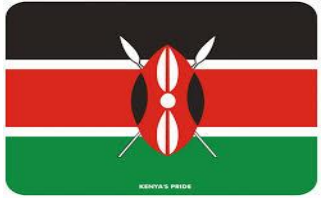


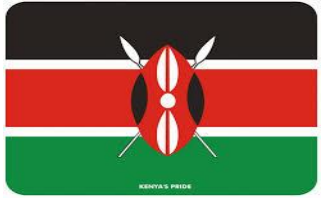
THE ROAD TO LABORATORY ACCREDITATION: KEY SUCCESS FACTORS

Presented by: THOMAS GACHUKI

National Public Health Laboratory Services Kenya

Risper Sewe, Jane Mwangi, David Turgeon, Mary Garcia, Elizabeth T. Luman, Mamo Umuro

In honour of the Late David M. Njogu



Presentation outline

- Overview of NHRL
- Baseline status
- Our experience
- Outcomes
- Challenges and solutions
- Success factors
- Lessons learnt
- Acknowledgement

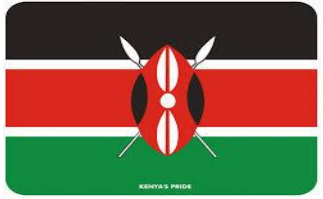
OVERVIEW

- NHRL was established in 2005, became functional in 2007
- To implement the QMS ,NHRL enrolled in the WHO-AFRO SLMTA in 2010
- Baseline audits done in 2010- *Zero stars*
- Improvements projects were undertaken to address gaps
- *Strategy*- development of work plans, team formation and staff mentorship

OVERVIEW..2

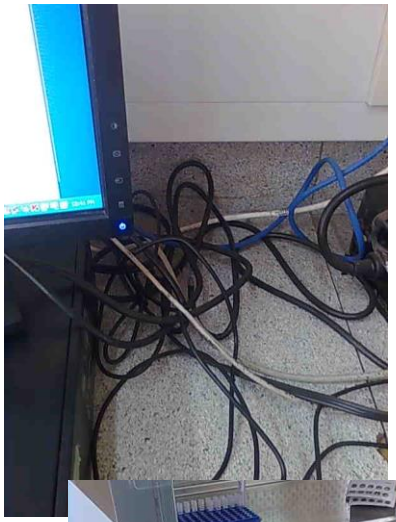
- Significant Improvements in the 12 QSE
- Achievement of SLMTA – 5 stars in 2011
- Engaged accreditation body for ISO 15189 accreditation in 2012
- Attained accreditation 2013

Baseline Status

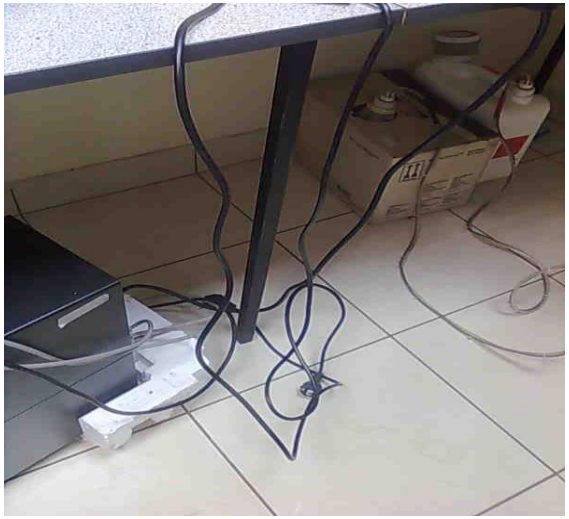


- Pre analytical- no standard procedures
- Analytical –Organization, process control, no IQC
- Post analytical No monitoring of customer care and feedback

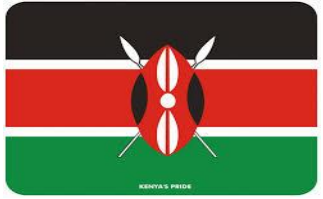
Zero stars(45%)



Baseline Status

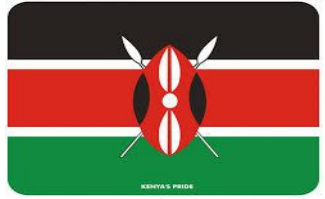


Baseline status



Our experience

Leadership and governance



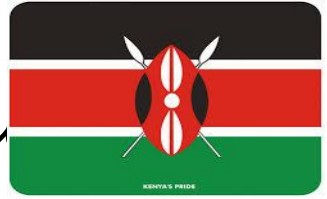
- Everything rises and falls on leadership- John C Maxwell

The laboratory organizational structure was redefined with formation of teams with specific objectives and work plans aimed at contributing to the overarching vision for accreditation

