

Importance of Quality Management Systems to Laboratory Reliability

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Reflection!

- The issue of quality – Everyday we demand that others deliver continuous quality services – water, lights, food, clothes, appliances, transport etc. Why should others expect less of a service that is so important it can mean the difference between *life* and *death*.
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Objective

- ❑ To share some thoughts on the importance of **quality** to laboratory reliability
 - ❑ To identify current opportunities for and barriers to quality management systems **implementation** and **sustainability** in our Caribbean laboratories
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Examples of the global burden of disease

- **HIV/AIDS** - > 40 million infections: a major development crisis – world bank 2000
 - **Tuberculosis** – 1.6 million deaths in 2005 - estimated economic cost in India \$US 3 billion
 - **Diabetes** – 171 million morbidity in 2000 and estimated 366 million in 2030
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Did you know that

- Patients and physicians routinely rely upon the results labs generate for decisions on diagnosis and management. These test results are estimated to trigger up to **75%** of all medical decisions.
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An Astonishing Statistic!

“ Experts estimate that as many as **98,000 people** die in any given year from medical errors that occur in hospitals. That’s more than die from motor vehicle accidents, breast cancer or AIDS.....problems extend to every healthcare setting. Add the financial cost to the human tragedy and medical error easily rises to the top ranks of urgent, widespread health problems”

To Err is Human – Building a safer Health System, Institute of Medicine (IOM), The National Academies, USA

IOM Conclusion

- Medical errors occur in ALL settings and are due most often not to 'Someone' but to multiple contributing factors. Preventing errors requires a **SYSTEMS** approach addressing the conditions that result in error. The problem is NOT bad people but **POOR SYSTEMS**

***NB:** Estimated Cost for preventable error in the US - \$US 17-29 billion*

Remember that

- ❑ “The absence of evidence is not the same as evidence of absence”
 - ❑ What we uncover is what we look for
 - ❑ Should we be concerned about the lack of laboratory systems?
 - ❑ What are the possible outcomes?
 - ❑ What does the evidence say?
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Is the occurrence of lab error common?

– *some global evidence*

- “From lab tragedy to industry reaffirmation: a perilous journey” – Congressional hearings, U.S. House of Representatives investigate cause of invalid HIV, HCV – Maryland (MGH) 2004
 - *“Does the experience of MGH expose cracks in the system” – Chairman, Congressional Subcommittee on criminal justice ...*
 - “Did lab error result in insulin error” – Case against hospital remanded for trial– Louisiana 2006 (incorrect glucose test result) – law suit pending
 - “Laboratory results that should be ignored” – 2006
 - *A study of 6370 specimens tested with a common latex agglutination test - 13 false -ve & 59 false +ve led to unnecessary treatment*
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Is the occurrence of lab error common?

– *some global evidence*

- “Medical Laboratory Faces Charges in Cancer Deaths” – [Wisconsin 1995](#) (misread pap smears) – doctors, lab, lab director and lab pathologists settled for \$US 9.8 million
 - “Lab error cost patient his stomach” – [Tampa, FLA 2006](#) (incorrect cancer result led to removal)
 - “Blowing the whistle on the tip of the iceberg” – message from [Dr Westgard 2005](#)
 - *Off the record – Gov’t agencies, accreditation organisations & professional associations are very concerned*
 - *Investigations following MGH identified serious problems in other hospitals in Maryland and Baltimore*
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Is the occurrence of lab error common in the Caribbean?

- ❑ 6/14 labs scored <50% in bacti EQAS
 - ❑ 7% major cytology errors with 84% having implications for clinical management in cytology EQAS
 - ❑ 25% - 257% variation in testing in a small reproducibility study
 - ❑ 30% rate of 'sero-reversion' in routine HIV testing
 - ❑ >50 % discordance in repeated HIV ELISA tests
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Facing reality

- Dr James O. Westgard 2005 commenting on the MGH debacle):
 - The proposed remedies for fixing labs must focus on improved production processes as well as improved inspection processes
 - NB: Fear does NOT work to improve quality it only leads to cover-ups
 - Improved communication between state and private agencies *will* help
 - The time for labs to speak out for QUALITY is NOW
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Why are wrong lab results provided?

- ❑ Lab error occurs because lab testing is a complex operation BUT is perceived by many (including lab staff) to be a simple operation and thus we fail to observe the normal rules that govern production in any other industry i.e attention to **systems, policies, processes, procedures** and **checks** (the PDCA cycle).
 - ❑ For example....
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Implementing a new test without evaluating: A major source of error

HIV Algorithm – Data Dec 2001 to June 2002:

Total # discordant rapid tests:	58/100 (58%)
HIV Spot +ve/Abbott Determine -ve:	3
HIV Spot -ve/Abbott Determine +ve:	55

The Laboratory is unable to judge kit performance in the absence of knowing the true sample result. Not sure which Rapid test was correct. Repeat testing. Waste of resources. Delayed patient management. Lost clients.

