The Laboratory Services Reform Programme

ADVICE NOTE

Laboratory services for children and pregnant and post partum women – managing issues related to reference intervals

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Document Owner / Author	Marie Culliton
National Service/Area	Office of the Chief Clinical Officer
Approved by:	Professor Martin Cormican
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The Laboratory Services Reform Programme offers the following advice:

1.1 Advice for Laboratory Users

1. Clinical samples from children and pregnant women may be processed by clinical laboratories that have the competence to perform the relevant analysis and report a valid measurement. There is no requirement that the laboratory be based in a hospital that provides paediatric or maternity services. Laboratory analytical methods are generally valid in measurement of parameters in samples from different age groups and physiological conditions
2. When submitting samples for analysis the date of birth should always be clearly legible and if a woman is known to be, or likely to be, pregnant or post-partum this should be clearly stated.
3. For a number of parameters the expected range of values for healthy children and for healthy pregnant/post-partum women may fall significantly outside of reference intervals developed from samples taken from otherwise healthy non-pregnant adults.
4. In all patients at all ages reference intervals are a guide to interpretation. A value within the reference interval is not an assurance of health and a value outside of the reference interval may be an expected physiological variation in certain population cohorts. Laboratory analytical measurements must always be interpreted by a person with appropriate expertise in the specific patient context.
5. It is particularly important when interpreting measured values from samples from children under 16 years old or from pregnant/post-partum women to be aware of variations from the expected range in otherwise healthy non-pregnant adults.

1.2 Advice for Laboratories

1. Laboratories based in a hospitals that do not provide paediatric or maternity services should continue to provide services for children and pregnant/post-partum women in the community in the absence of an alternative pathway, agreed with stakeholders, that ensures continuity of service
2. It is not practical and it is not essential for laboratories to generate in-house reference intervals for children and pregnant/ post-partum women in order to report analytical values for samples from children and pregnant/post-partum women.
3. Laboratories should indicate in their users-manual that reference intervals for the general population should not be assumed to apply to children and pregnant/post-partum women and should include a note on key points of variation in those cohorts OR provide reference intervals for those cohorts from an authoritative source OR point to a source of publically available guidance on interpretation of analytical values for those cohorts. Potential authoritative sources for paediatrics include data from 'the Celtic Ranges Project'[1]) or from the Canadian Caliper Reference Database [2, 3]
4. When reporting samples from children under 16 years old or from women known to be pregnant or post-partum laboratories should, whenever practical to do so, provide on the report reference intervals for those cohorts from an authoritative source OR point to a source of readily available guidance on interpretation of analytical values for those cohorts (as above).

2. Background

It is essential that there is ready access in hospital and community to routine and potentially urgent laboratory analytical services for children and pregnant/post-partum women. Undue delay in access is associated with significant clinical risk. In these cohorts of the population, the reference intervals developed for the general population may not be applicable for a number of parameters. This is also true for a number of other cohorts of patients with expected changes to values related to age, medication or other conditions.

The HSE's paediatric model of care, chapter 30, addresses Paediatric Laboratory Medicine [(1)]

'The vast majority of paediatric healthcare decisions are informed by diagnostic services, particularly radiology and laboratory results. A robust and responsive paediatric laboratory service is therefore vital to the provision of paediatric care. At present, these paediatric laboratory services are provided in laboratories throughout Ireland, reflecting the attendance of children across the full spectrum of primary, secondary and tertiary care paediatric services. In the majority of these laboratories, the samples from paediatric patients are managed within the same workflow as the samples from adult patients, which are also processed in these facilities. Such processing is readily achievable, given the small number of samples from paediatric patients relative to the number of samples from adults, and also given the low complexity of testing required for most primary and secondary care paediatrics. Specialist paediatric laboratory services are restricted to a small number of units, most notably the standalone paediatric laboratories in Temple Street Children's University Hospital (Temple Street) and Our Lady's Children's Hospital Crumlin (Crumlin). However, it is also recognised that many hospitals with maternity units manage significant volumes of laboratory tests on neonates, and that some specialised neonatal laboratory testing is also provided in these settings. In addition, it is acknowledged that a proportion of specialist paediatric laboratory testing is exported from these laboratories to large reference laboratories that provide testing for adult patients in Ireland, or to paediatric reference laboratories in the United Kingdom (UK) and elsewhere'.

Ideally, each laboratory would have reference intervals specific for cohorts of the population that vary significantly from the general population however this is often not practical. Declining service to children and to pregnant/post-partum women in the absence of an alternative appropriate pathway agreed with laboratory users is a much greater clinical risk than reporting valid measurements with less than ideal guidance on the expected range of values. Hospital laboratories that do not provide paediatric and maternity services should continue to provide services to children and to pregnant and post-partum women unless alternative appropriate pathway has been agreed with laboratory users. The risks associated with interpretation associated with reporting analytical values without in-house generated cohort-specific reference intervals can be managed in a practical and proportionate way as set out in this note.

3. Relevant Materials

1. Leonard A, Bolger T, Molloy E, Boran G. The CELTIC ranges project (comprehensive and effective laboratory test reference intervals for Irish children) methodology and results for renal profile tests in plasma on the Roche modularTM system. *Annals of Clinical Biochemistry*. 2023;61(3):163-172. doi:10.1177/00045632231202330

2. Adeli K, Higgins V, Trajcevski K, White-Al Habeeb N. The Canadian laboratory initiative on pediatric reference intervals: A CALIPER white paper. Crit Rev Clin Lab Sci. 2017 Sep;54(6):358-413. doi: 10.1080/10408363.2017.1379945. Epub 2017 Oct 11. Erratum in: Crit Rev Clin Lab Sci. 2020 Mar;57(2):145. doi: 10.1080/10408363.2019.1704475. PMID: 29017389.

3. CALIPER Pediatric Reference Interval Database https://caliper.research.sickkids.ca/#/

4. Paediatric Model of Care: Chapter 30 Paediatric Laboratory Medicine paediatric-laboratory-medicine.pdf

Authors: Developed by the Laboratory Services Reform Programme incorporating The National Clinical Pathology Programme.

Approved By: Martin Cormican MCRN 011105,
HSE Clinical Lead for Laboratory Services Reform Programme.

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