

Improving the Quality of Laboratory Services in Vietnam: Change made Sustainable!

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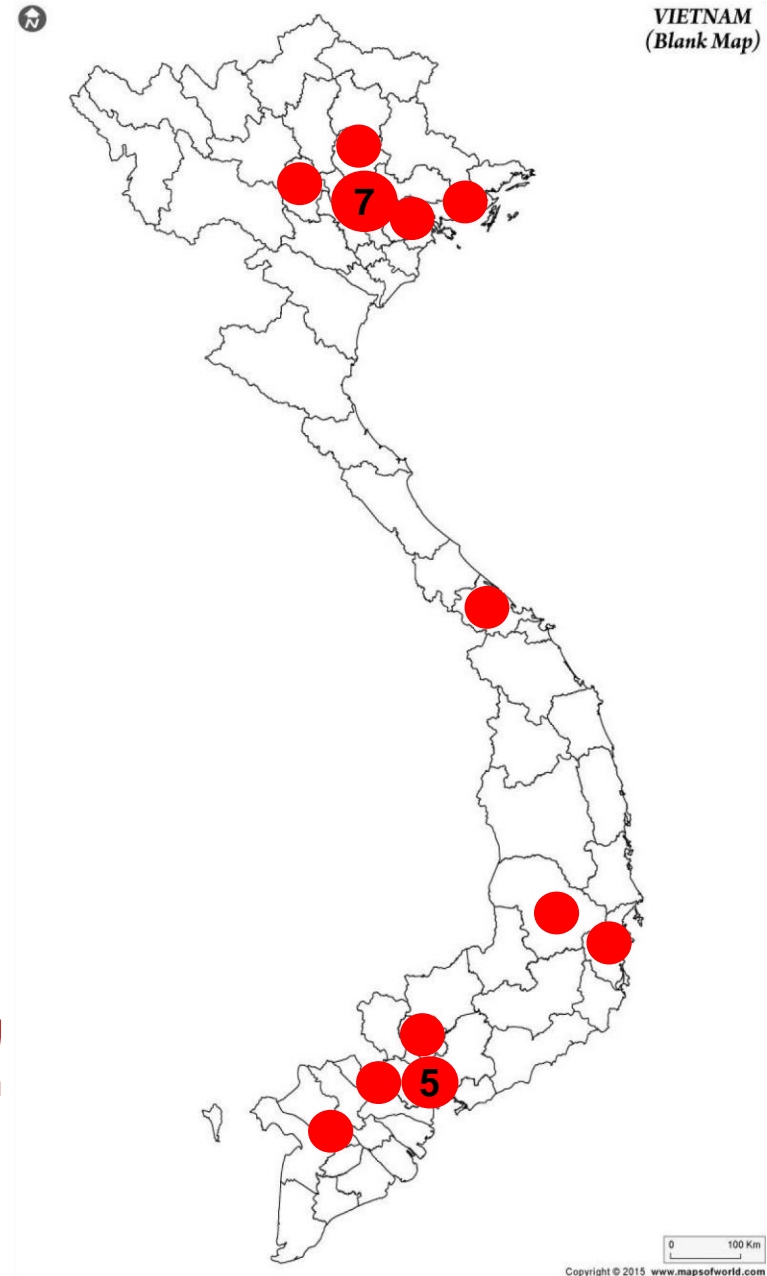
Laboratory Team Lead
Centers for Disease Control and Prevention-Vietnam



