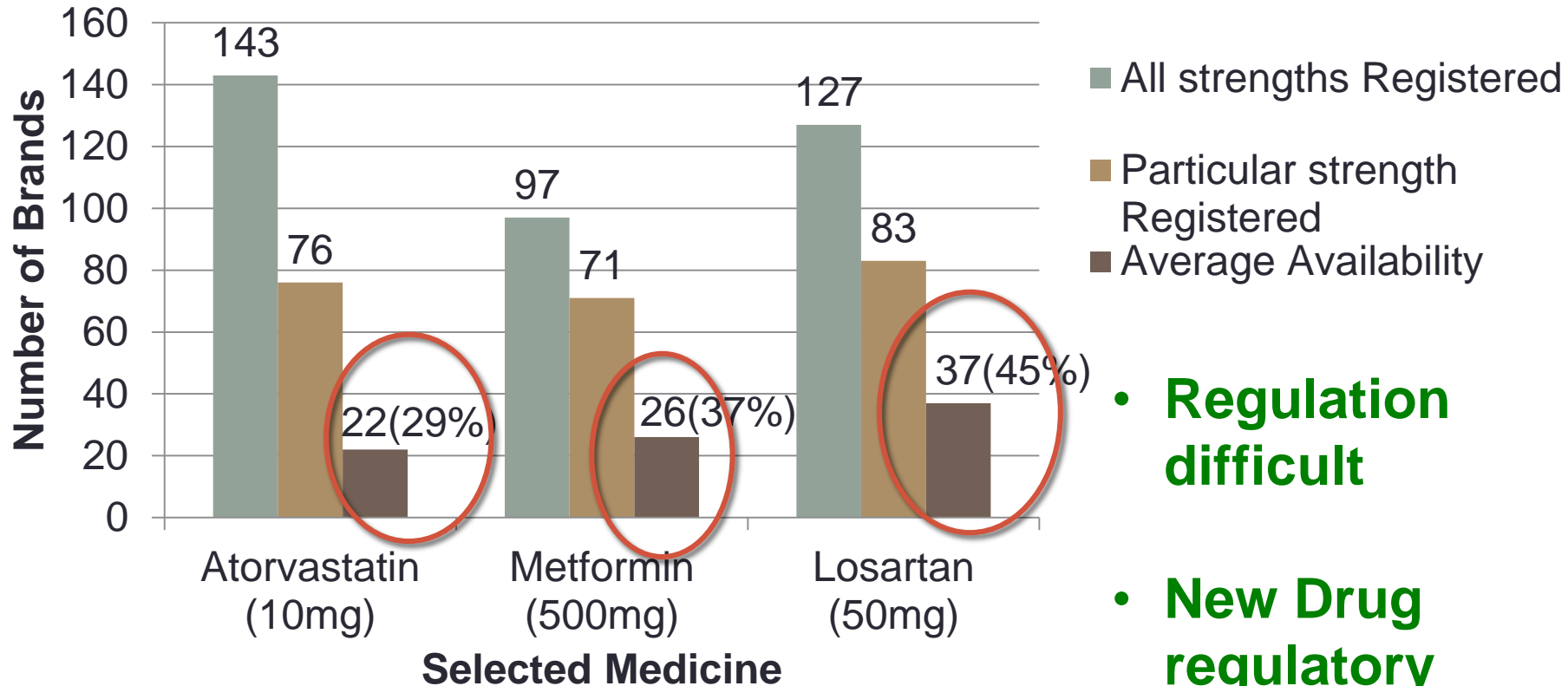
- Prevalence of - 8- 48% depending on the country
- Solutions
  - WHO pre-qualification programme.
  - Suppliers, donors and purchases adhering to quality standards.
  - LMIC to improve detection methods
    - *The global threat of counterfeit drugs why Industry and governments must communicate dangers. PLOS Medicine 2005*
    - *Substandard medicines in resource poor settings : A problem that can no longer be ignored. Tropical Medicine and International Health 2008; 13: 1062-72*



DOI: 10.1371/journal.pmed.0020100.g003

A collection of counterfeit pharmaceutical drugs seized by the NAFDAC in Nigeria  
(Photograph: NAFDAC/International Chamber of Commerce Counterfeiting Intelligence Bureau)

## Registration status and availability of the most commonly prescribed 3 medicines in Sri Lanka -2015



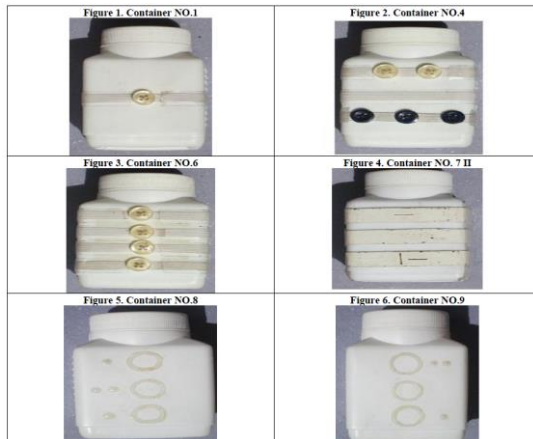
- Generic prescribing – 36 % in private sector
- With several brands - more prone to errors

