

# BRITISH MEDICAL JOURNAL

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*We may return unduly long letters to the author for shortening so that we can offer readers as wide a selection as possible. We receive so many letters each week that we have to omit some of them. Letters must be signed personally by all their authors. We cannot acknowledge their receipt unless a stamped addressed envelope or an international reply coupon is enclosed.*

## Diagnostic kits and the clinical chemist

SIR,—I was interested in the article on the self-monitoring of blood glucose levels in diabetic pregnancy (24 November, p 1333) and obviously this illustrates a specific advance in patient care. However, this type of test is the tip of an enormous iceberg resting with the manufacturing companies and, as a clinical chemist, I am concerned by certain aspects of tests performed outside laboratories that must be closely monitored.

Clinical chemistry itself has been the main target for diagnostic products and kits for many years and while many of these have been a significant influence on our work pattern and reliability many kits can be shown to be inaccurate and unreliable. As these are entering a laboratory environment in general they are nipped in the bud and quietly expire. Apart from this natural death the DHSS has a clinical chemistry section that can issue Hazard Notes or otherwise prevent the sale of unsuitable products. The reason that poor kits are released in the first place is that manufacturers just do not have at their disposal realistic testing materials or situations. It has taken many years for clinical chemists to present an organised front to these manufacturers, but now that this market is so controlled and particular an easier outlet is being sought. By defining a product as

suitable for ward use there is a direct entry into the hospital via pharmacy departments for kits and reagent strips that may or may not be accurate or reliable enough for the use to which they will be put. Manufacturing companies exist to make a profit not to provide the best service for the patient, and before clinicians adopt tests of this nature they need to take informed decisions. The clinicians need to establish whether there is an acceptable alternative and a trip to the local laboratory to discuss an alteration in work pattern may be a start. Laboratories are now emerging from a deluge of work, in the past channelled straight on to inflexible equipment, to ask such questions as whether we are actually providing the service clinicians require. When it has been decided that the laboratory cannot provide a service it is valid to consider the manufacturers' alternatives. The DHSS enters here as it runs evaluations of many products in a realistic fashion. It has, in fact, just completed an evaluation of glucose meters showing that not all are satisfactory. Once a basic validity has been established a local test needs to be performed using the operators who will, in fact, be providing the test results. In this way any rogue tests should be eliminated.

To return more specifically to glucose

strips and meters, many clinical chemists would agree that a highly motivated, specifically trained diabetic patient on an adequate meter will be all right. To take this meter into an intensive care unit is, however, a different situation entirely. Here you are faced with multiple operators, probably a poorly maintained machine, and a rapidly changing, metabolically complex patient. Often these patients are incapable of communication and no type of informed consent can be obtained. Within the South-western Region there have been two deaths in cases where incorrect clinical decisions have been based on strip results. There is no comeback to the manufacturers since the glucose stick and meter can be shown to be reliable if correctly stored, used, and operated. The sticks and meters often have relatively poorer performances at the clinically important upper and lower ends of the scale, once again limiting usefulness in the extreme situations liable to be found in an intensive care unit. The strips can vary from manufacturer to manufacturer; the Ames Kinetic type needs a stricter adherence to timing than the Boehringer endpoint type, though in the latter sensitivity is lost at high levels.

And so, in summary, please use the expertise of the British clinical chemist; we have a