In 2002/2003, the Canadian HIV/AIDS Legal Network held its first-ever nationwide essay contest for law students. There were two topic areas: one Canadian issue, and one international issue as it relates to Canada. This year, all the entries were on the international topic—a case comment on the 2001 ruling of the High Court of South Africa that the government was in breach of its constitutional obligations to provide a comprehensive national program to prevent mother-to-child transmission of HIV, including making antiretroviral drugs available for this purpose. Contest entrants were asked to discuss the implications this ruling might have regarding the right to health in Canada. In this issue, we are publishing an edited version of the winning essay. The second-place essay will be included in a future issue of the Review.

Canadian “medical necessity” and the right to health

In this article, Kathryn Garforth examines legal claims to health care in South Africa and Canada. Both countries face rising costs of health care that put a great strain on publicly funded systems, albeit in radically different contexts. Kathryn argues that despite these differences there are similarities in how litigants in South Africa and Canada have framed their claims to healthcare services, in how governments have responded, and in the factors courts have analyzed in reaching decisions. In South Africa, the leading case is Treatment Action Campaign (TAC) et al v Minister of Health et al, a constitutional challenge, while in Canada the relevant jurisprudence concerns the interpretation of the concept of medical necessity, articulated for the most part in non-constitutional cases.

Signatories to the Convention are obliged to take steps to realize this right, with the recognition that the obligation will differ for different states depending on their available resources. Faced with limited funds, many governments argue that they are unable to take the steps required to achieve the full realization of the highest attainable standard for their population. Countries with a commitment to socialized medicine face a particularly difficult challenge as the rising costs of health care put great strain on publicly funded medical systems.

The International Covenant on Economic, Social and Cultural Rights (ICESCR) recognizes “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”

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Both Canada and South Africa face this problem, albeit in different contexts. Canada is a wealthy country with a long history of socialized medicine. South Africa is a poorer state, emerging as a full-fledged democracy after a long history of apartheid. While the population sizes are not that dissimilar – about 44 million South Africans compared with about 32 million Canadians – South Africa does not have the infrastructure to properly serve the healthcare needs of many of its citizens. In addition, approximately 11 percent of the South African population is infected with HIV/AIDS, including 24 percent of pregnant women. HIV prevalence studies in Canada indicate an overall infection rate of 0.0016 percent and an infection rate among pregnant women of about 0.03-0.04 percent, although data for some provinces have not been updated for five or more years. So while access to healthcare may be a life-or-death situation for individuals in each country, in many ways the stakes are much higher in South Africa.

Despite these differences, there are similarities. In particular, these revolve around how individuals have sought to ensure access to healthcare in both these countries and how governments have tried to avoid committing additional resources to the public medical systems. In South Africa, the central case is TAC v Minister of Health, while in Canada the relevant jurisprudence concerns the interpretation of the concept of medical necessity. Comparing the South African case with the Canadian cases, we see that the arguments relied on by litigants seeking state-funded health care are strikingly similar. Moreover, in deciding such cases, both South African and Canadian courts have analyzed a number of factors, including the effectiveness of the treatment sought, whether or not the treatment represents an accepted standard of care in other jurisdictions, and the cost of the treatment.

**TAC v Minister of Health**

The decision in TAC v Minister of Health revolved around two main issues: (1) the availability of the drug nevirapine in public hospitals; and (2) the creation and implementation by the South African government of a mother-to-child transmission (MTCT) program to prevent the transmission of HIV during childbirth. In July 2000, the manufacturer of nevirapine offered to supply the drug to the South African government free of charge for a period of five years. Despite studies demonstrating the effectiveness of the drug in preventing MTCT, the government chose to limit the availability of the drug to a small number of pilot projects and refused to make it generally available for use in public-sector hospitals where most poor women are treated.

The government also refused to create and implement an MTCT prevention program. It suggested it was waiting for further research results on the effectiveness of nevirapine before planning an implementation program. When the study was completed and the government still did not act, TAC, supported by the Save Our Babies Campaign and the Children’s Rights Centre, initiated legal action. TAC challenged the government’s decision, arguing that it violated the right of access to health care, and the rights to equality, life, dignity, and reproductive choice.

This article will focus on the right of access to health care as set out in sections 27(1) and (2) of the Constitution of the Republic of South Africa, 1996. Section 27 grants everyone a number of rights, including the right “to have access to … health care services, including reproductive health care” and obliges the state to “take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation” of these rights.

