

Has Vietnam Reached a 'Tipping Point' for Laboratory Accreditation?



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What do we mean by 'Tipping Point'?

... the point at which an idea crosses a certain threshold and gains significant momentum, triggered by some minor factor or change

... the critical point in a system beyond which a significant and often unstoppable effect takes place.

What should go into this (informal) calculation?

- **Total number of labs in country. What percent ISO accredited**
- **SLMTA Impact/Expansion**
- **Supporting Policies**
- **Direct requests from MOH institutions**
- **'Funding vs Impact' Inversion**
- **Communications/Media**
- **Advocacy from the lab level.**

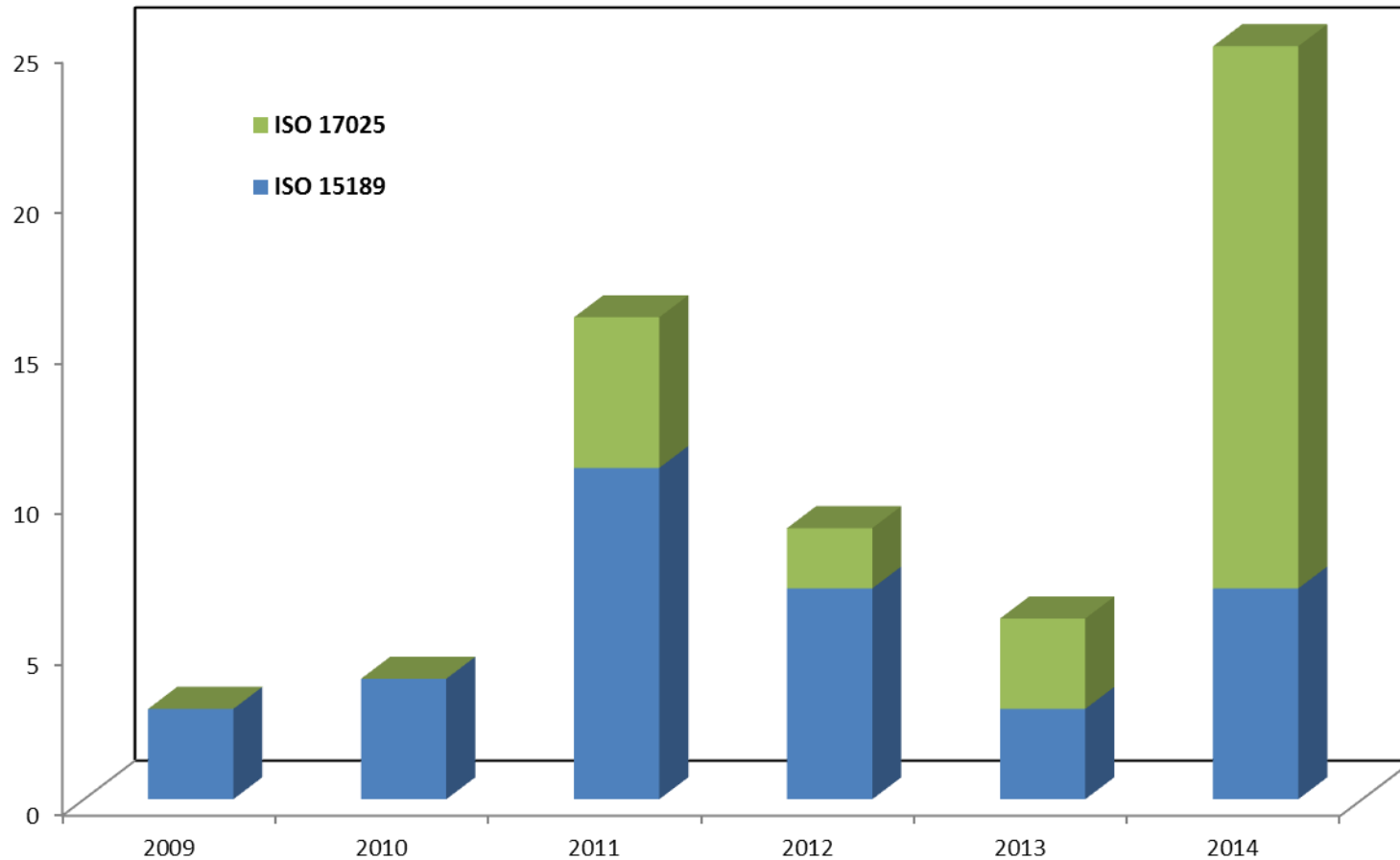
Number of Laboratories in Vietnam

	Lab Levels >>>>>>					
	National	Regional	Provincial	District		Total by System
Hospital	37	0	348	755		1140
Public Health	1	3	63	500		567
Tuberculosis	1	5	61	190		257
HIV	1	1	55	0		57
Other	15					15
Total by Level	55	9	527	1445		2036

Focus should be on National, Regional and Provincial level labs (600)

