

Strengthening Laboratory Quality and Workforce Capacity: What Works?

Lucy A. Perrone, MSPH, PhD

Project, Director, Laboratory Quality Improvement in Cambodia

International Training & Education Center for Health (I-TECH)

Assistant Professor, Department of Global Health, School of Public Health

Adjunct Assistant Professor, Department of Laboratory Medicine, School of Medicine

University of Washington, Seattle, WA, USA

perronel@uw.edu



Laboratories are an integral part of the health system

Policy and Strategic Planning

complex testing

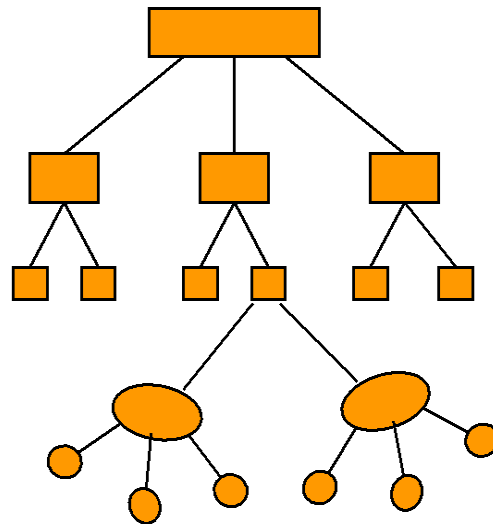
National Reference
Laboratory

Regional Reference
Laboratories

Referral Hospitals

Primary Hospital

Health Centers



Senior Health Scientists

Specialists
Senior Technologists
Program Officers

Doctors
Nurse Practitioners
Medical Assistants

Clinical Service Support

simple integrated testing

Health data



Laboratory Quality Management and ISO 15189



~60-80% of patient management decisions are based on clinical laboratory/diagnostic testing



ISO 15189 is the international standard for medical laboratory quality. Helps assure quality and competence in laboratories for accurate and reliable testing.



Improving quality management is critical to improving healthcare.

Challenges for Laboratory Managers

- Inadequate financial resources
- Inadequate network support- Absent functional linkages between labs
- Difficulties assuring consistent quality of reagents and equipment function
- Procurement challenges
- Limited HR capacity and high turnover of staff
- Staff competency and work ethic
- Infrastructure challenges like Inconsistent electricity and poor water quality
- Inadequate training in management of lab operations

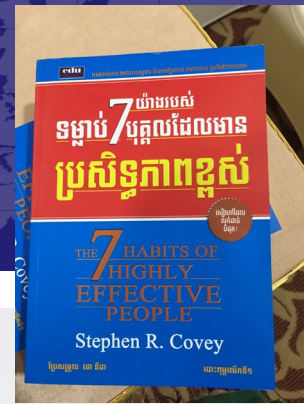


How can I-TECH help the MoH?

- Where to start?
- How to start?
- Who?
- What?
- When?
- What works?



Successful organizations start with effective people



1. **Be Proactive** (Achieve extraordinary results by consistently executing their resourcefulness and initiative to break through barriers.)
2. **Begin with the End in Mind** (Develop an outcome-oriented mindset in every activity they engage in—projects, meetings, presentations, contributions, etc.)
3. **Put First Things First** (Eliminate energy and time-wasting tendencies by focusing and executing on the team’s wildly important goals with a weekly planning cadence.)
4. **Think Win-Win** (Lead teams that are motivated to perform superbly through a shared expectation and accountability process.)
5. **Seek First to Understand, Then to Be Understood** (Create an atmosphere of helpful give-and-take by taking the time to fully understand issues, and give candid and accurate feedback.)
6. **Synergize** (Demonstrate innovative problem-solving skills by seeking out differences and new and better alternatives.)
7. **Sharpen the Saw** (Actualize the highest and best contribution of everyone on a team by unlocking the total strength, passion, capability, and spirit of each individual.)

“Create a vision”: Conducted two ISO 15189 Study Tours



How do adults learn? (Andragogy)

- **Need to know:** Adults need to know the reason for learning something.
- **Experience:** (including error) provides the basis for learning activities.
- **Self-concept:** Adults need to be responsible for their decisions on education; involvement in the planning and evaluation of their instruction.
- **Readiness:** Adults are most interested in learning subjects having immediate relevance to their work and/or personal lives.
- **Orientation:** Adult learning is problem-centered rather than content-oriented.
- **Motivation:** Adults respond better to internal versus external motivators.

Seven Principles of Adult Learning

1. Adults must want to learn
2. Adults will learn only what they feel they need to learn
3. Adults learn by doing
4. Adult learning focuses on problem solving
5. Experience affects adult learning
6. Adults learn best in an informal situation
7. Adults want guidance and consideration as equal partners in the process



What is Laboratory Mentoring?

“a sustained, collaborative relationship in which an experienced practitioner guides improvement in the quality of services delivered by laboratory workers and the laboratories where they work”



**“Seek first to understand,
then be understood”**



Tele-mentoring

Participant: K2101746 Fresh Koonarak Hospital (PKG)
 Subscription ID: 120452 BCH-E435 Chemistry/Immunology
 Results Deadline: 2018-Jul-18

