

Lab Accreditation for Clinicians

TMH Experience



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Accreditation- Journey at TMH

Disclosures...

Process started 12 years back...

TMH was 63 year old (75)...

Who wanted and started it all?

MDs or the Management

Process started 12 years back..

- Dr KA Dinshaw



Offer / Threat was for both

- Hospital
- Labs

Labs were smarter (*easy targets*)...

Process started 12 years back..

- Dr KA Dinshaw (NABL, JCI)
- Appointed QM

So, what we did...

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- QM
- Internal Audit Course for all technical staff (at TMH)

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- ***Learning and Teaching ISO***

Documentation & Implementation (clerical and labor staff)

Manuals, staff read/understand - tough

Understanding and signing the documents

So, what we did...

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- CVH – Our QM
- Internal Audit course for all technical staff (at TMH)
- Deputy QMs
- *Learning and Teaching ISO*
 - Documentation & Implementation (clerical and labor staff)*
 - Manuals, staff read/understand - tough*
 - Understanding and signing the documents*
- Internal Audit followed by MRM (Second Party Audit)
- Applied for NABL ISO15189...

Got it - 2006

Biochemistry

Got it all - 2007

Biochemistry

Histopathology

Cytopathology

Hematopathology

Microbiology

Transfusion Medicine

Cytogenetics

Molecular Pathology

Molecular Hematology

TMH experience - Labs

learnt during the process....

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We did not have....

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Much more...

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- Referrals / Second opinion
- Waste disposal, lab safety, sample storage, expired samples
- Computerization – No security, No validation

Define a Good Lab?

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- *Good doctors*

Define a Good Lab?

- *Good doctors*
- *Accreditation*

Define a Good Lab?

- *Good staff*
- *Accreditation*
- *TAT*

Happy Environment



TMH experience

learnt during the process....

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 - No certifying agency for in-vitro diagnostic tests
 - Reliance in manufacturer's validation

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TMH experience

No control...

- No control on Pre analytical phase: You versus Me. Phlebotomists under nurses, hence no QMS
- No control on Quality of Referral Samples: Though information on website. Still, no much rejection of samples
- Smart management wish to control replicating the work: ... Multiple labs within hospital using similar specialized tests....thus common facility...?advantage
- No control over “Routine tests”...

Replicating the work

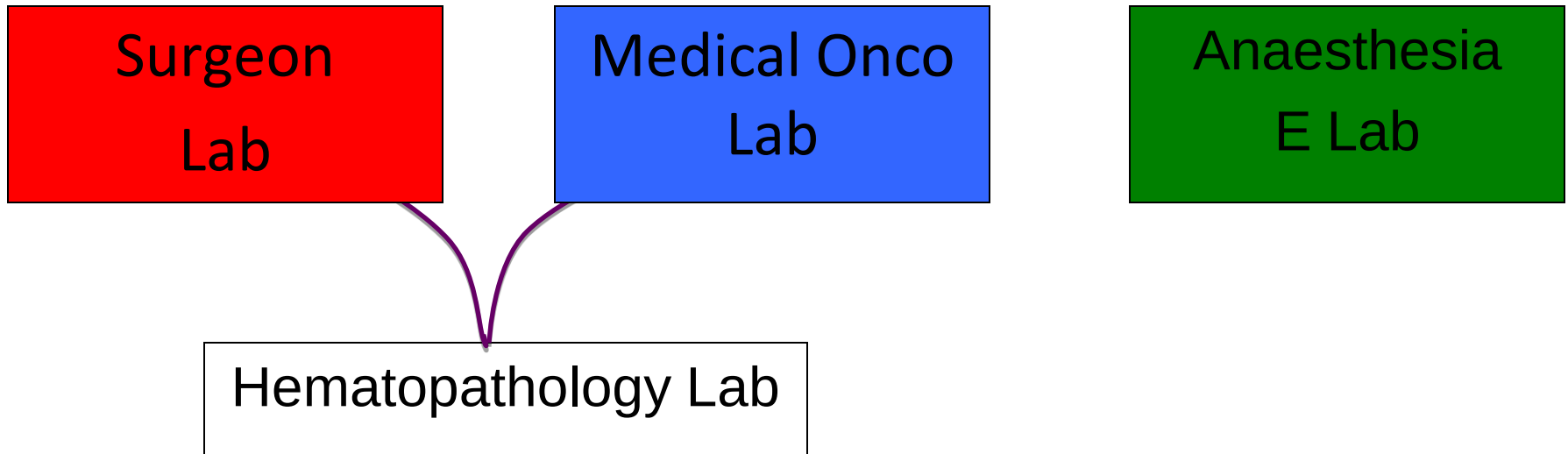
CBC in so many labs...