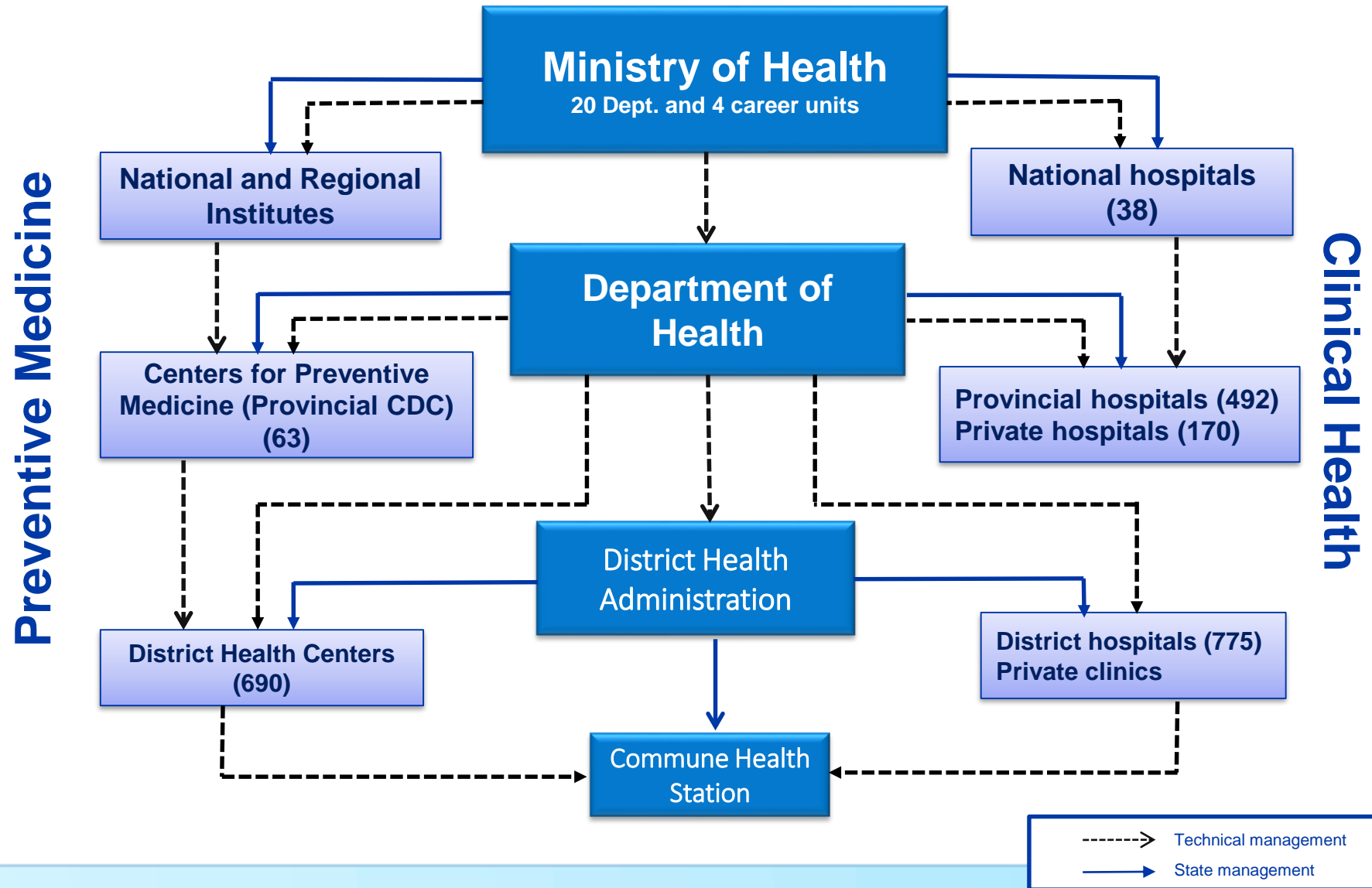
2013-2018:

- 16 of 41 SLMTA labs (39%) achieved ISO 15189 accreditation
- Another 5 national labs gained accreditation through the country's laboratory accreditation program

21 accredited in 5 years!!



Parallel Organizational Structure Over Laboratories



Challenges

- Low health provider confidences in laboratory services.
- High number of laboratories (>2000), not enough trainers and mentors.
- Inadequate budget for Laboratory Quality Management Systems (LQMS) activities
- It takes time to change people's habit!