Analyte / Sample	Result	Unit	Statistical Code	Mean	SD	CV%	Peer Group Code/Description	Acceptance Range	Established Criteria
Aspartate Aminotransferase U/L	401	U/L	INACC	11	117.0	91.4	SC/Random Hematocrit Series	201-367	Peer Group Mean = 25.2%
Cholesterol - Total mg/dL	265	mg/dL	INACC	18	201.7	24.7	MC/Human	228-277	Peer Group Mean = 0.0%
Protein - Total g/L	67	g/L	INACC	14	80.2	2.1	MC/Human	65-96	Peer Group Mean = 0.0%
A	79	g/L	INACC	14	82.4	3.7	MC/Human	51-89	Peer Group Mean = 0.0%
B	52	g/L	INACC	15	37.5	5.4	MC/Human	31-61	Peer Group Mean = 0.0%
C	94	g/L	INACC	16	82.4	11.0	MC/Human	31-61	Peer Group Mean = 0.0%
D	87	g/L	INACC	15	70.9	4.9	MC/Human	61-78	Peer Group Mean = 0.0%

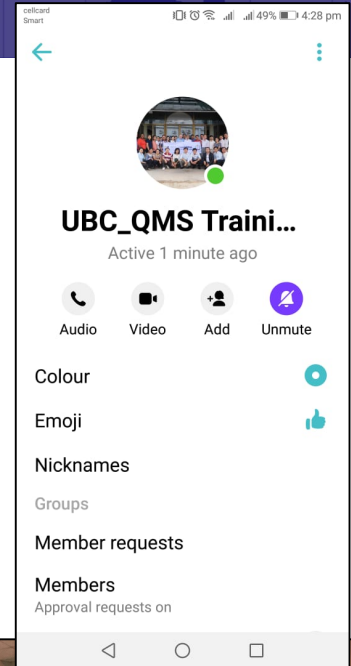
Question no.	Question	Available Score	Answer	Score	Comments	Standard
2	Is equipment installed and placed as specified in the operator's manuals and uniquely labeled or marked?	2		0		ISO15189:2012 Clause
3	Are equipment operated by trained, competent and authorized personnel?	2		0		ISO15189:2012 Clause
4	Are newly introduced equipment and methods validated/verified on-site and are records documenting validation available?	5	0	0		ISO15189:2012 Clause
5	Does the validation include:					
6	a) Are specific verification/validation protocols in place for each equipment and examination procedure?					
7	b) Is validation performed for all laboratory designed or developed methods, standard methods used outside their intended scope and validated methods that are subsequently modified?					
8	c) Has validation information been obtained from the manufacturer/method developer as part of the verification?					
9	d) Have performance characteristics been appropriately selected and evaluated as per intended use?					
10	a) Were the verification/validation studies appropriate and adequate?					

High variation in video conference participation time between laboratories

We have conducted 9 regional on-site workshops on specific lab QM issues in the past year



We have conducted a 9 month-long job-specific training for Quality Assurance Officers



Delivered two workshops on Leadership

- Laboratories need technical expertise *plus* effective management to succeed
- Complex, people-oriented systems require effective management
- Training and guidelines don't address all critical issues. Having “all the tools” is simply not enough



To learn more visit: www.go2itech.org/laboratory-systems

“Synergize/ collaborate”: Establishment of a new QAO network

Zoom Meeting ID: 373-325-274

	Kim I-TECH		
SAMBO PV	khemsereyroth	SHV Muoyleng	S.Sophea (THL)
Malai AD	Dany	Oudom (Kandal)	Choun Vanneth
	Samnang Takeo...	Khum Ravy PKH	

Participants (14)

Find a participant

- Kim I-TECH (Me)
- Choun Vanneth
- Dany
- khemsereyroth
- Khum Ravy PKH
- Malai AD
- Oudom (Kandal)
- SAMBO PV
- Samnang Takeo Lab
- savuth kampot
- SHV Muoyleng

Zoom Meeting Controls: Raise Hand, yes, no, go slower, go faster, more, Mute Me, Claim Host

Windows Taskbar: 3:00 PM 8/31/2018

KINGDOM OF CAMBODIA
NATION-RELIGION-KING



Ministry of Health

Cambodia Laboratory Quality Management
System (CamLQMS)
Checklist for Accreditation

For Clinical and Public Health Laboratories

Bureau of Medical Laboratory Services: Department of Hospital Services

Version 1: January 2018

AUDIT SCORING

Cambodia Laboratory Quality Management System (CamLQMS) Checklist contains 12 main sections (a total of 117 questions for a total of 275 points. Each item has been awarded a point value of 2, 3, or 5 points—based upon relative importance and/or complexity. Responses to all questions must be, "yes", "partial", or "no".

- Items marked "yes" receive the corresponding point value (2, 3, or 5 points). **All elements of a question must be present in order to indicate "yes" for a given item and thus award the corresponding points.**

NOTE: items that include "tick lists" must receive all "yes" and/or "n/a" responses to be marked "yes" for the overarching item.

- Items marked "partial" receive 1 point.
- Items marked "no" receive 0 points.

When marking "partial" or "no", notes should be written in the comments field to explain why the laboratory did not fulfil this item to assist the laboratory with addressing these areas of identified need following the audit.

Where the checklist question does not apply, indicate as NA. Subtract the sum of the scores of all questions marked NA and subtract that sum of NAs from the total of 275. Since denominator has changed, the level status is then determined using % score.

