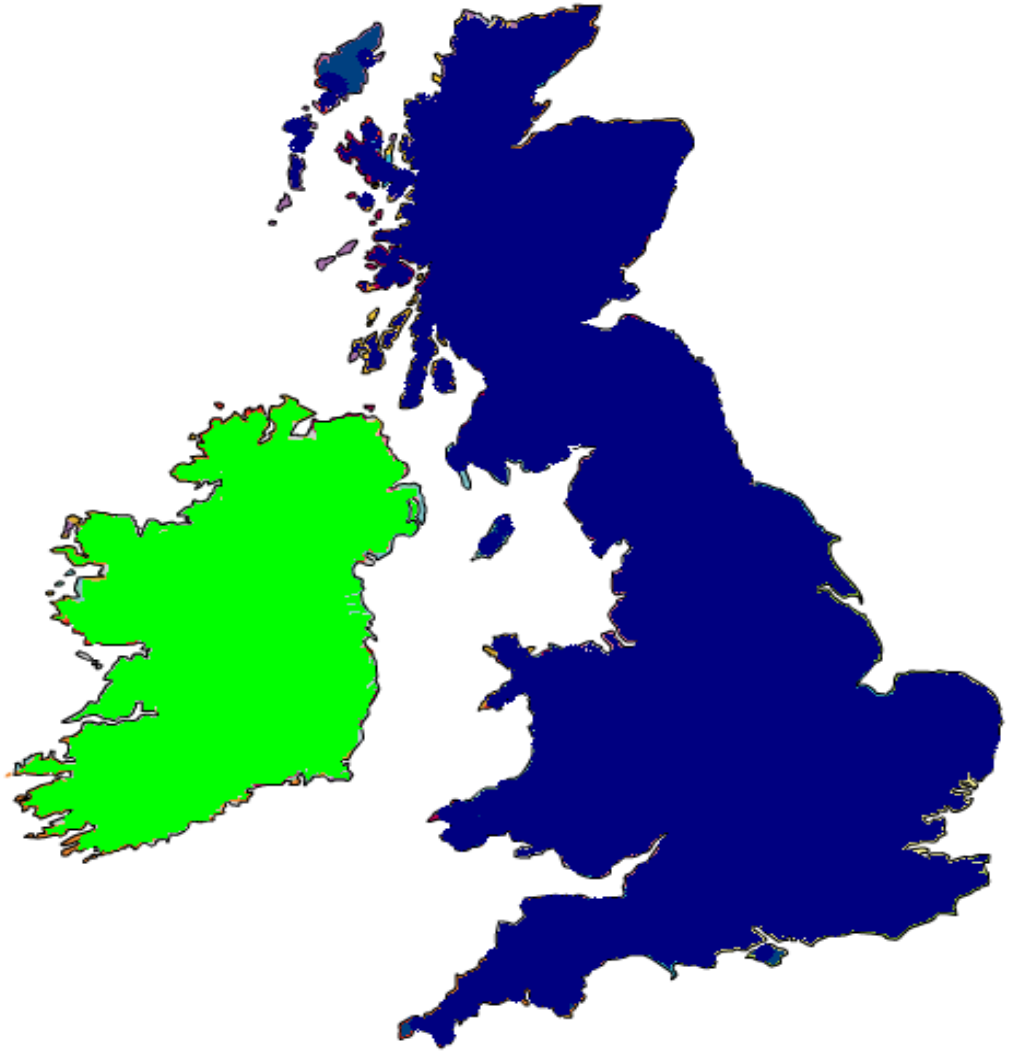
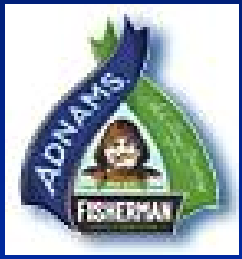
Laboratory Medicine EQA and Standardisation