TAC’s arguments regarding the right of access to health care centred on two points, namely that this right as contained in the Constitution created both a positive obligation on the state to provide such access and a negative obligation to refrain from activities that would impinge on the right of access. In making these arguments, TAC set out to establish the...
effectiveness of antiretroviral drugs, including nevirapine, the role of antiretrovirals in internationally accepted standards of care, and the costs and benefits of nevirapine.

The government responded with three arguments. First, it disputed the safety and the efficacy of the drug, arguing that more testing was needed before it could conclude that it was safe to use nevirapine to prevent MTCT. Second, it argued that making nevirapine and an MTCT prevention program universally available was prohibitively expensive. It said that nevirapine would gradually be made available to the public as funds allowed. Finally, it argued that the court would be making a policy decision if it granted the relief sought by TAC, something it had no authority to do.

In his ruling, Justice Botha framed the issue as being one of whether "the steps taken by the ... respondents with regard to the prevention of MTCT of HIV by establishing 18 pilot sites and confining the dispensing of Nevirapine to those sites, can be considered to be in compliance with the obligation of the State in terms of section 27(2) [of the Constitution]." He dismissed the government's argument that issuing an order would be a policy decision, finding that it was his role "to determine whether the steps taken by the respondents were, in the circumstances, reasonable." He then considered the existence and scope of the constitutional obligation of the government to make nevirapine available in public facilities outside the test sites.

Justice Botha largely agreed with TAC's arguments, and he followed the precedent set by Government of the Republic of South Africa v. Grootboom and Others. In that case, the Constitutional Court found that the government had both a positive obligation to ensure the progressive realization of rights in the Constitution and a negative obligation to desist from actions that would impinge on the progressive realization of these rights. Although the right to housing was at stake in Grootboom, Justice Botha applied the same reasoning to section 27(2) of the Constitution and its obligations concerning the right of access to health care.

In applying the test from Grootboom, Justice Botha found "that the policy of the ... respondents in prohibiting the use of nevirapine outside the pilot sites in the public health sector is not reasonable and that it is an unjustifiable barrier to the progressive realisation of the right to health care. It is a breach of their negative obligation ... to desist from impairing the right to health care." Relying on the situation in the Western Cape, a South African province where nevirapine was publicly available, he determined that it was possible for the government to sustain prescription of nevirapine in the public sector. He said that the drug's wide availability in the Western Cape had not caused "chaos or disarray" and the manufacturer's offer to supply the drug free of charge meant that the costs of the medication were minimal to nonexistent. While Justice Botha did not cite international law, his perception of a negative obligation is consistent with interpretive comments from the United Nations Committee on Economic, Social and Cultural Rights in reference to the right to health.

Finally, on the issue of the national implementation of an MTCT prevention program, Justice Botha used very forceful language to define the government's positive obligation: "About one thing there must be no misunderstanding: a country-wide MTCT prevention programme is an ineluctable obligation of the State." He agreed with TAC that a plan for national implementation did not exist and that the steps taken by the government could not be considered reasonable under section 27(2) of the Constitution. He recognized that the lack of resources was a difficulty, but stated that the availability of resources could only affect the pace of implementation of an MTCT prevention plan, not its existence. After finding the existence of both a negative obligation to avoid impairing the right to health care and a positive obligation to provide access to health care, Justice Botha ordered the South African government to make nevirapine available in public hospitals and "to plan an effective comprehensive national programme to prevent or reduce the mother-to-child transmission of HIV."

Canadian courts and medical necessity

Unlike South Africa, the Canadian Constitution does not contain an explicit right to health or health care.
Individuals have attempted to use the Charter of Rights and Freedoms to argue that the lack of public insurance for a particular treatment infringed their right to life or security of the person or constituted a prohibited form of discrimination. These cases largely focus on arguments about equality or about whether there is an economic component to the right to security of the person, rather than consider what constitutes a right to health or health care. Some litigants have taken an alternative path in seeking access to health services, basing their arguments on the medical necessity of particular treatments.

In Canada, both federal and provincial governments administer the healthcare system. Federally, the Canada Health Act governs the policy of the medicare system but does not explicitly grant Canadians a legal right to health care. Rather, the Act sets out the criteria that the provincial health insurance programs must meet in order for them to receive full federal funding under the Federal-Provincial Fiscal Arrangements Act. These criteria are the “famous five” of the Canadian healthcare system: public administration, comprehensiveness, universality, portability, and accessibility. Sections 8 through 12 of the Canada Health Act further define what a province must do to fulfill the five criteria. Section 9 addresses comprehensiveness and, when read in conjunction with the definition of hospital services in section 2, requires provinces to insure hospital services that are “medically necessary for the purpose of maintaining health, preventing disease or diagnosing or treating an injury, illness or disability.” The difficulty is that “medically necessary” is nowhere defined in the Canada Health Act.