Implementing a new test without evaluating: A major source of error

Two-ELISA HIV Algorithm – Data February to May 2002

screens that were First ELISA +ve;
Repeat negative on second ELISA and
reported as negative: **254**

The Laboratory is not sure about the performance characteristics of either the first or second ELISA. Quite possible that false negative results have been released.

Example: MTCT programme CMC site testing results

Total # Confirmed: **190** (137+ve/53-ve)

Abbott Determine

Total # False +: **20** (37.7% of negatives
incorrectly diag)

HIVSpot

Total # False +: **33** (62.2% of negatives
incorrectly diag)

Determine + HIVSpot

Total # False +: **2** (3.8% of negatives)

Danger: treating truly uninfected women

Survey outcomes: 6 Caribbean countries

Clinicians said (142 respondents):

- Use of lab results to initiate patient care
 - Often (45%)
 - Occasionally (32%)
 - Always (9%)
 - Never (3%)
 - Top 4 reasons for not using lab results for patient care
 - Results received too late (59%)
 - Results do not match clinical picture (33%)
 - Results not received at all (13%)
 - Errors in the report (12%)
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Survey outcomes: 6 Caribbean countries

Technologists said (165):

- Most frequently occurring impactors in the pre-analytical phase
 - Poor completion of forms by clinicians (59%)
 - Illegible handwriting (56%)
 - Inadequate staff (44%)
 - Insufficient sample volume (24%)
 - Incorrect sample labelling (18%)
 - Inappropriate sample containers (12%)
 - Poor sample collection technique (12%)
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So!
Let's talk about Laboratory Quality

Choices

Reliance on Personal Skills

Or

Reliance on Systems

To do the right thing right every time

Quality Control

- ❑ A process of ensuring that the TESTING performed by the lab is performed correctly
 - ❑ Ensures that all instruments, kits and reagents are working to operational specifications
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Quality Assurance (QA)

- A process of:
 - Establishing performance expectations (PE) for pre-analytical, analytical and post-analytical phases
 - Establishing PE in consultation with user-physicians
 - Conducting periodic audits against the PE
 - Participating in PT/EQAS or inter-lab comparison programmes
 - Periodically reviewing lab operations against validated benchmarks or best practices
 - Reviewing QA findings by mgt. team
 - A philosophy that assigns blame to people as a first step in trouble shooting
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Quality Management (QM)

A process of:

- Looking at what is done in the lab
 - Looking at how it is done
 - Identifying opportunities for improvement
 - Making the appropriate changes
 - Assessing the impact
 - Can be applied to everything we do
 - A management philosophy that assigns blame to **systems or processes** as a first step in trouble shooting
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Quality Improvement

- ❑ A process of continually reviewing operations, looking for the opportunity to improve operations, implementing change, assessing the impact and seeking feedback from staff and clients
 - ❑ Includes use of quality indicators
 - ❑ Emphasis is on improving performance
 - ❑ Focus is on process and procedures rather than people
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Elements of a Quality Management System

- ❑ Quality Policy (Quality Philosophy)
 - ❑ Quality Manual (Total Overview of lab operations)
 - ❑ Policies (governing all aspects of lab operations)
 - ❑ SOPs (principles & strategies)
 - ❑ Test methods (instructions)
 - ❑ Records (evidence or proof of compliance)
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CAREC/HEU (UWI) QMS Study

- ❑ Belize HIV Testing process
 - ❑ Direct and Indirect Costs examined
 - ❑ Economic cost of error estimated
 - ❑ Possible that > 7 million US spent annually in the absence of an effective QMS system
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The ISO 15189:2003 Standard:

- ❑ Defines essential elements of the QMS
 - ❑ Contains all the requirements labs have to meet to demonstrate that they operate a quality system & are able to generate consistently **technically valid** and **competent** results.
 - ❑ Is the international lab standard against which accreditation will be carried out for medical labs.
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Purpose of the Standard

- ❑ For use by laboratories (as a guide) in developing their quality, administrative and technical systems to a competent level
 - ❑ For use by accreditation bodies involved in evaluating and recognising the competence of laboratories
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Requirements of the ISO

Management Requirements

- 4.1: Organisation & Management**
 - 4.2: Quality Management System**
 - 4.3: Document Control**
 - 4.4: Review of Contracts**
 - 4.5: Examination by referral laboratories**
 - 4.6: External services and supplies**
 - 4.7: Advisory services**
 - 4.8: Resolution of complaints**
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Requirements of the ISO

Management Requirements

- ❑ **4.9: Identification and Control of non-conformities**
 - ❑ **4.10: Corrective action**
 - ❑ **4.11: Preventive action**
 - ❑ **4.12: Continual improvement**
 - ❑ **4.13: Quality and technical records**
 - ❑ **4.14: Internal audits**
 - ❑ **4.15: Management review**
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Requirements of the ISO