Number of ISO Accredited Lab in Vietnam

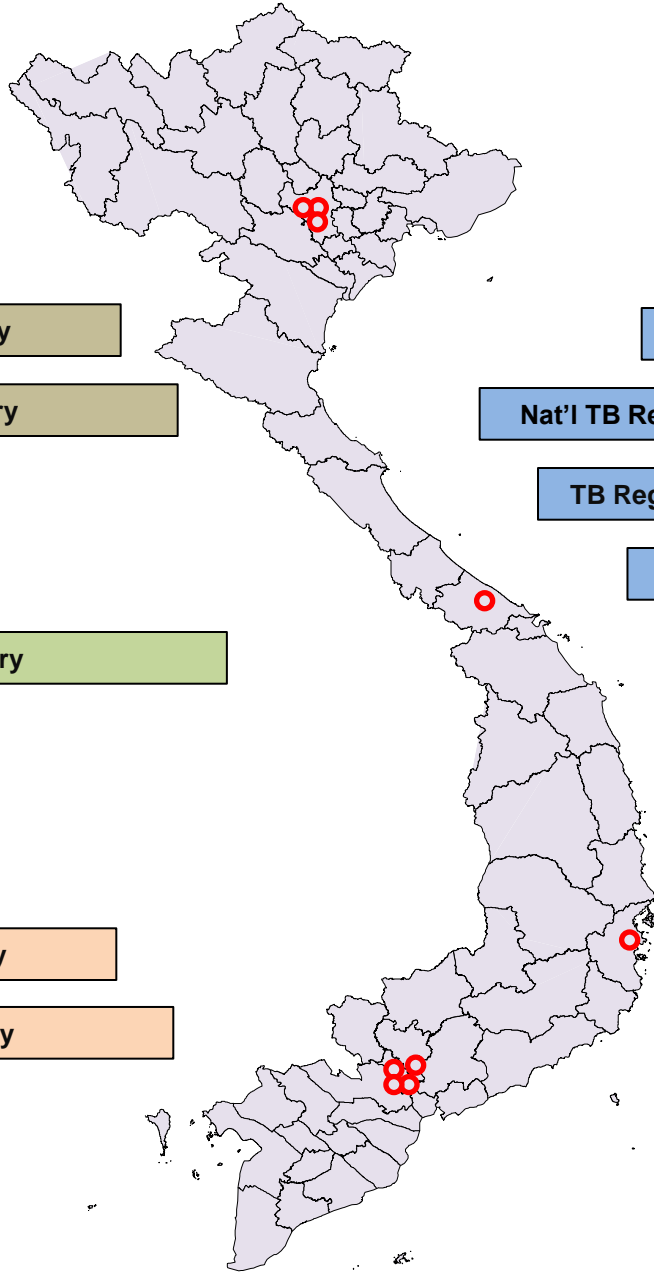
Currently 36 lab are ISO accredited (17 hospital / 19 public health labs)



Three tracks for Reaching Accreditation

- **Funding Only (2)**
 - Funds provided, labs identify own resources
- **TA Model (10)**
 - FHI360 created 12 month training/mentoring program
 - MOH (hospital system) administer the program
 - Piloted at various types of labs (hospital, public health, HIV)
 - Success rate has been high: 83% (5/6)
- **SLMTA as Stepping Stone (1)**
 - Single lab: Hai Duong Preventive Medicine Center
 - Low baseline score, graduated from SLMTA w/ four stars
 - Pursued ISO, was awarded accreditation only 6 months later