Dr Pat Twomey
St Vincentâs Hospital Dublin
West Suffolk Hospital UK

THE BRITISH ISLES



SUFFOLK BEER

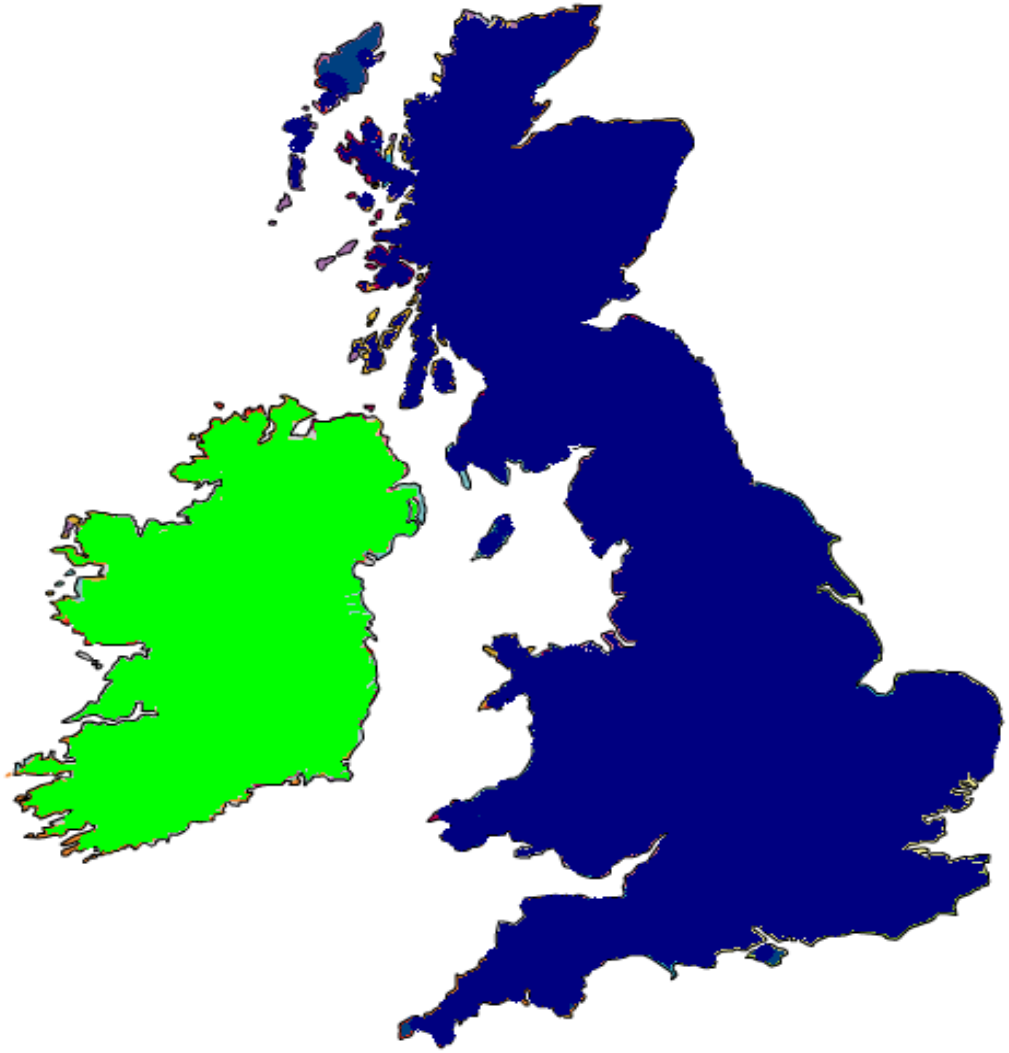


IRISH STOUT

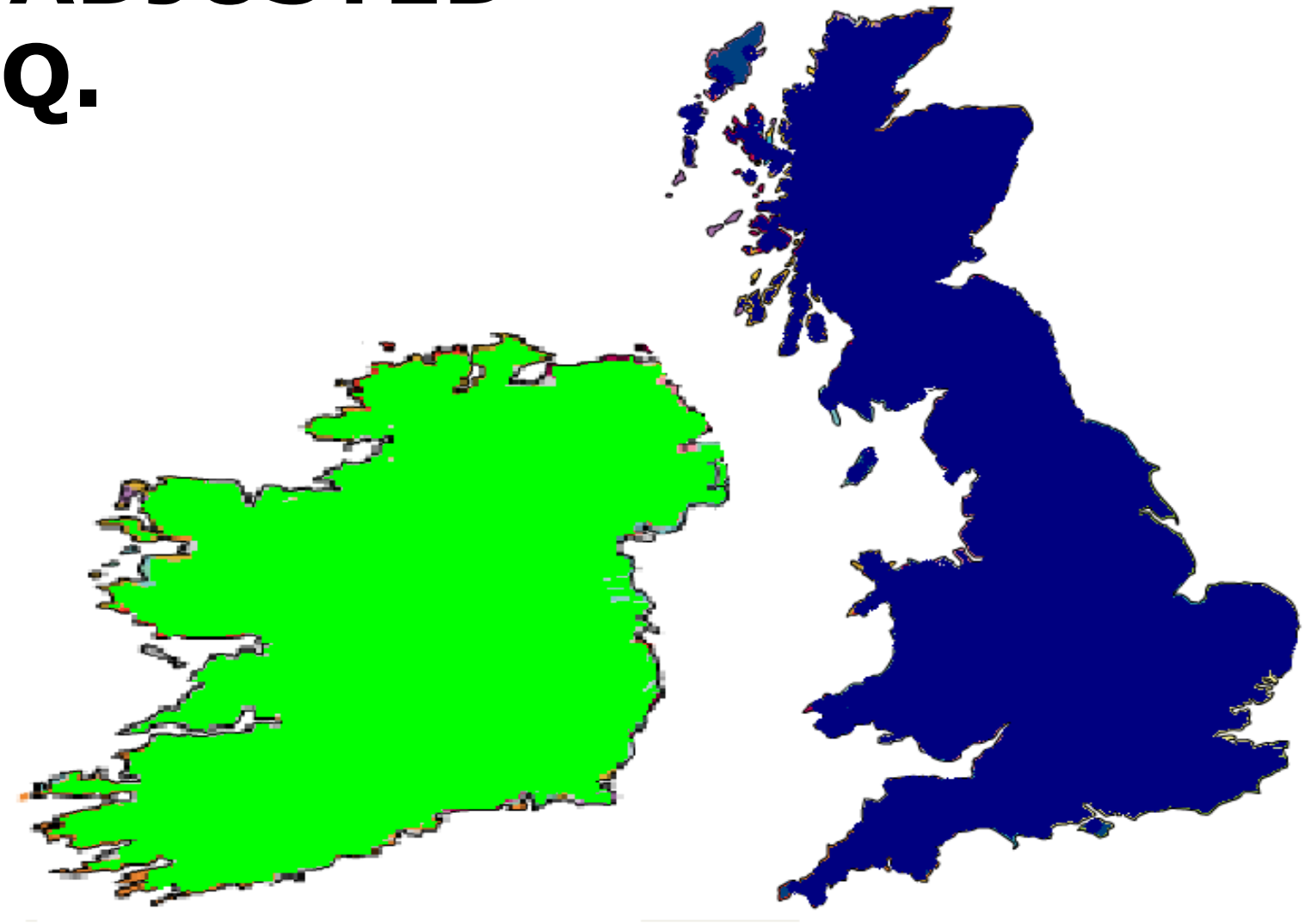

17
59
GUINNESS
DRAUGHT
NNESS
RAUGHT


Cork's finest stouts proud
to be working together.
MURPHY'S
BEAMISH
IRISH STOUT

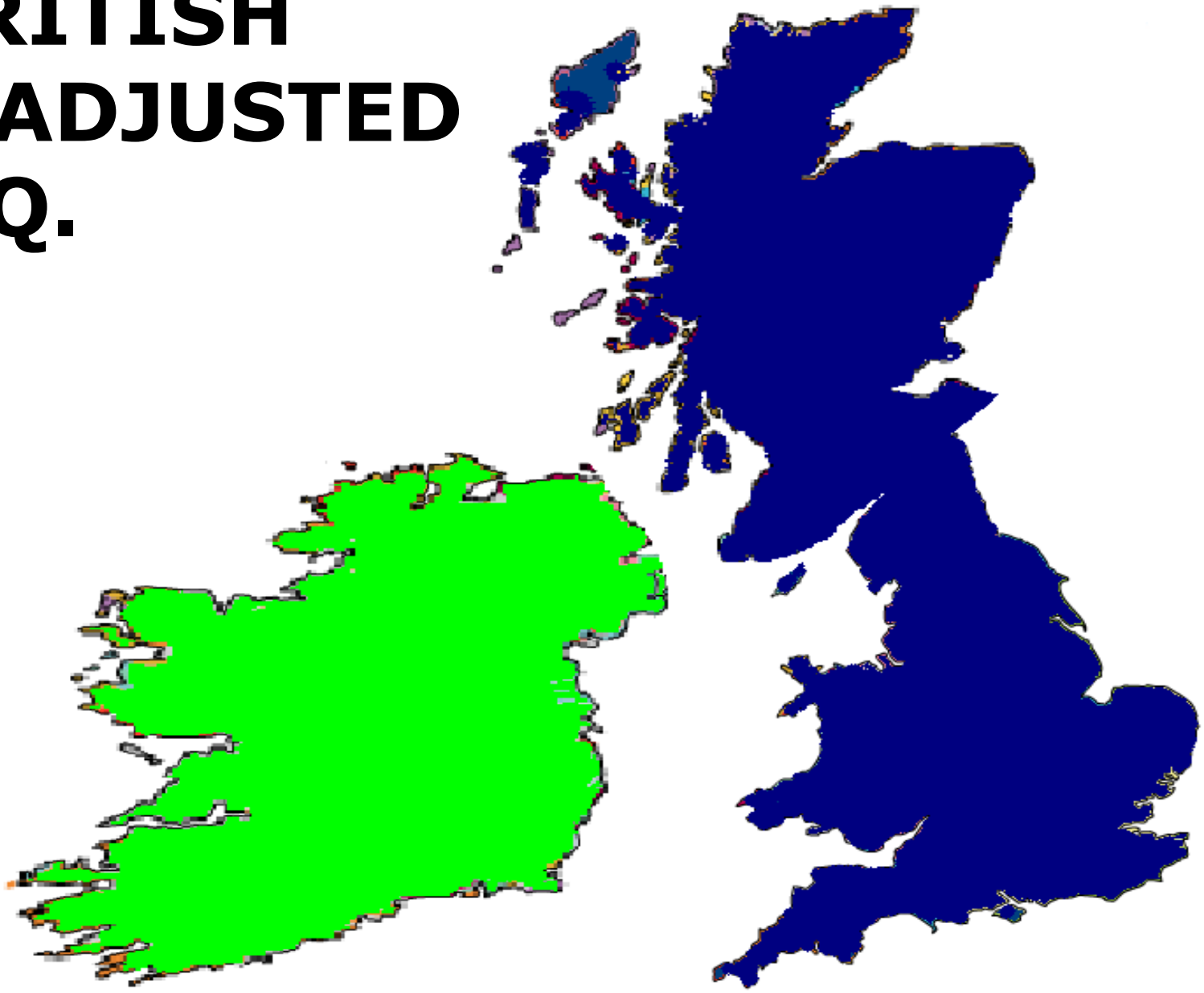
THE BRITISH ISLES



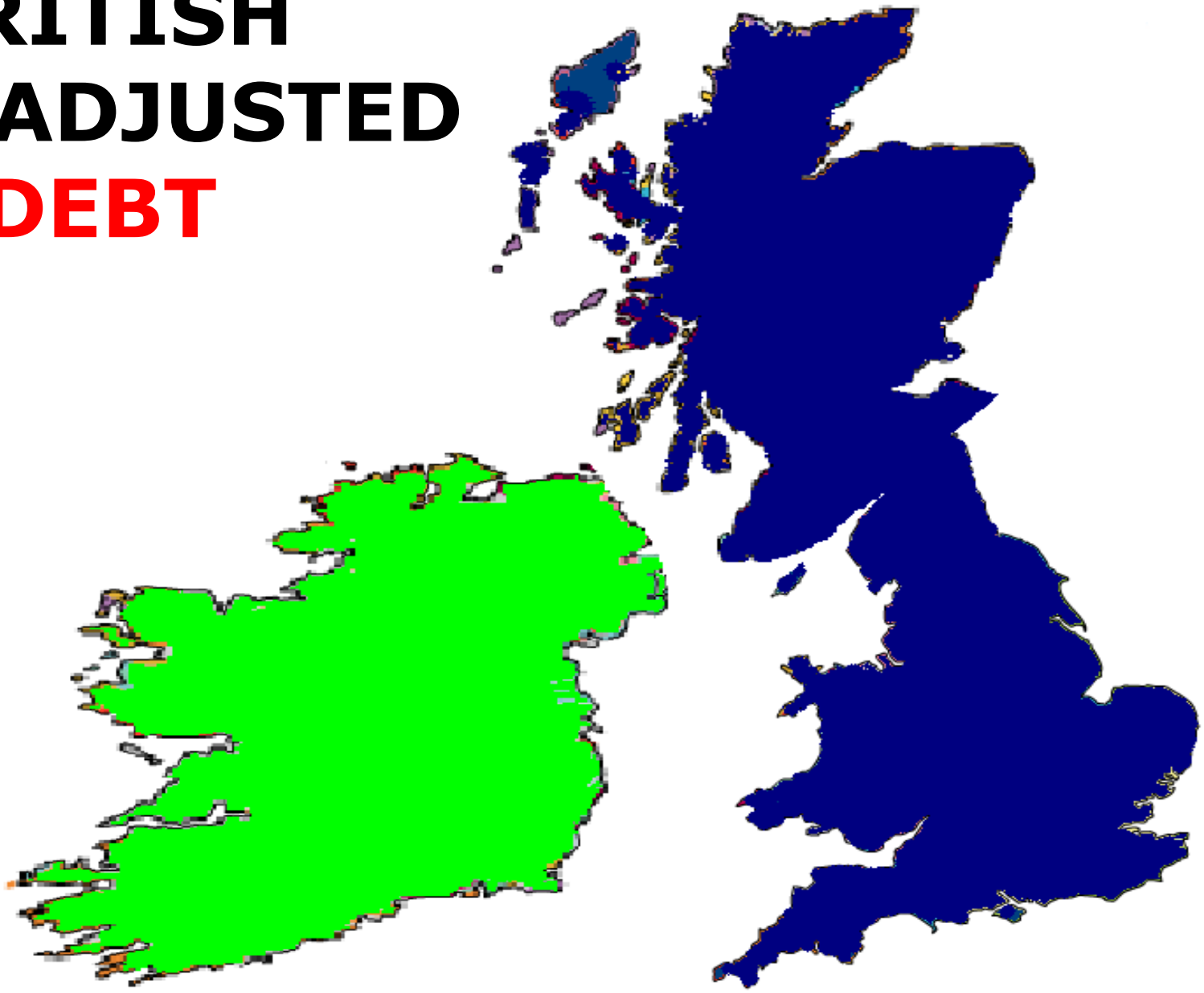
THE BRITISH ISLES ADJUSTED FOR I.Q.



THE BRITISH ISLES ADJUSTED FOR I.Q.



THE BRITISH ISLES ADJUSTED BANK DEBT



DISCLOSURE

Å I have many roles

- National Quality Assurance Advisory Panel Chemical Pathology
- Royal College of Pathologists
- Association of Clinical Pathologists
- UEMS
- EFLM
- British Medical Association

STANDARDISATION

- Standardization or standardisation is the process of developing and implementing technical standards. Standardization can help to maximize compatibility, interoperability, safety, repeatability, or quality. It can also facilitate commoditization of formerly custom processes.

http://en.wikipedia.org/wiki/Standardization

External quality assessment: best practice

- **David James, Darren Ames, Berenice Lopez, Rachel Still, William Simpson, Patrick Twomey**
- J Clin Pathol 2014;0:1ï 5. doi:10.1136/jclinpath-2013-201621

PATIENTS

THE WORLD IS CHANGING

Pope Francis: Who am I to judge gay people?

http://www.bbc.com/news/world-europe-23489702

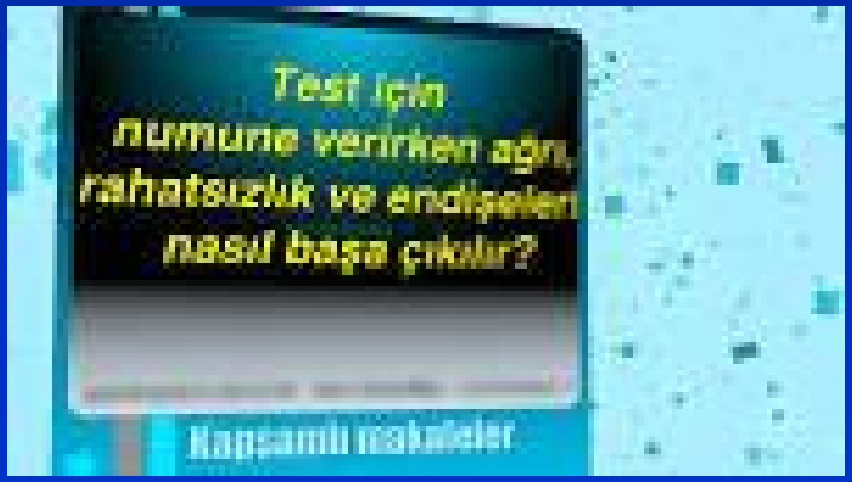
The New Patient Portal

View test results and recent medical records at the click of a button.

Learn More »


Lab Tests Online


Lab Tests Online


Test için
numune veriken ağrı,
rahatsızlık ve endişeler
nasıl başa çıkılır?
Kapsamlı makaleler

HEALTHCARE IS A SERVICE