ROLLING UP OUR SLEEVES…

- Gaps with action items with specific timelines posted in a central place for all staff to view
- Action items linked to staff appraisal: reviewed periodically
- Accreditation main agenda in every staff meeting with updates from all
- Formation of sectional teams each responsible for filling gaps, regularly reviewed, all played a part
- Mentorship visits by all staff in accredited laboratories

Leadership and governanc ..Building the team



Leadership is the art of getting someone else to do something you want done because he wants to do it.- Dwight D. Eisenhower

- Appointment of key personnel and deputies
- Institution of management review meetings for NHRL management
- Regular open staff meetings: brainstorming then followed by collegiate decisions on the needed improvements
- Annual staff retreats

NATIONAL PUBLIC HEALTH LABORATORY SERVICES
NATIONAL H.I.V
REFERENCE LABORATORY
NOTICE
AUTHORISED PERSONNEL ONLY
ILANI
HAKUNA KUINGIA BILA RUHUSA
PULL
UNIVERSAL PRECAUTIONS

Personnel management

- Delegation of Responsibilities of Lab Manager, Supervisors and staff
- Implementation of Quality Management policy
- Implementation of the information flow system from manager
- Organizational chart developed
- Competency assessments, retraining and orientation schedules

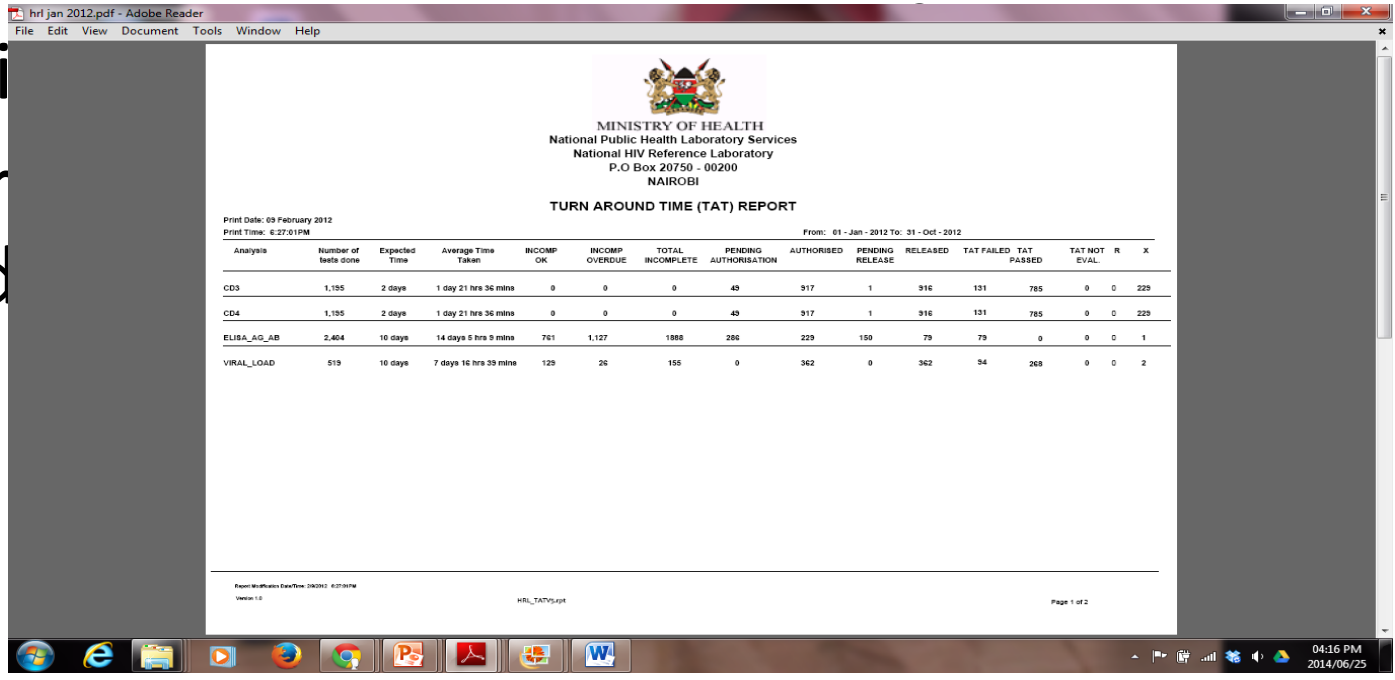
ROLLING UP OUR SLEEVES...

