Technological challenges in diagnosis and management of HIV infection in resource limited settings

Relatively quick and cheap tests can work but must be properly monitored

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With the HIV epidemic in its third decade, appropriate use of technology in resource limited settings has taken on added importance as priorities shift from detection and prevention to care and support for people living with HIV. At the same time, there is a continuing need for evaluation of and improvement in the critical diagnostic tools, such as rapid tests for HIV, which have become indispensable in settings with a high prevalence of infection.

In this week's *BMJ* two studies look at such evaluations. MacLennan and colleagues[1] assess the diagnostic accuracy and clinical utility of a simplified flow cytometry method for measuring CD4 counts that promises a more affordable alternative for routine clinical use in resource limited settings. Gray and colleagues[2] highlight problems encountered with the use of rapid tests for HIV screening in rural Rakai, Uganda.

As the world moves towards universal access to antiretroviral treatment, healthcare providers are confronted with many complexities in providing uninterrupted lifelong care. Clinical staging of HIV disease does not fully predict immunological status, and hence CD4 cell counts remain the most effective indicator for starting therapy and assessing immunological response to drug regimens. The World Health Organization has noted that "one of the most crucial needs in the developing world is universal access to affordable and locally usable CD4 testing technology."[3] The current shortage of laboratories that can perform counts in resource constrained settings jeopardises the success of campaigns to scale up antiretroviral treatment and distribute lifesaving drugs to millions of people living with HIV.

Current flow cytometry methods for CD4 counting, with reagents that cost from $3 (£1.50; €2.20) to $6 per test are expensive and possibly too complex for many resource constrained settings. MacLennan and colleagues compared BlantyreCount, a simplified counting method, with TruCount for both accuracy and clinical utility at a clinic for antiretroviral therapy in southern Malawi.[1] BlantyreCount comprises "primary CD4 gating" using one antibody against CD4 and side scattered light to discriminate between lymphocytes and monocytes. This single platform method reduces the costs of reagents by more than 91% and makes laboratory procedures much simpler than those for existing flow cytometry methods. The authors show that the limits of agreement for BlantyreCount and TruCount are excellent (–48.9 to 27.0 cells/µl for absolute counts in the CD4 range <400 cells/µl, and –2.42% to 2.37% for %CD4/lymphocytes) but note that even this simplified method still requires a level of technical expertise not always present in resource poor settings. More importantly, the paper correctly points out that non-reagent costs, especially capital expenses and maintenance, which often come to more than $100 000 for a flow cytometer instrument, may still limit applicability in many settings.

Gray and colleagues examine the issue of false positive tests during screening for a randomised trial of male circumcision for HIV prevention in Rakai, Uganda.[2] The trial used a rapid HIV test algorithm to screen potential participants. Tests yielded "weak positive" bands that resulted in low specificity and low positive predictive values when confirmed using an enzyme immunosorbent assay and western blot. When weak positive bands were excluded, the number of false positives fell. This is an important finding because previous research had shown that algorithms combining two or more rapid tests resulted in very high levels of sensitivity and specificity.[4-7]

Although more research is needed to establish whether these results can be generalised to other populations and specific HIV subtypes, the study raises an important question that needs further exploration. Clearly, there is a compelling need to re-examine the performance of rapid tests in various settings using a gold standard such as enzyme immunosorbent assay and western blot to verify results. Reducing the risk of false positives is important in both research and HIV testing programmes because of the stigma associated with a positive HIV test.

What are the larger implications of these findings? Firstly, it is important that we continuously improve on existing technologies to make them more affordable, accurate, and widely available. Although the cost of flow cytometry is initially high, strategically located facilities such as regional centres for antiretroviral treatment can provide the high volume of patients needed to offset the capital investment, as long as reagents are affordable. Secondly, there is no dearth of talent in resource constrained settings; only a lack of political will to make the necessary investments in training and quality control. Finally, as HIV is such a serious and stigmatised condition, it is essential that we exercise vigilance to ensure that technologies are performing optimally. As Gray and colleagues suggest, it is prudent to routinely retest a sample of specimens using a gold standard method to maintain quality control.