Audit Score Sheet

Section	Total Points
Section 1: Documents & Records	28
Section 2: Management Reviews	14
Section 3: Organization & Personnel	22
Section 4: Client Management & Customer Service	10
Section 5: Equipment	35
Section 6: Evaluation and Audits	15
Section 7: Purchasing & Inventory	24
Section 8: Process Control	32
Section 9: Information Management	21
Section 10: Identification of Non Conformities, Corrective and Preventive Actions	19
Section 11: Occurrence/Incident Management & Process Improvement	12
Section 12: Facilities and Biosafety	43
TOTAL SCORE	275

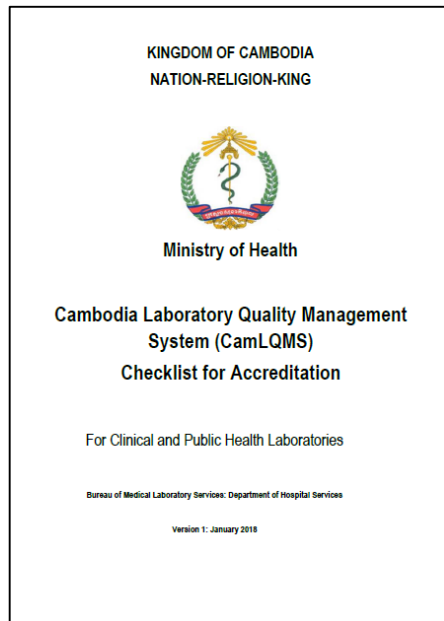
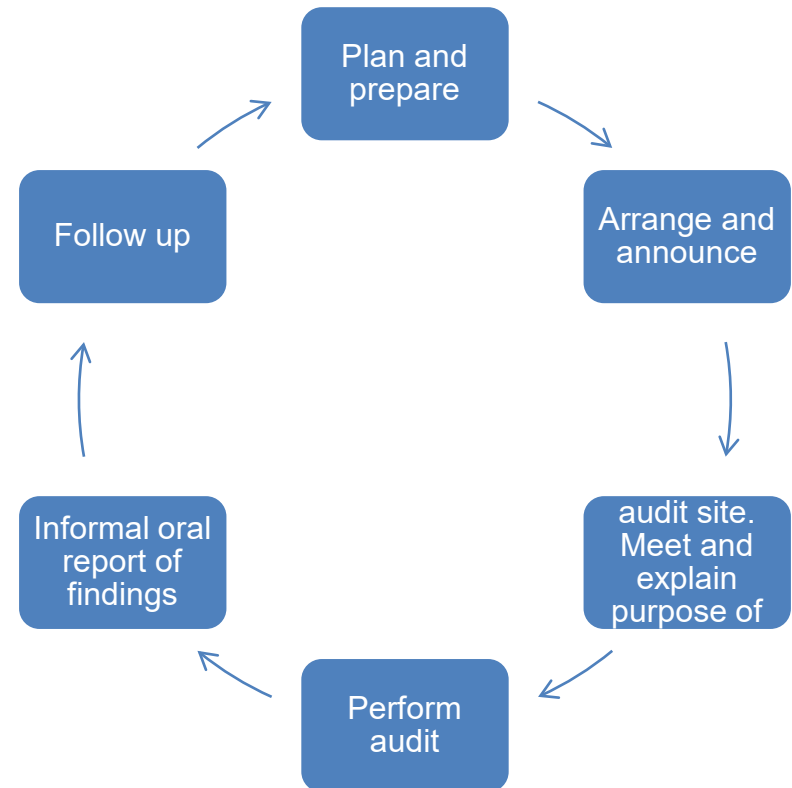
Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
(0 – 150 pts)	(151 – 177 pts)	(178 – 205 pts)	(206 – 232 pts)	(233 – 260 pts)	(261 – 275 pts)
< 55%	55 – 64%	65 – 74%	75 – 84%	85 – 94%	≥95%

Trained a new cadre of quality auditors

- Session 1: January 16, 2019
- Session 2: January 30, 2019
- Session 3: February 20, 2019
- Session 4: February 26, 2019
- Session 5: March 13, 2019



Steps to performing a quality audit



Conducted two rounds of lab audits (Dec 2017- Jan 2018, March-Apr 2019)



- Section 1: Documents & Records
- Section 2: Management Reviews
- Section 3: Organization & Personnel
- Section 4: Client Management & Customer Service
- Section 5: Equipment
- Section 6: Evaluation and Audits
- Section 7: Purchasing & Inventory
- Section 8: Process Control
- Section 9: Information Management
- Section 10: Identification of NCs ,Corrective and Preventive Actions
- Section 11: Occurrence/Incident Management & Process Impvmt
- Section 12: Facilities & Safety