Technical Requirements

5.1: Personnel

5.2: Accommodation and environmental conditions

5.3: Laboratory equipment

5.4: Pre-examination procedures

5.5: Examination procedures

5.6: Assuring quality of examination procedures

5.7: Post-examination procedures

5.8: Reporting of results

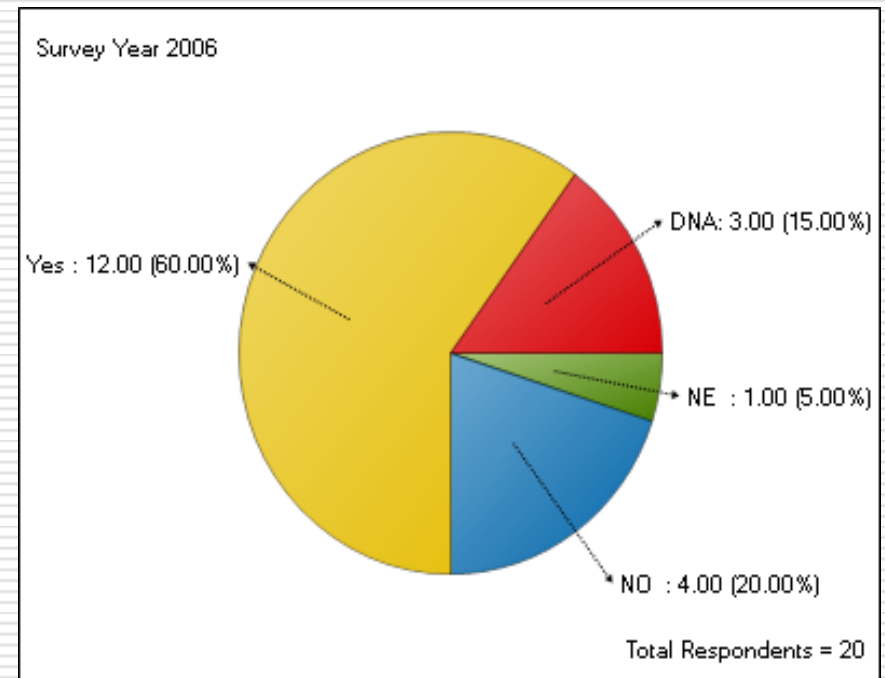
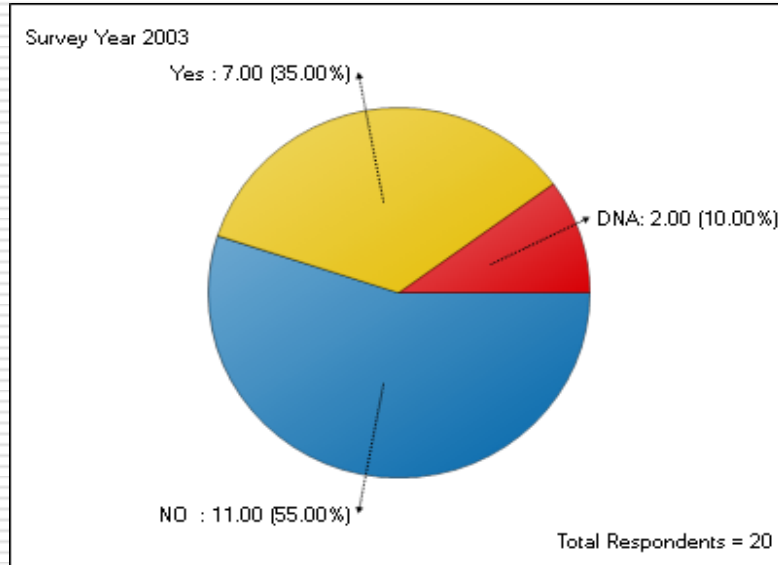
QMS Umbrella

