CREATING A LEAN COST-EFFECTIVE QMS
Clerk to Lab assistant to Lab Technologist

Scientist MMed Science/ PhD -

Director of Lab – 11 sites

36 000 samples per year

Test profiles (all types, HPLC/MS; NGS) Clinical pathology etc etc

Trainer Registrars /Medical Technologists

Auditor Sanas and HPCSA
BACKGROUND

- NHLS/ State Labs – 25 years - Large personnel – 5000 samples a day – always short of money
- MRC / Clinical Research – FDA Drug studies - GREAT we get USA Funded - Dollars
- Private/ Academic Lab - 392 Staff complement – Madly competitive/ Hectic deliverables
  (Lowest cost/ Highest Quality) – You can get taken out of the market very quickly
WE ALL KNOW THIS
HOW DO WE IMPLEMENT, these are my own experiences

- **PERFECTION** (training, monitoring, evaluation, giving levels of responsibility based on Trust/Trust must be assessed – eg if You assigned a task to Person A and B who will you Trust and Why) Benchmark, Eventually with increasing Morale, people aim to become Trust worthy ………more and more quality is achieved

  (Training – No end to this process. Not even the highest level manager cannot learn from the most junior staff) – I interact with all levels – Because I really believe this is key

  **Please Expose Hands on persons**; Why do just Supervisors and Managers attend training, conference trips, workshops – THIS IS REALLY NOT PROGRESSIVE (eg Roche Diagnostics has an annual End of Year Scientific Gratitude event/ included is a prestigious speaker eg from Mayo Clinic USA, the rest is a gratitude event – really exclusive event- I SEND MY LAB SCIENTISTS who are users of the Roche system – am the only lab that does this)
PERFECTION AS A HIGHLY COST EFFECTIVE TOOL

- Planning comes before Perfection

(Every Protocol is Planned with the Entire Team) - it's not just presented; It’s a joint INPUT/EFFORT – gosh if anything works – JOINT TEAM EFFORT is the KEY

Eg if the Data capturer suggests a way to save time – which is money – Listen, assess, correct in a way using the 9 Pros and 1 cons approach; sometimes you want to reverse this but its very simple to change the cons to appear like it is Pros) – BELIEVE ME if the IDEA COMES FROM THE PERSON, they WILL MAKE IT WORK, this is boosting confidence

Again The Team tasks out the Protocol, You as the upper management/Director are here to ensure that the Key components are adhered to; give them the opportunity to tease out
PERFECTION is KEY TO COST SAVING

- Usually first time correct, occasionally concern noted
- Less and Less Repeat testing
- WASTE – due to Pre-analytical errors; Analytical errors and Post Analytical errors

Implement DISCREET QC checks to cover all 3 aspects AT ALL 3 PHASES
DEFINE A LABORATORY

- IS A COURIER ON WHEELS

  Hence Where DOES QUALITY START

  Don’t NOT TAKE RESPONSIBILITY OF THE PREANALYTICAL PROCESSES

  (You don’t have to be accountable BUT take responsibility)
RISK ASSESSMENT

PATIENT SAMPLES
- Sample Quality
  - Haemolysis
  - Lipaemia
  - Clotted samples
  - Interfering substances
  - Incorrect collection container
  - Insufficient sample

TESTING PERSONNEL
- Human Resources
  - Training & competency
  - Adequate staffing
  - Appropriate staffing

ENVIRONMENTAL CONDITIONS
- Environment & Utilities
  - Temperature control
  - Dust & Sterility
  - Humidity
  - Water pressure & quality
  - Electrical supply

POTENTIAL RISKS
- Quality of Reagents, Quality Control & Calibrators
  - Shipping and delivery
  - Storage
  - Expiry dates
  - Preparation

- Instrument Malfunction
  - Software failure
  - Power failure
  - Poor or insufficient maintenance procedures

INCORRECT RESULTS

REAGENTS

ANALYSERS
PREANALYTICAL PROBLEMS

- (incorrect sample; inaccurate sample labelling; poor sample collection, inadequate sample tracking; inappropriate sample transport)

- POOR CHAIN OF CUSTODY / INADEQUATE MONITORING PROCESSES

Answer: Use Technology to support eg Electronic Temp Monitoring; Electronic tracking etc

Initial cost – ultimate MASSIVE COST SAVING
ANALYTICAL PROBLEMS

- Simple not followed SOPS – catch it and sort it – weekly training in the lab on SOPs; hadoc Witnessing – the QA team will perform this – looking at whose on shift (Minimum of once in 6 months on all assays performed by the tech – We run 120 assays in the lab)