ACROSS BORDERS

COMPARISON

LED, LCD and plasma TV reviews

LED, LCD and plasma TV

Read the Which? reviews of LCD, LED and plasma HDTVs to cut through the jargon and select the best television for your needs.

BEST BUY

Best Buys

The top 19 LED, LCD and plasma TVs we recommend

DON'T BUY

Don't Buys

The 11 LED, LCD and plasma TVs we think you should avoid

http://www.which.co.uk/technology/tv-and-dvd/reviews/led--lcd-and-plasma-tv/

COMPARISON

Brand & model name	Price	Which? Ratings	Score
 Marks & Spencer MS2269F	£249.00 Exclusive to 1 retailer COMPARE PRICES	Scart RGB picture: ★★★☆☆ Freeview picture: ☆☆☆☆☆ HD upscaling: ☆☆☆☆☆ Overall SD picture: ★★★☆☆	33% DON'T BUY
 Bush BPDP423DHD	£649.00 Typical price - what is this?	Scart RGB picture: ★☆☆☆☆ Freeview picture: ★★☆☆☆ HD upscaling: ★★☆☆☆ Overall SD picture: ★★☆☆☆	25% DON'T BUY

http://www.which.co.uk/technology/tv-and-dvd/reviews/led--lcd-and-plasma-tv/dont-buy/table/

HOW GOOD IS

My Hospital?

My Lab?

My Doctor?

My Pharmacy?

pathologyharmony.co.uk

working to harmonise standards in UK pathology

Pathology Harmony

Pathology Harmony is an initiative working towards harmonisation in UK pathology laboratories which was established in January 2007.

If you wish to comment, join or contribute ideas, please email secretary@pathologyharmony.co.uk

Haematology

Haematology units of measurement

For the latest statement on the standardisation of reporting units for haematology, issued December 2012, please click here.

The information regarding the standardisation, issued in April 2012, can be viewed here

Full access to site

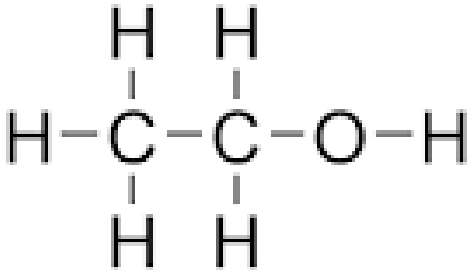
Access to the full site is restricted. If you already have a user name and password enter here.