- ❑ Everything - from time a client accesses the health care system to the time a client receives treatment based on a lab result - is captured under the QMS umbrella
 - ❑ This applies to ALL aspects of lab operations and for ALL diseases whether e.g HIV/AIDS related, Tb or diabetes and whether within traditional labs or at POCT sites
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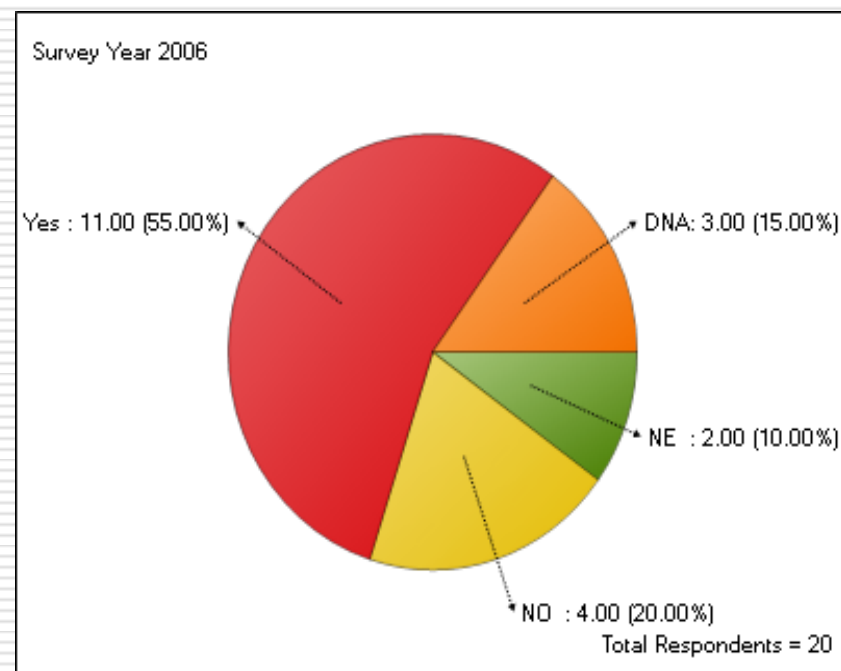
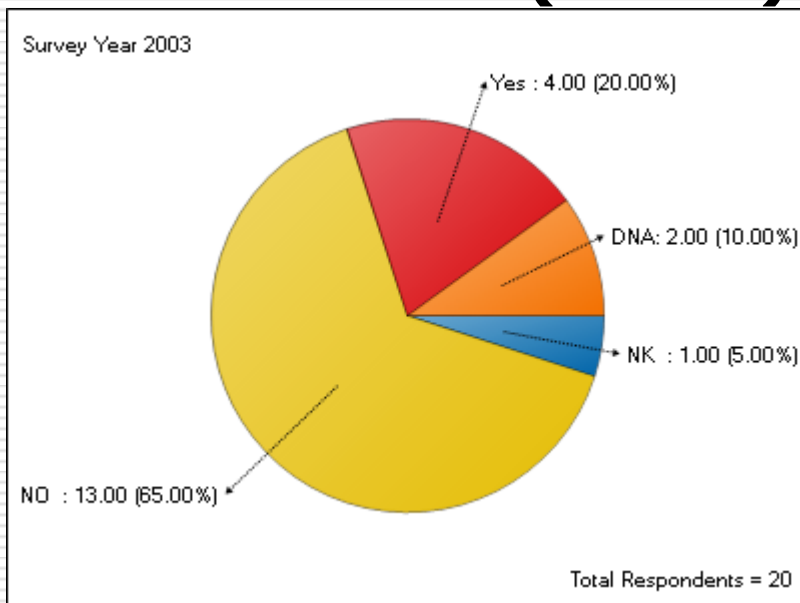
Regional Response to QMS

- EU Med Labs Project (2002-2007)
 - Greater focus at national level on QMS implementation
 - Greater awareness of Lab Quality needs
 - www.c-medlabs.carec.org
 - Establishment of 2 Accreditation Bodies – TTLABS & JANAAC
 - Establishment of CLAS
 - Limited implementation of legislation and/or licensing
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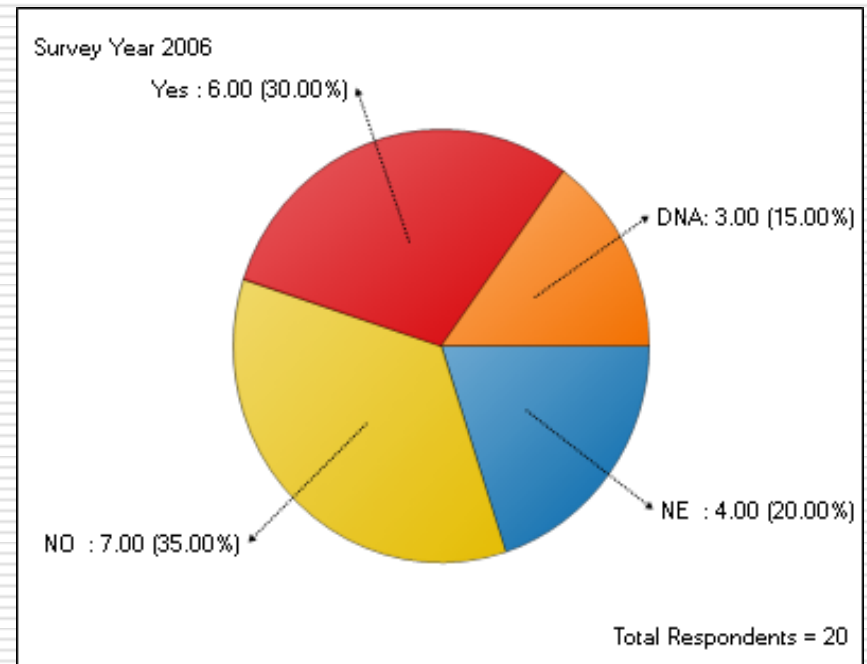
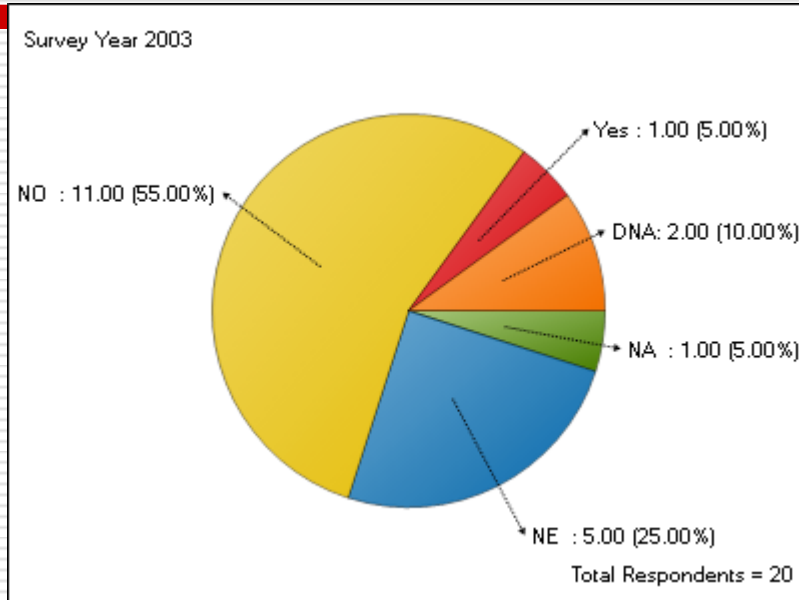
Staff with specific responsibility for quality oversight? 2003 & 2006 (n=20)