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Body mass index cut offs to define thinness in children and adolescents

A new chart will be most useful in countries in social, economic, and nutritional transition where both undernutrition and overnutrition are prevalent

RESEARCH, p 194

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Assessment of risk for overweight by monitoring body mass index is now recommended in developed countries and more recently in urban areas of less developed countries. Body mass index is known to track significantly from childhood, to adolescence, and then to adulthood.[1] Body mass index should therefore be assessed and monitored during childhood and adolescence to allow for early, and perhaps more effective, intervention strategies. Tim Cole and colleagues' validated thresholds or cut offs for body mass index, recommended by the International Obesity Task Force to define and identify overweight and obesity in childhood,[2] are internationally recognised.

Rather less attention has been paid, however, to the importance of assessing body mass index to monitor undernutrition. In this week's *BMJ*, Cole and colleagues extend this work to provide cut offs for body mass index to define "thinness" in children and adolescents.[3]

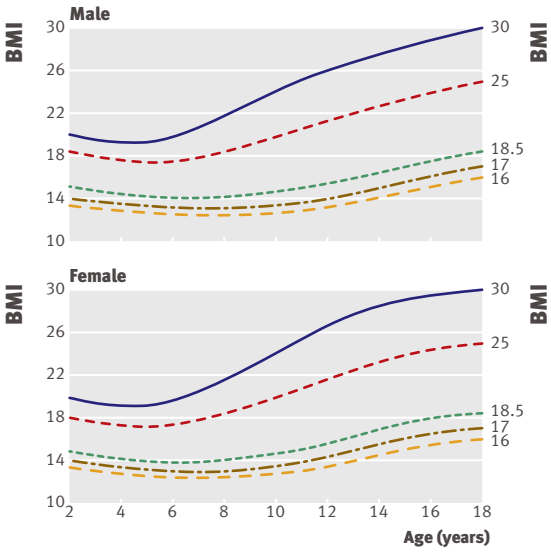
Malnutrition, or more specifically undernutrition, in children has long been defined in terms of height and weight in relation to age in relation to various cut offs, which are usually based on representative samples of European or American children. The choice of cut off is fundamentally important to identify correctly those children at risk and, ideally, should be related to known outcomes for morbidity and mortality. Yet, while adult body mass index values of 25 (overweight) and 30 (obesity) are related to morbidity, evidence on morbidity related to cut offs for thinness, particularly in children, is less clear. Current cut offs for thinness in children are related to either the third or fifth centile of reference charts for body mass index and cut offs for malnutrition (undernutrition) to weight for height z scores (standard deviation scores).

In France, for instance, the third centile of the French reference chart for body mass index is recommended for defining thinness in adolescents,[4] while the World Health Organization (WHO) expert committee on anthropometry[5] recommends the fifth centile of the American National Health and Nutrition Examination Survey (NHANES) reference database to define thinness in adolescence.[6] Cole and colleagues argue that the current WHO recommendations for defining thinness are inappropriate because the NHANES dataset dates from the early 1970s and is of "uncertain validity." In addition, the latest WHO growth standards[7] are truncated at age 5, leaving no current reference that effectively covers the age range of childhood to adolescence.

Cole and colleagues' response to this void is to use the same technique on a sample of almost 200 000 subjects from six countries (Brazil, United Kingdom, Hong Kong, the Netherlands, Singapore, and the United States), the source of the data for the International Obesity Task Force reference standards for overweight and obesity, to generate cut offs throughout childhood and adolescence that identify the child at risk because of thinness. The chosen cut off is a body mass index of 17 kg/m^2 at age 18 coinciding with the WHO grade 2 cut off for thinness in adults, and to a value of –2 z scores for body mass index in Cole's combined dataset.

In addition, cut offs of 18.5 kg/m^2 and 16 kg/m^2 are also included to coincide with WHO grade 1 and grade 3 thinness in adults and allow the distinction between different grades of undernutrition and thus different levels of risk in children. This is important, given that the prevalence of child mortality is directly related to the degree of malnutrition.[8] Furthermore, a value of –2 z scores has the added advantage of being about 80% of the median body mass index and is equivalent to the WHO definition of wasting (low weight for height).

These new cut offs are most suitable for use with samples of children in comparative studies of the prevalence of thinness, rather than as references or standards for current or recommended body mass index by age and sex. Limitations are that they use the same cut offs for males and females and do not adjust for pubertal development or the tempo of adolescent growth and maturation. Both sex and pubertal development are associated with dramatic changes in body composition and detailed statistical control of both variables is usually needed during analyses.