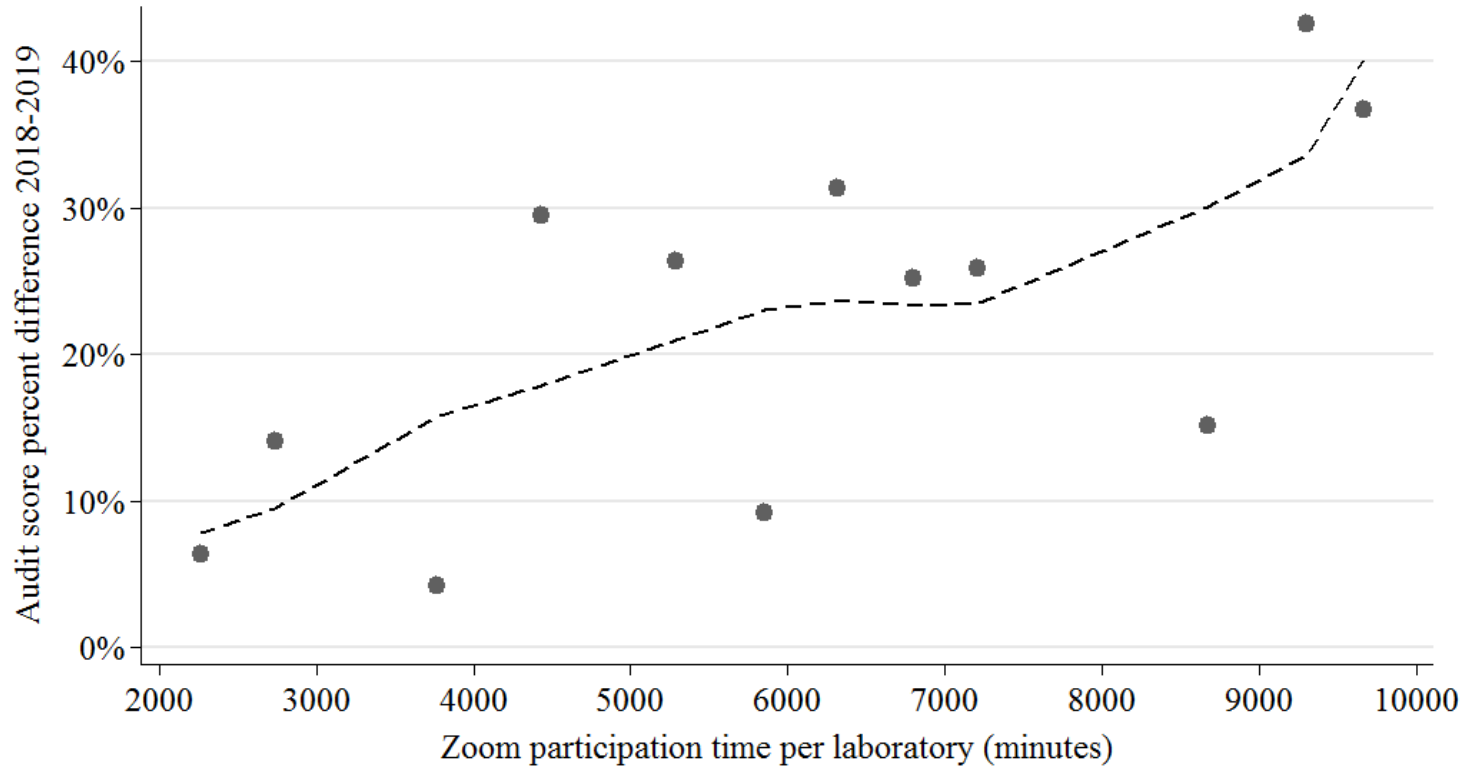
Conducted 3 National LQMS Review Meetings in the past 5 years



Inputs vs. audit scores. What works?

	Number of completed trainings of intended participants (total participants)	Mentor days on site per laboratory	Video conference participation time (minutes)	Audit score percent difference
Labs	19 (25)	9	3766	4%
	21 (26)	10	5855	9%
	24 (25)	10	2742	14%
	23 (25)	10	6320	31%
	25 (29)	13	9302	43%
	24 (37)	13	9664	37%
	23 (24)	9	6800	25%
	21 (27)	13	5290	26%
	28 (36)	13	7210	26%
	22 (24)	8	4434	29%
	22 (26)	10	8675	15%
	22 (26)	12	2263	6%
Group mean ± SD	23± 2 (28±4)	11±2	6027±2454	22%±12%

What is the impact of remote/zoom mentoring on audit scores?