Development of National Regulatory Framework for Laboratory Quality Management System (LQMS)

Official Policy

Circular 01

Ministry of Health
SOCIALIST REPUBLIC OF VIETNAM
Independence – Freedom – Happiness

Number:
01/2013/TT-BYT

Hà Nội, date 11 month 01 year 2013

CIRCULAR

Guidance for implementation of laboratory quality management at health care facility

Instruction

Decision 5530

Ministry of Health
SOCIALIST REPUBLIC OF VIETNAM
Independence – Freedom – Happiness

Number
5530/QĐ-BYT

Hà Nội, date 27 month 12 year 2015

DECISION

Guidelines on development of standard operation procedure in Laboratory Quality Management System

Budgeted Proposal

Decision 316/TTg-2016

Proposal for
Strengthening Quality
Management Capacity in
Medical Laboratory
2016-2025

National Standards

Decision 2429/QĐ-BYT

National Laboratory
Quality Management
Standards

2013

2015

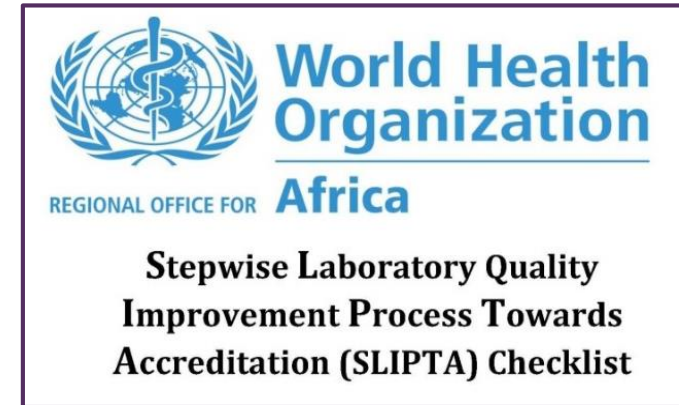
2016

2017

Mandatory for all medical laboratories

National Laboratory Quality Management Standards (Decision 2429/QĐ-BYT)

- Adapted from WHO AFRO SLIPTA
- Officially adopted in 2017
- Mandate for clinical laboratories
- Based on SLIPTA and ISO 15189 standards:
 - 12 chapters correspond to 12 quality system essentials
 - 169 criteria
 - max. 268 points



