

The value of Guidelines in Laboratory testing

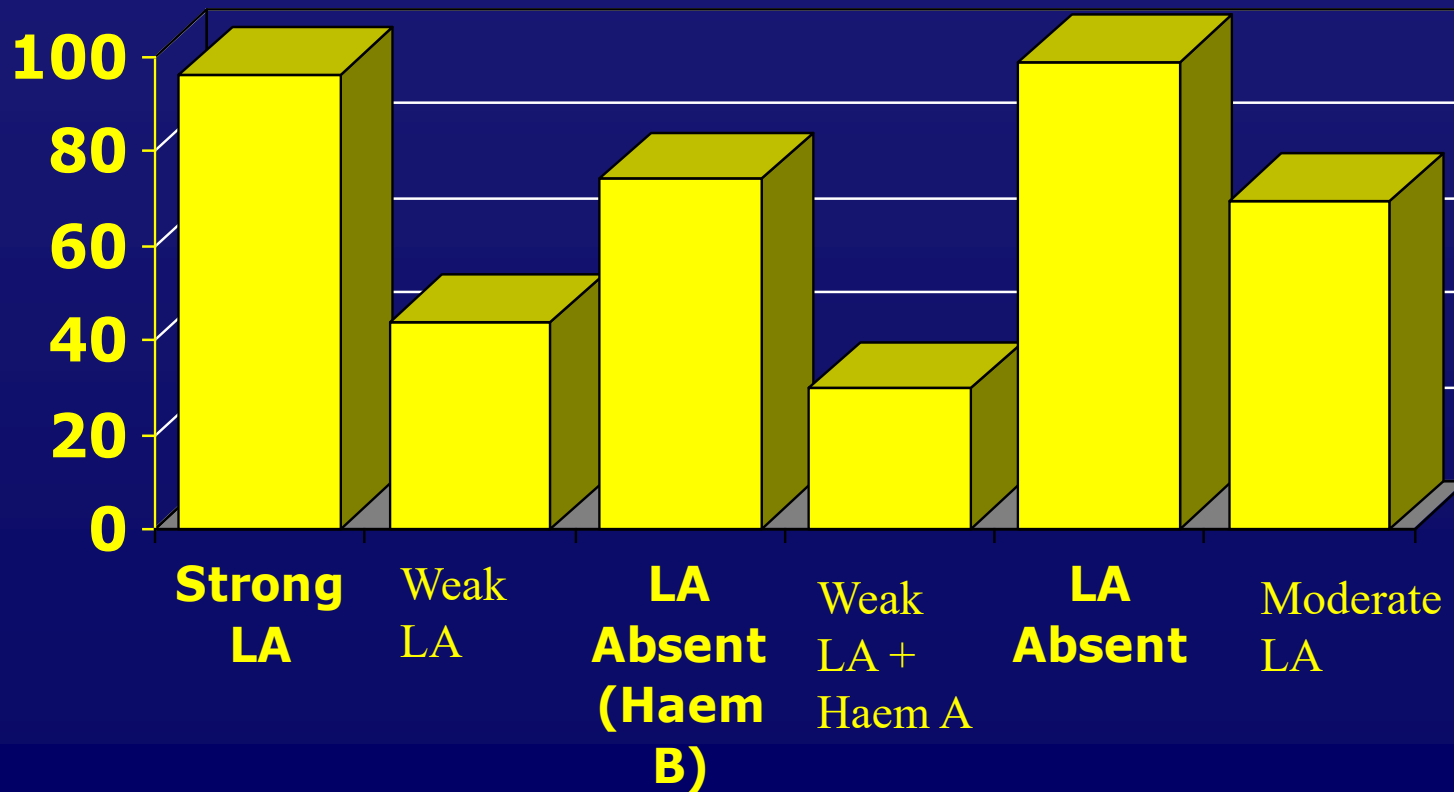
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Do guidelines improve practice?

Correct Diagnosis of LA : Data from UK NEQAS exercises

% correct interpretations



Do labs following BCSH Lupus guidelines do better?

