

INTERNATIONAL TRAINING & EDUCATION CENTER ON HIV

### Experiences in Strengthening Health Laboratories in Resource Limited Countries

#### UBC Program Office Laboratory Quality Management Conference 18 October 2015

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#### ■ I-TECH

- Where we work
- Identifying the needs
- Experiences
  - WHO/EMRO Countries
  - Cambodia and Laos
  - Kazakhstan
  - South Africa



#### + I-TECH at the University of Washington



#### 

## International Health Regulations 2005

International Health Regulations



Animal Health



## Millennium Development Goals



- Eradicate extreme poverty and hunger
- Achieve universal primary education
- Promote gender equality and empower women
- Reduce <u>child mortality</u>
- Improve <u>maternal health</u>
- Combat <u>HIV and AIDS, malaria, and other</u> <u>diseases</u>
- Ensure <u>environmental sustainability</u>
- Develop a <u>global partnership for</u> <u>development</u>

### WHO International Health Regulations

IHR(2005) adopted by all Member States and entered into force on 15 June 2007 and fully compliant by 2012

The national public health system should establish the laboratory capacity to identify, monitor and report to the health authorities on agents that may cause epidemics and emergencies, including those of international importance in a safe, timely and reliable manner.





 US Agencies Involved in Laboratory Capacity Development and Global Disease Surveillance

- Agency for International Development
- Department of Agriculture
- Department of Defense
- Department of Energy
- Department of Health and Human Services
- Department of State

### **Our Mental Image of a Laboratory:**













### + Clinical Laboratory Improvement Amendments (CLIA)

Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing





- Objective ensure quality laboratory testing.
- Standards based on complexity of testing.
- Law applies to virtually all US clinical and public health laboratories (about 225,000).

Centers for Medicare & Medicaid Services







#### Education

#### Information Systems

#### Law and Regulation

Functional Laboratory System Quality Systems

#### **Most Resource-Limited Countries:**



- Limited or no gov't. oversight
- Few or no national policies
- No or weak laboratory network
- No registration of labs, no accreditation of laboratories
- No process for procurement of laboratory reagents/kits
- Few professional organizations
- Limited testing menu
- Weak academics for lab medicine







- Must be country-owned and country driven, and
- in a broad health and development context



#### ■Goal 2:

To improve laboratory operations for patient care and for biosurveillance and biosecurity through improved laboratory quality assurance and management practices for the entire laboratory.



## Implementation of Laboratory Capacity Strengthening in Cambodia

#### **I-TECH Implementation Sites**



## The I-TECH team

- Cambodia:
  - Vireak Veourng, PharmD. MSc. PhD, Project Coordinator
  - Sophat Sek, Senior Laboratory QI Mentor
  - Sophanna Song, SeniorLaboratory QI Mentor
  - Tous Chansamrach, Laboratory QI Mentor
  - Nora Vong, Laboratory QI Mentor



- Seattle:
  - Robert Martin, MPH, DrPH, Project PI, Professor of Global Health
  - Lucy Perrone, MSPH, PhD, Assistant Professor of Global Health
  - Jean-Frederic Flandin, PhD, Laboratory Systems Specialist
  - Debbie Confer, Program Manager



## The LQSI Process

Laboratory Quality Stepwise Implementation

- A tool to assist laboratories in the implementation of a quality management system that meets international standards.
- LQSI translates the requirements of ISO 15189 into step-bystep activities divided in 4 phases, structures them in an interactive roadmap, and provides many user-modifiable support materials such as document templates and SOPs available online.



Laboratory Quality Stepwise Implementation (LQSI) Process



Phase 1: Assure technical competency of testing Phase 2: Implement QC measures, create traceability Phase 3: Establish the policy cycle with proper management, leadership and planning Phase 4: create CQI, document progress

## **The Mentoring Process:**



- Multiple mentor calls to labs every week
- Mentor meets with Lab Manager daily and Hospital Director weekly
- Weekly team call
- Weekly progress reports
- Monthly progress reports
- Bi-monthly team meetings in PP



# Mentors follow an action plan, use a daily checklist (in Khmer) and measure progress weekly

	Checklist Phase 1		QSE		How	□□□□□( How)	Indicator	
	<b>*</b>	<b>•</b>	-	-	▼	▼	▼	Indicator
	1 Have the staff		Facilities		<b>1</b> . Identify the pathogens most		1. Presence of the list for	
	adequately	בתתחתתה כו בוביביו	and Safety		frequently worked with in the	ביניניניניינייט בין בין בינינינייט בין בינינייט אוויינייט ב	pathogens and its symptoms	
	instructed on			$\overline{}$	laboratory.		for the most pathogens	
	the symptoms				2. Identify the symptoms of		frequently worked with in the	2
	of infection	רה התחתור בירי החתחה			diseases caused by these		laboratory.	
	with				pathogens.		<b>2</b> . Presence of the minute of	•••••••••••••••••••••••••••••••••••••••
	pathogens				3. Present and discuss the		meeting/record on the	
	in the	ניתראו היו כי היו היו היו היו היו			symptoms of the diseases		discussion and explaination of	
	laboratory?				caused by these pathogens		the symptoms of the diseases	
				Activity	with all staff. And explain to	3	caused by these pathogens	
					the staff members what they		with all staff; and explain to	
					should do when they have		the staff members what they	
					these symptoms.		should do when they have	
					<b>4.</b> Develop policy to allow staff		these symptoms.	
					to be vaccinated; and regular		<b>3.</b> Presence of policy that staff	4
					check of TB.		need to be vaccinated and	
					5. Vaccinate to staff against	_	regular check for TB.	
					Hepatitis B and organize regular		<b>4.</b> Presence of the certificate	
					checks for TB.		of vaccination of staff against	
_			-	0	··· · · ·		Hepatitis B.	4
	2 Is there a		Facilities		1. Write/develop/collect the	1//	<b>1.</b> Presence of pre-exposure	1.
	procedure on		and Salety		procedure on what to do when	pre-exposure prophylaxis	prophylaxis and post-	pre-exposure
	how to act in			<u> </u>	staff members (potentially)		exposure prophylaxis. And	
	case of a				have become infected in the	post-exposure prophylaxis.	put the its flow charts at the	prophylaxis
	suspected			Activity	laboratory, including the		place that all staff could see it	post-exposure
	laboratory				administration of PEP and		easily.	
	associated				visiting of medical services (pre-			prophylaxis
	atory	רורדין התחתהורין רין החוד			exposure prophylaxis and post-			
	accident				exposure prophylaxis)			لیا ہے جا پی میں پر محمد محمد محمد
	whereby a							