Vietnam Labs Accredited to International Standard



TA Model

Bach Mai Hospital, Microbiology Lab

National Pediatric Hospital, Hematology Laboratory

National Pediatric Hospital, Biochemistry Laboratory

Nat'l TB Reference Lab: National Lung Hospital Microbiology Lab

TB Regional Reference Laboratory Phan Ngoc Thach Hospital

Preventive Medicine Center-HCMC, Microbiology Lab

Children's Hospital Number 1, HCMC

Children's Hospital Number 2, HCMC

Pasteur Institute Nha Trang

Hue Central Hospital

Funding Only

HIV National Reference Laboratory

HIV Regional Reference Laboratory

SLMTA-ISO

Hai Duong Public Health Laboratory

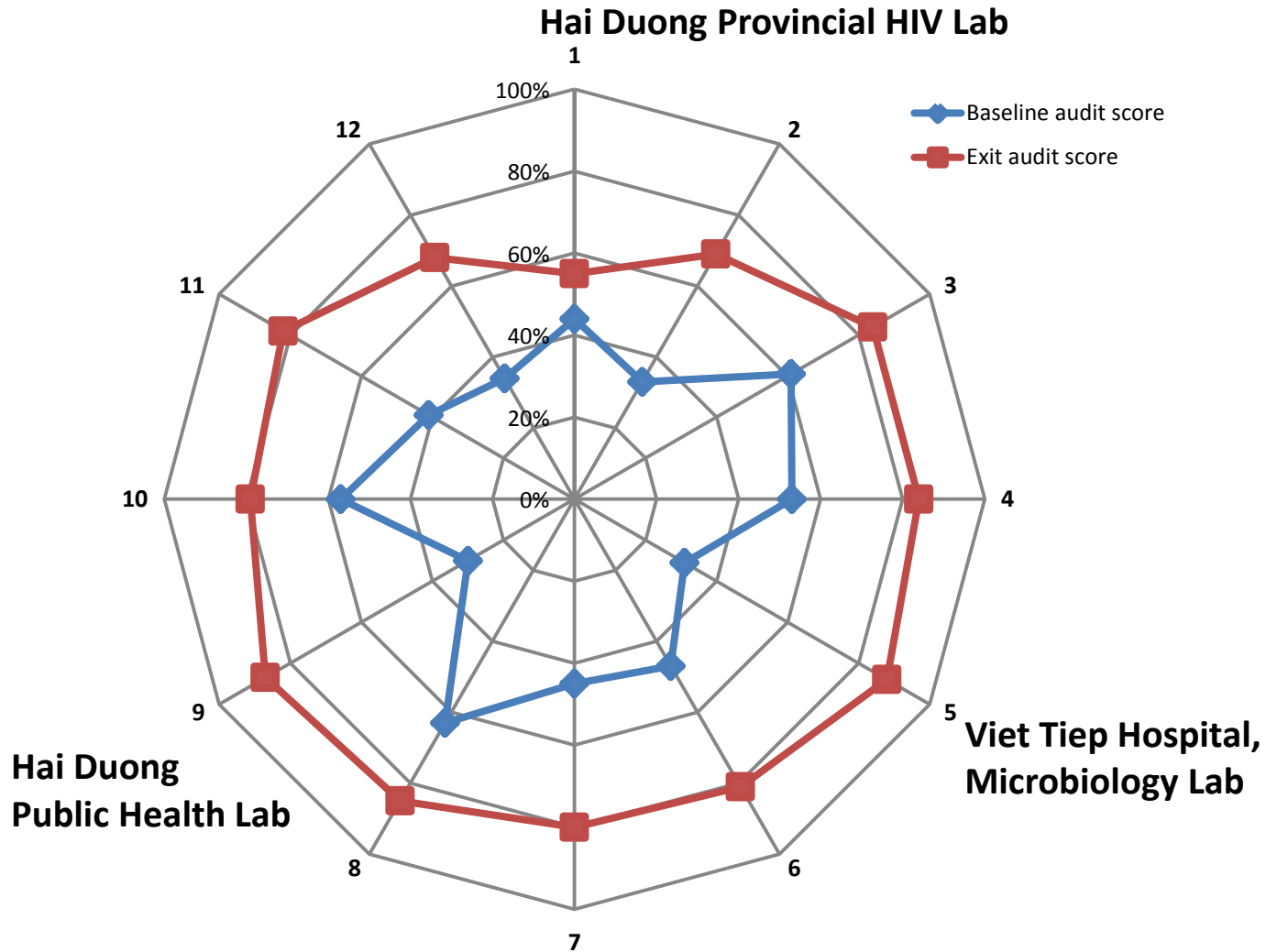
WHO HIV DR

HIV National Reference Laboratory

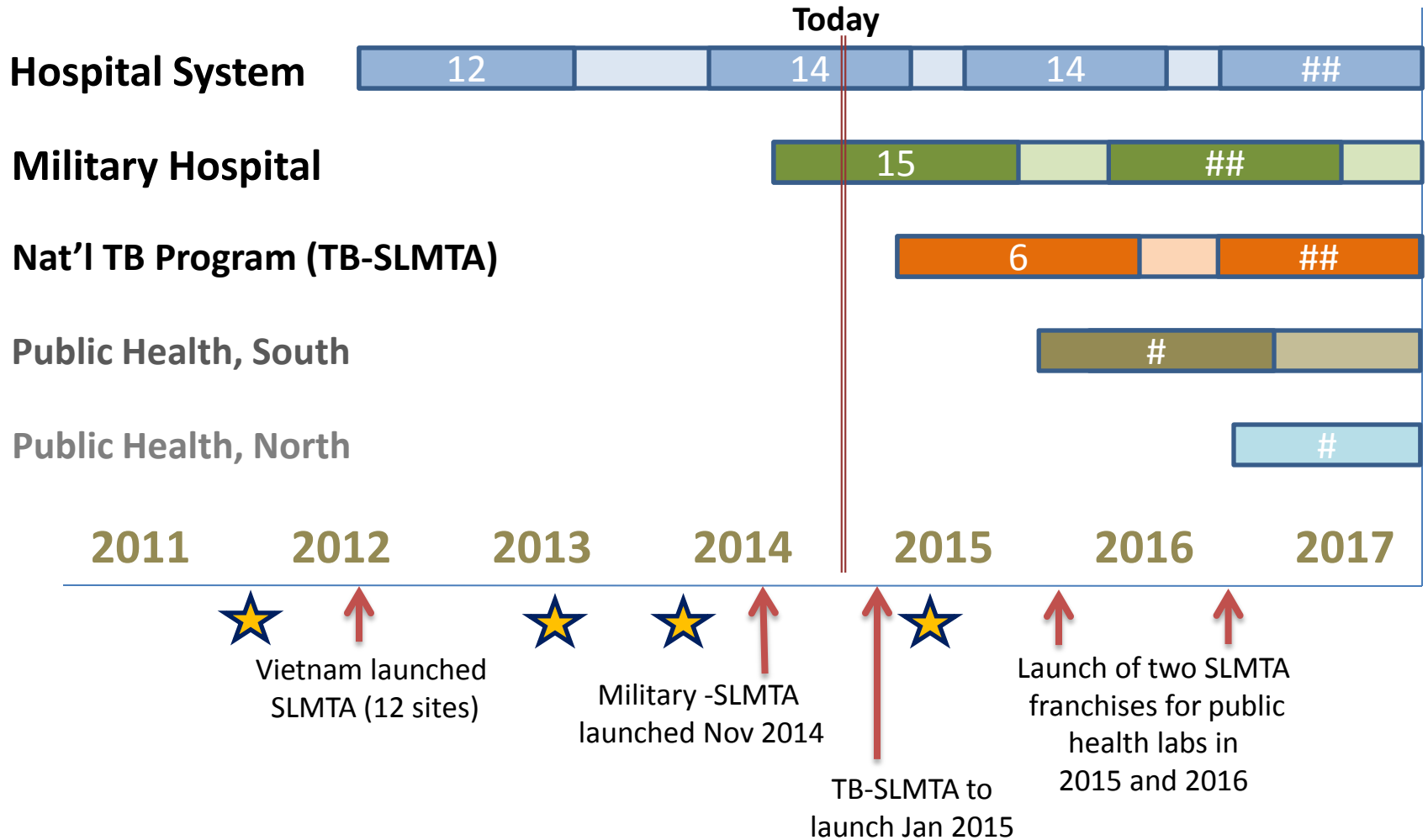
HIV Regional Reference Laboratory

Strengthening Laboratory Management Towards Accreditation

Results from SLMTA-Vietnam Pilot



SLMTA-Vietnam Expansion Timeline



★ - Delivery of SLMTA TOT in Vietnam (including TB-SLMTA TOT)

Proliferation of EQA Programs

- **HIV (HIV Ref Lab) 2007**
- **CD4 (Nat'l Hosp Trop Disease) 2008**
- **Biochemistry/Hematology (Hospital Quality Control Lab System) 2012**
- **Microbiology (Hospital Quality Control Lab System) 2014**