Surgeon
Lab

Medical Onco
Lab

Anaesthesia
E Lab

Labs Merger



Labs Merger

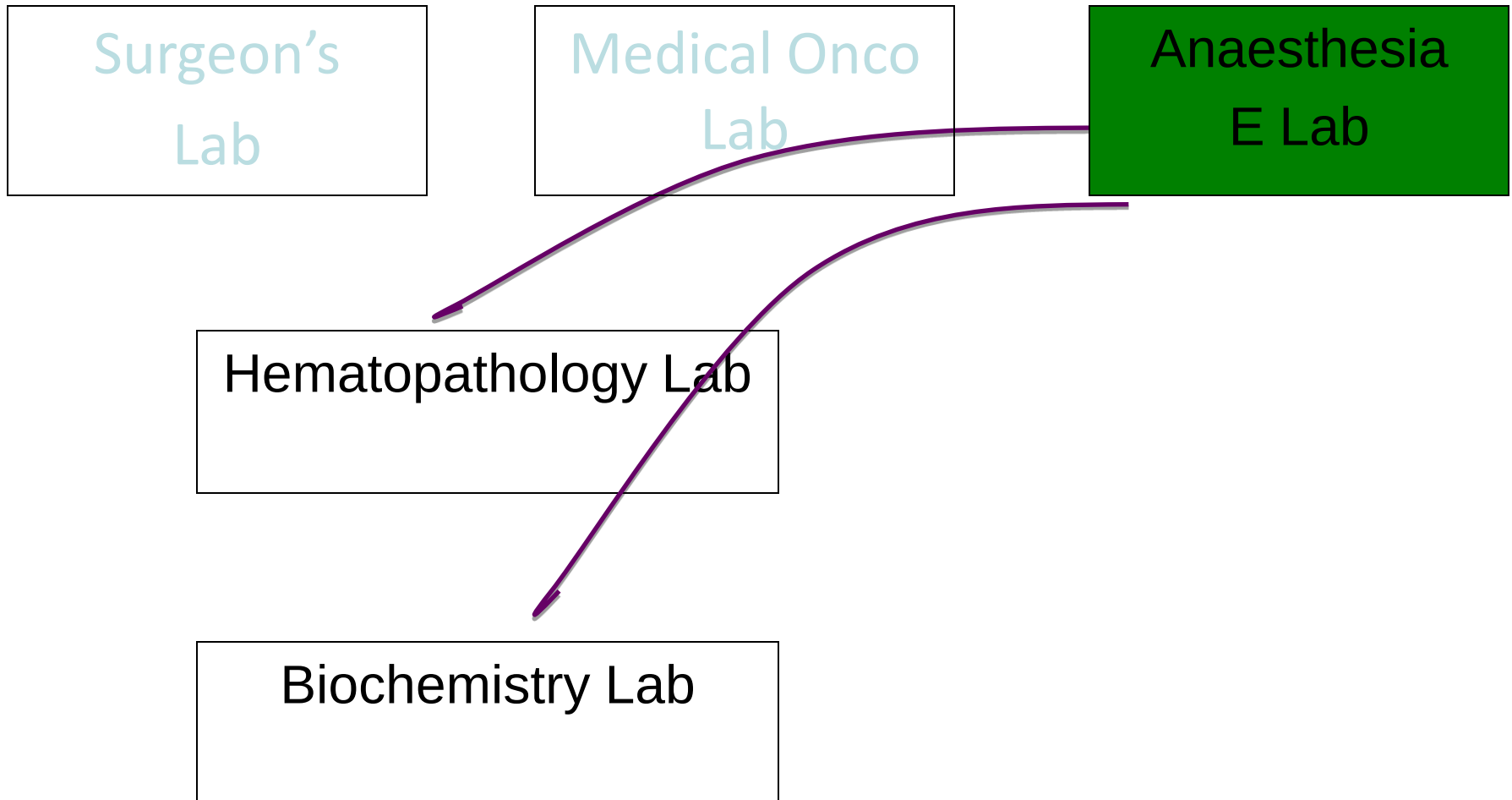
Surgeon
X
Lab

Medical Onco
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Lab

Anaesthesia
E Lab

Hematopathology Lab

Labs Merger



So now we have.....