Trainings done:

- ISO sensitization
- Good Laboratory Practice
- Biosafety
- Internal audi
- Skill based tr in accredited

Monitoring quality indicators:

- Turn-around time
- Specimen rejection rates
- Service interruptions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MINISTRY OF HEALTH
National Public Health Laboratory Services
National HIV Reference Laboratory
P.O Box 20750 - 00200
NAIROBI

TURN AROUND TIME (TAT) REPORT

Print Date: 03 February 2012
Print Time: 6:27:01PM

From: 01 - Jan - 2012 To: 31 - Oct - 2012

Analysis	Number of tests done	Expected Time	Average Time Taken	INCOMP OK	INCOMP OVERDUE	TOTAL INCOMPLETE	PENDING AUTHORISATION	AUTHORISED	PENDING RELEASE	RELEASED	TAT FAILED	TAT PASSED	TAT NOT EVAL.	R	X
CD3	1,155	2 days	1 day 21 hrs 36 mins	0	0	0	49	917	1	916	131	785	0	0	229
CD4	1,155	2 days	1 day 21 hrs 36 mins	0	0	0	49	917	1	916	131	785	0	0	229
ELISA_AG_AB	2,404	10 days	14 days 5 hrs 9 mins	761	1,127	1888	286	229	150	79	79	0	0	0	1
VIRAL_LOAD	519	10 days	7 days 16 hrs 39 mins	129	26	155	0	362	0	362	94	268	0	0	2

Report Modification Date/Time: 2/6/2012 6:27:01PM
Version 1.0

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Page 1 of 2

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2014/06/25

Improving service delivery

- Information Management
  - LIMS utilized
  - Web based reporting
- Client handbook
- Training on specimen collection
- Cold chain maintenance
- Customer contracts
- Trained users on standardized reporting form

Improving service delivery

- Documents and Records
  - Developed a document control policy, QA manual and policies
- Occurrence management
  - Occurrence documentation in place
- Assessment: External and Internal
  - Internal audits conducted twice a year

Infrastructure and commodity management

Environment and Facilities

- Access control
- Environmental control
- Improved infrastructure – renovation of cold room, store ,painting

Process control:

- IQC
- EQA

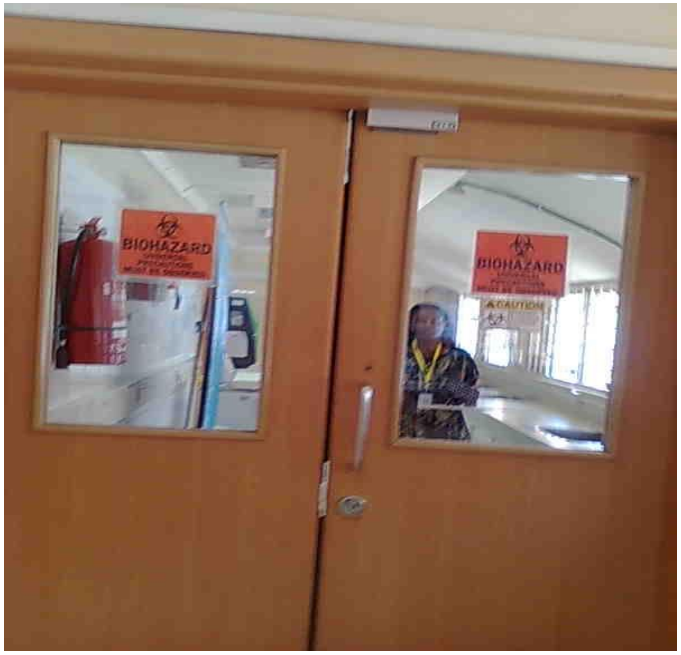
Inventory management

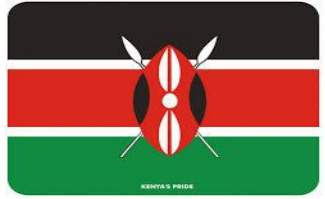
- Electronic Commodity management system
  - Forecasting, tracking , ordering and purchase

Equipment management:

- Verification
- Preventive maintenance
- Service contracts
- Capital Equipment procurement plan