- **Viral Load (HIV Ref Lab) 2015**

Laboratory Accreditation-Related Policies

- **National Laboratory Strategic Plan**
- **National HIV Master Plan**
- **National HIV Laboratory Standards**
- **National Circular on Implementation of Laboratory QMS**
- **National HIV Laboratory Standards**

Vietnam National Laboratory Strategic Plan

Articulates Vietnam MOH's vision for it all health laboratories 2010 to 2020

Socialist Republic of Vietnam

NATIONAL LABORATORY SYSTEM

STRATEGY PLAN TO 2020



2010

2011

2012

2013

2014

- Core functions of the National Laboratory System, Creation of Bureau of Quality Management (2011) / Lab Quality Control Centers, QCC (2012)
- Set Target for ISO accreditation: 30 labs by 2014 80 labs by 2020

National HIV Master Plan

Covers HIV-related laboratory activities

Socialist Republic of Vietnam

NATIONAL LABORATORY SYSTEM
STRATEGY PLAN TO 2020



MINISTER
OF HEALTH

SOCIALIST REPUBLIC OF VIETNAM
Independence – Freedom – Happiness

No: 909 /QĐ-BYT

Hanoi, March 21, 2013

DECISION

Approving of the laboratory master plan in HIV/AIDS prevention
and control, phase 2013-2017

MINISTER OF HEALTH

2010

2011

2012

2013

2014

- Sets targets for ISO accreditation of HIV labs: 12 labs 2015 30 in 2020).