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Quebec is the only province with a statutory right to health care. It is circumscribed, however, by fiscal considerations. Laws in the other Canadian provinces, much like the Canada Health Act, state that they will insure medically necessary treatments and services but, again, do not define what constitutes “medically necessary.” According to the Canadian Bar Association Task Force on Health Care Reform, this amounts to:

- an expressed or implied right to health insurance under provincial health insurance acts but this does not constitute a right to health care because there is no guarantee of content of health insurance (i.e., provinces may de-insure services as they choose.)
- Further, there is no guarantee of procedural fairness in how insured services are selected or delisted.

Not content with an empty right to health insurance, some Canadians have gone further, pressing for some guaranteed content in their public health insurance to meet their specific medical needs. While individual Canadians do not have standing to sue under the Canada Health Act, they can and do bring actions against provincial authorities that argue that certain aspects of health care are medically necessary. The arguments both for and against medical necessity in Canadian case law contain loud echoes of the arguments in Stein v Minister of Health.

In Stein v Quebec (Regie de l'Assurance-maladie), the Régie de l'Assurance-maladie du Quebec refused to pay for Barry Stein's out-of-country medical expenses. Among other things, Stein wanted the Régie to pay for a device known as an Infusaid pump that had been implanted in him by a physician in New York. The Régie refused to pay for the pump, claiming it was an experimental treatment and not available in Canada. In reviewing whether the pump was in fact experimental, the Quebec Superior Court considered evidence from Stein’s American surgeon that the pump is standard procedure in cancer centres in the US. It also referred to the Régie’s own doctor, who said the pump is not available in Canada because of its cost. The fact that the pump had been effective in treating Stein also seemed to play a role in the court’s decision.

In ordering the Régie to pay for Stein’s surgery, the court implied that the treatment was medically necessary regardless of its cost.

In Cameron v Nova Scotia (Attorney General), Alexander Cameron and his wife Cheryl Smith turned to intracytoplasmic sperm injection (ICSI), a form of in vitro fertilization (IVF), after their other attempts to have a baby were unsuccessful. When the province refused to cover the procedures under the Nova Scotia Health Services and Insurance Act, the couple brought an action claiming, among other things, that the treatment was medically necessary and that the wording of the Regulations thus required it to
be insured. The action was dismissed at trial. On appeal, Justice Chipman reviewed the evidence of the medical experts, who agreed that IVF is a standard treatment and that ICSI is currently, or is becoming, the treatment of choice. The trial judge felt that "neither 'medically indicated' nor 'standard medical procedure' equates to 'medically required'" and Justice Chipman refused to find this to be an error. Justice Chipman also found cost to be a factor in why the province did not consider IVF and ICSI to be medically necessary:

I much prefer, however, the primary approach of Dr. Collins which simply was that in the scheme of things - in the order of priorities - these two procedures, having regard to costs, the limited success rate and the risks do not, at this time, rank sufficiently high to warrant payment for them from public funding.... I am satisfied that this is the real explanation why these procedures were considered not medically necessary.

He went on to give his own interpretation of what must be considered in determining medical necessity:

Of necessity, what is or is not medically required must be judged by those placed in charge of the administration of the policy. The judgment call requires an appreciation not only of medical procedures, but the availability of funds to finance them.

In sharp contrast to Stein, where the court ignored costs in determining medical necessity, the court in Cameron explicitly incorporated financial considerations into the definition of what it considered to be medically necessary. According to this interpretation, what is medically necessary treatment is not determined solely by a patient's condition but also takes into account the ability of the province to pay for a given treatment.

Finally, in Auton (Guardian ad litem of) v British Columbia (Minister of Health), a group of autistic children and their guardians brought an action against the BC government claiming, among other things, that the government's treatment programs for autistic children were insufficient. The applicants sought coverage for early intensive applied behavioural analysis (ABA) techniques.

The child petitioners had each received Lovaas Autism Treatment, a form of ABA, which had cost their guardians between $45,000 and $60,000 a year per child. At trial, the petitioners argued "that Lovaas Autism Treatment is a medically necessary service insofar as it significantly improves the condition of these children." In assessing medical necessity, the court weighed the scientific evidence for and against Lovaas Autism Treatment and concluded that the most effective therapies for autism are those based on ABA. The court then examined the treatments provided by the BC government for autistic children, which, it concluded, were "positively discredited by one of the Crown's own expert witnesses." Finally, the court examined government-supported treatment for autism in other jurisdictions - Canadian, American, and British - and found that numerous other governments funded ABA therapies for autistic children. As a result, the court found ABA treatment generally, although not Lovaas Autism Treatment specifically, to be a medically necessary service.

