

BIVDA: tech safety drive “a missed opportunity”

The British In Vitro Diagnostics Association (BIVDA) has mixed feelings over the way the UK public is being encouraged to improve the safety of the self-care segment of medical technology use (see page 2).

Citing this week's launch of such an initiative by the Medicines and Healthcare products Regulatory Agency (MHRA), the association's director general, Doris-Ann Williams, told *Clinica* that, with regard to improving the safe access to, and use of, home testing kits, it lacked due focus on highlighting key safety guarantees already in place, namely through the CE mark. Particularly given the burgeoning internet-based market for self-care testing, she noted, the CE mark provides the best guarantee of quality and safety.

“BIVDA applauds the MHRA's initiative in raising awareness regarding safety in the general public. However with regards to home testing it was very disappointing to see that information was not provided to warn people to look for the CE mark on the packaging to ensure they are purchasing a bona fide product,” said Ms Williams.

“This seems to be a missed opportunity, especially as it is illegal to place a non-compliant product – i.e. without a CE mark – on the market,” she added.

With regard also to wider device-related reporting, she believes “a trick has been missed in the provision of information about CE marking on the packaging”.

Commenting on her being approached by some of the UK's leading mainstream media, Ms Williams found cause to warn that the general tone of the press release issued by the MHRA is, she believes, “rather alarmist and could engender a lack of confidence in medical devices among the public”.

UK: renal investments, step change in care

Last year's introduction by the UK NHS' of eGFR (estimated glomerular filtration rate) as a standard measurement of kidney function, together with better case reporting, was a significant factor in detecting 1.5 million cases of chronic kidney disease (CKD) in the year to the end of March 2007.

This is one of the highlights of the second progress report on the implementation of the national service framework (NSF) for renal services. Historically, the report acknowledges, CKD has been “grossly underdiagnosed”, leading to a costly emergency dialysis regime that can be avoided through early diagnosis.

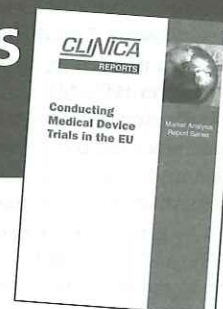
An “ever-expanding need for renal replacement” – 45,000 by 2014

However, despite the “step change advancement” in early detection, the challenges posed by CKD are not being met. The “ever-expanding population requiring dialysis” is expected to see 45,000 patients require renal replacement therapy by 2014 in England alone, compared to 27,000 in 2001. Dialysis currently costs the NHS £20,000-25,000 (\$39,400-49,250) annually per patient.

Since the previous progress report (September 2005), investments in renal care facilities have led to the opening of three main units (of between 12-20 dialysis stations) and 11 satellite units. A further six satellite units are due to open “within the coming months”.

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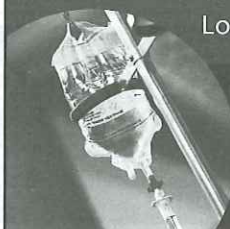
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