Cut offs for thinness by age and sex defined to pass through BMI 16, 17, and 18.5 at 18 years, with the international cut offs for overweight and obesity based on BMI 25 and 30[3]

Moreover, body mass index is not a direct measure of total body fat or total body lean mass, even though it correlates surprisingly well with fat and lean tissue.[9]

The new cut offs proposed by Cole and colleagues need to be tested in studies of the association between thinness and morbidity in children and adolescents. They are potentially most useful in countries that are experiencing social, economic, and nutritional transition such as South Africa, Brazil, China, and Russia,[10] and in which both overnutrition and undernutrition are prevalent. Having a single chart that is consistent at both ends and is constructed from international data is helpful in both epidemiological and clinical settings.

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Rediscovering dignity at the bedside

It is possible to teach the ABCD of preserving patients' dignity

ANALYSIS, p 184

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It was a comfort when Gerasim sat with him sometimes the whole night through . . . Gerasim was the only one who did not lie; everything he did showed that he alone understood what was happening, and saw no need to conceal it . . . and so the relationship was a comfort to him.
From Leo Tolstoy, *The Death of Ivan Ilyich*

The *Oxford English Dictionary* defines dignity as "the state of being worthy of honour or respect" or "high regard or estimation." The 1948 universal Declaration of Human Rights and article 1 of the Charter of Fundamental Rights of the European Union recognise dignity as a human right.[1] Improving dignity in care is a core theme in guidance from many governments across the globe. For example, in England the Department of Health launched a policy earlier this year to "create a zero tolerance of lack of dignity in the care of older people in any care setting."[2] But how are we to achieve dignity in care? It is easier to identify when dignity is lacking than to define what it means. So what does make care dignified?

The article in this week's *BMJ* by Chochinov offers clinicians a straightforward empirical framework to help them achieve dignity conserving care.[3] Chochinov focused on dignity after finding fluctuations in the will to live of patients approaching the end of life. Factors associated with the loss of will to live were: feeling a burden on others; depression; and other symptoms, including breathlessness.[4] Dignity appeared to be a core concept underlying these factors. A European programme, including participants from Spain, Slovakia, Ireland, Sweden, France, and the United Kingdom, found that despite a wide range of backgrounds and situations, there was a sustained level of agreement about the meaning and experience of human dignity in the lives of participants. Three overarching themes were identified: respect and recognition; participation; and dignity in care.[5] Loss of independence, fear of becoming a burden, not being involved in decision making, lacking access to care (including palliative care facilities), and some attitudes of staff, especially when people felt vulnerable and lacked power, were all identified as fracturing their sense of dignity. Spiritual matters, also important in dignity, are strongly associated with communication, both between professionals and patients, and between patients and families.[6]

Adapting the well known mnemonic "airway, breathing, and circulation (ABC)" Chochinov has developed

an ABCD framework for dignity conserving care that is easy to remember and understand. His A—attitude—has strong resonance across other research. Parallel work in examining training of communication skills has also shown that changing attitudes is fundamental to ensuring sustained improvements to communication skills.[7] However, changing attitude is not as easy as checking the airway. It should begin early in training but, as Walsh has argued, many medical students hear the same message again and again without a stepwise approach to developing skills. Fallowfield found that it is possible to teach communication skills using individually suitable approaches similar to many of those outlined in Chochinov's article.[8]

Perhaps changing attitudes needs to pervade all medical school teaching. When visiting a Buddhist medical school in Taiwan one of us (IJH) was impressed to see that from day one medical students were taught to respect the people who had donated their bodies for anatomy dissection. Pictures and accounts of the person during life were placed at the head of each cadaver. Before starting any examination the medical students paused and gave thanks to the person for donating his or her body for study.

The introduction of the arts in many medical school curriculums may help to achieve Chochinov's B and C, changing behaviour and ensuring compassion. In many countries medical students are being placed within larger colleges and universities which have many faculties, including the humanities, ethics, theology, health policy, as well as the social sciences (psychology, sociology, anthropology). Understanding the different cultural meanings of symptoms, needs, and dignities is important in most countries because doctors encounter patients from different cultural and ethnic backgrounds.[9 10]

Ensuring dignity within a tight budget may be challenging. Chochinov's D—for dialogue—requires time with patients. As the quotation from *The Death of Ivan Ilyich* shows, spending time with patients is important; this is not easy to measure in the performance targets set by healthcare funders. Thus time, dialogue, compassion, and empathy can be devalued. Here, Chochinov's article is particularly helpful. His tables provide simple guides to the types of attitudes, behaviours, compassion, and dialogue that could be easily adopted and form the basis for teaching and providing care in many health and social care settings, both in the community and in institutions. Perhaps Chochinov's ABCD should be the first mnemonic we teach all professionals entering health and social care, even before airway, breathing, and circulation.

