

target for prevention, is matched by a similar increase in symptomatic intracerebral haemorrhage and the absolute rates of both events are similar.<sup>9-11</sup> Worse still, the risk factors for VTE and symptomatic intracerebral haemorrhage are similar (eg, age and severity) so it is not possible to identify patients who are at high risk of VTE but not bleeding. Thus, prophylactic heparin cannot be recommended routinely after ischaemic stroke. However, low-molecular-weight heparin (which is more effective than unfractionated heparin<sup>12</sup> and only needs to be given once daily) should probably be used in patients who are at very high risk of VTE, such as those with previous VTE, known thrombophilia, or morbid obesity.

In summary, GCS do not reduce DVT or overall VTE in patients with recent stroke; indeed, they damage the skin and might promote limb ischaemia. GCS should not be used after stroke and current guidelines<sup>13,14</sup> will need to be amended. No specific prophylaxis appears to be necessary, although early rehydration, mobilisation, and aspirin are key cornerstones of good stroke care. Prophylactic heparin should be used only in patients at very high risk of VTE; routine use, as currently recommended in guidelines,<sup>13,14</sup> is not appropriate because of the increased risk of intracerebral haemorrhage. The role of GCS now needs to be assessed urgently in other settings where they might also lack efficacy, including in general medical patients.

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## Understanding childhood sexual abuse in Africa

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In *The Lancet* today, Avid Reza and colleagues present survey data on sexual violence in girls in Swaziland.<sup>1</sup> In this survey, one of the few nationally representative samples from Africa, a third of girls and women aged 13-24 years reported some form of sexual violence before age 18 years. Most perpetrators were men from their own household or in the immediate neighbourhood. These data should dispel perceptions that Africa has somehow escaped this global tragedy.

Sexual abuse of girls is widely reported by Africa's popular press, often in the context of school.<sup>2</sup> However, few studies have examined the frequency and nature of sexual violence

in a representative manner from national or subnational populations. Where studies have been done, methodology and definitional issues have limited comparability across sites. Nonetheless, the patterns from population and anecdotal studies in east Africa and elsewhere have found widespread sexual abuse of girls in patterns consistent with those reported from Swaziland.<sup>3-6</sup> Reza and colleagues sought information about multiple types of sexual violence against girls, and their work can form a benchmark for future studies. Results from sexual-abuse surveys are thought to widely underestimate prevalence, because the trauma surrounding events might affect recall and the

willingness to disclose the traumatic event and circumstances. Additionally, as noted by Reza and colleagues, sexual violence is often a recurring event. Understanding the dynamics and predisposing circumstances for recurrence is central to the establishment of measures for prevention and intervention.

In addition to documentation of abuse patterns, Reza and colleagues examined the longer-term consequences of childhood sexual abuse. Other studies have found links between abuse and substance-use disorders, anxiety disorders, depression, suicide, and risky sexual behaviours;<sup>6</sup> many of these factors were present in Swaziland as well. Resulting problems in mental health cause substantial strain on family and communities, individual functioning, and socio-economic productivity.<sup>6</sup> The adult HIV prevalence of 26% in Swaziland adds significantly to the risks of sexual abuse. The widely held African belief that an infected male can be “cleansed” of HIV through sexual intercourse with a virgin puts younger girls at particular risk in communities with a high prevalence of HIV.

Certainly, better data are needed to characterise the scale of abuse problems in Africa, against boys as well as girls. In particular, a clearer understanding of the links between sexual violence and mental health issues in varying cultural contexts will help improve assistance, and methods now exist for examining this link.<sup>7</sup> However, further characterisation of sexual violence must not deter the formation of a strong service-oriented response to what is clearly a major health issue. Concerted action is required both to address prevention of sexual abuse and to support those who are abused. Taking proactive measures to reduce the negative effects of abuse and trauma on mental health can prevent the extensive long-term psychological sequelae that result from, and create, cycles of violence. These measures can also prevent maladaptive behaviour patterns, such as risky sexual behaviour, and help the survivors themselves prevent recurring abuse or violence towards themselves, their family, and the wider community.<sup>8,9</sup> Many of these services can be provided through community organisations.

Within health services, changes must aim to make clinicians aware of the trauma associated with sexual violence, give them the skills for effective interventions, and ensure access for individuals in imminent need. Strengthening this capacity within frail African primary-health-care systems remains a challenge.