Surgeon's
Lab



Medical Onco
Lab



Anaesthesia
Lab



Hematopathology Lab
24x7

Biochemistry Lab
24x7

Outsiders help...

PT Programs

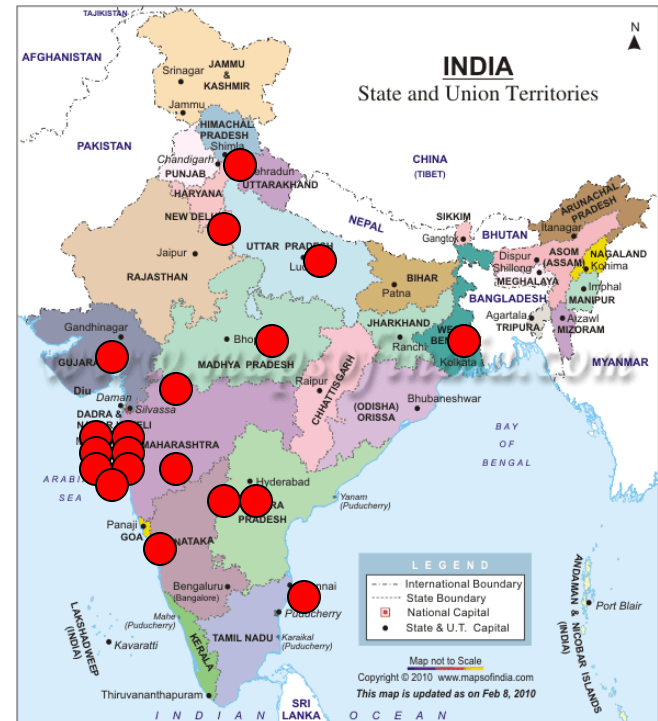
- *Non existent Indian PT/EQA programs.*
- *Expensive CAP/RCPA/UKAS*
- *Last decade: many PT centers started in India*
- *TMH: Cytopathology, Histopathology, Flow cytometry*

FCI – PT program

5 city labs in 2005

16 national labs in 2012

32 national labs in 2017



But NABL...

No clear cut criteria for

- Adequacy of space, staff and training
- Working hours not defined
- Signatory authority
- Incomplete scope inclusion
- PT/EQA participation...CAPA
- Star rating
- Similar NCs recur after a gap....
- Sample collection centers

We are 75 year old...

Hospital Accreditation...

- Hospital is state of art but still procedural delays (?babudom)
- Training of labor staff – non existent
- Big challenge is “Contract Staff” (leave substitutes). No onco trained nurses, hence no consistency in care. Tough May/June
- Transfer of staff to another department, specialty and city, hence no consistency in care

- Staff and space (not the budget). Bhool bulaiya, no directions...
- Hygiene, Few toilets
- Poor control of number of visitors. Attendants collect reports (pneumatic chute and DIS)
- Poor control on hand/take over of duties (nurses, techs etc)
- Stand alone Cancer Hospital. No MOU with any of the hospitals

Main complaints:

- Rude behavior – Labor & Clerical staff
- Delay in starting treatment

Accreditation – Lab and Hospital

Journey at TMH

At TMH...

NABL followed by Association of the Accreditation of Human Research Protection Program (AAHRPP)

Started with JCI.....Moved to NABH...

Many of TMH staff are NABL and NABH Assessors

Most Technical staff are Trained Auditors

Positives...

- Lots as mentioned before...
- Everyone accountable, Dedicated QM
- Smart card with photo ID, Unique ID Number
- HIS
- Staff Grievance Cell

Positives...

Major learning exercise to all staff

MBBS / MD / DMLT training: Technical and Medical staff learnt practical work related to QMS - Job of Medical College training

Obsolete medicines/tests/methodologies are stopped - Job of MCI

Tough...

Started with a bang

Maintenance has been tough

Few Non Conformances recur: RCA, CAPA

Different issues....Medical College, Govt Hospital, Large to small sized lab...

Hospital Accreditation is next goal...

- Staff at different levels – Involve all
- Happy atmosphere, inter personal relations
- Administrators (Heads) to be motivating, good mentors

It's a beginning, we are still not there...

Defining quality





Mostly

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Thanks