- Regulation difficult

- New Drug regulatory Act (NMRA Act) -2015

# Low cost innovative methods to minimize errors

- Labeling and storage of LASA medicines



- Labeling for partially sighted and blind
- C Weeratne et al International J of Pharmacy review and research 2015*

# Patients in RLS

- Poor knowledge on medicines– 46%
- High rates of self medication – 35%
  - Allopathic medicines self medication 8-12%
- Discharge summaries in native language improved knowledge score on medicines
  - *Wijesinghe PR, et al Prevalence and predictors of self-medication in a selected urban and rural district of Sri Lanka.*
  - *Perera T, et al Knowledge of prescribed medication information among patients with limited English proficiency in Sri Lanka. BMC research notes. 2012 Nov 29;5(1):658.*
  - *Perera KY, et al . Medium of language in discharge summaries: would the use of native language improve patients' knowledge of their illness and medications?. Journal of health communication. 2012 Feb 1;17(2):141-8.*

# Summary of key issues in RLS

1. Lack of data from large scale studies
2. Systems and practices are lacking or minimally effective
3. Ineffective medicines regulation
4. Poor reporting of errors and lack of preventive actions
5. Illegible prescriptions and error prone abbreviations
6. Poor dispensing indicators
7. Lack of Clinical pharmacy services effective in RLS
8. Substandard and counterfeit medicines
9. large number of brands and low generic prescribing
10. Poor medication literacy, self medication and languages barriers in communication

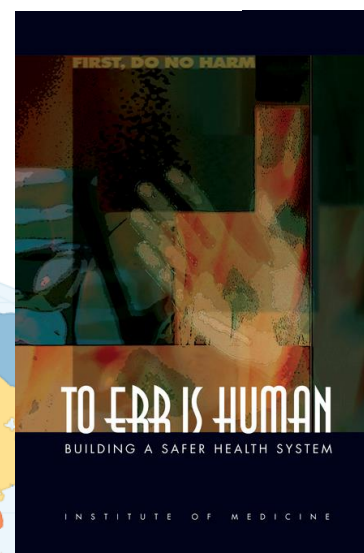
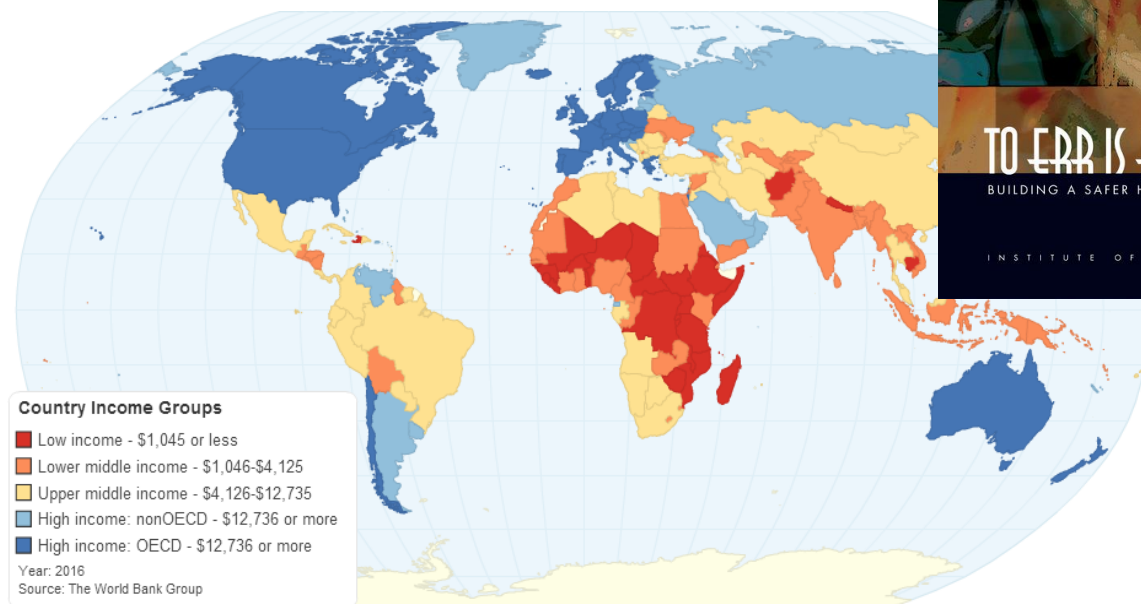


# Possible solutions

1. Performing systematic review for each country
2. Individualized action plan
3. Stringent regulatory mechanism for medicines
4. Employing clinical pharmacists into wards
5. Prevention using innovative low cost interventions
6. Educate HCP and encourage corrective actions
7. Improve medication literacy of people
8. Focus on most commonly used and high risk medicines
9. Media campaigns using electronic and print media
10. Involvement of patients/public and NGO

# TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM

- Urgent priority for RLS



Thank you