A QUALITY VIEW OF VIROLOGY

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THE MANY FACES OF VIROLOGY

- Fundamental research
- Research and Development – vaccines, drugs
- Clinical research
- Epidemiological research
- Diagnostic virology
- Biosecurity

WHAT DO WE MEAN BY 'QUALITY'

- First principles – the best quality
- Good laboratory practice - GLP
- Organisational perspective – quality system
- Process perspective – quality assurance (QA)
- Daily tasking – quality control of instruments or assays (QC)
- Benchmarking – external quality assessment (EQA or PT)

RESEARCH vs DIAGNOSTICS

What do we look for in research?

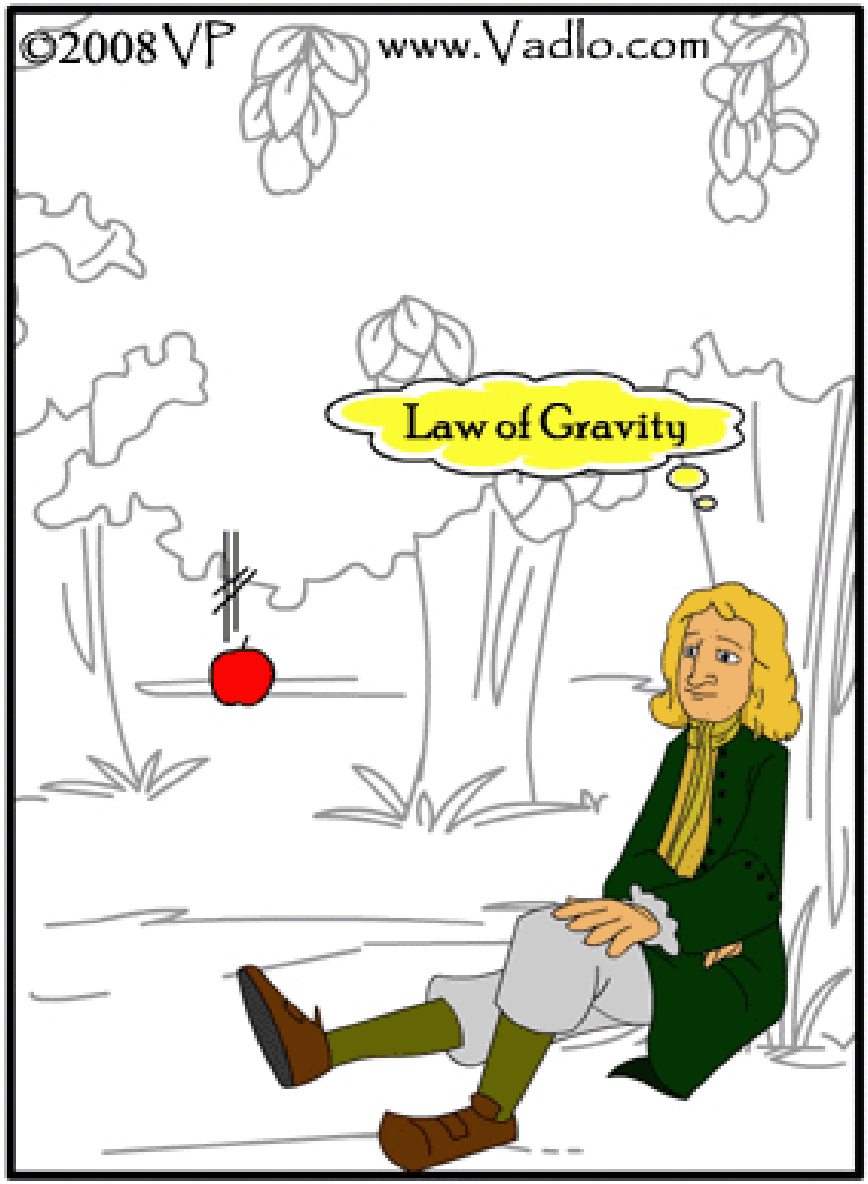
- Innovation
- Variation
- Exploration

What do we want in diagnostics?

- Controlled methods and processes
- Quality systems - documentation
- Quality assurance – QC and EQA

ASSESSING QUALITY IN RESEARCH

- Novelty and innovation
- Addressing areas of fundamental importance – e.g. clinical relevance in medical research
- Obtaining peer-assessed research funding (and possibly salary support)
- Patent or publication?
- Patents leading to commercialisation and royalty streams
- Publication in high-impact journals



High Impact Paper

Low Impact Paper

ASSESSING QUALITY IN DIAGNOSTICS

- There is a requirement for medical diagnostic laboratories to be accredited to receive Medicare funding
- ISO 15189 is the current laboratory standard
- Laboratories must operate under an ISO quality system
- Participation in External Quality Assessment is mandatory for all tests reported, and satisfactory performance is required

WHAT EQA DO WE OFFER FOR DIAGNOSTIC LABORATORIES?

- Proficiency testing programs in all disciplines of pathology, including serology/virology, microbiology and biosecurity
- These are sent to participants on a regular basis, results returned and performance benchmarked against peer groups
- The programs may include diagnostic, educational and technical components

IS THERE A PLACE FOR EQA IN A RESEARCH LABORATORY?

- Pure proficiency testing is unlikely to be relevant as there is often no ‘right’ answer
- There may be a role for technical assessments as part of a training regimen
- Dedicated educational and training programs may be useful in assessing the acquisition of technical competency
- Formal assessment of competency may substantiate participation in clinical trials

The honest package you will never see!

IN CONCLUSION

- We should all strive for quality in what we do
- Diagnostic laboratories have developed a ‘culture of quality’ – they have to!
- Research laboratories require a similar striving for the highest quality in their results
- There are no real structures for assessment and benchmarking of quality in research
- Perhaps some of the mechanisms of diagnostic EQA could be used

Thank you