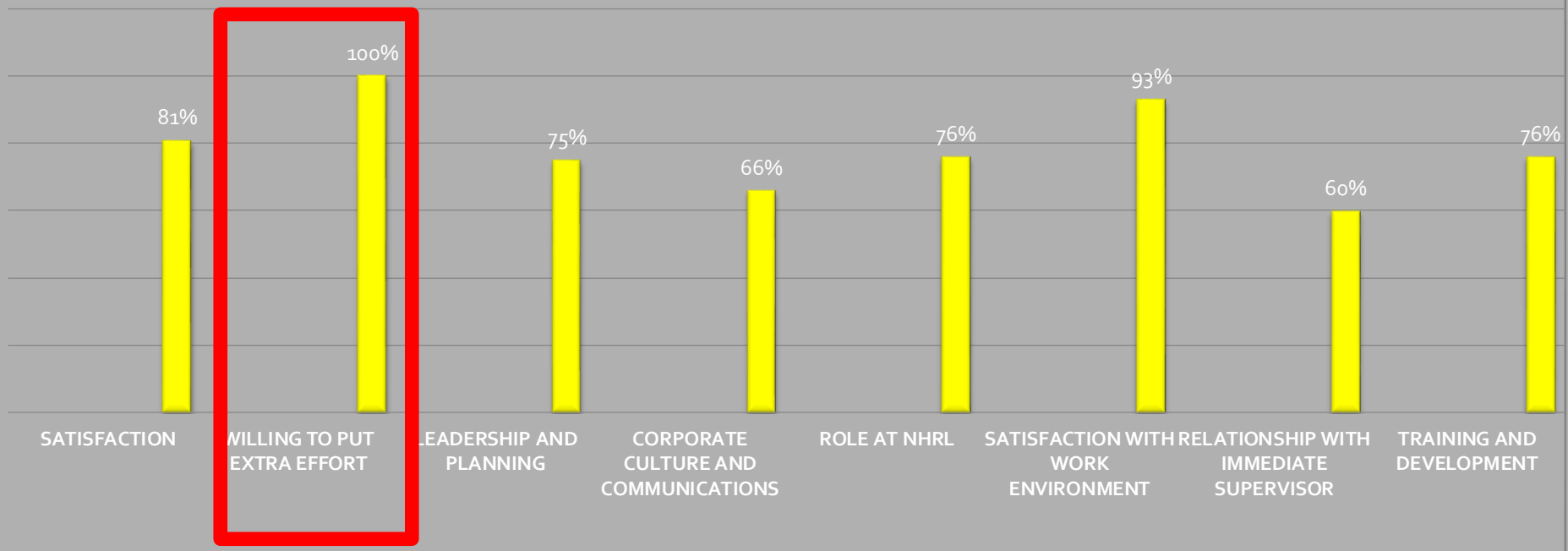
Improvement projects



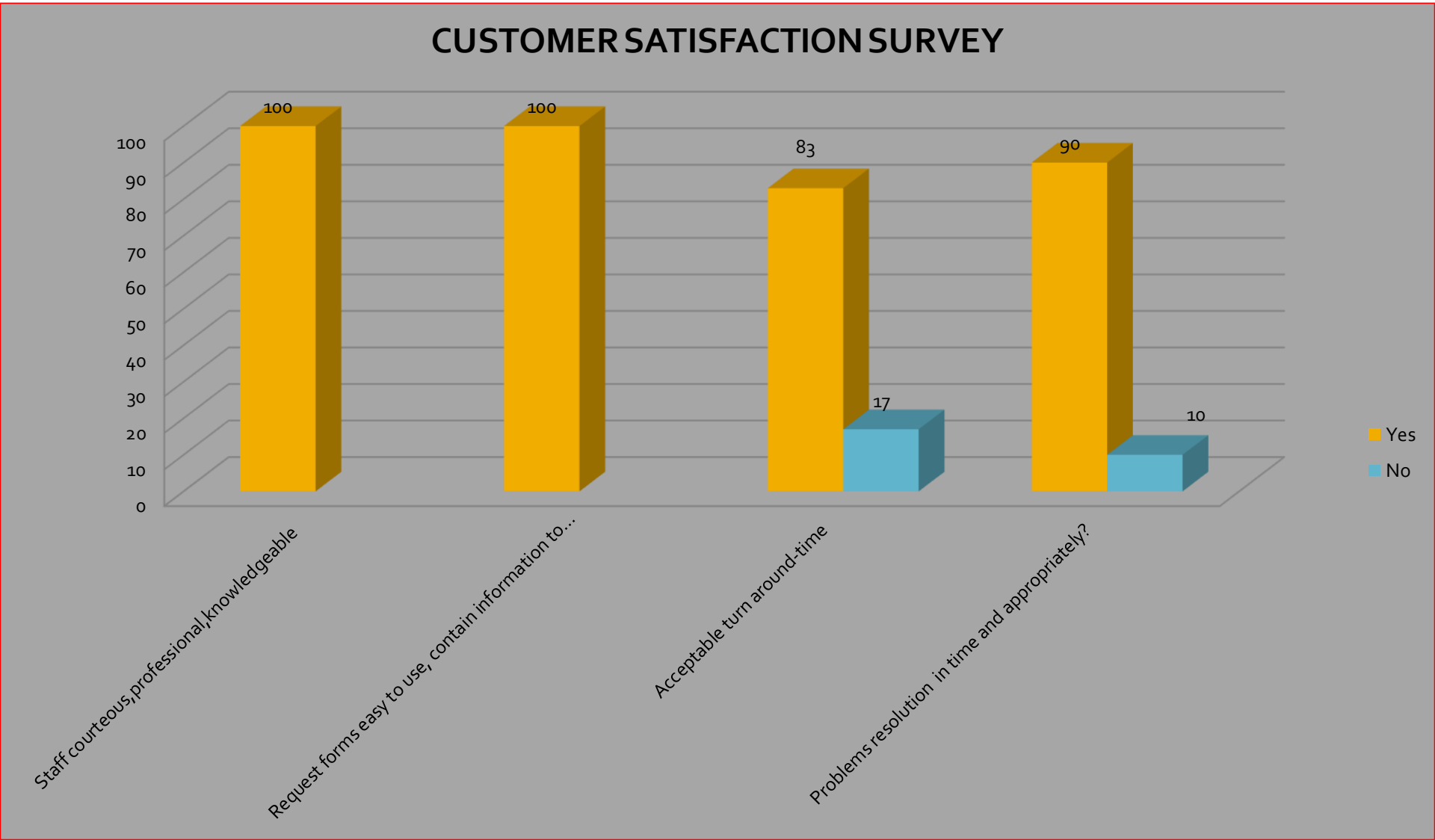


Outcomes

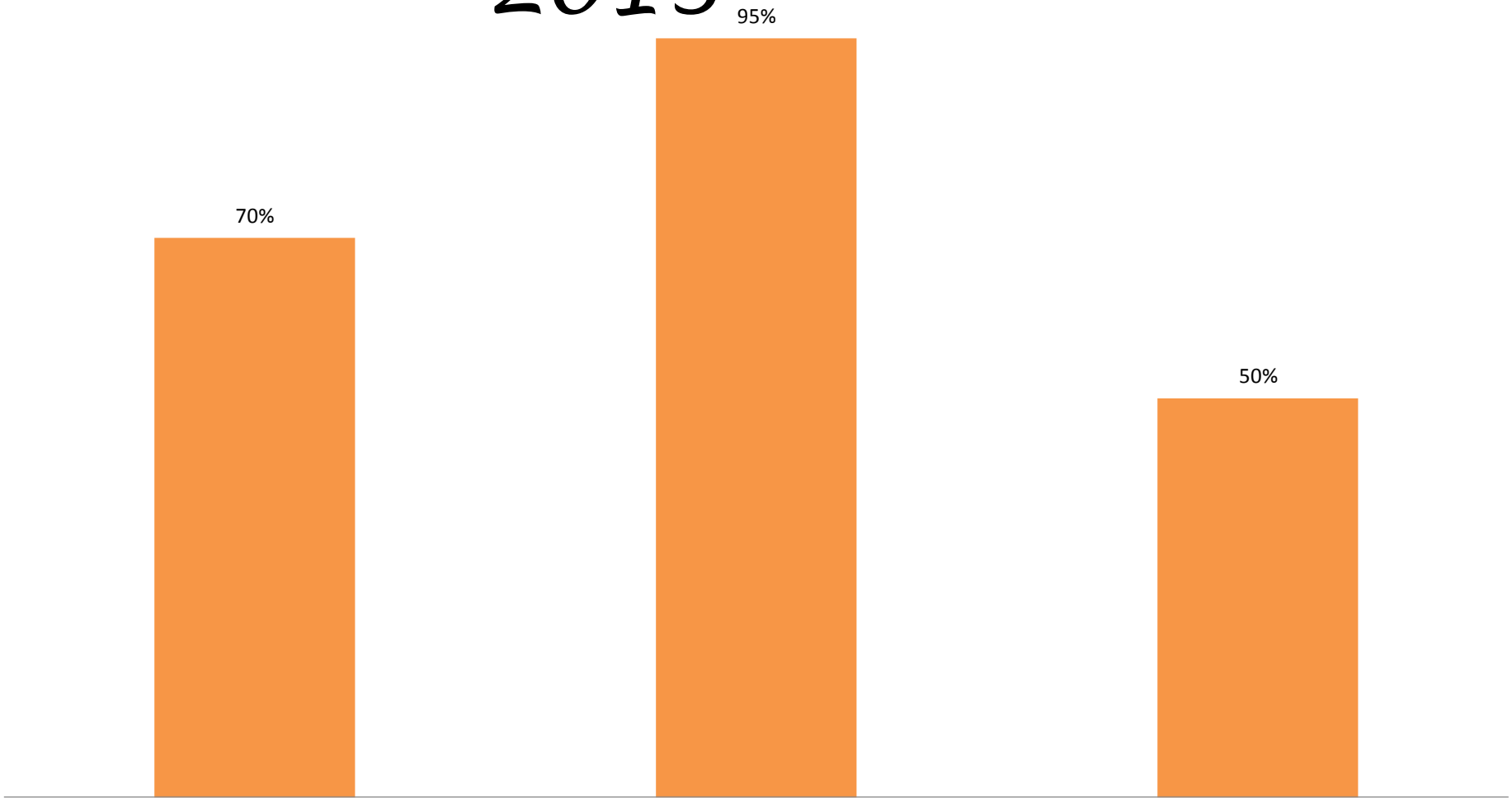
Personnel.. employee satisfaction



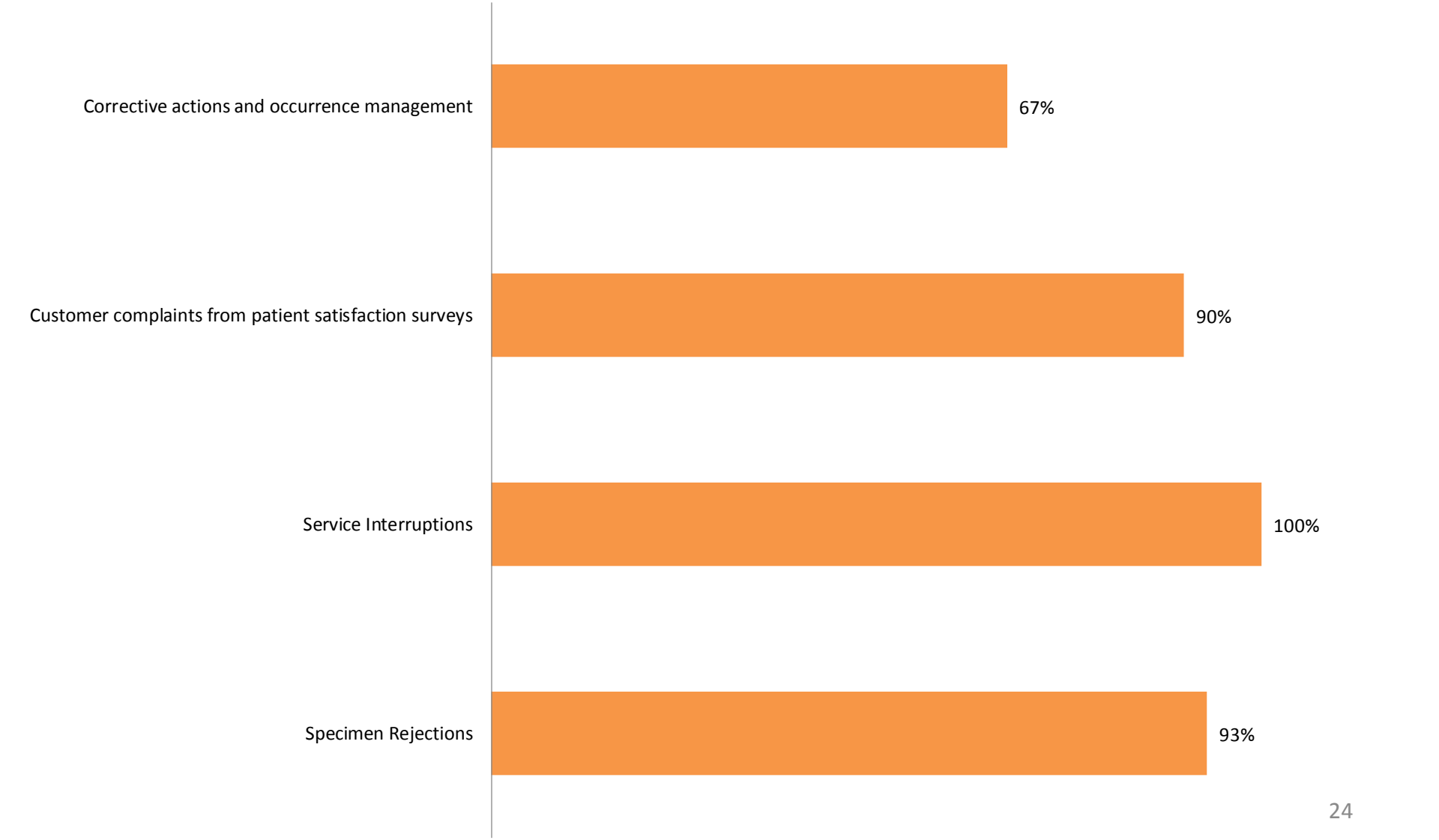
Improving service delivery



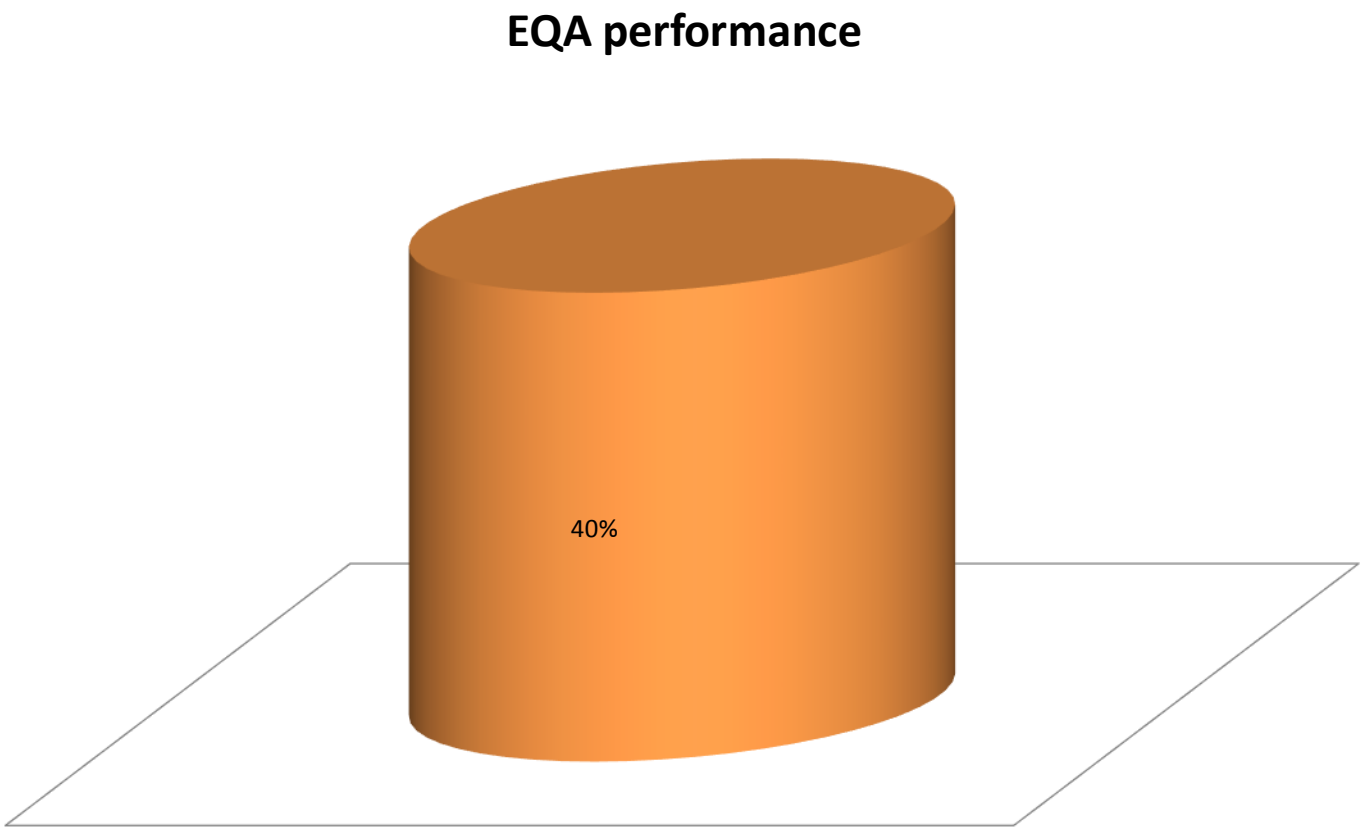
Average TAT % Reduction 2010 to 2013



Quality indicator % Reduction 2010 to 2013

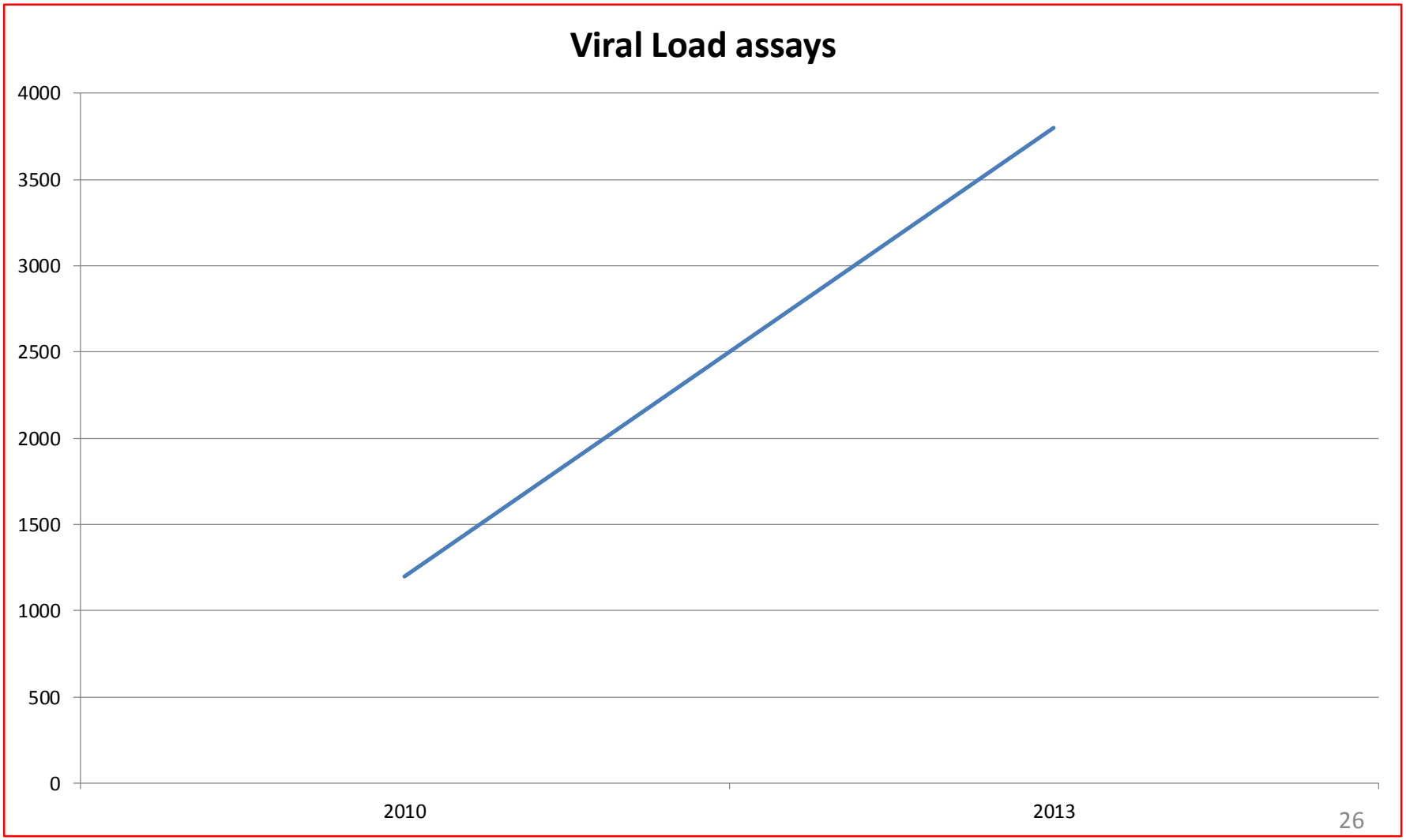


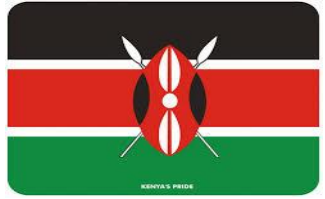
