**Slack, Strode and Essack reply:** Professor Naidoo argues that an 'appropriate approach' to child research is that the 'research should be of minimal risk and consent for minors must be obtained from the parent or legal guardian in all but exceptional instances' and, moreover, that this is consistent with South African national ethical guidelines and international practice.

On the contrary, it is not clear why this proposal is appropriate in all instances, and our South African ethical-legal framework does not provide unqualified support for such a position.

Current South African ethical guidelines, including the *Good Practice* guidelines[1] and the general ethical guidelines *Structures, Principles and Processes*,[2] provide that in certain circumstances children are permitted to be enrolled in research that presents more than minimal risk. Where the research procedures hold out the prospect of direct benefit, there is no express cap on the risk level, although the risks must be reasonable in relation to the anticipated benefit (and appropriately minimised); and where the research procedures do not hold out the prospect of direct benefit, the risks must represent a minor increase over minimal risk.[3] This position is echoed in international frameworks, such as the Code of Federal Regulations in the USA.[4] Should children's participation in research be limited exclusively to minimal-risk research, it is difficult to see how children would ever be enrolled in clinical trials of experimental products.

Furthermore, in current South African ethical guidelines child participation in research is sometimes permissible even when parental or guardianship consent is not obtained, for example *Structures, Principles and Processes*[2] (correctly) allow older adolescents to participate in minimal-risk research with independent consent. The *Good Practice* guidelines[1] also recognise the ability of caregivers providing long-term day-to-day care of children to provide proxy

## Mini-slings – concern regarding marketing of these devices in South Africa

**To the Editor:** Aggressive marketing of medical devices impacts on the day-to-day practice of clinicians. The marketing of the mini-sling devices for stress urinary incontinence (SUI) in women is an area of major concern to us. SUI is the involuntary leakage of urine from the urethra with exertion, or on sneezing or coughing, and affects up to 35% of women.[1] It is a distressing condition and significantly impacts on quality of life.

Traditional interventions include pelvic floor exercises and open retropubic colposuspension. Ulmsten in 1995 introduced an effective minimally invasive option for surgically managing SUI, the 'tension-free vaginal tape' (TVT) (Gynecare, Ethicon, Somerville, USA).[2] This was followed by development of the transoburator-type sling, which avoided the risks of bladder, bowel and major vascular injury.[3] Both slings are made of synthetic mesh and are placed mid-urethrally, and their placement is the most commonly performed surgical procedure for SUI.

Long-term follow-up of Ulmsten's original series found an objective cure rate of 90% at 10 years. Level 1 evidence found efficacy to be equivalent to that of colposuspension. Meta-analysis has further shown equivalence in terms of cure between the trans-obturator and retropubic placement of mid-urethral slings.[4]

Mid-urethral slings therefore offer a highly efficacious minimally invasive surgical option with low postoperative morbidity. Device manufacturers have in the past 5 years introduced and strongly promoted eight further so-called 'mini-slings' that are claimed to be less invasive, and are placed via a small single vaginal incision.

There is little quality evidence to support the use of mini-slings. Nearly all the available studies show inferior efficacy. The most studied device, the TVT-Secure, was the subject of a 12-month outcome study

that reported an objective cure rate of 76%, considerably lower than the 90% reported long-term cure rate for the standard TVT.[5] The other widely marketed device, the Mini-Arc, also has inconsistent outcomes with some studies showing cure rates as low as 62%.[6]

Gynaecologists and urologists need to be aware of these poorer outcomes, for the TVT-Secur and the Mini-Arc in particular. While mini-slings hold future promise, present products are inferior to standard sling operations and their use should be discouraged.

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## Health professionals should be speaking out about the victimisation of doctors in Bahrain

**To the Editor:** Doctors in Bahrain who treated people wounded during and after demonstrations have been arrested, tried by a military court and given sentences of up to 15 years' imprisonment. A report by the Physicians for Human Rights[1] recounts the result of an on-the-spot inquiry as follows: 'Our investigators spoke to eyewitnesses of abducted physicians, some of whom were ripped from their homes in the middle of the night by masked security forces ... [the report] documents other violations of medical neutrality, including the beating, abuse and threatening of Shi'a physicians at Salmaniya Hospital; government security forces stealing ambulances and posing as medics; the militarisation of hospitals and clinics, thus obstructing medical care; and rampant fear that prevents patients from seeking urgent medical treatment.' Most of the doctors are women, and there have been reports of torture, including electrocution and threats of rape while in detention.[2]

These accounts are shocking and remind South Africans of a sorry history where human rights abuses at the hands of security forces were allowed to go unchecked and where the health sector was drawn willingly and unwillingly into violations of the rights of patients and professionals.[3] Not surprisingly, there has been sustained outcry from the medical profession in other parts of the world.[4-7] Following the exposé by Physicians for Human Rights, and pressure by the World Health Organization and the World Medical Association, it was announced by a civilian court that some charges against 20 health professionals would be dropped and that a new trial would begin to assess the allegations.[8]

We ask why there has been so little outcry in South Africa, a country whose history should make it acutely aware of the consequences of the political abuse of doctors. The South African Medical Association released a Medigram reporting the resolution of the WMA,[9] but has not taken any proactive steps to champion