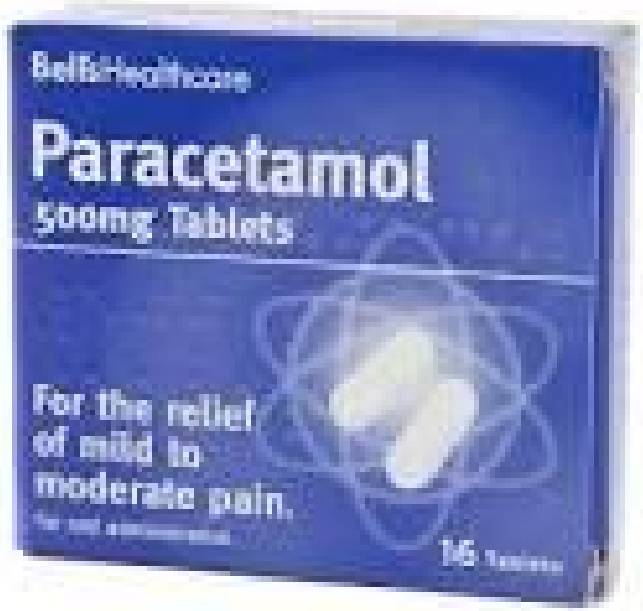
New users should email info@pathologyharmony.co.uk and will receive an email with a username and password

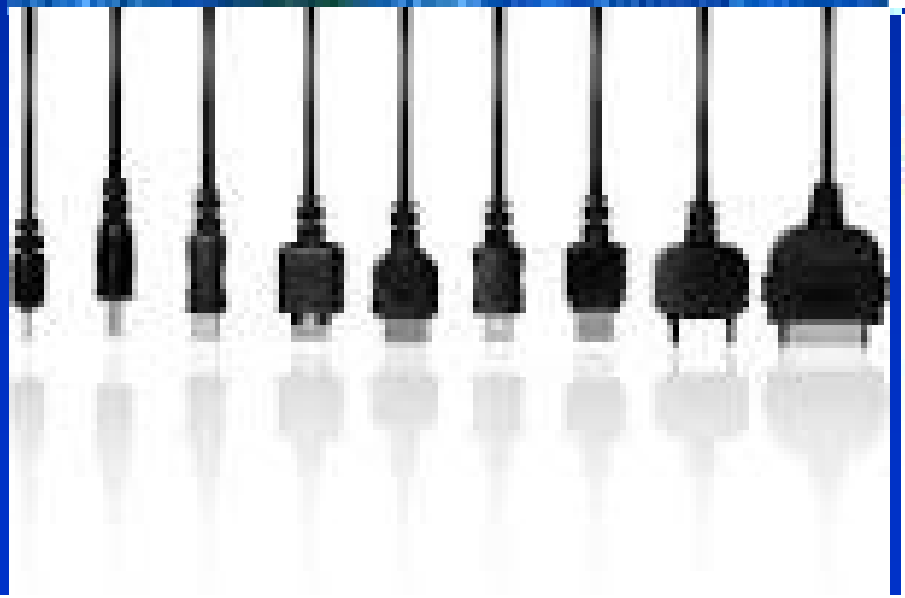
FAQ No 3

The third factsheet in our FAQ series can now be viewed in the main site. This factsheet contains responses to questions on albumin, adjusted calcium and the concepts behind Pathology Harmonisation.


Standardisation




BelbHealthcare
Paracetamol
500mg Tablets
For the relief of mild to moderate pain.
16




UK

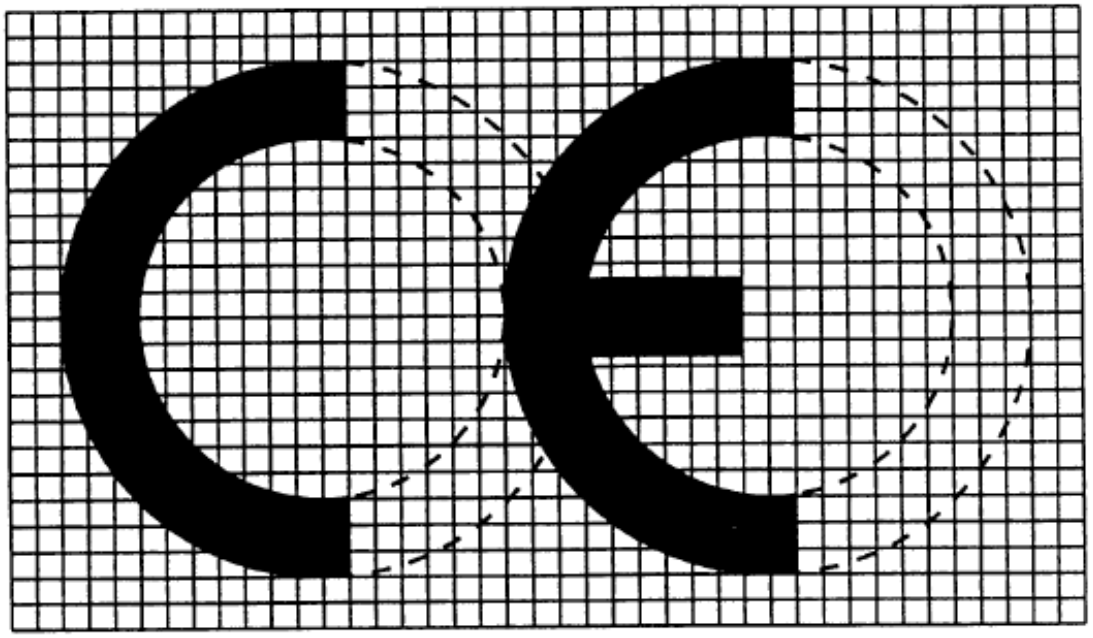
CE Marking

7.12.98 EN Official Journal of the European Communities L 331/37

ANNEX X

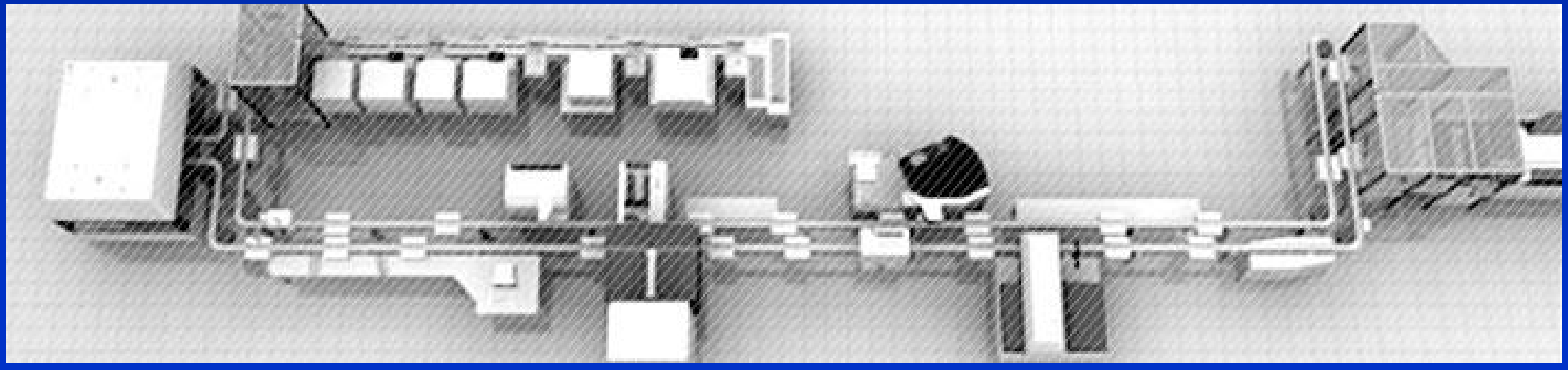
CE MARKING OF CONFORMITY

The CE conformity marking shall consist of the initials 'CE' taking the following form:



CE Marking

CE Marking



CE Marking

Press release: Regulator warns against purchasing all HIV and non-compliant self-test kits over the internet

Notes to Editor

1. A medical device cannot be marketed in the UK without carrying a CE Mark of Conformity. A CE mark is applied by the manufacturer to denote that the device meets the relevant regulatory requirements and performs as intended. For all but the very lowest risk devices, such as unmedicated bandages, an EC Certificate of Conformity must be obtained from an independent certification organisation, called a Notified Body, before the CE marking can be affixed. The MHRA is responsible for designating UK Notified Bodies and regularly audits them to ensure that they continue to perform to the required standards.
2. Adverse incidents relating to medical devices can be reported to the MHRA website www.mhra.gov.uk. Information and printed incident report forms are available from: the MHRA Adverse Incident Centre on 020 3080 7080 or email: aic@mhra.gsi.gov.uk

IVD CE Marking

- Means the result is ñtraceableò to a primary standard
- Denotes that the device meets the relevant regulatory requirements and performs as intended by the manufacturer

(h) 'intended purpose` means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions for use and/or in promotional materials;

- CE Marking does not mean that the test is
  - Accurate
  - Fit for clinical purpose

FIT FOR PURPOSE?

Objective

To evaluate Liaison Diasorin's automated ACTH assay.

Design

We investigated the limit of quantification (LOQ) and simulated the usage of the analyzer using our ACTH results database.

Results

The LOQ was close to the cut-off determining Cushing's syndrome ACTH dependency. 25% concentrations of normal subjects were lower than the LOQ. Although biased, the results were concordant with those of an IRMA assay.

Conclusion

This assay is not sensitive enough to diagnose ACTH-independent Cushing's syndrome.