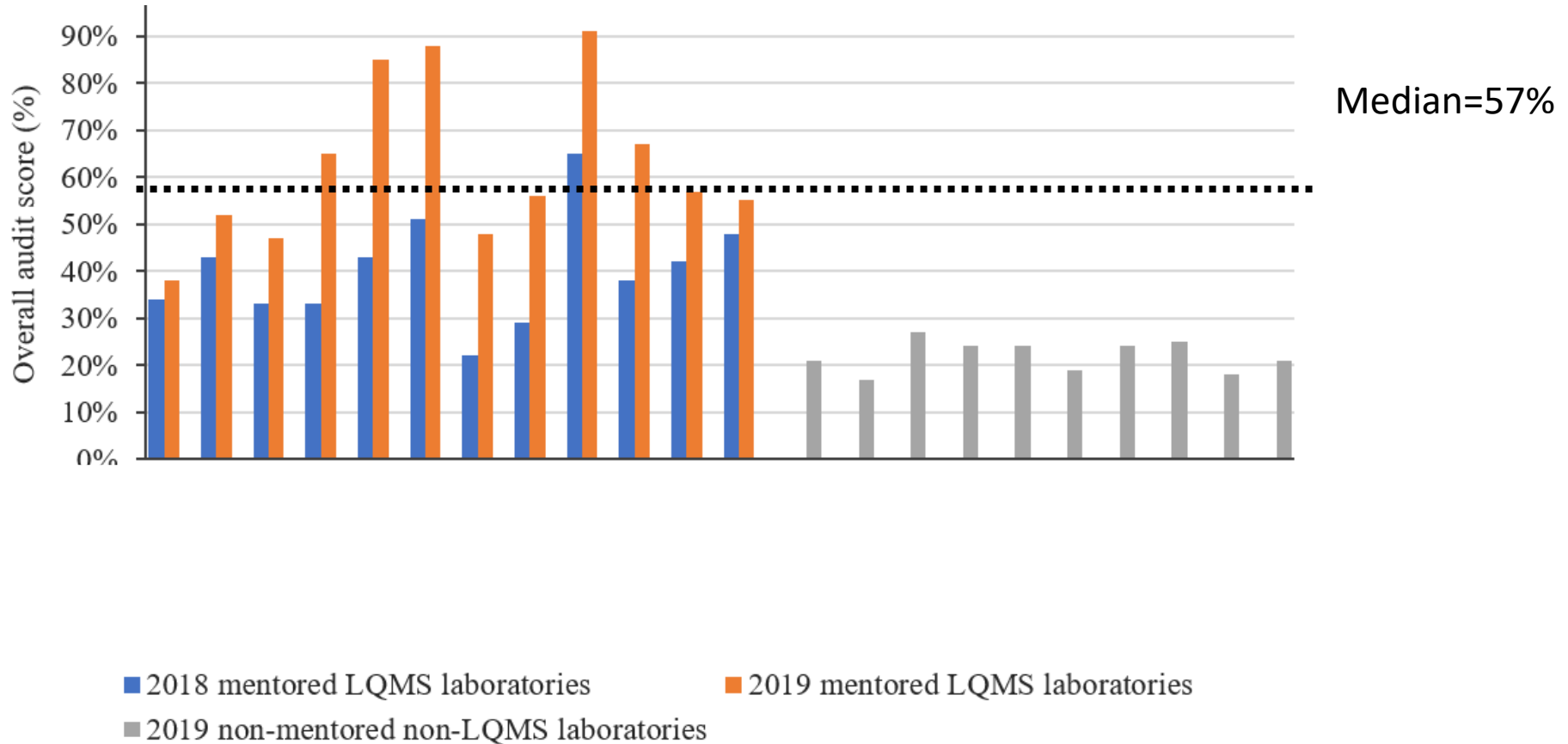


Strong relationship between laboratory participation in Zoom mentoring and differences between audit assessments ($r_s=0.66$, $p=0.02$)

Scatter gram represents the percent difference in mentored LQMS audit scores plotted against video conference participation time by lab.

Line represents a locally weighted scatterplot smoothing of the data (LOWESS curve).

Training and mentoring works.



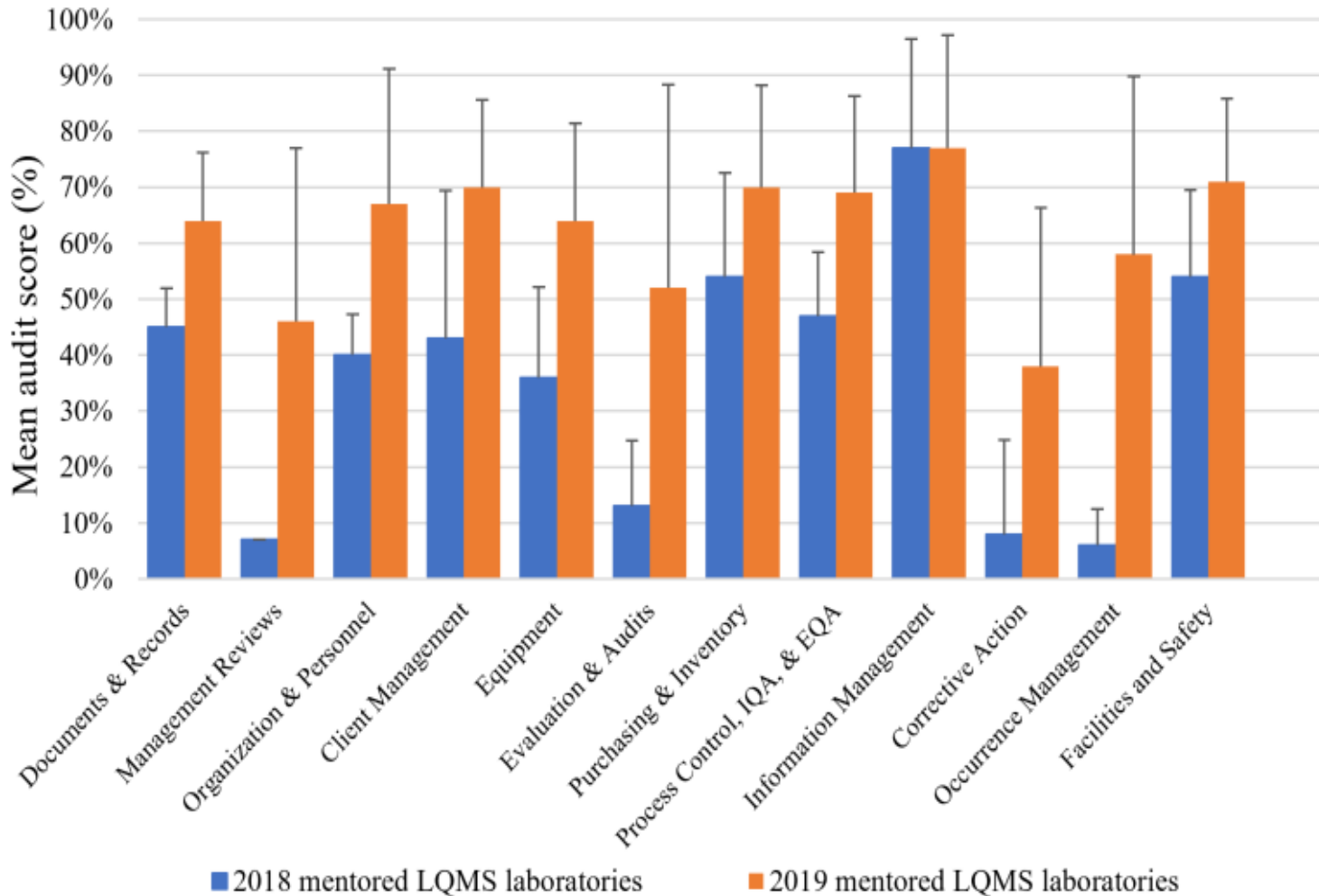
Overall, audit scores for mentored LQMS laboratories in 2019 **were significantly higher** than audit scores for non-mentored, non-LQMS laboratories (median=23%) in the same year ($z=3.96$, $p=0.0001$).