- Review of Raw data – ongoing adhoc –

- Review of IQC real time – Analyser trends on frequency of reruns and Who is the common Lab tech – who reruns – TRAIN AND RETRAIN - and Take action if you fail

  Take note IQC is the MOST EXPENSIVE Component of a lab (frequency of running IQCs cannot be compromised but you also have to contain costs – eg in a 24 hour lab All levels of IQCs must be run minimum 8 hourly – volume of patient sample dependent – DONOT COMPROMISE THIS – SAVES you ultimately
ANALYTICAL PROBLEMS- Our labs experiences

- How long does it take to solve /identify IQC failures / and how expensive is it – VERY EXPENSIVE – eg Biorad used in our Lab

(How often do we fail Westgaurd Rules )? – WESTGAURD IS OUR GURU

Please do not trouble shoot for ever ; and coincidently when you get it right after 5 times then you accept the Results – because you will FAIL THE NEXT RUN – if the problem is NOT LAB TECH incompetency related –

(Set very stringent Failure rules in YOUR LAB – this saves money/ time/ effort)

How often to we consult and talk to the Service providers or Reagent suppliers

(Eg after we wasted Folic acid calibrators/controls/ rerun rerun rerun rerun –weeks later to be told by the supplier – other users have complained , we have a Batch No ... is problematic) – too late to reverse wastage -, LAB TECHS MUST BE smartly taught.
ANALYTICAL COST SAVING

- Stringent IQC process
- Real time action

- OWN INTERNAL / ADDITIONAL / INCREASE YOUR CONFIDENCE IQC

(Do we realise VIRAL LOAD testing Analytical QC is based Only on the Reagents and Apparatus) –

What about Sample (pre-analytical IQCs – create your own processes – Please – Run at least 2 levels of Your own validated IQC samples with every batch - This reduces query repeats/ increases your confidence/improves quality at all levels – LONG TERM saves
ANALYTICAL COSTS

- Other **Major cost** in a lab – MANPOWER

(Please teach people to be Multi skilled – Not beyond their scope though)

Eg In the Viral load lab – THEY must KNOW how to spot DBS cards, Extract / Test etc etc

(I worked at facilities where one will fold their arms whilst the other is preparing the samples ) – WHY – I encourage end to end processing – 2 FACTORS – cost saving PLUS full accountability

(I employ staff and I take full accountability for the training – making me accountable for what I produce- all aspects)
AUDITS – a tool to save Costs

- Internal audits – (staff with technical knowledge from a completely unrelated department to cross audit) PLEASE do-not schedule because ISO requires proof of twice a year – USE THIS AUDIT to identify Problems/ failures/ etc – AND WORK ON IT REAL TIME, it will ultimately save you money, time, IMPROVES QUALITY

(Highlight problems /resolve – Monitor/ recurrence will be less and Less)

PLEASE do-not put things under the carpet – MY STAFF are taught ‘Get it out, and FIX it)

(Frequently Please – Decide on your staff no and sample no)
AUDITS to Save Costs

- External Audits/ External Eyes - Eg Our Lab – Audits by
  1. Every Research org that works with us – If we have 5 Orgs – all 5 will audit / by our request
  2. Frequency – monthly plus quarterly – minimum

Our Lab has the ffl audits
  1. Monthly – Caprisa
  2. Quarterly HSRC
  3. Twice a Year HPP
  4. Twice a year HPP
  5. Annual Sanas
  6. Annual PPD (You would hate working in my Lab)- But after a while it becomes a lifestyle because audits can be done today for today – ??? Extreme cases – But at least announced a week in advance
INTERNAL AUDITS

- 27 were scheduled and were completed, 2 scheduled for December
WE ALL KNOW THIS

5 Leadership Principles for Lean

1. Challenge the status quo
2. Continuous improvement
3. Go and see
4. Teamwork
5. Respect the front line
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PLEASE FOLLOW THIS PRINCIPLE
TEAM WORK

- BE - FIRST
- DO - BE A DOER, get the knowledge, run the tests yourself, calculate the results
- SEE –
- THEN ONLY TELL – ie give out your Expectations

- HOW CAN A SUPERVISOR/MANAGER DICTATE BUT NOT LEAD BY EXAMPLE
CASE SCENARIO

- FIRST VIRAL LOAD OF 26 COPIES /ML

- (SADGURU – DR WESTGAURD)

- (IMPORTANT, MOST IMPORTANT GURU – A MISTAKE – LEARN NEVER TO MAKE IT AGAIN) -how, Empower, BY TRUST
WORKING TOGETHER IMPROVES QUALITY AND SAVES MONEY
THE ONLY WAY

Power of working in Team, Team Work!
The power of teamwork, make the impossible possible!