National HIV Laboratory Standards

Created for the HIV system

Socialist Republic of Vietnam

NATIONAL LABORATORY SYSTEM
STRATEGY PLAN TO 2020



MINISTER
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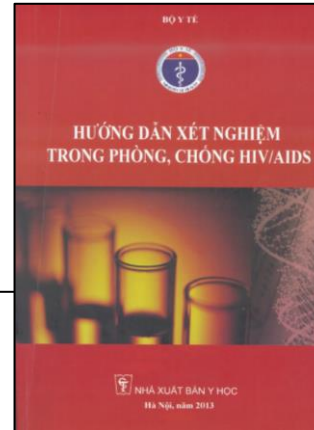
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MINISTER OF HEALTH



2010

2011

2012

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2014

- Lab standards described for HIV, CD4 and VL testing labs

Circular #1 Implementation of Laboratory QMS at Health Care Facilities

Socialist Republic of Vietnam

NATIONAL LABORATORY SYSTEM
STRATEGY PLAN TO 2020



MINISTER
OF HEALTH

No: 909/QĐ-BYT

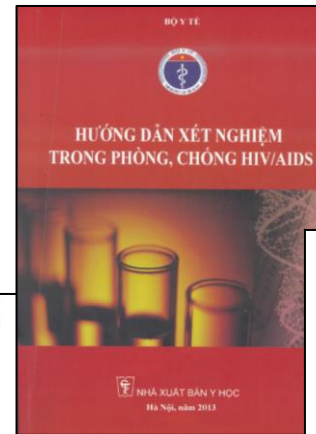
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Ministry of Health

Number:
01/2013/TT-BYT

SOCIALIST REPUBLIC OF VIETNAM
Independence – Freedom – Happiness

Hà Nội, date 11 month 01 year 2013

CIRCULAR

Guidance for implementation of laboratory quality management at
health care facility

2010

2011

2012

2013

2014

- Set requirements for health care laboratories: creation of IQC program, participation in EQA, improved record keeping, staff personnel records,...
- All are requirements under ISO.

National Laboratory Standards

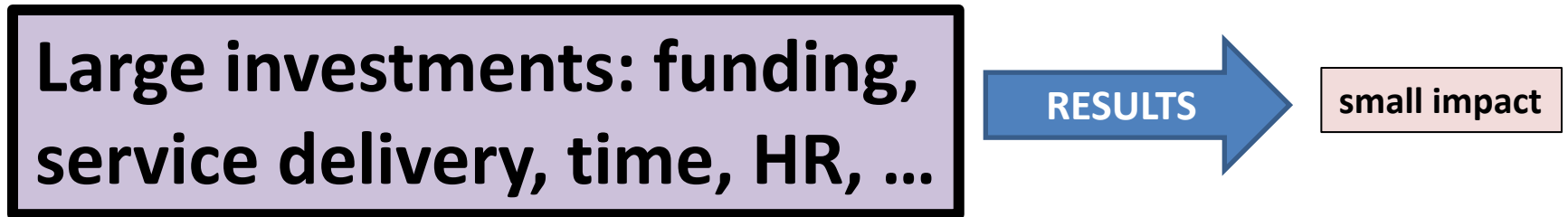
- Currently under development Vietnam MOH
- To be published in 2015
- Will be similar to SLIPTA and ISO standards

Direct request from MOH institutions to support accreditation

- No request in 2008... in 2014 there are many
- All recent policies from MOH include goals/indicators for ISO accreditation

Inversion: Investment vs Impact

Early on in PEPFAR.....