2019 mentored LQMS laboratories

Documents and records ^b	Management reviews ^b	Organization and personnel ^b	Client management and customer service ^b	Equipment ^b	Evaluation and audits ^b	Purchasing and inventory ^b	Process control and internal and external quality assessment ^b	Information management ^a	Corrective action ^b	Occurrence management and process improvement ^b	Facilities and safety ^b	Overall score ^b
46%	14%	41%	40%	33%	13%	46%	50%	87%	5%	17%	44%	38%
64%	14%	45%	60%	55%	13%	58%	57%	87%	16%	42%	70%	52%
54%	43%	50%	70%	33%	40%	50%	47%	73%	16%	25%	60%	47%
82%	43%	68%	70%	79%	47%	54%	73%	60%	26%	50%	74%	65%
75%	71%	100%	90%	82%	100%	96%	94%	93%	79%	100%	84%	85%
61%	93%	100%	90%	82%	100%	83%	97%	100%	79%	100%	88%	88%
57%	21%	45%	50%	64%	7%	50%	57%	100%	11%	17%	53%	48%
68%	36%	45%	70%	58%	20%	67%	60%	42%	37%	58%	72%	56%
71%	100%	100%	90%	82%	100%	96%	91%	100%	79%	100%	98%	91%
82%	57%	82%	60%	76%	73%	88%	57%	47%	21%	75%	70%	67%
46%	14%	55%	70%	61%	20%	67%	66%	73%	47%	67%	72%	57%
61%	14%	45%	70%	61%	47%	75%	66%	73%	16%	33%	60%	55%
11%	7%	18%	0%	24%	0%	25%	33%	64%	0%	0%	37%	21%
21%	7%	27%	10%	24%	0%	17%	17%	46%	0%	0%	19%	17%
29%	0%	27%	10%	36%	0%	71%	18%	64%	0%	0%	35%	27%
11%	0%	23%	10%	30%	0%	42%	25%	91%	0%	0%	40%	24%
25%	0%	27%	30%	24%	0%	17%	28%	67%	0%	17%	37%	24%
18%	0%	18%	10%	15%	0%	42%	17%	55%	0%	0%	30%	19%
29%	7%	27%	10%	33%	0%	25%	33%	40%	0%	8%	33%	24%
25%	0%	27%	20%	30%	0%	21%	30%	85%	0%	0%	35%	25%
0%	7%	23%	20%	15%	0%	33%	18%	37%	0%	0%	35%	18%
18%	14%	32%	10%	9%	0%	38%	28%	37%	0%	8%	33%	21%

2019 non-LQMS comparison laboratories

Laboratories in the mentoring program are improving, but there is variation within the cohort



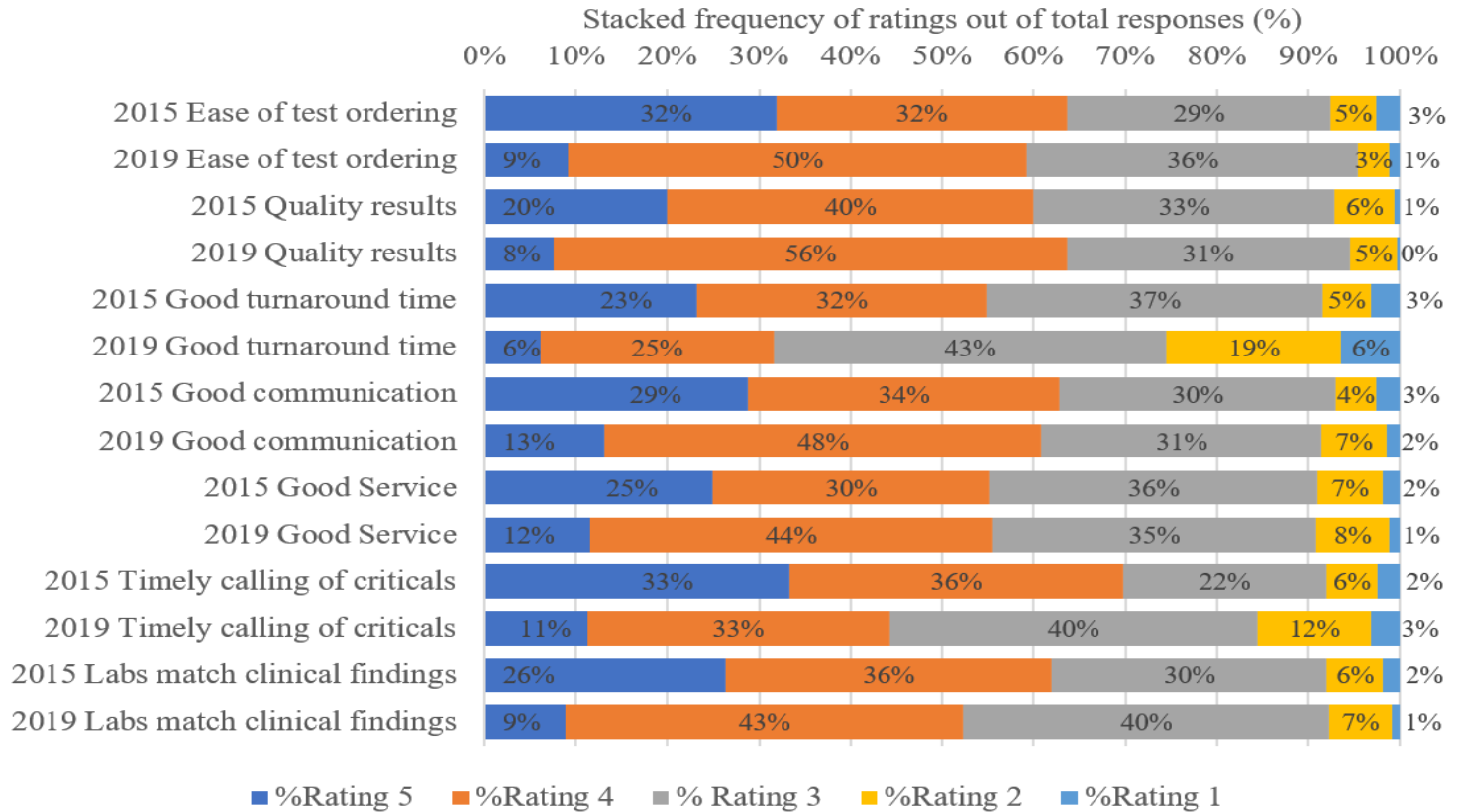
Wilcoxon Signed-Ranks Test indicated that mean audit scores for 11 out of 12 audit sections have improved significantly ($p < 0.01$) between assessments, with *information management* being the exception