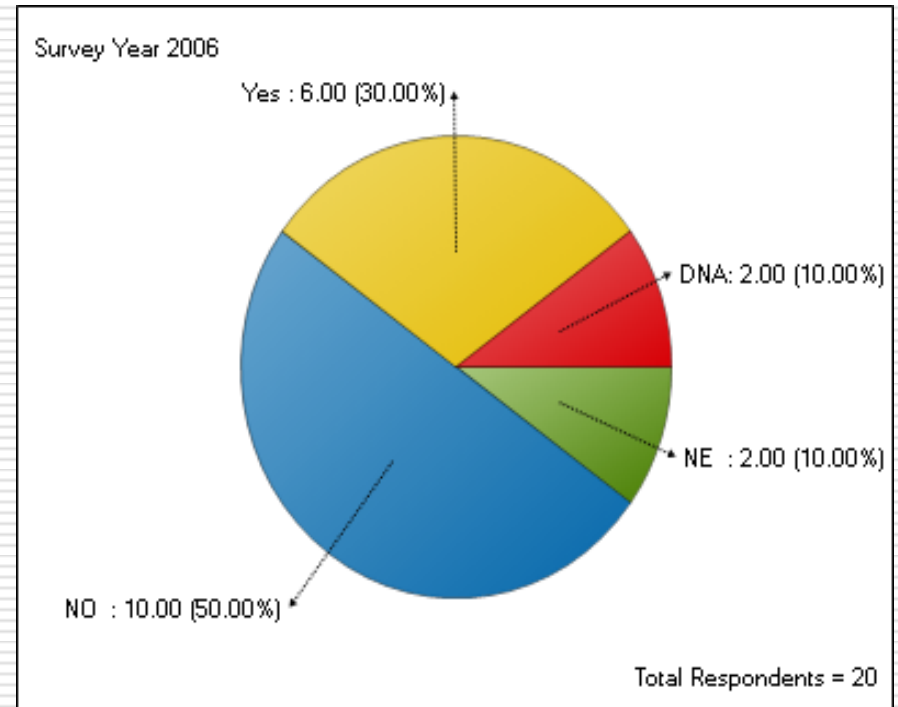
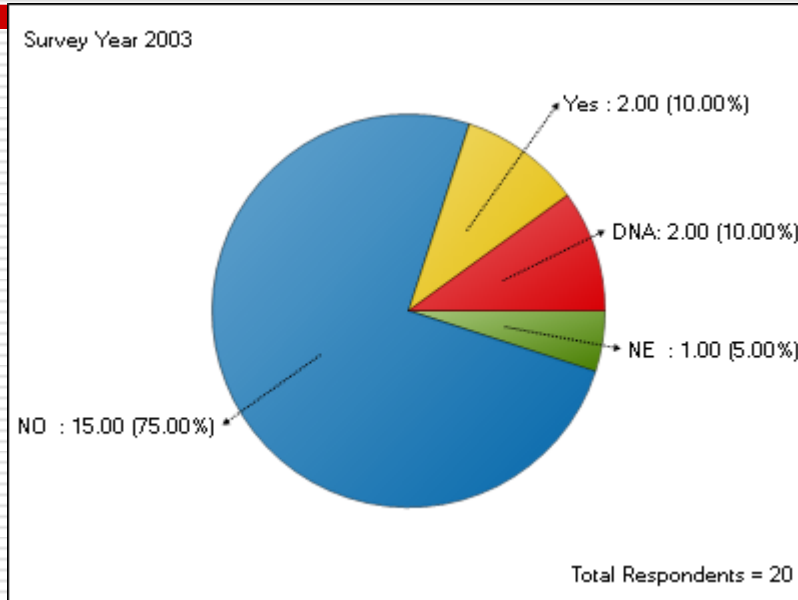
Laboratory Quality Manual? 2003 & 2006 (n=20)



