

Standardisation of Reporting Units for extended Full Blood Count in Haematology

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Date

23rd December 2015

Introduction and background

The full blood count (FBC) is the most frequently requested test in laboratory haematology worldwide. Reporting units used for the FBC currently vary around the world, from country to country and also within countries between laboratories. This variation is perceived to be a potential problem in the era of rationalisation of pathology services, re-structuring of pathology providers, and increase in point-of-care provision. There has been an agreement in the United Kingdom (UK) to standardise the reporting units used for the extended FBC nationwide using the accepted SI (International System) units from April 2013¹. In addition there is a current international project under the auspices of the International Committee for Standardization on Haematology (ICSH) to address this issue worldwide and make a recommendation for standardization. A standardization exercise similar to that carried out in the UK was previously completed among five Scandinavian countries (Norway, Sweden, Finland, Denmark and Iceland) by the Nordic Reference Interval Project (NORIP) group². The SI reporting units adopted in the UK are the same as those adopted by NORIP.

In the Republic of Ireland (RoI), a survey of all haematology laboratories conducted by the ACSLM jointly with IEQAS in 2012, revealed some variation in the reporting units in use for the extended FBC. It also surveyed opinion of laboratory professionals in regard to standardization along the line adopted in the UK, and found that the majority were in favour, subject to the project being supervised nationally and to include advance notification to service users. The issue was also discussed with representatives of Irish professional bodies in 2013 as described below.

The planned introduction of a national laboratory information system (MedLIS) for the Republic of Ireland beginning in 2015 will require the adoption of single reporting units for all laboratory tests. This therefore represents an opportunity to standardize the reporting units for the FBC in line with the International Committee for Standardization on Haematology (ICSH) recommendations which are expected to be published in early 2016.

The following reporting units for the extended blood count, which follows the original ICSH guideline³ were agreed and adopted in the UK from March 2013¹:

Table 1: SI Reporting units for the Blood Count adopted in the United Kingdom which are the same as those used in Scandinavia

Pathology Harmony Proposal Analyte	Units
White blood cell (WBC) count	$\times 10^9/L$
Neutrophil count	$\times 10^9/L$
Lymphocyte count	$\times 10^9/L$
Monocyte count	$\times 10^9/L$
Eosinophil count	$\times 10^9/L$
Basophil count	$\times 10^9/L$
Nucleated red blood cell (NRBC) count	$\times 10^9/L$
Red blood cell (RBC) count	$\times 10^{12}/L$
Haemoglobin (Hb)	g/L
Haematocrit (Hct)	L/L
Mean cell volume (MCV)	fL
Mean cell haemoglobin (MCH)	pg
Mean cell haemoglobin concentration (MCHC)	g/L
Red cell distribution width (RDW)	%
Platelet (PLT) count	$\times 10^9/L$
Reticulocyte count	$\times 10^9/L$

Results of the survey of Republic of Ireland Laboratories 2012

The results of this survey, which gathered information both on reporting units used and opinion on the merits of standardisation, are summarised as follows:

- A wide range of cell counting instrumentation for the FBC is used (all major manufacturers are represented).
- 43 laboratories responded of which 96% (41 laboratories) currently report haemoglobin and MCHC as g/dL which is not a true SI unit, while 4% (2 laboratories) already report these parameters as g/L.
- All laboratories already report total RBC count as $\times 10^{12}/L$ and total WBC count as $\times 10^9/L$ as per the UK and Scandinavian adopted units.
- 79% of laboratories (34) report the WBC differential as $\times 10^9/L$ while 21% (9 laboratories) report as both $\times 10^9/L$ and as a percentage.
- Reticulocyte reporting is more mixed, but the majority (63%) already report as $\times 10^9/L$ or both (28%) with only 9% reporting as percentage.
- Nucleated red blood cell (NRBC) reporting is the most mixed, with 26% of respondents reporting as $\times 10^9/L$, 58% as "number per 100 WBCs" and 16% as both.
- Despite the finding that the majority of laboratories report Hb as g/dL along with some perceived disadvantages and issues to be addressed, a clear majority of 93% (39 labs) are in favour of harmonising to SI units in principle, with only 7% selecting "Don't know". No laboratories answered that they would be opposed to standardization.
- The majority of perceived disadvantages and issues to be addressed concern IT systems, Point-of-Care testing devices and related costs of change for both, advance notification and education of users. They include managing the change and impact on delta checking and archived results.
- Those laboratories that already report haemoglobin as g/L, reported that there had never been any incident where the haemoglobin level was misinterpreted and that the clinicians who had rotated from other hospitals adapted with no problem to the different reporting units.