### Cohort 1 (blue) and 2 (red) – Phase 1

## Cohort 1 (blue) and 2 (red) – Phase 2



## **Strengths of approach**

- Detailed action plans for each phase in Khmer
- Regular mentor schedule and embedding of mentors
- Establishing a culture of CQI
- MoH (BLMS) support
- Maintaining weekly contact with mentors
- Teambuilding!!





## Challenges

- Culture of professionalism
- Economics (country and individual)
- Leadership support
- Law and Regulation
- Education
- Procurement



U.S. Food and Drug Administration

Protecting and Promoting Your Health







National Accrediting Agency for Clinical Laboratory Sciences

## **Clinical utilization of laboratory**

Improve Laboratory Utilization by Clinicians  Survey doctors and nurses on lab utilizationdiscuss results with the TWG for clinical education

- Design intervention strategies:
  - Lab Medicine rounds/case studies
  - Lab Medicine CME
  - Medical education –Lab Med elective at UHS
  - Tablet based learning?





RED

Started February, 2015

- MOH engagement
- Site selection
- LQSI tool being translated
- 2 job advertisement (Project coordinator and mentor)



## LQSI in Laos PDR



Cohort 1 Sites: (n=12) Zone 1

Louang Namtha Prov. Hosp. Oudomxai Prov. Hosp. Luang Prabang Mil. Hosp. #107 Luang Prabang Hospital (1)

Zone 2 NLCE (1) *IPL (1) Vientiane Mil. Hosp. #103 (1) LOMWRU Micro lab (1)* Mahosot Hospital (1) Mother and Child Hosp. (1) Mitaphab Hosp.(1) Settha Hosp.(1) *CICML/Merieux (1) NAHL (1)* 

#### Zone 3

Savannakhet Prov. Hosp.(1) Champasak Prov. Hosp.



## **Laboratories Need Leaders**

 Many laboratory Directors have ascended to their position through seniority or a strong grounding in technical skills, but have limited skills in leadership and management.





### Certificate Program in Laboratory Leadership and Management

Collaboration with WHO-EMRO

 Laboratory Directors from both private and public sectors





## **Participants and Mentors:**

- Proficiency in English
- Good Computer Skills
- Participants envision a career with increasing leadership role
- Mentors: Senior level scientist with experience in laboratory management.
  - Motivate, encourage and challenge
  - Support work on Capstone projects





## Learning Goals:

• Apply leadership and management skills

• Implement quality assurance practices

 Apply critical analyses to laboratory data and communicate results and interpretations in an impactful way.







## **Program Elements:**



#### 9-MONTH PROGRAM



http://edgh.washington.edu/lab-certificate











#### Strategic Planning for the Clinical Laboratory Sector in Kazakhstan



Booz | Allen | Hamilton



UNIVERSITY of WASHINGTON





T R A I N I N G & E D U C A T I O N CENTER ON HIV

### Strengthening the Clinical Laboratory Profession in South Africa

## Core Group Meeting August 20, 2015





#### I-TECH-CDC-PEPFAR grant (2014-19) Laboratory Project Goal:

Support South Africa's laboratory workforce development activity through strengthened <u>preservice</u> and <u>in-service</u> education and training of laboratory professionals.



## **Core Group Representatives**

- Universities of Technology
- Academic Universities
- Private Laboratories
- Health Professions Council of South Africa
  Medical Technologists
  Medical Scientists
- SANAS

+

Department of Education

#### ■ NHLS

### Conclusions

- Assess current curriculum against appropriate standards.
- Reduce variability among university programs through stronger accreditation process.
- Provide faculty development opportunities.
- Strengthen training laboratories (curriculum, education, training).
- Strengthen affiliate agreements (e.g., require Technical Program Coordinators and assurance of professional participation in educational process)
- Examine process for development and ongoing review of board exam.

## + Observations from our work:

- Strengthening laboratories is one of many competing priorities for countries
- Limited resources available for implementing key components of laboratory quality
- Cultural changes in the work environment
- Less reliance on a disease specific approach to strengthen laboratories.
- Quality Laboratory Practice Unrealistic expectations of funders
- Law, regulation, education, management requires more attention and long-term commitment