How well are indicators of quality changing *as a result* of improved quality management?

Changes in physician ratings of satisfaction between 2015 and 2019

What dropped:
Ease of test ordering, communication, turnaround time, timely calling of critical results, and test corroboration of clinical findings

What dropped a lot:
Turnaround time and timely calling of critical results



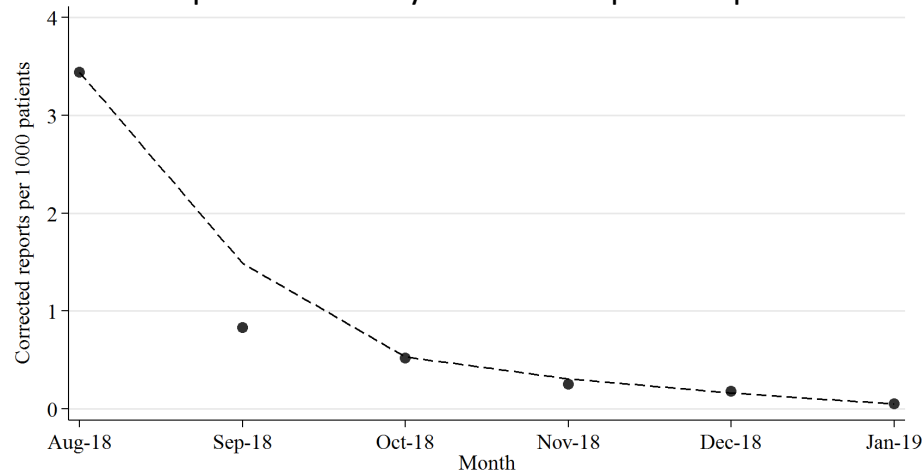
Why did physician ratings decrease? Did quality go down or did physician expectations go up?

Corrected report frequencies show no overall change over time.
A longer study may provide additional insight.

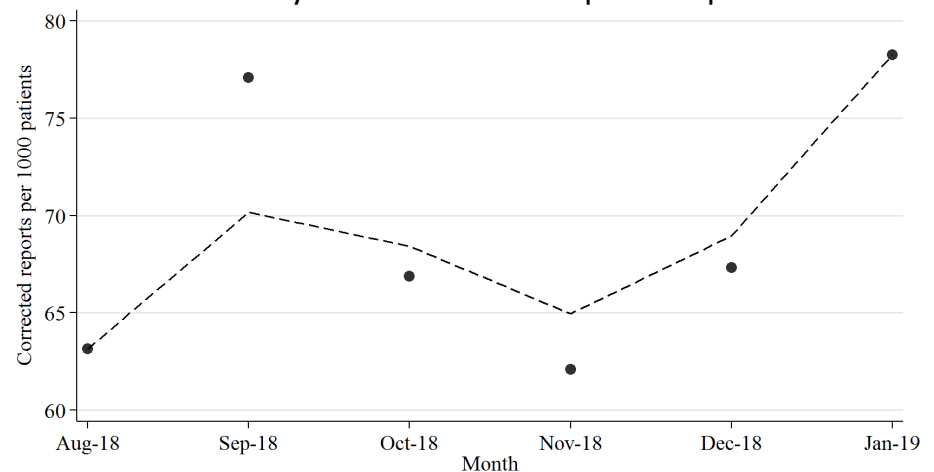
Changes in corrected report frequencies between August-2018 and January 2019

Laboratory	Month						Spearman r_s	
	Aug-2018	Sep-2018	Oct-2018	Nov-2018	Dec-2018	Jan-2019	r_s	p
	4.3	0.37	0.058	0.30	0.21	0.034	-0.83	0.04
	13	55	51	92	26	130	0.6	0.2
	2.0	0.79	2.3	1.7	0.66	0.21	-0.71	0.1
	1.8	1.1	1.1	1.4	2.0	1.0	-0.26	0.6
	320	480	370	330	330	320	-0.086	0.9
	16	9.7	7.6	7.7	1.9	37	-0.086	0.9
	0.84	1.4	4.8	0.93	0.46	0.82	-0.54	0.3
	3.4	0.83	0.52	0.25	0.18	0.051	-1.00	<0.001
	35	24	33	19	37	25	-0.03	1.0
	290	270	260	230	340	330	0.37	0.5
Mean±SD	7.3	6.2	9.7	3.6	2.8	6.1	-0.66	0.2
	63±120	77±155	67±125	62±112	67±133	78±130	0.43	0.4