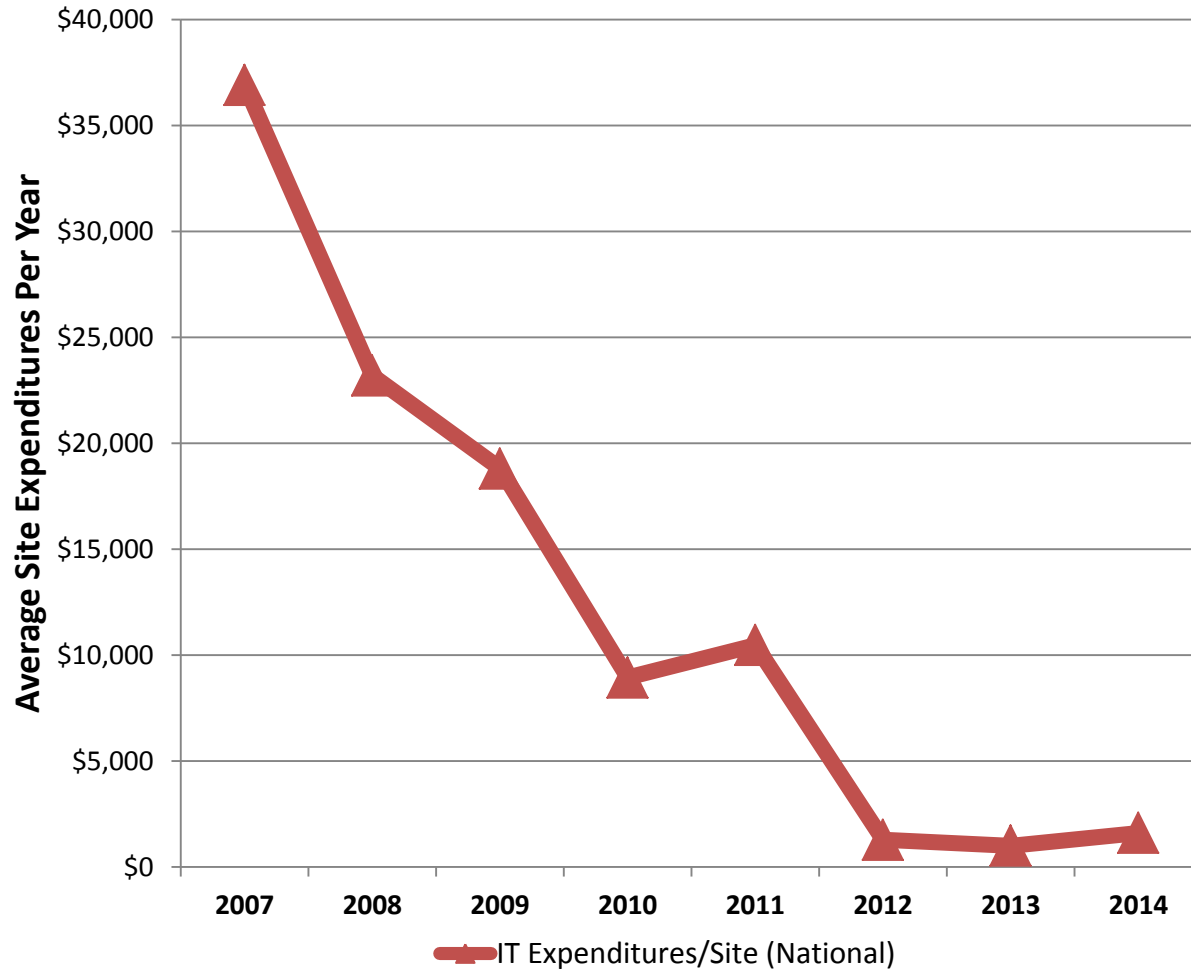


Now...