	Correct Diagnosis (n)	Incorrect Diagnosis (n)
Compliance with guidelines*	102 (84%)	19
Non-compliance with guidelines*	51 (65%)	27

* P<0.002

Bridging the Gap between Point-of-Care Testing and Laboratory Testing in Hemostasis

Dianne P. Kitchen, FIBMS¹ Ian Jennings, PhD, CSci, FIBMS¹ Steve Kitchen, FIBMS, PhD¹
Timothy A. L. Woods, MBA, CSci, FIBMS¹ Isobel D. Walker, MD, MPhil¹

Semin Thromb Hemost 2015;41:272–278.

Data from the questionnaire also focused on the relevant guidelines that were available at the time of the questionnaire's distribution. Users were asked if they had read the following four guidelines:

- Guidelines for POC testing: hematology¹²
- An evidence-based review and guidelines for patients' self-testing and self-management of oral anticoagulation¹⁵
- Management and Use of IVD Point of Care Test Devices. Medical Devices Agency Bulletin¹¹
- BCSH/NPSA: Safety indicators for inpatient and outpatient oral anticoagulant care⁵

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Responders showed that the most widely read guideline was Briggs et al 2008,¹² which 40% had read. In total, only 10% of the responders had read all four of the stated guidelines and a shocking 52% had read none. These figures appear to have decreased since our last questionnaire in 2011,¹⁴ when 13% had read all the four guidelines and 48% had read none.

Bridging the Gap between Point-of-Care Testing and Laboratory Testing in Hemostasis

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Table 3 Frequency of internal quality control testing for point of care^a

When do you test your IQC samples?	%
With a new batch of test strips	29
Other	26
With each clinic	15
Not available for our device	13
If unexpected results occurs	9
Monthly	3
Weekly	3
Never	2

Abbreviations: IQC, internal quality control.

^aData from questionnaire to UK National External Quality Assessment Scheme for Blood Coagulation users.

GUIDELINES FOR WHO GUIDELINES

EIP/GPE/EQC/2003.1

1. Definition. **Guidelines** are systematically developed evidence-based statements which assist providers, recipients and other stakeholders to make informed decisions about appropriate health interventions.

ISTH/SSC Guidance or Guidelines?

Enough evidence ? – Guidelines

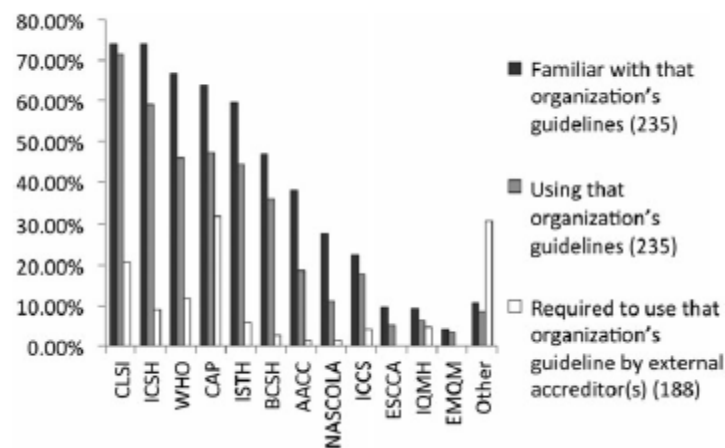
Mainly opinion ? - Guidance

Report on the International Society for Laboratory Hematology Survey on guidelines to support clinical hematology laboratory practice

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Figure 1. Familiarity and use of guidelines from different organizations. Bars compare the percentage of survey participants that were familiar with, used, and were required to use the guidelines of the listed organizations. CLSI, Clinical and Laboratory Standards Institute; ICSH, International Council for Standardization in Haematology; WHO, World Health Organization; CAP, College of American Pathologists; ISTH, International Society on Thrombosis and Haemostasis; BCSH, British Committee for Standards in Haematology; AACC, American Association for Clinical Chemistry; NASCOLA, North American Specialized Coagulation Laboratory Association; ICCS, International Clinical Cytometry Society; ESCCA, European Society for Clinical Cell Analysis; IQMH, Institute for Quality Management in Healthcare; EMQN, European Molecular Genetics Quality Network.