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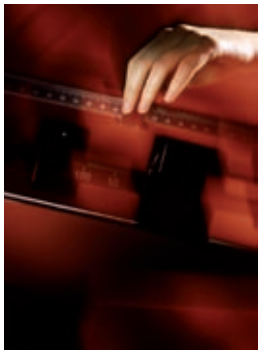
MARK THOMAS/SPL

Weight and pregnancy

Women who maintain a normal healthy weight, before, during, and after pregnancy have better outcomes



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Women of reproductive age are bombarded with messages about diet, weight, and body image. There is growing concern on the one hand about an epidemic of obesity, and on the other about a culture that promotes "size zero" as desirable, irrespective of a woman's natural build. Pregnancy is one of the most nutritionally demanding periods of a woman's life, with an adequate supply of nutrients essential to support fetal wellbeing and growth.[1] With at least half of all pregnancies unplanned, women need to be aware of the implications of their weight for pregnancy, birth, and the health of their babies. However, the potential to provide women with conflicting information about weight, weight gain, and weight loss extends to pregnancy and birth outcomes.

Over one billion adults in the world are now overweight, with more than 300 million clinically obese.[2] In the United States, the prevalence of obesity in women aged 20-39 years rose from 9% in 1960-1962 to 28% in 1999-2000.[2] While weight and obesity have long concerned women in relation to body image and lifestyle matters, the association between weight gain and adverse pregnancy outcomes is less well recognised.

A recent nationwide Swedish cohort study involving 207 534 women from 1992 to 2001 examined the associations between changes in body mass index from the beginning of the first pregnancy to the beginning of the second in relation to adverse maternal and perinatal outcomes.[3] Significantly increased rates of pre-eclampsia, gestational diabetes, pregnancy induced hypertension, and large for gestational age infants (odds of an adverse outcome were almost twofold in each case) were evident with increases in body mass index of just one to two units, and they increased progressively thereafter. An increase of greater than three body mass index units significantly increased the rate of term stillbirth, independent of obesity related diseases. Importantly, weight gain during the interval between pregnancies was strongly associated with major maternal and perinatal complications, independent of whether women were overweight (body mass index >25) by definition or not.

The key message is that women of normal weight should avoid gaining weight between pregnancies. In addition, overweight and obese women (body mass index ≥30) are likely to benefit from weight loss before becoming pregnant. However, while the authors have argued convincingly for a causal relation between maternal weight gain and adverse pregnancy outcomes, the advice given must be balanced to avoid weight swings in the opposite direction.

The association between low body mass index and subfertility is well known. Much less publicised is the association between low body mass index or substantial weight loss and pregnancy related complications, such as preterm birth and low infant birth weight. A second cohort study evaluated the impact of changing maternal nutritional status on the risk of prematurity, and specifically whether increasing or decreasing body mass index altered this risk.[4] Overall, women whose body mass index fell by five or more units between pregnancies had a higher risk of preterm birth than women whose weight remained stable or who gained weight. The increased risk was particularly pronounced for women who had already experienced a preterm birth (80% *v* 28%). We should ensure that women of low body mass index attain a healthy weight before conception to reduce the risk of preterm birth and low infant birth weight. We should also counsel women with a history of previous preterm birth to maintain a healthy weight to prevent recurrence. In the context of the neonatal morbidity and mortality associated with preterm birth, low body mass index is one of the few modifiable risk factors.

The challenge for healthcare professionals is in interpreting these findings and advising women accordingly. Women are at increased risk of different but equally serious adverse pregnancy outcomes if they gain or lose an excessive amount of weight between pregnancies. Although apparently conflicting, these studies show how important it is to attain and maintain a normal healthy weight before, during, and after pregnancy. Most women wish to achieve the best start in life for their babies. This powerful motivation could be used to achieve behavioural changes in terms of a healthy balanced diet and maintaining a stable weight within the normal range for the woman's build. This approach offers long term health benefits for women and their babies. Certainly, any woman who has had a poor obstetric outcome should be encouraged to achieve an optimal weight before planning another pregnancy. The challenge for many women of achieving a stable body mass index cannot be underestimated, and this may require professional support and advice.