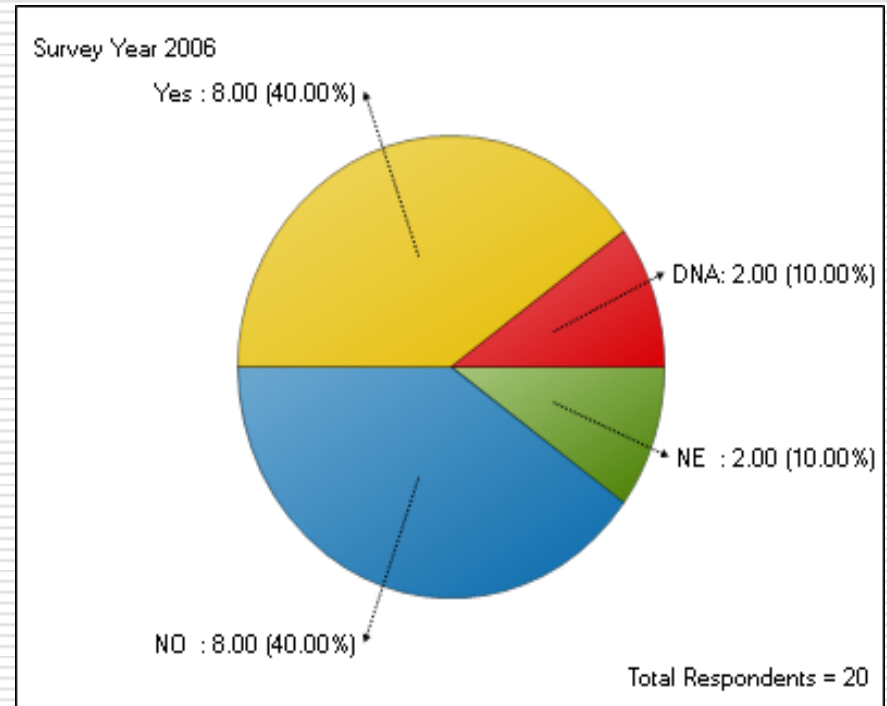
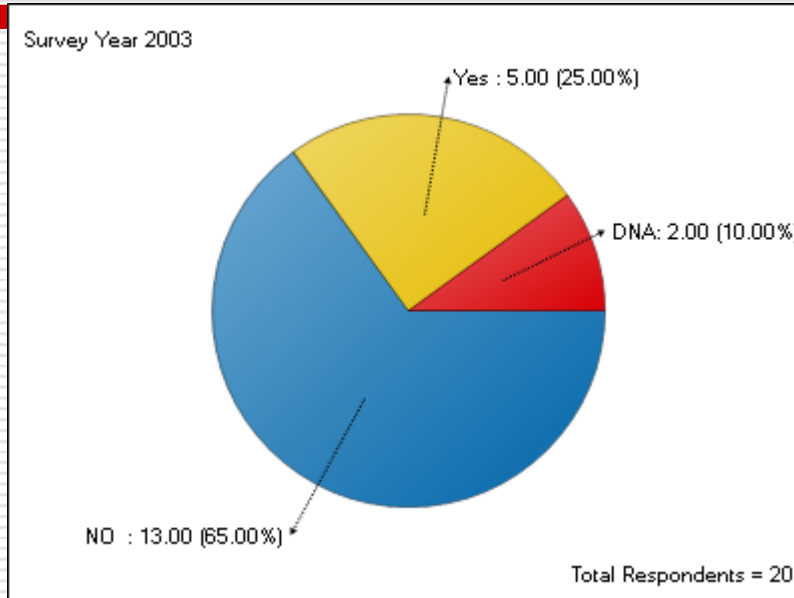
Laboratory Quality Plan that defines how standards will be met? 2003 & 2006 (n=20)