Guidelines and standards for haemostasis labs

- International Standards - requirements for laboratories (ISO 15189 etc)
- Guidelines and Guidance – ISTH /SSC
- Guidelines - CLSI

International Guidelines in Haemostasis

	2001-5	2006-10	2011-2016
CLSI	4	3	2
ISTH/SSC	1	2	8

Assembly and evaluation of an inventory of guidelines that are available to support clinical hematology laboratory practice

C. P. M. HAYWARD^{*†‡}, K. A. MOFFAT^{*†‡}, T. I. GEORGE[§], M. PROYTICHEVA[¶]

ICSH - Involved in Haemostasis in early days

Thromb Haemost. 1986 Feb 28;55(1):143-4.

**Partial thromboplastin time test--proposed performance guidelines.
ICSH Panel on the PTT.**

Koepke JA.

Abstract

The partial thromboplastin time (PTT) test is widely used as a screening test for the detection of hemophilia. It is also used to monitor patients on heparin anticoagulation. This proposal from a ICSH Panel proposes guidelines for the performance of this test, including comparable reference ranges, precision and sensitivity requirements

ICSH - Involved in Haemostasis in early days

J Clin Pathol 1985;**38**:133–134

ICSH/ICTH recommendations for reporting prothrombin time in oral anticoagulant control

International Committee for Standardization in Haematology and International Committee on Thrombosis and Haemostasis

Published in 9 different journals!

ICSH new initiatives in Haemostasis

- Three guidelines approved by Council
- Pre Analytics/Sample acceptance criteria (S Kitchen)
- DOACs and haemostasis tests (R Gosselin)
- FVIII/IX Inhibitors (P Meijer)
- Contributors – USA, Canada, Brazil, India, Australia, China , UK, Italy, Netherlands,

Pre analytics

(Sample acceptance, processing and stability)

Chair – Steve Kitchen (UK)

- Guiseppi Lippi (Italy)
- Ian Mackie (UK)
- Suresh Nair (India)
- Richard Marlar (USA)
- Dot Adcock-Funk (USA)
- Ray Dauer (Australia)

Causes of sample rejection

	Clotted	Under-fill	Labelling	Haemolysis
2010	411	356 (0.6%)	327	119 (0.2%)
2011	439	349 (0.6%)	255	247 (0.4%)
2012	204	434 (0.7%)	141	650 (1.1%)
2013 (Accident and emergency)		0.9%		2.6%

Are rejected samples replaced?

1077 samples rejected in a 3 month period (2014)

- (~3% of all samples)

520 (48%) not replaced within 24 hours

- (including 106 INRs)

313 (29%) not replaced within 7 days

- (including 24 INRs)

Automated detection on coagulation analysers

- Sysmex
- Werfen/IL
- Stago
- Others in development

ICSH recommendations on which samples are suitable for tests of haemostasis

- Anticoagulant/tube
- Filling of tube and haematocrit
- Haemolysis, Lipaemia, Iceterus
- Labelling of tube
- Sample stability
- Same processing
- Sample storage

DOAC and Lab tests

Chair – Bob Gosselin (USA)

- Dot Adcock - USA
- Shannon Bates - Canada
- Jonathan Douxfils - Belgium
- Emmanuel Favalaro - Australia
- Steve Kitchen - United Kingdom
- Edie Lindhoff-Last - Germany

Lab testing for Inhibitors to FVIII and FIX

Chair Piet Meijer (Netherlands)

- Flora Peyvandi (Italy)
- Rajiv Pruthi (USA)
- Guy Young (USA)
- Silmara Montalvão (Brazil)
- Clarence Lam (Hong Kong)

Proposal under review

- Prof David Fitzmaurice
- Primary Care Point of Care testing in Haemostasis
- ICSH FBC POC doc but not focussed on primary care requirements
- Gap to fill

Proposed scoping survey

- European Primary Care Cardiovascular Society (EPCCS)
- World Organisation of National Colleges, Academies and Academic Associations of General Practitioners/Family Physicians (WONKA)

Some key requirements for optimal impact of International Guidelines

- Guidelines should set practice not follow it
- Construction by experts
- Suitable for use emerging and established countries (input from different regions).
- Peer review
- Available (open access, no fee)

ICSH Haemostasis guidelines

- Published in peer reviewed literature - concise
- Free to download – unrestricted access worldwide
- Writing groups constructed to be inclusive
- Review of drafts by industry (but not co – authorship)