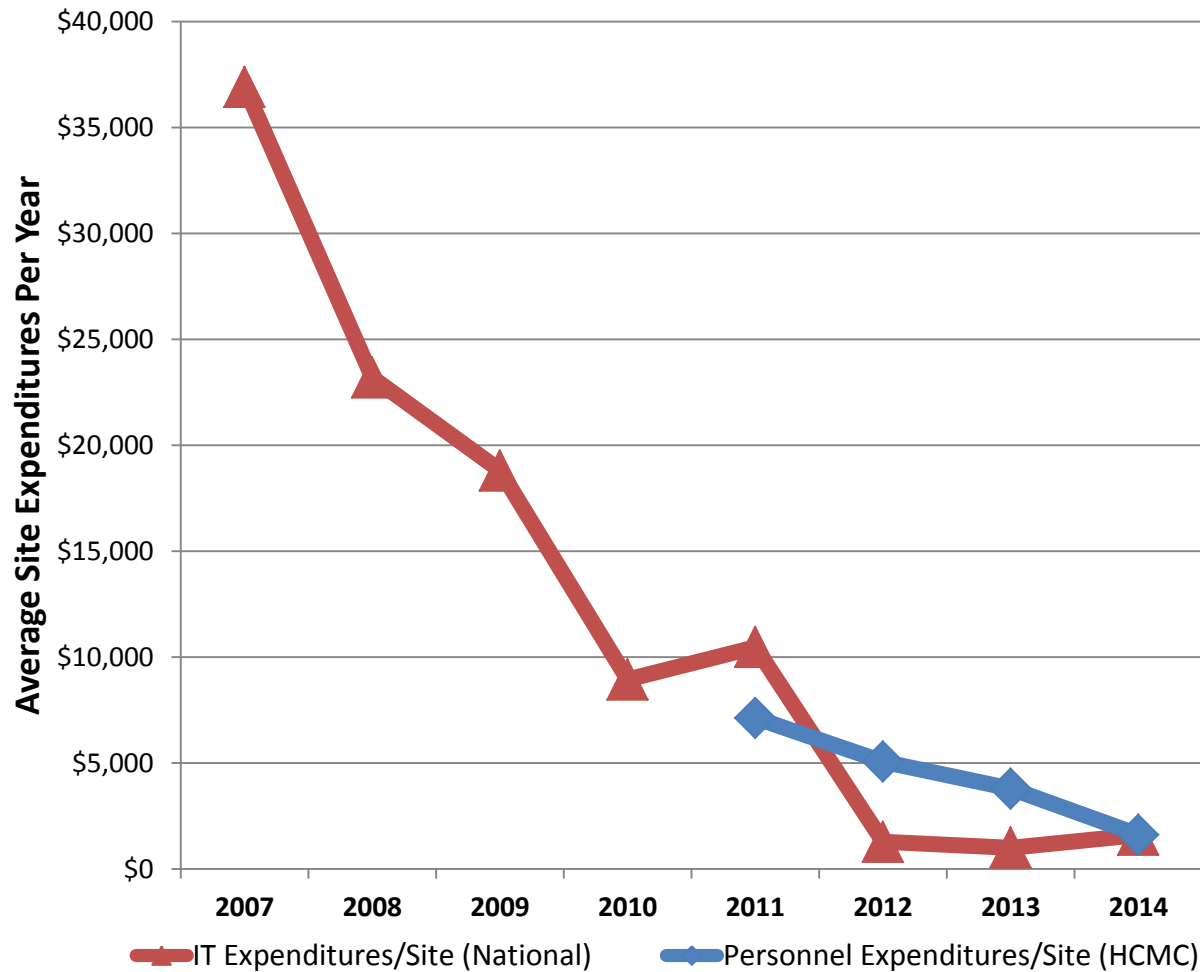


Two examples.... LIS Implementation, QMS Basic Training

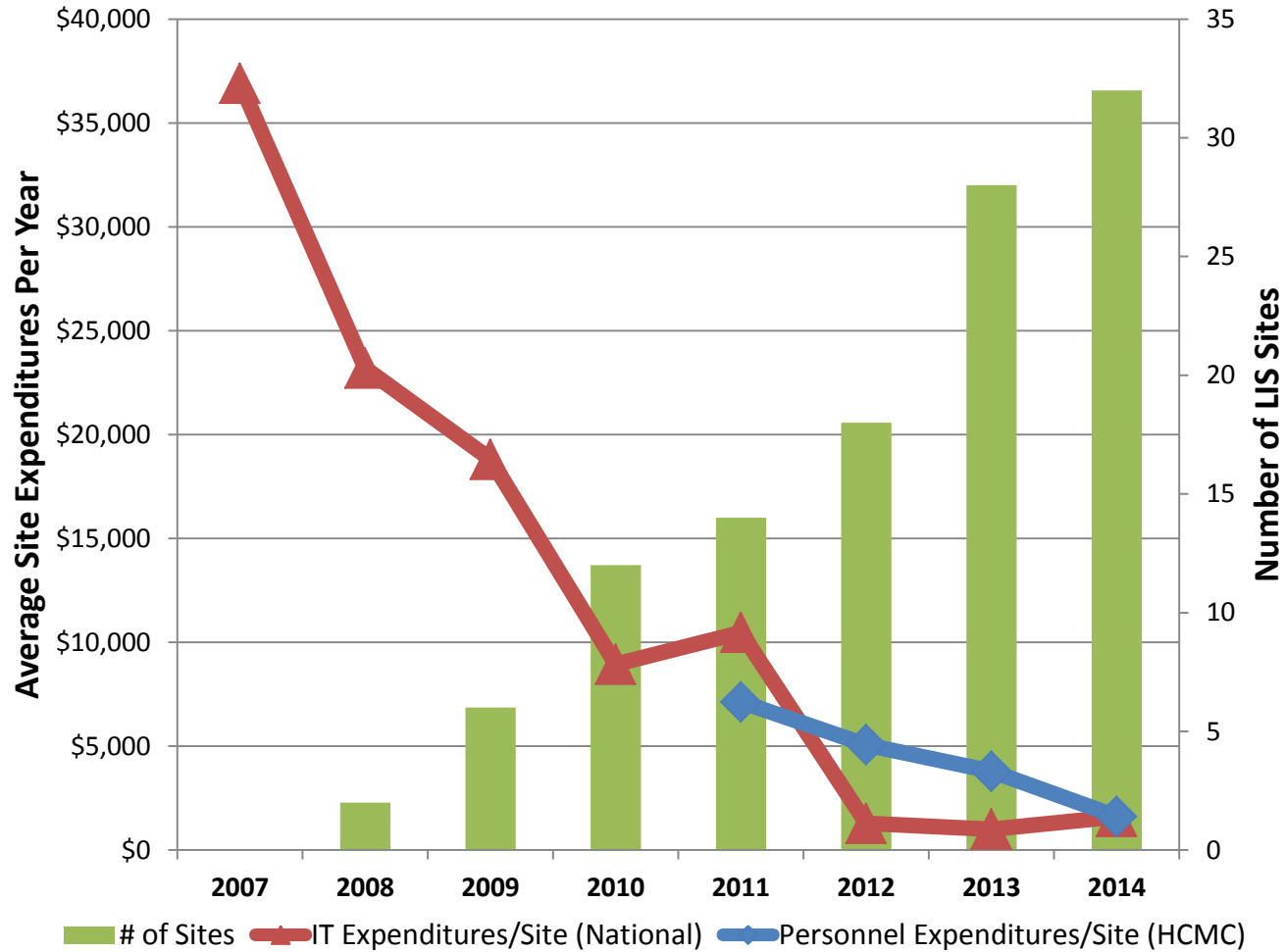
Laboratory Information Systems Scale-Up & Transition



Scale-Up & Transition of LIS Program



Scale-Up & Transition of LIS Program



QMS Basic Training Package

- August CDC and MOH delivered a TOT on QMS Basic
- September the An Giang Provincial Health department delivered training to all district level hospital lab staff.
- Required all labs to participate and charged fee to fund exercise.