Brossaud J et al. Use of an automated ACTH assay for the diagnosis of pituitary and adrenal-related diseases. Clinical Biochemistry 2011; 44:1160ï 1162 http://dx.doi.org/10.1016/j.clinbiochem.2011.06.002

PIP Breast Implant Concerns Raised In 2005

comments 18 +1 4 Recommend 62 Tweet 402

6:02pm UK, Friday January 06, 2012

Sky News investigations team

Sky News has discovered there were concerns about the safety of breast implants manufactured by *Poly Implant Prothese at least seven years ago*.

It has also been revealed the French company (PIP) were accused by their insurers in 2006 of deliberately concealing complaints from regulators.

A report by a consultant plastic surgeon in Los Angeles in 2005 warned that PIP implants were three-and-a-half times more likely to rupture than a test group.

Dr Grant Stevens compared 500 PIP implants with 500 implants manufactured by Mentor Siltex.

Perspective

Medical Devices — Balancing Regulation and Innovation

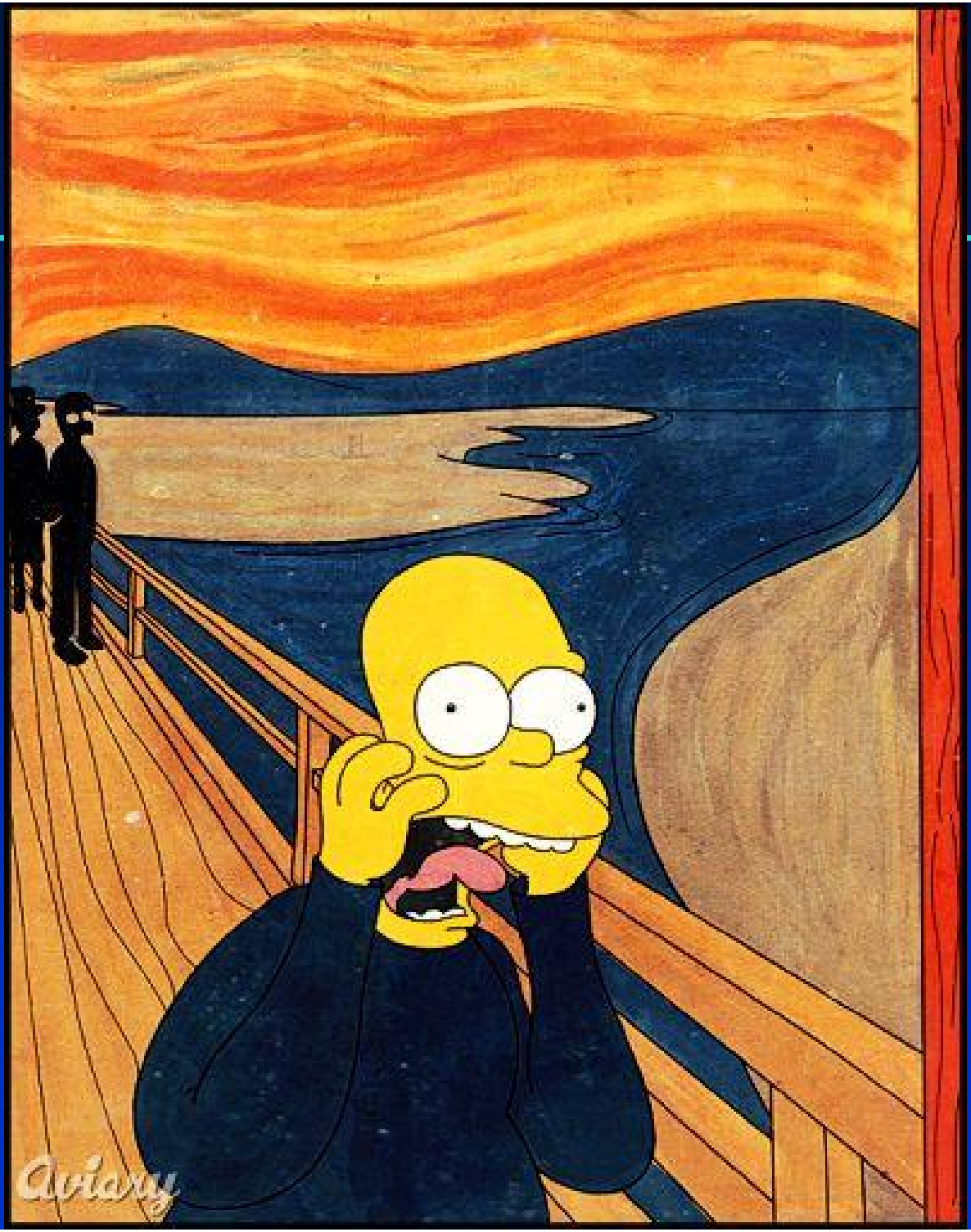
Gregory D. Curfman, M.D., and Rita F. Redberg, M.D.

N Engl J Med 2011; 365:975-977 | September 15, 2011

Comments open through September 21, 2011

One metal-on-metal design is the DePuy (Johnson & Johnson) ASR XL Acetabular System, which was introduced into the U.S. market in 2005. The ASR was cleared by a Food and Drug Administration (FDA) process known as 510(k), which refers to the section of the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act that created it. Under that section, the criterion for clearance of a new medical device is that it be "substantially equivalent" to an already-marketed device (a "predicate"); clinical data are not required.

It soon became clear that the device failed at the astonishing rate of at least one in eight. According to a recent report presented at the British Hip Society Annual Conference, 21% of these hips have had to be replaced (revised) by 4 years after implantation, and the revision rate rises to 49% at 6 years, as compared with 12 to 15% at 5 years for other devices.[2] Failure appears to be due to erosion of the metal in the articular surfaces and migration of metallic particles into the surrounding tissues and the bloodstream. Thus, the innovation led to tragedy for many patients.[3] Before it was recalled in 2010, the ASR had been implanted in nearly 100,000 patients, and the result was a public health nightmare.


Aviary

IVD Regulation

PATIENTS

Factors influencing choice of External Quality Assessment (EQA) Scheme

Å **Range and number of EQA samples.**

- ï **Range of values to verify performance across clinically relevant concentrations.**
- ï **Each cycle should supply sufficient samples to provide evidence of reproducibility, e.g. 3ï 4 samples**
- ï **Samples should be ôblindedô to participants in relation to expected results.**

Analytical Range

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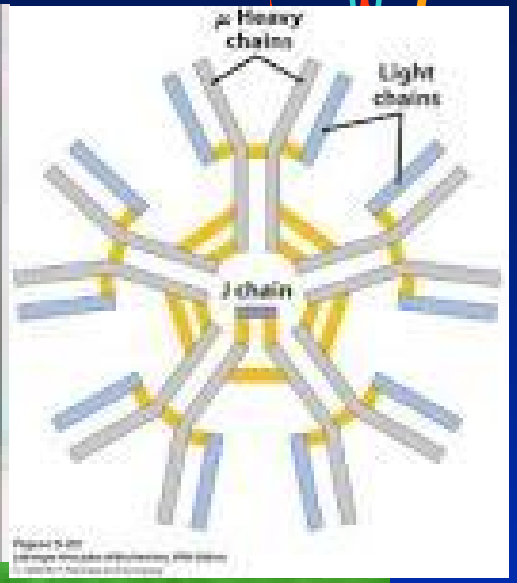
Range and number of EQA samples

Sample	Creatinine (umol/L)
Early July	134
Mid July	140
Early August	379
Mid August	134
Early September	396
Mid September	127
Early October	133
Mid October	362

Assessment of the laboratory data shows that the concentration range has been very limited with 2 limited concentration ranges (127 - 140 and 362 to 396 umol/L).