These cases point to the need for a three-pronged analysis in determining medical necessity: a review of the effectiveness of the treatment in question; a review of the services the government already insures for the malady in question; and a review of whether the treatment is standard in other jurisdictions. The court in Cameron also added a fourth element: cost.

A belief in the apparent effectiveness of the treatment played a role in Justice Botha's order that the government make nevirapine publicly available.

Access to medically necessary services in Canada and South Africa: a comparison

How does the test for medical necessity articulated by Canadian courts relate to TAC v Minister of Health? It is, in fact, very similar to the arguments raised by TAC in its affidavit and largely adopted by Justice Botha. The effectiveness of nevirapine was an issue for both TAC and the South African government. Justice Botha commented on the apparent effectiveness of nevirapine and how its conditional registration with the national drug authority pointed to its being "safe and efficacious." As was the case in Stein and Auton, a belief in the apparent effectiveness of the treatment played a role in Justice Botha's order that the government make nevirapine publicly available.

The second element of the test concerns the services already insured by the South African government for treating HIV/AIDS. TAC made the
point that nevirapine and information on MTCT was not available to women in public hospitals outside the 18 pilot project sites. Justice Botha found there to be "incontrovertible evidence that there is a residual or latent capacity in the public sector outside the 18 pilot sites to prescribe Nevirapine." This is very similar to the situation in Auton, where the poor to non-existent nature of publicly insured services for auti-stic children was a factor in the court's decision ordering the government to pay for ABA treatments.

The third element of the test is the use of the treatment in other jurisdictions. In its affidavit, TAC did not do much review how standard the use of nevirapine or the implementation of an MTCT prevention program was in other countries, but instead focused on the recommendations of the World Health Organization. These recommendations included placing nevirapine on its Essential Drugs List and suggesting alternatives to breastfeeding for HIV-positive mothers. Justice Botha chose to focus on the experience in the Western Cape, where nevirapine is widely available. The experience there pointed to a more equitable access to treatment as well as a contribution to the progressive realization of the right to health.

The final element of the test, used by both TAC and the South African government, was cost. Justice Botha did not state whether he thought that an MTCT prevention program would actually save money in the long term; rather, he believed cost was not a consideration in the progressive realization of the right to health care. Progress would have to be made and the resources would have to be found gradually. The cost issue was also considered in Cameron. But the approach taken by Justice Chipman in that case is in sharp contrast to that of Justice Botha in TAC. The former believed cost to have a role in determining medical necessity; the latter, while not phrasing his decision in the same terms, essentially believed cost not to be relevant in determining medical necessity and what constitutes a right to health care.

The decision in TAC v Minister of Health may help Canadian advocates enunciate claims to health and health care in the language of human rights. This could have numerous beneficial consequences, including pushing Canadian governments to realize commitments under the ICESCR, and helping courts to clearly define the substantial interest in health care at stake in cases like Stein, Cameron, and Auton. A commitment to insure what is medically necessary is vague and unclear; a commitment to insure services and treatments that contribute to the realization of a right to health should make it easier for the courts to appropriately judge the competing interests.

Conclusion

Traditionally, Canadian courts have not turned to their South African counterparts when seeking possible interpretations of Canadian law. That said, the South African Constitution contains many more specific rights such as the right to health care than does our Charter of Rights and Freedoms. As the South African courts interpret and apply these rights, they are increasingly likely to become a source of inspiration for other jurisdictions.

Although they are couched in different terms, the tests for determining what constitutes medical necessity, and when the right to health care is being impinged upon by the state, involve common considerations. What TAC v Minister of Health contributes to this discussion is that not only is there a right to health, and not only do governments have an obligation to progressively realize this right, but these same governments must also be sure not to stand in the way of the realization of this right. The acknowledgment of this negative obligation makes the right to health that much more forceful. A similar acknowledgment in the Canadian test for medical necessity has yet to arise, but if Canadian judges look to their South African counterparts, we may come that much closer to enunciating our own right to health here in Canada.