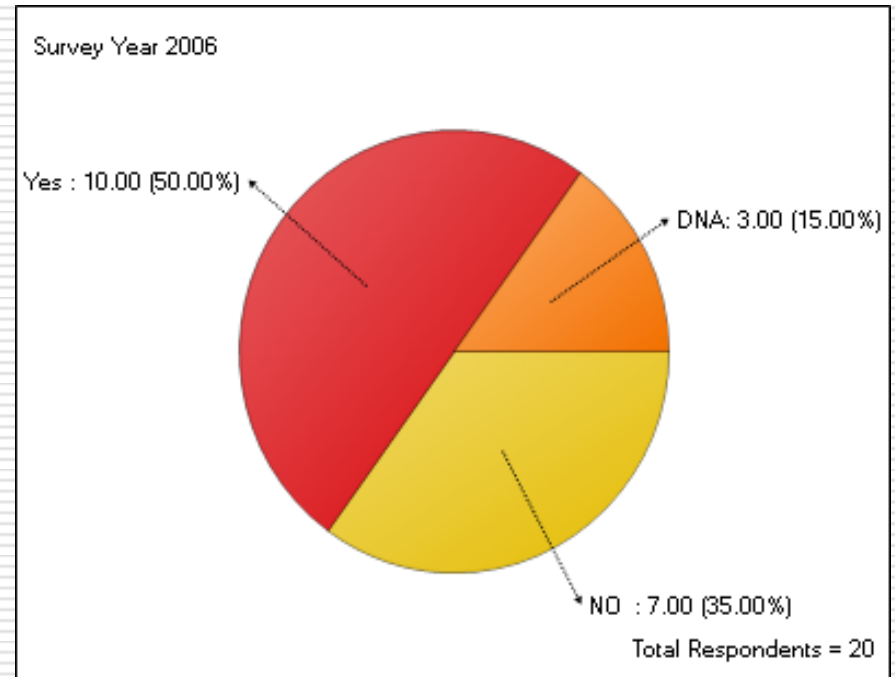
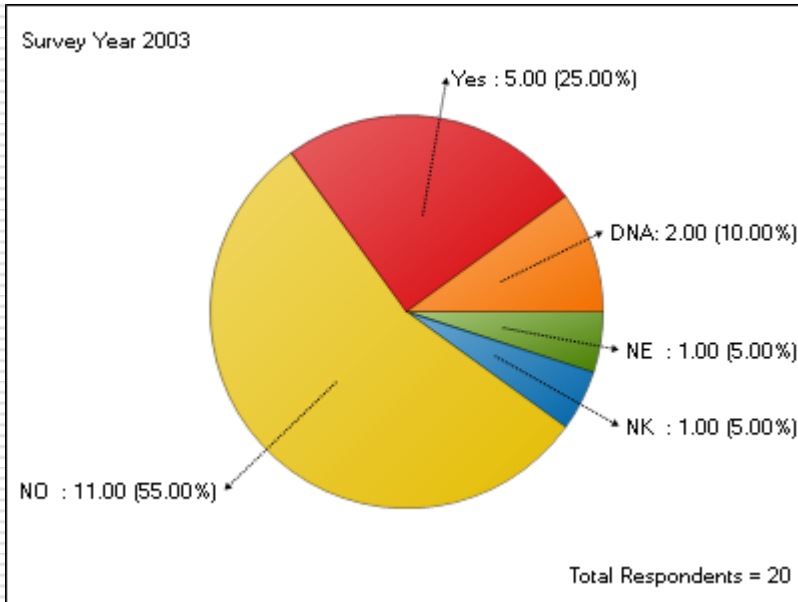
Policy for HR/ staff Development? 2003 & 2006 (n=20)