## The printed journal includes an image merely for illustration

It is important to recognise that the trauma resulting from sexual violence worldwide goes beyond the circumstances described by Reza and colleagues. Driven by increasing economic strictures, children are sexually exploited for cash or in-kind remuneration in many countries, are trafficked, or both. In conflict settings, girls might be seized by insurgents to serve as combatants or sex slaves. These events create a heavy burden of psychological trauma and sequelae that persist for years, if not life. The clear priority is to develop creative approaches to prevent and treat childhood sexual abuse. These approaches should go beyond the limits of the health system to involve community-based organisations and non-governmental organisations, including the active religious groups in Swaziland and throughout much of Africa. Governments must actively support such initiatives; and the first steps towards these initiatives are to face up to the extent and consequences of the problem.

To date, health programmes have largely avoided the needs of children who have been sexually abused, as such programmes seek a wider focus in reproductive health and gender-based violence in adults. A shift in focus to include children is even more urgent in regions with high seroprevalence of HIV. This persistent global tragedy for children is too large to continue ignoring.

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## Translating statistical findings into plain English

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Clinical trial reports usually give estimates of treatment effects, their confidence intervals, and p values. The statistical methods and their technical meaning are well established. There is less clarity about the concise interpretative wording that authors should use, especially in the abstract and conclusions and by others in commentaries. The following guidance assumes that one short sentence needs to capture the essence of a trial's findings for the primary endpoint.

Various scenarios can arise (figure). Scenario A has the treatment effect very highly statistically significant ( $p < 0.001$ ); in, for example, the comparison of everolimus with placebo for progression-free survival in advanced renal-cell carcinoma.<sup>1</sup> Such strong evidence provides proof of treatment efficacy beyond reasonable doubt, justifying the statement "everolimus prolongs progression-free survival". However, even extreme p values are not definitive proof.

Scenario B has greater uncertainty even though the (artificial) barrier of  $p < 0.05$  is reached: eg, the LIFE trial.<sup>2</sup> There is some evidence of efficacy but  $0.01 < p < 0.05$  means the play of chance (ie, no true effect) cannot be dismissed, and the lower confidence limit close to zero means the true effect might be small. Hence some doubt is appropriate: "treatment X seems superior to treatment Y" or "patients receiving treatment X had significantly fewer primary events". The absolute benefit and its confidence interval<sup>3</sup> are an important guide to clinical interpretation. In LIFE,<sup>2</sup> treatment with losartan led to 4.1 fewer cardiovascular events per 1000 patient-years than did atenolol (95% CI 0.6–7.6,  $p = 0.021$ ), which is small enough to justify "losartan confers modest benefits".

Scenario C casts further doubt on whether true efficacy exists, with a p value slightly above 0.05: eg, the TORCH trial<sup>4</sup> with  $p = 0.052$  for mortality. Remember the correct

interpretation of p values:<sup>5</sup> statistical significance is on a continuous scale, the smaller the p value the stronger the evidence, and  $p < 0.05$  is an arbitrary cutoff with no rational justification.  $p = 0.049$  and  $p = 0.051$  carry essentially the same information, but in view of the misguided (but seemingly inevitable) wish to interpret them differently, some extra doubt can be expressed when p is slightly above 0.05. Such weak evidence means treatment X "might be superior" or "this trial is inconclusive". TORCH's conclusion that "the reduction in death...did not reach the predetermined level of statistical significance" seems too guarded. The word "trend" is sometimes used in this context, but is best avoided because it implies special pleading when evidence is slim. After all, authors usually decline to mention trends in the opposite (harmful or "wrong") direction.

Scenario D depicts the disappointing situation in which the p value is quite large (eg,  $p = 0.3$ ), which indicates no evidence of a treatment difference, and one concludes "the trial did not show superiority" or "treatment X seems not to be superior". However, if the trial was too small (underpowered) to reliably detect clinically important effects, one might state there was insufficient evidence and the trial was "inconclusive".  $p > 0.05$  should not be labelled as a "negative" finding, because the possibility of a true treatment difference cannot be dismissed. Equally the label "positive" trial is best avoided when  $p < 0.05$ .

Non-inferiority (or equivalence) trials, designed to examine whether a new treatment has comparable efficacy to an active control, are increasingly common and present particular interpretive challenges.<sup>6</sup> Key is whether the 95% CI for the primary endpoint's treatment difference excludes a prespecified non-inferiority margin,  $\delta$ : any true inferiority less than  $\delta$  is deemed acceptable.