As there have been no specimens with low or normal concentrations nor challenging samples provided

CHALLENGING SPECIMENS



Factors influencing choice of External Quality Assessment (EQA) Scheme

Å **Commutable materials**

- ï **EQA providers should demonstrate use of commutable materials.**
- ï **If a material is not commutable, then it cannot provide assurance re the quality of the laboratory or the method.**
- ï **Clinical vs. statistical**

Factors influencing choice of External Quality Assessment (EQA) Scheme

Å **Accreditation status of provider.**

- ï **Preference here for ISO 17043 accreditation**
- ï **If based on ISO15189 and not ISO17025**

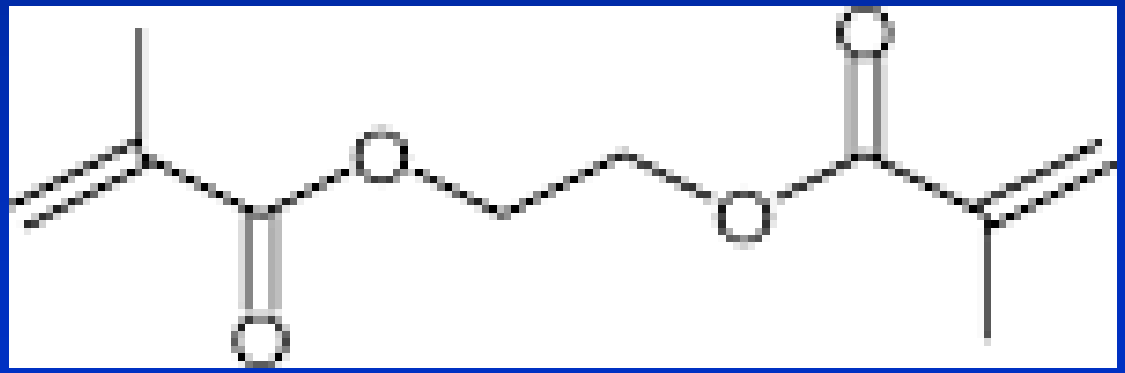




Factors influencing choice of External Quality Assessment (EQA) Scheme

Å **Appropriateness of distribution frequency.**

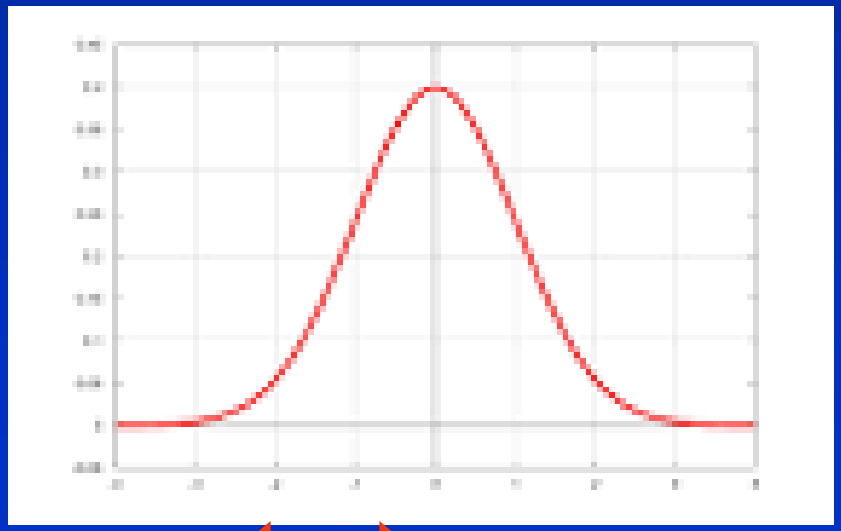
- ï **Distributions should be at a frequency sufficient to identify performance issues in a timely manner.**
- ï **For core tests, this probably equates to at least monthly distributions.**



Factors influencing choice of External Quality Assessment (EQA) Scheme

Å **Scheme management and development.**

- ï **The scheme should be designed and overseen by appropriately competent professionals (clinical, technical and statistical).**
- ï **The scheme should also have an independent medical and scientific committee.**



Factors influencing choice of External Quality Assessment (EQA) Scheme

Å **Poor performance issues.**

ï **Mechanisms should be in place for reporting of poor performance to the appropriate regulatory/oversight body.**

Factors influencing choice of External Quality Assessment (EQA) Scheme

Å **Education.**

- ï **Educational input should be provided.**

Factors influencing choice of External Quality Assessment (EQA) Scheme

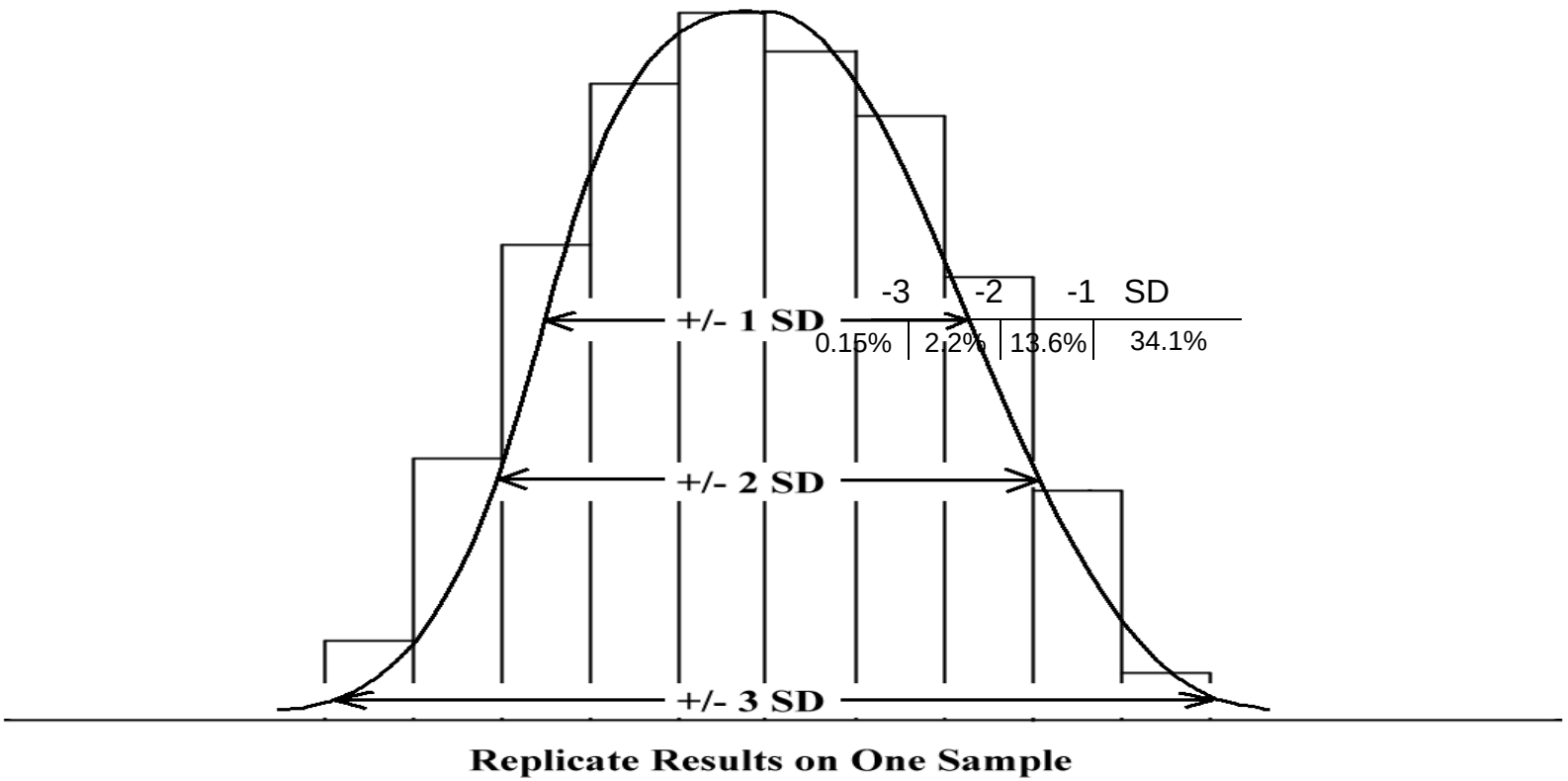
- **Post marketing surveillance**
  - **Participation of the EQA provider in post marketing vigilance of in vitro diagnostics.**




WHAT IS IN A NAME?

- **Proficiency Testing: ñA program in which multiple samples are periodically sent to members of a group of laboratories for analysis and/or identification; whereby each laboratoryôs results are compared with those of other laboratories in the group and/or with an assigned value, and reported to the participating laboratories and other**
- **EQA schemes provide an assessment which laboratories use for assurance of quality.**
- **The primary intention of EQA programme in pathology is to support quality improvements for the benefit of patients.**

Statistics: Robust or not?



WHO CARES?

Data don't make any sense, we will have to resort to ***statistics****.*

"Our statistician will drop in and explain why you have nothing to worry about."