% Improvement in EQA performance



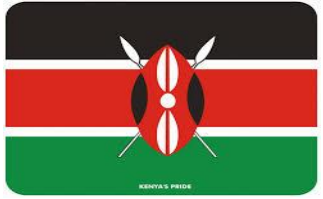
Impact

Increased uptake of services

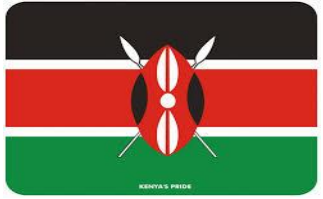




CHALLENGES & Solutions

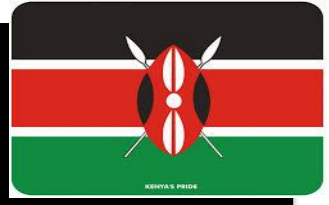


- Staff attitude and motivation – *involvement of all in IP, mentorship in accredited laboratories*
- Knowledge on ISO 15189 - *training ,all given a copy*
- Back up laboratories - *evaluation of nearby public laboratories*
- Method validation - *training*
- Numerous experts and mentors- *overcome by setting in place proper engagement structures*
- Facility had major safety deficiencies and space shortage - *overcome by acquiring space in nearby facilities*



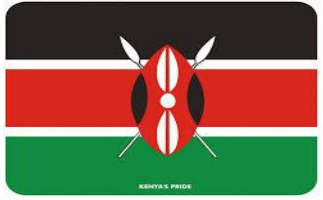
- *Cost - equipment placement , leveraging on support partners took up the various costs ,Staff immunization was done by the division of vaccination in the MOH , pooled resources with other laboratories undergoing the SLMTA process*

- Corrective forms and occurrence management -*ISO Training , involvement in revision of existing corrective action form*
- Procurement - *ensuring top management buy in, Management support and financial support*
- Internal audits- *training internal auditor and schedule*



Factors that led to success were leadership commitment, team formation ,structured mentorship , Training And Funding

Lessons learnt



- Substantial improvements to laboratory quality require focused mentorship and total commitment of government and laboratory staff
- Countries wishing to achieve accreditation must ensure adequate funding and support

Next steps

Outreach: Mentoring regional public labs

The prize....

Accreditation Certificate
National HIV Reference Laboratory

WORLD CLASS LABORATORY

AKNOWLEDGEMENT

- *NHRL Team*
- *MOH Kenya*
- *CDC (DGHA)*

Kenya and Atlanta

ASANTE SANA