– Kathryn Garforth

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1 Details of the contest can be found at www.aidslaw.ca/Maincontent/lawessaycontest.htm.
2 Case No. 21182/2001, 14 December 2001, High Court of South Africa (Transvaal Provincial Division). Reported in 2002(2) BCLR 356 (T). 2001 SACLR LEXIS 123, and available via www.tac.org.za [hereinafter TAC v Minister of Health], cited to LEXIS, which has its own internal page numbering for the judgment, which numbering is used in the following notes. The Order of the High Court was varied on appeal to the Constitutional Court of South Africa, Case CCT 8/02, 5 July 2002, available at http://www.concourt.gov.za/files/tac/tac.pdf. The Constitutional Court generally ordered the South African and state government to devise and implement within its available resources a comprehensive and co-ordinated program to realize progressively the rights of pregnant women and their newborn children to have access to health services to combat mother-to-child transmission of HIV. For the full Order of the Court, see the decision at para 135.
4 Ibid at article 12(1).
The overall HIV infection rate in Canada can be obtained by dividing the estimated number of HIV-positive people living in Canada (49,800 in 1999) according to Health Canada, HIV/AIDS Epi Update: Prevalent HIV Infections in Canada: Up to One-Third May Not Be Diagnosed. Ottawa, April 2003) by the population estimate for the same year (30,403,900 according to Statistics Canada, available at www.statscan.ca/english/Pgdb/demo02.htm). For the situation of pregnant women see Health Canada, HIV/AIDS Epi Update: Perinatal Transmission of HIV Ottawa, April 2003. The provincial range is from 1.9/10,000 (Ontario 1991-1992) to 8.7/10,000 (Newfoundland 1991-1993) and large metropolitan areas have higher rates (4.7/10,000 for Vancouver versus 3.4/10,000 for the rest of BC in 1994, and 15.3/10,000 for Montreal versus 5.2/10,000 for the province of Quebec in 1990). However, even provinces without large metropolitan areas have significant rates (for example, 4.1/10,000 in New Brunswick for 1994-1996), and data from Manitoba suggest an increasing trend of HIV infection among women of childbearing age (from 0.7/10,000 among the approximately 72 percent of pregnant women who agreed to voluntary testing in the third quarter of 2002.

7 TAC v Minister of Health, supra, note 2 at 15.

8 All future references to TAC refer to the three applicants in the case.


11 Gemholtz, ibid.

12 See supra, note 9.

13 Section 27 reads:

27. (1) Everyone has the right to have access to:

a. health care services, including reproductive health care;

b. sufficient food and water; and

c. social security, including if they are unable to support themselves and their dependants appropriate social assistance.

(2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.

(3) No one may be refused emergency medical treatment.

14 TAC v Minister of Health, supra, note 2 at 24-25.

15 Ibid at 26-27.

16 Ibid at 56.

17 Ibid at 64.

18 Ibid at 67.

19 2001(1) SA 46 (CC).

20 TAC v Minister of Health, supra, note 2 at 59.

21 Ibid at 77.


23 TAC v Minister of Health, supra, note 2 at 83.

24 Ibid at 86.


26 Sections 7 and 15.

27 See, eg, Brown v British Columbia (Minister of Health) (1990), 66 DLR (4th) 444 where a section 7 argument for provincially funded access to AIDS medication was dismissed. See, eg, Eldridge v British Columbia (Attorney General), [1997] 3 SCR 624 for a successful s 15 argument for access to health services and Cameron, infra, note 41, for an unsuccessful s 15 argument.

28 RSC 1985, c C-6.


30 Supra, note 28, s 2, definition of "cash contribution;" s 4. The Federal-Provincial Fiscal Arrangements Act is RSC 1985, c F-8.

31 Supra, note 28, at s 7.

32 Health and Social Services Act, RSC, c S-4.2, s 5.

33 Ibid at s 13.


36 Ibid at paras 1-3.

37 Ibid at para 27. Experimental treatments are not considered to be medically necessary: This creates an incentive for cash-strapped provincial health insurance plans to label expensive new treatments as experimental in order to avoid having to pay for them. See M Somerville. The Ethical Canary: Science, Society and the Human Spirit Toronto: Penguin Books, 2001, at 228.

38 Supra, note 35 at para 40.

39 Ibid.

40 Ibid at para 43.


42 RSNS 1989, c 20.

43 Supra, note 41 at paras 28, 70.

44 Ibid at para 41.


46 Ibid at para 87.


48 Somerville, supra, note 37 at 233-234.


50 Ibid at para 8.

51 Ibid at para 24.

52 Ibid at para 29.

53 Ibid at paras 51-52.

54 Ibid at para 66.

55 Ibid at paras 69-83.

56 Ibid at para 102.

57 TAC v Minister of Health, supra, note 2 at 73.

58 Ibid at 75.

59 Ibid at 77.