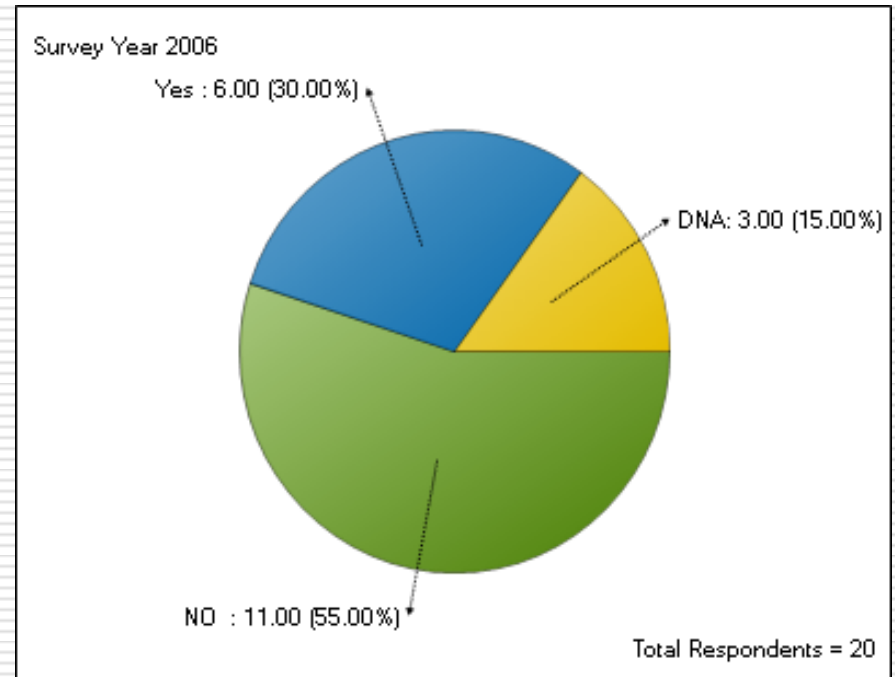
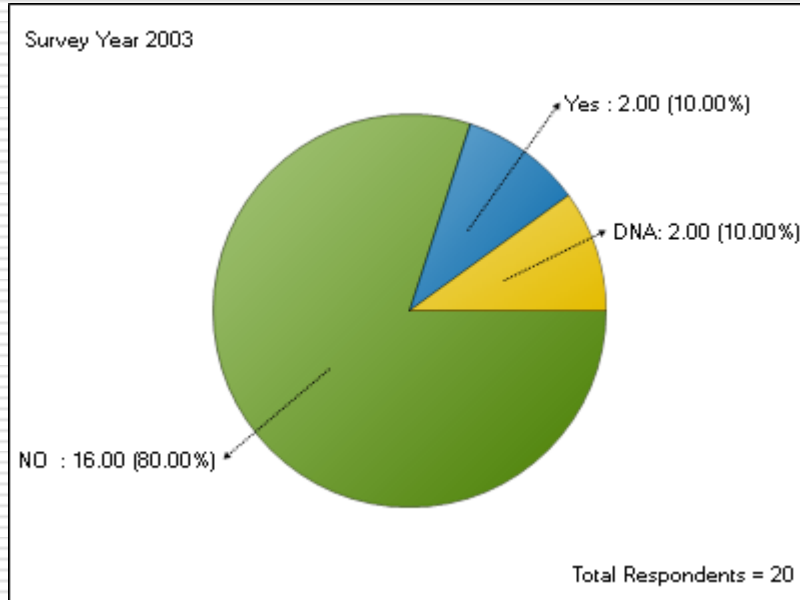
Policy for Quality Assessments? 2003 & 2006 (n=20)



Specific allocation/ budget for procurement of lab supplies? 2003 & 2006 (n=20)



Procedure for the control or management of documentation? 2003 & 2006 (n=20)



Challenges to QMS Implementation

- ❑ Defining roles & responsibilities
 - ❑ Uncertainty about starting point
 - ❑ Cost & mobilisation of resources
 - ❑ Perception of lack of time
 - ❑ Lack of management commitment & political support
 - ❑ Resistance to change & managing change in an evidence-based system
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Key Recommendations

- WHO/CDC 8/8/2008
 - Organise national structures to support lab quality system
 - Establish national lab quality standards
 - Implement lab quality system programmes
 - PAHO Guideline for HIV Testing 2008
 - Commitment & leadership from the top
 - National QM office & Quality Manager
 - Multisectoral team to address QMS holistically
 - QMS must engage all levels in lab network & all service providers
 - National policies & strategic plan for HIV testing
 - Systems monitoring & corrective action
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What's next - way forward

- ❑ Labs commit to the accreditation goal
 - ❑ Labs initiate gap analyses & QMS implementation – lots of reference material available
 - ❑ Strategic plans are a must
 - ❑ Advocacy for legislation is critical
 - ❑ National focal point for Quality essential
 - ❑ Focus on ensuring staff competency is essential
 - ❑ Structured staff training is key
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What's next - way forward

- ❑ Clinicians become VERY versed in the requirements of the ISO 15189 standard for medical laboratories
 - ❑ Clinicians be updated on the elements of a laboratory quality management system & their role in assisting with the establishment and maintenance of the QMS
 - ❑ Mechanisms for ongoing joint decision-making among clinicians and lab staff be established with urgency
 - ❑ Medical labs and clinicians be cross-represented on their respective key decision-making bodies (e.g CASMET, Medical Associations)
 - ❑ Clinicians partner with laboratories and training institutions to forge strategic alliances with business partners e.g insurance companies, suppliers etc. and to ensure that they advocate for strong high quality lab services with one voice
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References - Publications

- ❑ Preparing for Accreditation: A simple Guide for the Implementation of QMS in medical labs – CAREC/Med Labs
 - ❑ WHO - CDC: Weekly epidemiological record No. 32/2008 (www.who.int/wer) Joint WHO-CDC conference on lab quality systems ` April 2008
 - ❑ PAHO – Guidelines for the implementation of reliable and efficient diagnostic HIV Testing – 2008
 - ❑ Caribbean Regional Competency profile for MLTs – CAREC/Med Labs
 - ❑ Managing Laboratories to Assure Quality – A “How-To” Guide: Modules 1-8: 2002 reprinted 2007
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Managing Laboratories

“How to Guide”

1. An overview of the Laboratory in Modern Health care
 2. Laboratory Management
 3. People Management
 4. Operational Systems
 5. Laboratory Design & Layout
 6. Workplace Health & Safety
 7. Tips for Decision-makers
 8. Self-assessment Exercises
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Thank you for your patience