Số 4340
THỨ BA
30-9-2014
(7-9 Giáp Ngọ)

An Giang

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ĐÀI PHÁT THANH - TRUYỀN HÌNH AN GIANG
AN GIANG RADIO - TELEVISION STATION

Nâng cao chất lượng xét nghiệm

Bệnh viện Đa khoa Trung tâm An Giang phối hợp cơ quan Phòng, chống và Kiểm soát dịch bệnh Hoa Kỳ (CDC Việt Nam) vừa khai giảng khóa đào tạo “Bảo đảm chất lượng xét nghiệm” lần thứ nhất cho 40 cán bộ quản lý, kỹ thuật viên phòng xét nghiệm các huyện, thị xã, thành phố trong tỉnh.

Các nội dung đào tạo, gồm: Tổng quan về quản lý chất lượng; tầm quan trọng của quy trình xét nghiệm chuẩn (SOP) và hướng dẫn viết SOP chuẩn; giới thiệu sổ tay lấy mẫu; mối liên quan Thông tư 01 của Bộ Y tế và bảng kiểm; sử dụng dụng cụ thông thường trong phòng xét nghiệm; sử dụng kính hiển vi quang học; thực hiện xét nghiệm chẩn đoán; ... Khóa đào tạo nhằm nâng cao chất lượng xét nghiệm, tiến tới tự các phòng xét nghiệm đánh giá các tiêu chí chất lượng của bảng kiểm theo Thông tư 01 của Bộ Y tế về “Nâng cao chất lượng xét nghiệm tại các cơ sở khám, chữa bệnh”.

Tin, ảnh: THANH HÙNG


Các cán bộ y tế làm bài kiểm tra tại khóa học

ng chủ Tin tức Truyền hình Phát thanh Chương trình nhân đạo

11/2014, 11:14 (GMT+7)

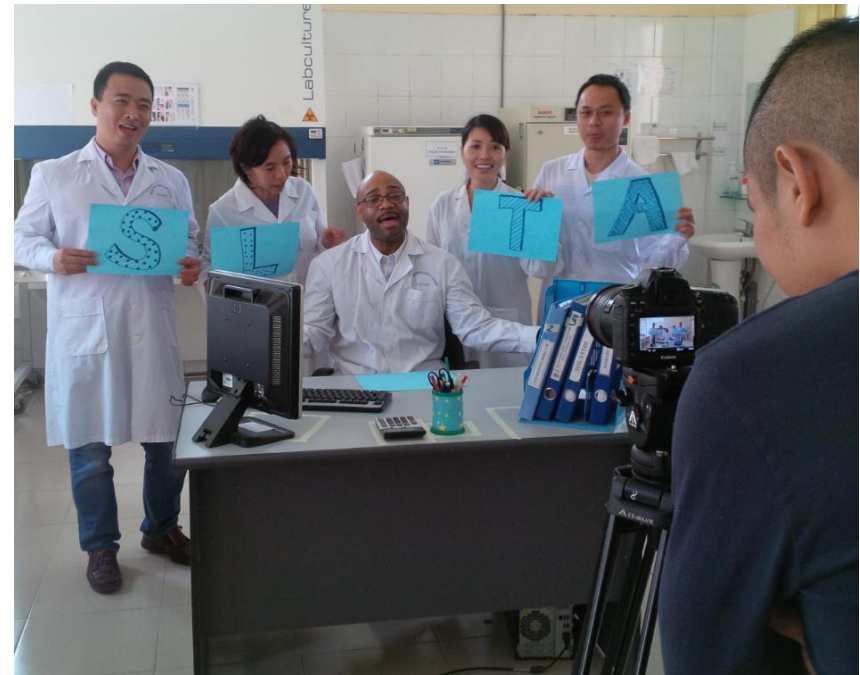
SỰ

Thời sự tối (29-09-2014)



Media Attention

- Bad press
 - Encourages MOH / specific sites to respond, look for solutions
- Positive Media Attention
 - Competition created between the sites
 - Tool for raising public awareness reaching the Tipping Point
 - Indicator that you have reached your Tipping Point



Advocacy from the Lab Level

- Quality Management Systems – Lab Leadership (QMS-LL) Certificate Program
 - This innovative new lab leadership program has resulted in the creation of 44 ‘ambassadors for QMS’ represented 16 national institutes, laboratories, universities...
 - Developed in partnership with CLSI
 - Graduates now have the capacity to both create national/local level lab policy and run a laboratory with a QMS (accreditation) focus
 - This program is now being transitioned to a local medical university

Conclusion

- All indicators suggest that Vietnam has reached a 'Tipping Point' for lab accreditation.
- But TA and support are still needed to maintain momentum.

Acknowledgements

- Vietnam MOH
 - Vice Minister Xuyen
 - Vietnam Administration for Medical Services
 - Vietnam Authority for HIV/AIDS Control
- CDC-Vietnam Laboratory Team