



# Critical biochemistry values and patient safety in primary care

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## Introduction

In 2001, the lack of a quality assurance framework was listed as a principal inadequacy in the current system of primary care [1]. In 2010, I suggested that requirement of the direct personal cell phone number of all off-site requestors of laboratory biochemistry tests be incorporated into governance arrangements for clinical laboratory accreditation. Successful communication to general practices of critical values which may be immediately dangerous for patient survival is an important aspect of test reporting. When implementing the system, 2.5% of GPs refused to submit their phone numbers and were asked to send their patient samples elsewhere. For the 2 years after the introduction of this policy, there were no cases where the laboratory could not find the relevant GP [2]. In a level 3 hospital where a similar policy was implemented, there were six incidents where the primary care provider could not be contacted out-of-hours.

Smartphones and artificial intelligence will change the clinical contact in the immediate future. Much medicine will be carried out from the home [3]. A national identity card could become the default identification number for electronic medical record and will allow the patient to be contacted directly by medical services when a critical value either in laboratory medicine or imaging is found.

## Government policy on patient safety

‘Healthy Ireland’ the Irish Department of Health statement of strategy 2016–2019 states that the Health Information and Quality Authority is the independent agency whose purpose

is to drive continuous improvement in the health and social care services including specifically safety and quality. A Patient Safety Licencing Bill is intended to regulate public and private health care providers [4]. To strengthen patient safety, the plan included the establishment in 2017, of the National Patient Safety Office and the National Advisory Council for Patient Safety. Furthermore, the intention to make a decisive shift towards primary care is reiterated. The government intends to support better integration between primary and secondary care.

Under the new Health Information and Patient Safety Bill 2017, the new Authority may set standards for the processing of personal health data but the minister must consult with the Data Protection Commissioner on any such standards [5]. The Strategy Plan also intends to make mandatory the reporting, to the authorities and to the patient harmed, of specified patient safety incidents or serious reportable events. It will be an offence not to do so.

In 2010, a national review of GP out-of-hours services was published by the Health Service Executive in Ireland [6]. There were clinical governance arrangements in place for medical/nursing staff. Triage by a nurse following protocols was routine. In defining the guiding principles, the welfare of the patient is paramount. Risk management is listed as a bullet point in the standard service-level agreement for GPs.

The Royal College of Pathologists published latest guidelines on the communication of critical and unexpected pathology results in 2016 [7]. For electrolytes, urea, creatinine and glucose, communication of critical results must be made within 2 h usually by telephone. The action limits for serum or plasma K are  $\leq 2.5$  and  $\geq 6.5$  mmol/l for both primary and secondary care. The listed comment states ‘Exclude haemolysis/old samples/EDTA contamination first. Exclude, by consensus, expected results or those being monitored such as renal dialysis patients or known chronic kidney disease’. The critical value for urea is 30 mmol/l for adults. The listed comment states ‘exclude by consensus expected results or those being monitored such as renal dialysis patients or known chronic kidney disease’. The value for plasma or serum

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creatinine is 354  $\mu\text{mol/l}$  for adults and the comment states ‘exclude by consensus expected results or those being monitored such as renal dialysis or chronic kidney disease patients’. The critical value for total creatine kinase is  $\geq 5000$  U/l. The accompanying comment states ‘agree specific cut points with key users locally (A&E, liver unit/medical admissions, GI medicine’.

## Local experience

A level 3 hospital processed 242,461 and 227,024 blood samples in 2016 and 2017 respectively in the routine chemistry laboratory. Forty percent of samples originate from general practice. The number of sodium/potassium samples reported was 106,138 and 121,450 in 2016 and 2017 respectively. In the immediate catchment area of the hospital, there are 87 GPs listed by the Irish Medical Directory for 2016. A diary record of phone calls from the laboratory staff to the author consultant chemical pathologist to report an inability to find a clinical recipient for a critical value for patients outwith the hospital in primary care was kept covering the period from 2016 to 2018.

There were eight patients during the period September 2016 to February 2018 with critical biochemical values, as defined by the 2016 limits published by the Royal College of Pathologists, where the primary care service for the specific patient was uncontactable from the laboratory. Locum covering services are inadequate in these circumstances because they do not have access to the patient’s data or the patient themselves. These were three cases of hyperkalaemia— $\text{K}^+$  6.5, 6.5 and 6.8 mmol/L, one case of uraemia with urea 31.3 mmol/L with creatinine 479  $\mu\text{mol/L}$ , another case with urea 170 mmol/L, two cases with raised total CK of 8561 U/l and CK 11182 U/L with left-sided chest pain, and one case with sodium of 161 mmol/L. The results in all cases were also routinely transmitted electronically to GPs by HealthLink on the day of processing.

Not all laboratory professionals agree on the exact definition of a critical value. In 2012, the GP liaison group in the Lothian area of Scotland published their agreed abnormal laboratory results to guide contacts with practices [8]. The limits were more conservative than those of the RCPATH. Potassium values  $> 6.1$  and  $< 3.0$  mmol/L were to be phoned as were sodium values  $< 125$  mmol/L and  $> 150$  mmol/L. The similar plasma creatinine values were  $> 250$   $\mu\text{mol/L}$  and urea  $> 30$  mmol/L.

Using these values as a guide to the necessity for phoning, an additional 15 cases of hyperkalaemia between 6.2 and 6.5 mmol/L were recorded. The values were  $6.2 \times 5$ ,  $6.3 \times 6$  and  $6.4 \times 4$  mmol/L. There was one case of hypokalaemia  $\text{K}^+$  2.6, one case of hyponatraemia sodium 122 and one case of renal failure with creatinine 333  $\mu\text{mol/L}$  and urea of 28.1 mmol/L. Thus, a total of 23 cases occurred involving

21 different GPs where the laboratory could not directly access the GP practitioner to report the result. That is about 24% of the catchment area practitioners. The phone calls were made from 3.45 pm to 8 pm followed by text messages where a cell phone number was available. The laboratory manual logging system did not capture the appropriate cell phone details when new GPs commenced practice in the catchment area. This remains a patient safety risk and requires repeated annual audits.

Worldwide for decades, measurements of serum sodium and potassium are by far the most common blood tests performed in all routine biochemistry laboratories. Recent reports underscore the need for continuous education and re-education in the interpretation and treatment of basic electrolyte abnormalities [9, 10]. In the recommendations of the O’Hara inquiry into hyponatraemia deaths in children, the issue of continuous re-education in common electrolyte abnormalities is not emphasised [9]. Furthermore, the NHS issued a safety alert on the safe and timely management of hyperkalaemia in August 2018. The warning on hyperkalaemia across the NHS service providers has already been addressed by good practice in UK laboratories as noted in an immediate e-mail comment by the Association of Clinical Biochemists [11].

Patient safety means putting the patient really first with communications, knowledge and regulation. Never order a test if you avoid critical communications and are incompetent in the interpretation and treatment of biochemical common abnormalities. There is clearly a problem in general practice.

Out-of-hours GP locum services and co-operatives are not the answer even though many of their leaders resist this. Text messages with the result included seems the best option particularly with apps like ‘whatsapp’ where there is a tick when the message is received. It is in the patients’ interest that laboratories insist that such communication is available to contact all laboratory users.

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