EQA vs. PT

- **Education and support** ð EQA providers should be able to provide support for laboratories in resolving poor performance, being knowledgeable in aspects of method application and problems.
- **Method performance** ð identification of poor performance issues related to methods rather than laboratory issues: Post marketing vigilance.
- Assessing a laboratoryôs ability to report appropriately where samples may pose a **challenge**, for example, presence of interferent or antigen excess.
- **Clinical relevancy**

Assays must be safe

- Bias at clinical decision points
- Precision at clinical decision points
- Stability of assay over time

Minimum Analytical Performance Standards (MAPS)

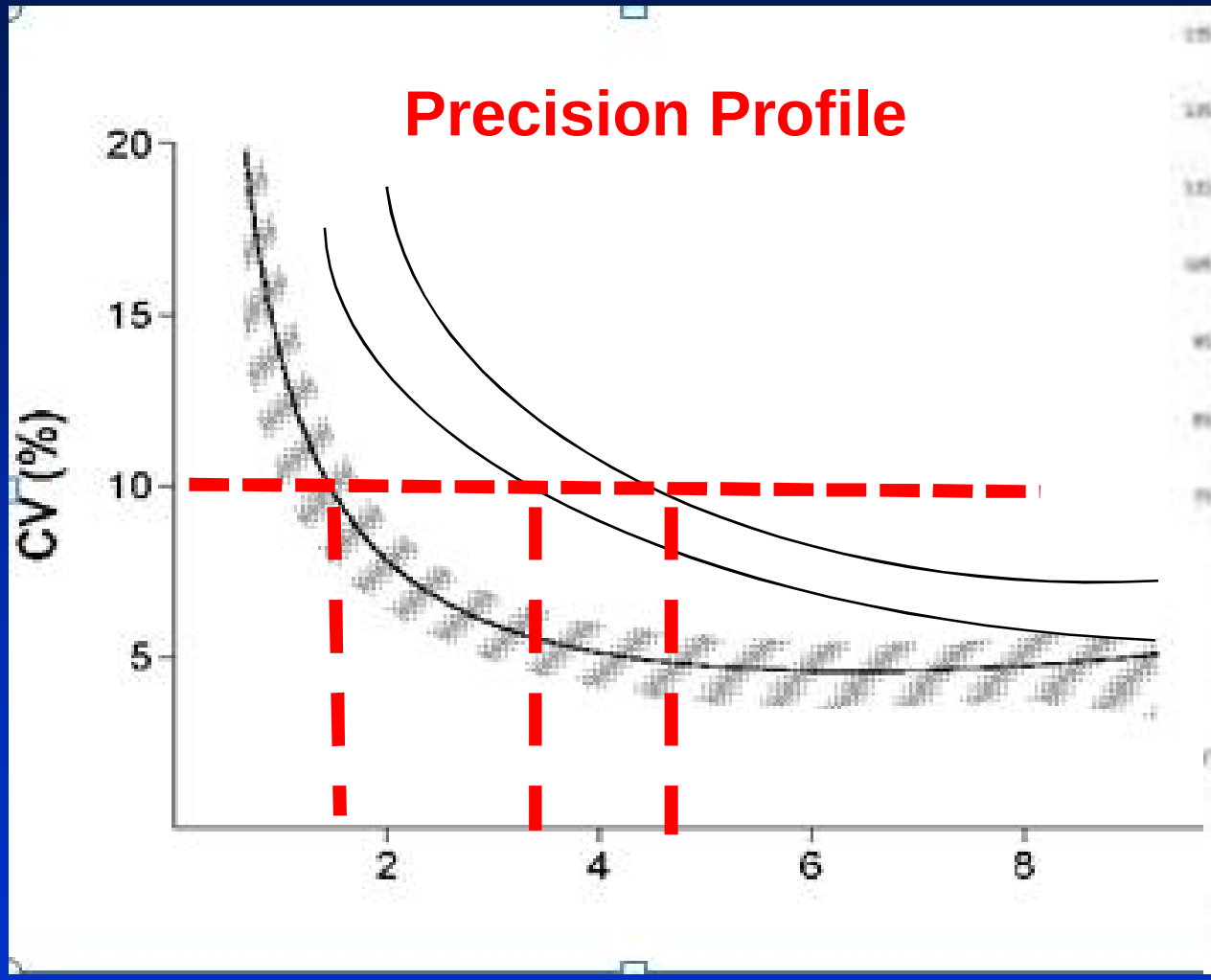
- Initial steps to define and pilot a definition of poor performance to be applied across EQA providers for UK labs
- The aim is to avoid difficulties in defining poor performance, and to make an assessment of performance which is clinically relevant, rather than a pure ôstatisticalô ranking.

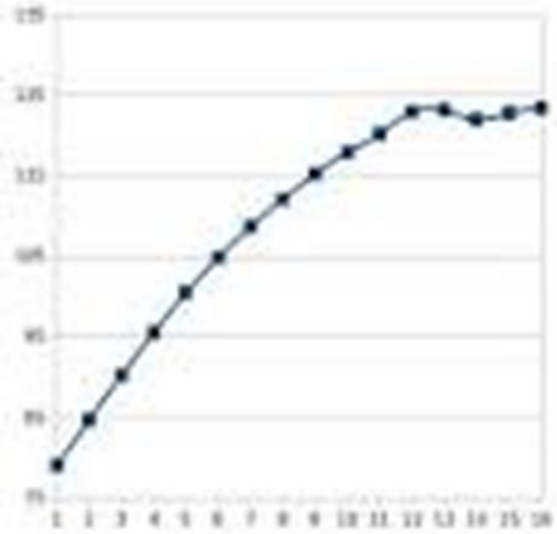
http://www.rcpath.org/Resources/RCPath/Migrated%20Resources/Documents/N/NQAAP_ChemicalPath_MAPS%20pilot2010_22.05.13.pdf

MAPS - CHOLESTEROL

Test Name ï Cholesterol level	NLMC1389		
Standard options	CDC-Validated		
Critical level for performance	5.0 mmol/L		
Performance criteria			
Concentration	Allowable Bias	Allowable Variability	Allowable TE
5.0mmol/L [Desirable[1]]	4.0%	2.75	8.5%