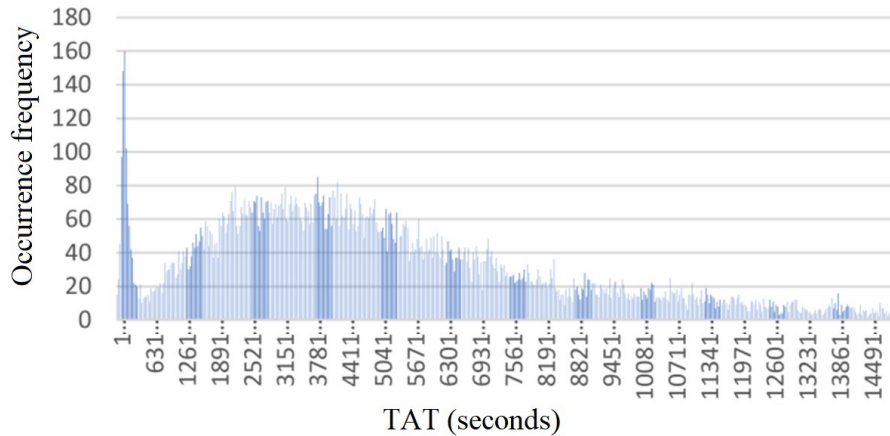
X Hospital Laboratory corrected report frequencies



Interlaboratory mean corrected report frequencies



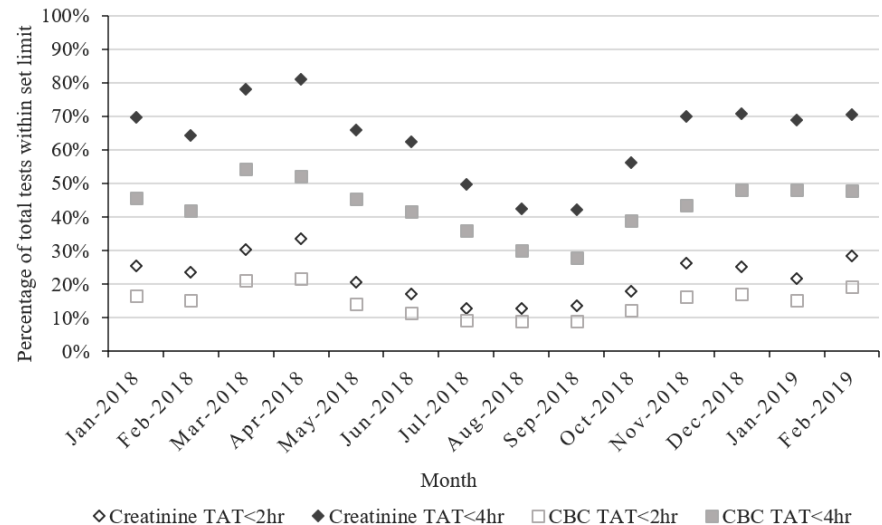
Turnaround time (TAT) analysis



Only one laboratory provided accurate data for turnaround time analysis due to poor recording practices within laboratories
-No trend is identified-

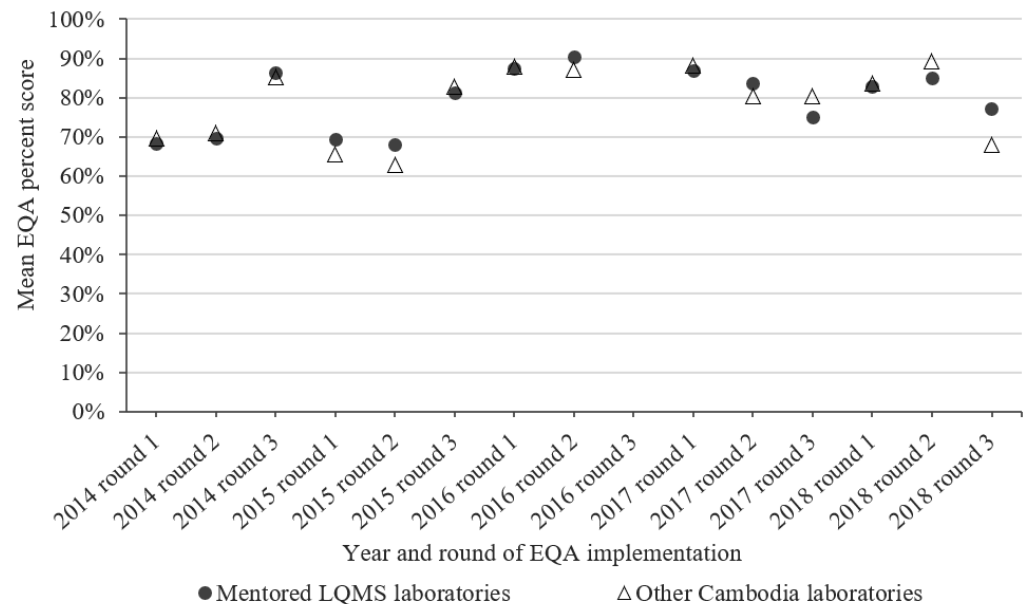
To improve laboratory timeliness, documentation practices need to be improved

Percentage of tests completed within lab TAT goals



Proficiency testing (External Quality Assessments)

Although I-TECH mentored LQMS laboratories increased in EQA program participation and compliance, average external quality assessment scores in intervention laboratories do not differ from those of other Cambodian laboratories



Key findings

- Significantly improved quality management systems
- Strong association between remote mentorship and improved LQMS
- Data from the Cambodia laboratory information system helped to identify gaps in laboratory quality
- Gaps in accurate recordkeeping may hinder process improvement, particularly in improving timeliness

Limitations

- Small sample sizes
- Confounding associations
- Missing data: Zoom calls and EQA
- Audit scores are not equal between sections, thus interpreted with caution.

Shared successes

While significant progress has been demonstrated, accreditation has still not yet been achieved, laboratories in Cambodia should continue to implement stepwise improvement programs toward accreditation with increased emphasis on improving the quality of performance indicator data for effective quality improvement.