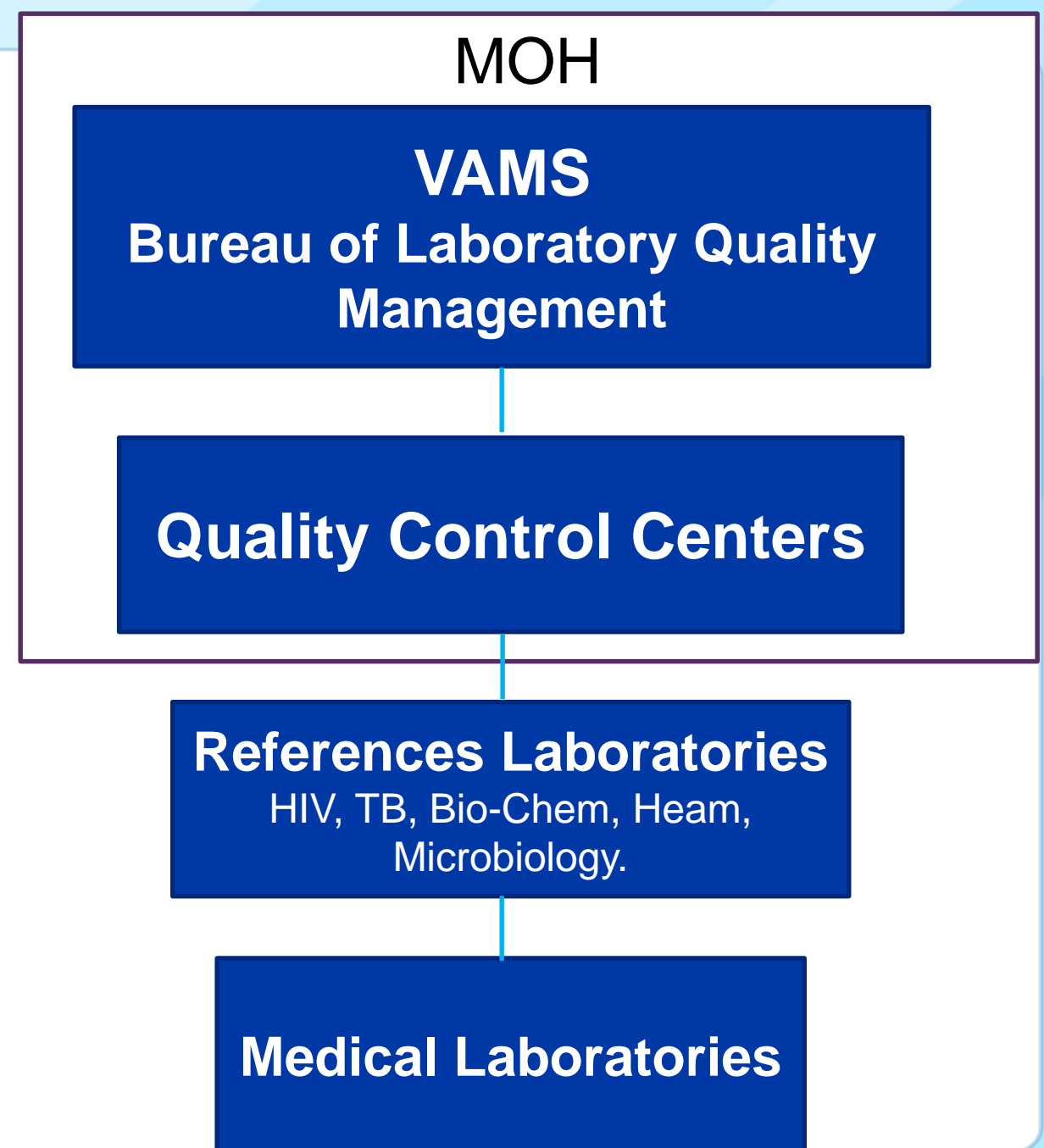
Audit Sections	Score
Section 1: Documents and Records	25
Section 2: Management Reviews	17
Section 3: Organization & Personnel	20
Section 4: Client Management & Customer Service	8
Section 5: Equipment	30
Section 6: Internal Audit	10
Section 7: Purchasing & Inventory	30
Section 8: Process Control and Internal & External Quality Assessment	33
Section 9: Information Management	18
Section 10: Corrective Action	12
Section 11: Occurrence Management & Process Improvement	12
Section 12: Facilities and Safety	43
TOTAL SCORE	258

National Laboratory Strategic Plan 2010-2020

Vision: A national lab system to serve the people of Vietnam that meets and exceeds national or international standards.

Long-term goal: to establish national quality-assured networks of tiered laboratory services, includes organizational structure, legal policies and documentation, national standards on quality, laboratory management, laboratory infrastructure, biological safety, training and quality management.

New Organizational structure Created From NSLP



The Beginning of Our Journey

Symposium on Quality Management for Medical Laboratories - March 2011



MARCH 2011-BANGKOK - SYMPOSIUM ON QUALITY MANAGEMENT FOR MEDICAL LABORATORIES: Representatives from Thailand, Vietnam & Cambodia together advocate for improved quality of lab services.

Meeting Achievement

- Sensitization of Policy Makers on LQMS
- Commitment from MOH and national institute leaders
- Sharing of best regional practices