Discussion at National Laboratory Handbook Meeting 2013

A meeting was arranged between all the relevant Irish professional bodies to form a national view. This was chaired by Dr. Gerard Boran, Clinical Lead of the HSE National Clinical Programme in Pathology, as part of a meeting on the National Laboratory Handbook in April 2013. The meeting included representatives of the ACSLM, IEQAS, the Faculty of Pathology of the Royal College of Physicians of Ireland (RCPI), and the ICGP. The Irish Haematology Society (IHS) was invited but unable to attend. This meeting concluded that there was merit in principle in adopting the UK reporting units in the interests of harmonisation. It was not felt that the change would pose any difficulty to clinicians, provided that sufficient advance notification was given. The meeting also recognised however, that the necessary inclusion of point-of-care devices and IT systems in the change may well have resource issues and also that the change would have to be managed carefully as a national project. It was concluded these aspects needed to be explored further and that we must also take account of the new National MedLIS project. Funding issues for a national change would be a matter for the HSE. Subsequently the chair of the Haematology Advisory Body of the ACSLM made contact with the Quality & Change manager of the National MedLIS project to report the conclusions of this meeting.

International Dimension

A survey of international practice was conducted by the ICSH in 2013, to which the Republic of Ireland survey data was submitted. This international survey revealed quite a great diversity in reporting units being used around the world. It showed that only two countries, the Netherlands and now the UK, have nationally agreed units of measurement, although Australia reported a very good consensus and the NORIP data from Scandinavia was later obtained. The ICSH adopted a formal project to agree and publish a recommendation for standardisation of reporting units to be used for the extended blood count in October 2013. This was led by Michelle Brereton, Manchester and the project team included Richard McCafferty, Republic of Ireland and contributors from Australia, Spain, Korea, China, Japan, Germany, France, the Netherlands and USA. This paper has now been finalised and agreed at the last ICSH General Assembly held in Shenzhen, China in October 2015. It has been submitted for publication in the International Journal of Laboratory Haematology which is expected in early 2016. The paper recommends that the original ICSH guidelines for use of SI reporting units for the blood count from the 1970s and 1980s^{3,4}, which the UK and Scandinavian groups have followed in their recent national and network standardisations, should be used internationally where possible to improve standardisation.

Current Position and Conclusion

Harmonisation of reporting units in pathology is an issue currently being addressed worldwide. Reporting units for the full blood count have been standardised in Ireland's nearest neighbour the UK and also in Scandinavia. A new international recommendation for standardisation by the ICSH has been finalised and is currently in press as described above. Experience in Ireland, the UK (where there has been a long transition phase to the agreed units) and in Europe has shown that the use of different reporting units can co-exist within countries without adverse clinical consequences. However, the merits of standardization are well described and accepted. These include, for example, the ability to directly compare laboratory results for the purposes of clinical trials and when patients travel between jurisdictions. It may well also be the case that laboratory equipment, point-of-care devices and cell counter analysers supplied to the Republic of Ireland in the future by UK-based suppliers, will express results by default in the UK-adopted units and may require resetting to express results in other units. This will have particular relevance for reporting of haemoglobin concentration which is now expressed in g/L in the UK and Northern Ireland but as g/dL by the majority of Republic of Ireland laboratories. The view of the Irish professional bodies arising from the joint meeting of 2013 is that adoption of the reporting units used in the UK, now also endorsed internationally by the ICSH, would be advantageous for the reasons described above. However the implementation of such a national change will be dependent on logistical and cost issues. These must include the availability of HSE funding for any resource issues identified, such as the need for administrative support for national change management, advance notification of service users, and conversion of cell counters (if needed), point-of-care devices and IT systems. The latter will include hospital IT and Electronic Patient Record (EPR) systems as well as Laboratory information systems. The survey of Irish laboratories has shown that FBC reporting is already mixed within the country so this is a pertinent issue. The work already done by the ACSLM, IEQAS and consideration of the issue by the Irish professional bodies, in addition to the anticipated international recommendation, all serve as resources available to the HSE and the MedLIS project to move forward on this issue.

Proposal

It seems logical to synchronise the potential change in reporting units to the timescale for the National MedLIS project roll-out, which represents both an opportunity to introduce standardisation of reporting units for the FBC and an obligation to make a choice regarding which reporting units to adopt, since only one type of unit can be used for each parameter of the FBC. The ICSH published recommendation will shortly be available to support this proposed strategy from the scientific point of view. This will bring the advantages of adoption of an international recommendation already used by Ireland's nearest neighbour the UK as described above, thus providing future-proofing for Irish pathology practice in this area. Finally, given that it is already the case that different reporting units are used by different hospitals within Ireland; the change could in fact be implemented on a hospital-by-hospital basis according to the timescale for implementation of MedLIS. This would make the changeover more manageable in the first instance and allow each hospital in turn to benefit from the experience of those who are the first to implement MedLIS. The resources of the HSE, MedLIS project group and the Irish professional bodies who have already contributed to this project could all be used and co-ordinated towards ensuring a successful implementation of this important development.

References

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