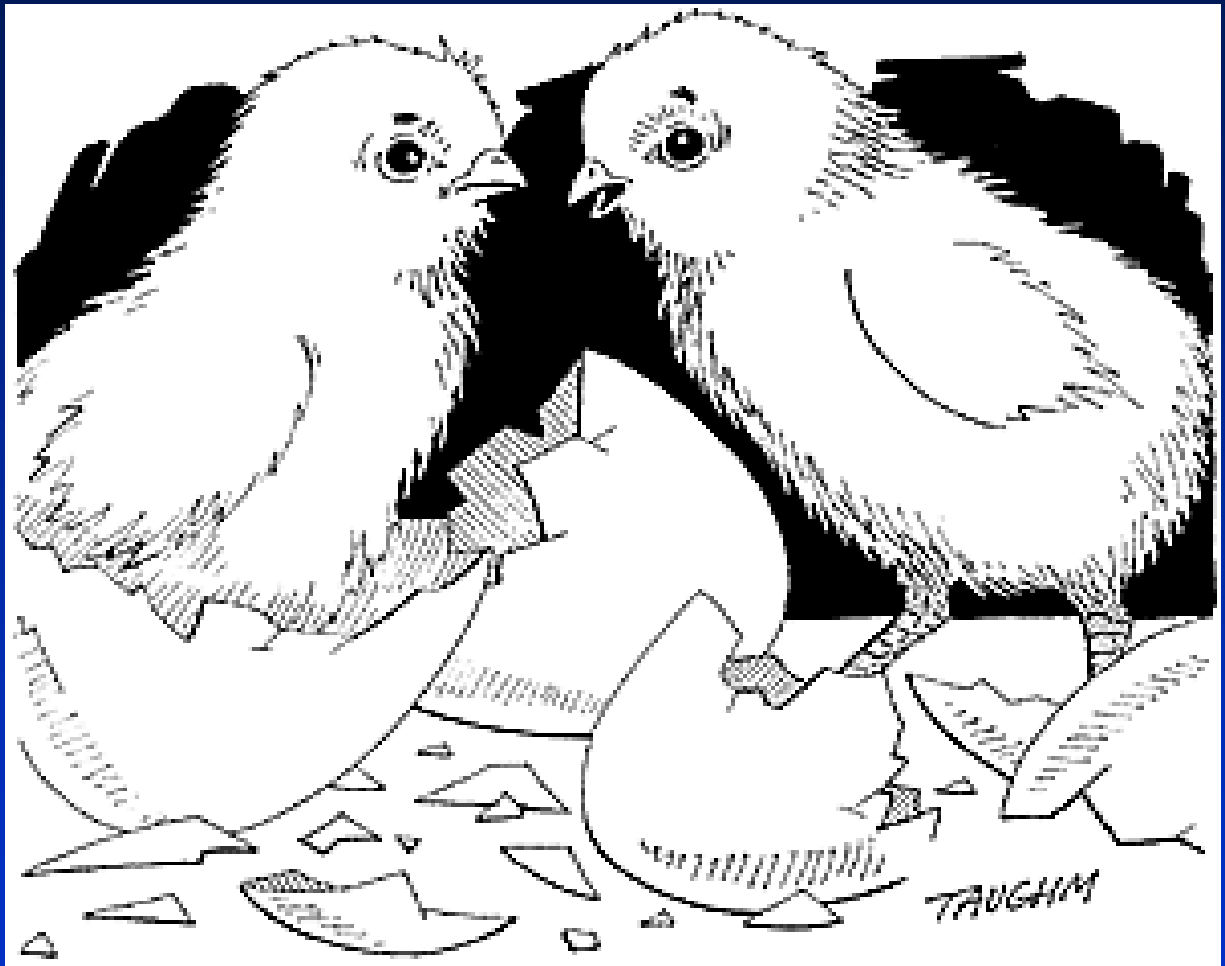
Other Analytical Issues





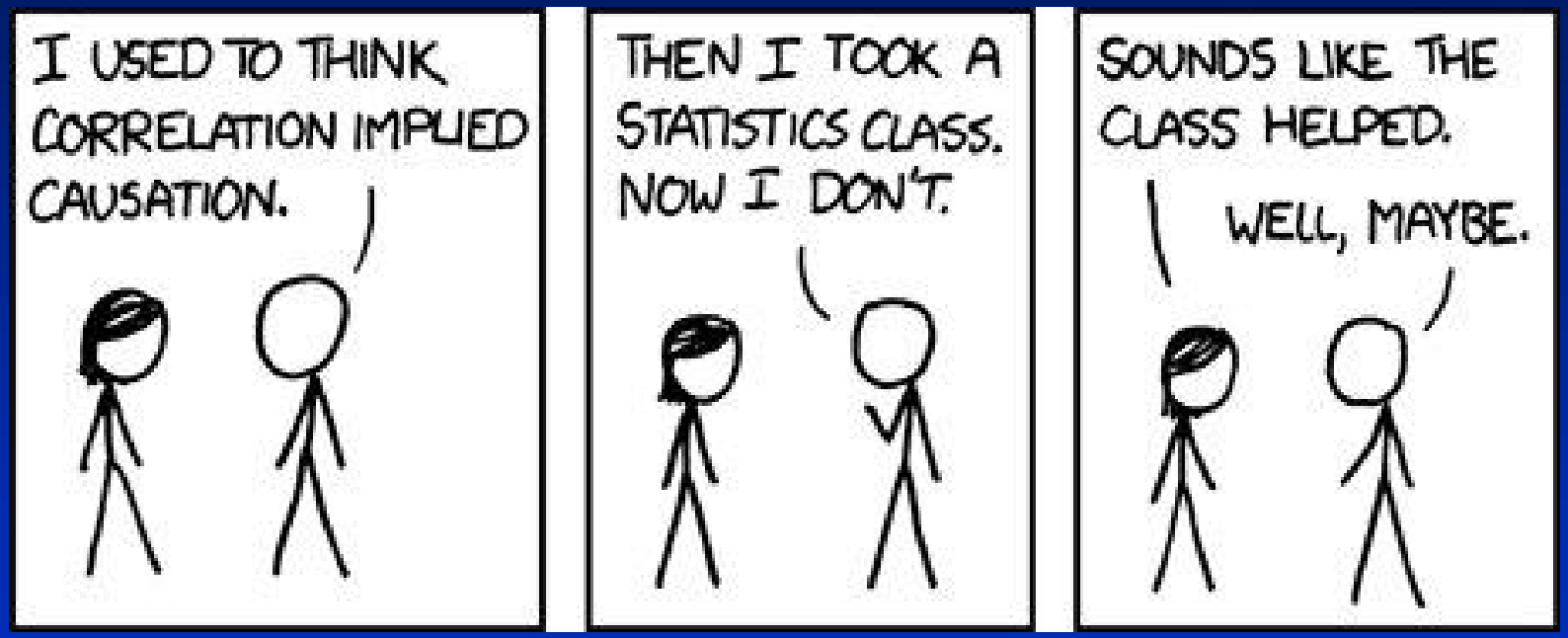
Feuentes-Arderiu X, Gonzolez-de-la-Presa, Cuadros-Munoz J. Uncertainty of measurement and heteroscedasticity , eJIFCC vol 14 no 1: http://www.ifcc.org/ejifcc/vol14no1/140103200306n.htm.

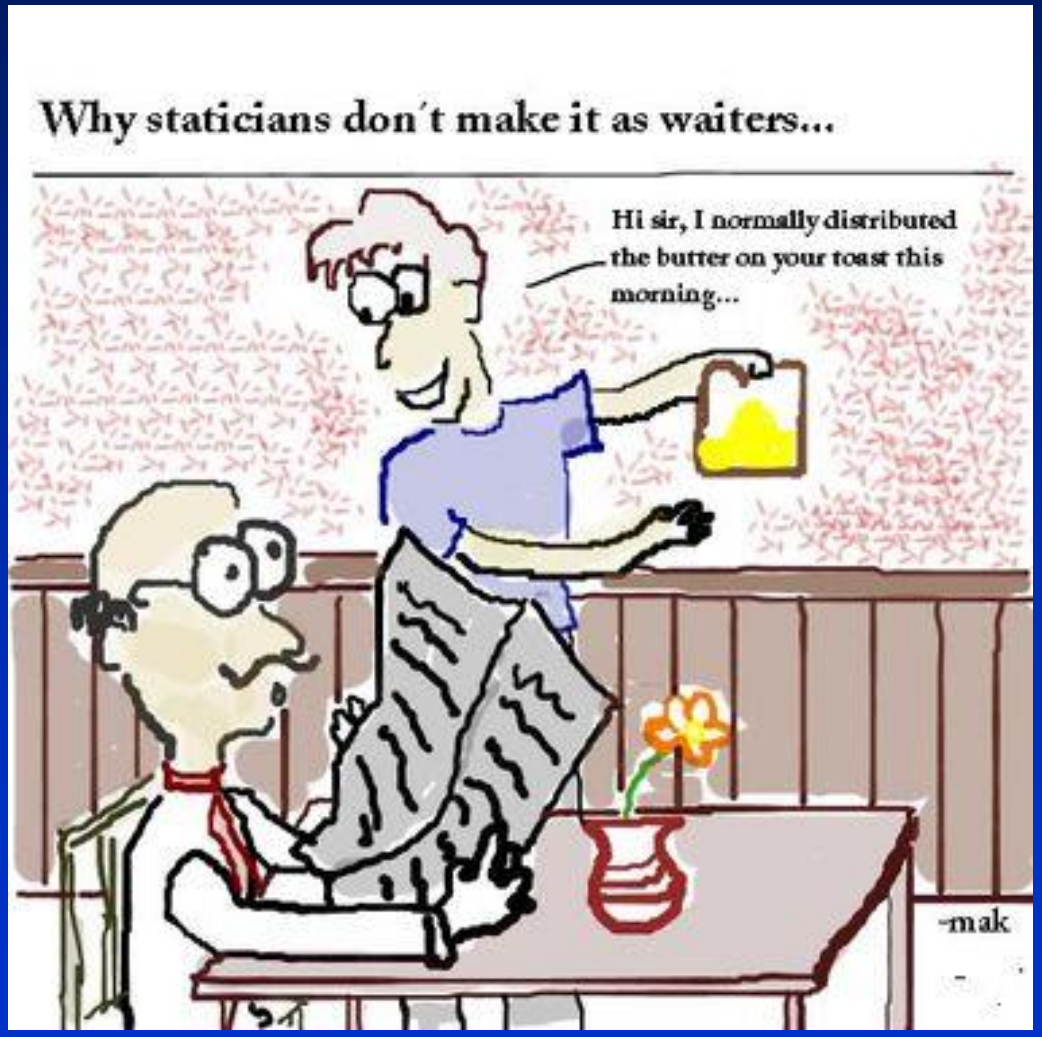
THANK YOU



"Whew! I'm glad that's over - all that cholesterol was killing me!"

Medscape ® http://www.medscape.com


I USED TO THINK CORRELATION IMPLIED CAUSATION.
THEN I TOOK A STATISTICS CLASS. NOW I DON'T.
SOUNDS LIKE THE CLASS HELPED.
WELL, MAYBE.


Why staticians don´t make it as waiters...
Hi sir, I normally distributed the butter on your toast this morning...
-mak