Graduated Training Program

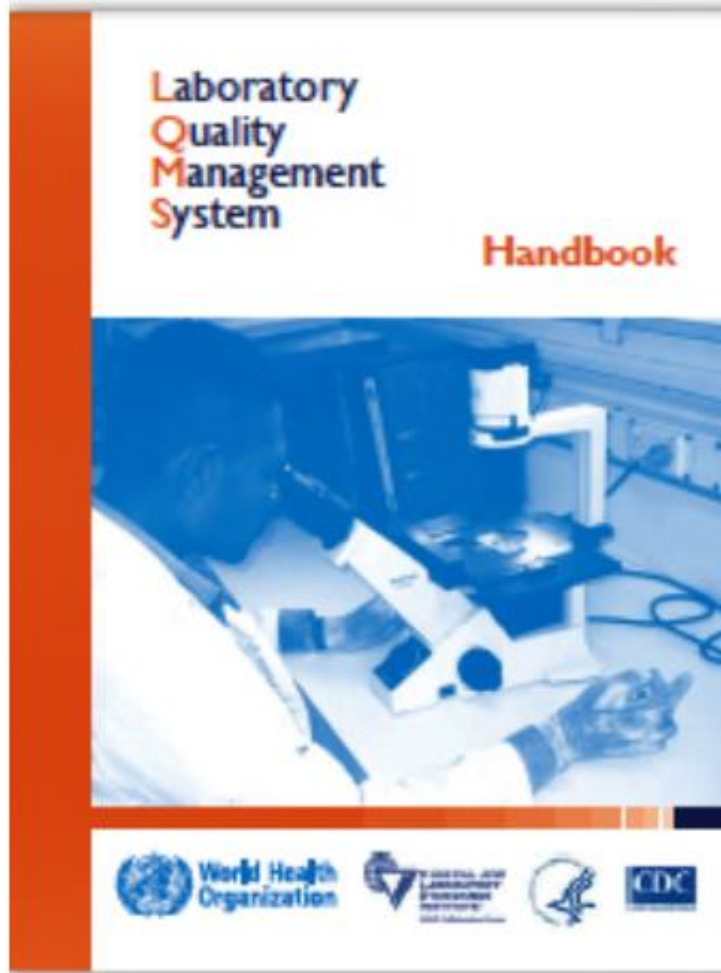
Training Program	Target Audience	Objective
LQMS Leadership Program	For leadership and policy makers	Create Champions Build Support network
Basic QMS Training Program	Labs that are rated zero stars	Provide basic LQMS Knowledge
SLMTA	Labs with one or more stars	To implement effective QMS
Lab Accreditation Program	Labs with 4-5 stars	To achieve ISO 15189 accreditation

LQMS Leadership Training Program

- One-year long
- Developed in partnership with CLSI
- Produced 44 “ambassadors”
- Graduates have the capacity to create national/local level lab policy and run a laboratory with a QMS (accreditation) focus



Basic Quality Management System Training



- Basic principles of LQMS
 - 12 quality system essentials
- Two 4 day workshops, separated by a 4-6 months implementation phase
- Designed for facilities with little LQMS capacity (Zero Stars)

SLMTA Training

- 1st TOT training was provided for key personnel from Vietnam, Thailand, and Cambodia in 2012.
- 4 SLMTA cohorts
 - 41 Clinical, Public Health, HIV/TB and Military Laboratories.
- Intensive planning, implementation and mentoring – as guided by SLMTA program.



Laboratory Accreditation Program

- For SLMTA graduated labs and national labs
- Intensive mentoring from CDC, FHI 360 and CDC Thailand
- Duration: 12 months
- Based on SLMTA and WHO-CDC-CLIS LQMS Toolkit

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Sustaining LQMS Training Programs

- 3 main medical universities now provide LQMS training:
 - Hai Duong Medical Techniques University: started 2013
 - Hanoi Medical University: started 2015
 - Ho Chi Minh Medicine and Pharmacy University: started 2015
- LQMS training programs now integrated into the university training curriculum
 - Pre-service: Formalized College Courses required for a Bachelor and Master degrees in Medical Laboratory Science
 - In-service LQMS courses also provided CME

Conclusion

“The road towards laboratory improvement is a continuous one; however, in Vietnam, it has been well paved towards a better future.”

- High commitment from MoH/GVN to improve lab quality.
- Policies and regulations on LQMS were developed.
- Implementation of LQMS is mandatory
- LQMS training programs were developed for both in-service and pre-service training.

Acknowledgements

- Vietnam Ministry of Health
 - Vice Minister Xuyen
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 - Vietnam Authority for HIV/AIDS Control
 - General Department of Preventive Medicine
- CDC-Vietnam Laboratory Team