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What to do with insolvent hospitals

Will politicians allow providers to fail?

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The progress made by the NHS in England in converting a net deficit of £547m (€812m; $1121m) in 2005-6 into a net surplus of £510m in 2006-7 has given the government a breathing space. Yet behind the headline figures lies a picture that is more complex and promises to become more troubling as the programme of health reform gathers pace.

The net surplus in 2006-7 resulted from a gross deficit of £911m and a gross surplus of £1421m.[1] Moreover, the gross deficit was concentrated in a small number of organisations, some of which face financial difficulties that cannot be easily resolved. To address these difficulties the Department of Health is working with strategic health authorities to identify long term solutions, focusing on 17 NHS trusts with the greatest challenges.

The experience of converting deficits into surpluses has shown that there are three main approaches to dealing with NHS providers in difficulty.[2] The first is to develop recovery plans tailored to the circumstances of providers, often linked to the provision of loans.

In many cases, these recovery plans focus on reducing pay costs by cutting the use of agency staff, eliminating unnecessary management posts, and improving the control of staff vacancies. Recovery plans have also found savings in non-pay costs, such as improving office supply purchasing, reducing furniture costs, rationalising estate costs, and improving the effectiveness of information technology.

The second approach is to merge providers with neighbouring providers that have a record of sound financial performance. The first example of this was the merger of the Heart of England NHS Foundation Trust with Good Hope Hospital NHS Trust in April 2007.

In this case merger was preceded by a partnership between the two organisations in which the Heart of England trust lent its management expertise to Good Hope Hospital to convert a loss of £6m to a surplus of £1.7m. The path to a full merger was cleared by dealing with Good Hope Hospital's historic debt through the issue of £18m of public dividend capital, with the interest on the capital being paid by the strategic health authority. Freed of the need to pay back the debt, the Heart of England trust could then take over Good Hope Hospital.

The third approach is to recognise that providers may have to "exit" the emerging healthcare market. This is an option being considered for NHS trusts with the biggest deficits and also for NHS foundation trusts that find themselves in serious financial difficulty. Financial failure on this scale is likely to be unusual, but the architects of the reforms argue that the threat needs to be real enough to create incentives for providers to continuously improve their performance.[3]

If a hospital or other provider is to close arrangements will have to be made for the continued provision of essential NHS services to the populations served by that provider. The government's consultation document on regulation made it clear that this was the responsibility of commissioners, but this is a new role for commissioners and it is not clear that they have the ability to deal with the consequences of large scale financial failure. The consultation document also announced that proposals were being prepared to establish an insolvency regime for foundation trusts, and the time it is taking to develop such a regime is a sign of the complexity of deciding how insolvency should be handled.[4] Foundation trusts, unlike others, are free to borrow money from commercial lenders, but the lack of an insolvency regime means that commercial lenders are uncertain about the protections available to creditors in the case of a trust failing financially.

To invoke the language of insolvency, exit, and merger is to signify the transformation that is taking place in the NHS in England as the current round of health reforms are implemented. The conundrum for the government is how to reconcile the development of a more transparent and businesslike way of dealing with financial difficulties and ultimately failure with the public's expectation that services will continue to be available in each locality.

Also, when the consequences of competition collide with the reality of politics, will ministers follow the logic of the reforms and allow unsuccessful providers to fail, or will they intervene in the market to preserve access to services?[5] The last time this question arose, under the Conservative government's internal market reforms in the 1990s, politicians lost the courage of their convictions and acted to blunt the impact of competition. Government intervention was most evident in London, where additional funds were given to help hospitals in financial difficulty and commissioners were told not to move their contracts in order to prevent instability among providers. Subsequently the Tomlinson inquiry was set up to prepare a plan for the future of health services in London as politicians acknowledged that the internal market might result in unacceptable consequences for hospitals.[6]

An early challenge for Gordon Brown as the new prime minister will be whether to do the same or to keep faith with the policies of his predecessor and accept the pain that will undoubtedly accompany the reconfiguration of services in areas where NHS providers fail financially. The way in which he responds to this challenge will provide important clues to the direction of the NHS under his stewardship.

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