

CONFLICT OF INTEREST, PHYSICIANS AND PHYSIOTHERAPY

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In Brief • En bref

Since Ontario introduced auto-insurance legislation that guaranteed extensive physiotherapy treatment for people who have been in car accidents, the cost of outpatient claims to insurance companies has skyrocketed. However, there has not been a measurable improvement in patient outcomes. At the same time, the average in-hospital stay for patients receiving hip and joint replacements has decreased greatly. Dr. Murray Waldman thinks these divergent trends in rehabilitation can be attributed to physician self-interest.

Depuis que l'Ontario a mis en œuvre une mesure législative sur l'assurance automobile qui garantissait des traitements de physiothérapie prolongés aux victimes d'accidents de la circulation, le coût des réclamations pour services externes présentées aux compagnies d'assurance a grimpé en flèche. Il n'y a toutefois pas eu d'amélioration mesurable des résultats chez les patients. Par ailleurs, la durée moyenne de l'hospitalisation des patients qui ont subi une arthroplastie de la hanche et d'autres articulations a diminué considérablement. Le Dr Murray Waldman pense que ces tendances divergentes au niveau de la réadaptation peuvent être attribuées à l'intérêt personnel des médecins.

The past 3 years have witnessed two major divergent trends in rehabilitation. On the one hand, the cost of inpatient rehabilitation for people with serious injuries or who have undergone major surgery has been declining annually as lengths of stay decrease. At St. John's Rehabilitation Hospital in Toronto, the average length of stay for a patient with a fractured hip has decreased from 56 days in 1992 to 24.2 days in 1995. This has been done with no

decrease in the quality of care or patient outcomes, because the criteria for discharge have remained the same.

On the other hand, the cost of outpatient rehabilitation, especially for people who have been in motor-vehicle accidents, has been skyrocketing. According to data from the Insurance Bureau of Canada, the average cost per claim for rehabilitation has risen from \$2108 in 1989 to \$25 305 in 1994, but there has been no change in the amount of time an accident victim is off work.

The reason for both trends is clear: physician self-interest. On the

inpatient side, hospitals face declining funding and are looking at new costing formulas based on "case costing." In its most basic form, case costing means that a hospital receives a fixed amount for treating a patient based on diagnosis, regardless of length of hospital stay. Under this formula, it is in the best interests of the institutions and the doctors who work there to treat patients in a way that will minimize their length of stay. By doing this, beds can be turned over more rapidly, more patients can be treated and money can be saved. At St. John's Rehabilitation Hospital, where I am the medical director, the length of stay for total joint replacements has decreased from about 31.8 days in 1992 to 17.5 days in 1996.

The exact opposite is true in the treatment of patients who have suffered relatively minor injuries in automobile accidents. In these cases, the cost of rehabilitation has almost doubled in 2 years. The reason for this is Bill 164, auto-insurance legislation that was enacted in Ontario in January 1994.

One of its provisions is that anyone injured in a motor-vehicle accident is entitled to up to \$1 million in medical and rehabilitation costs. Furthermore, the insurance companies are obliged to pay whatever is billed; if they disagree with the bill's amount

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they can challenge it — after it has been paid.

This legislation arrived at the same time as the fees paid to physicians through the Ontario Health Insurance Plan (OHIP) were being capped and clawed back. The new bill meant there was no ceiling nor any control over what could be charged for the delivery of rehabilitation services, because these bills went directly to insurance companies; they had nothing to do with OHIP or any other government agency.

Some physicians who also owned

actions are described in the article on page 1744. — Ed.]

This situation was eloquently described by George Bernard Shaw in the introduction to *The Doctor's Dilemma*: "That any sane nation, having observed that you could provide for the supply of bread by giving bakers a pecuniary interest in baking for you, should go on to give a surgeon a pecuniary interest in cutting off your leg is enough to make one despair of political humanity, but that is precisely what we have done. . . . It may be necessary to hang a man or to pull down a house.

I believe that the medical profession should take a firm stand against self-referral clinics. Section 45 of the CMA Code of Ethics states that an ethical physician "will avoid any personal profit motive in ordering drugs, appliances or diagnostic procedures from any facility in which the physician has a financial interest."

rehabilitation facilities quickly realized that as gatekeepers who decided which patients required physiotherapy they could refer patients to their own facility, and earn money that was exempt from government caps and clawbacks.

The practice of referring patients to facilities in which a physician owns an interest is a major ethical concern.¹

According to the University of Toronto's Presidential Commission on Conflict of Interest, "a conflict of interest arrives when one (i.e., a physician) is placed in a position where one's personal interest, often a financial interest, conflicts with one's obligation to, or the interests of, the institution (or one's patient)." [In February, the College of Physicians and Surgeons of Ontario announced that it was moving the issues of self-referral and conflict of interest to the top of its agenda. Its

But we take good care not to make the hangman or house breaker judges of that. If we did, no man's neck would be safe and no man's house stable."

Are doctors' treatment decisions really influenced by their own financial concerns? The answer, sadly, is yes. There are numerous examples: the ordering of medications from pharmaceutical companies that provide free trips or other perks, the ordering of tests from laboratories in which doctors have a financial interest, or the referral of patients to therapy centres that are owned by physicians.

How widespread is this practice in Ontario? Since Bill 164 was introduced, the number of doctor-owned rehabilitation facilities has increased significantly and new facilities continue to open.

What about the cost of treatment? Before the advent of Bill 164, pa-

tients could be treated in either private or OHIP-funded clinics. The private clinics had appeared because for the last 20 years there has been a moratorium on issuing new licences to open OHIP-funded clinics. However, those clinics did very well financially — so well, in fact, that whenever one was sold the price often exceeded \$1 million. In 1994, a clinic in Burlington, Ont., was on the market for \$1.4 million.

These clinics bill OHIP about \$15 per session for rehabilitation services. In the clinics that bill insurance companies, session fees range from \$37.50 to \$65. In a clinic that bills OHIP, a physiotherapy assessment done by a physiatrist — a physician with 5 years' postgraduate training in physical medicine — is billed at \$53.60; consultations by a neurosurgeon are billed at \$84.50. Clinics billing the insurance industry charge \$150 to \$290 for a physiotherapy assessment.

According to industry sources, the higher costs and numbers of rehabilitation services have not resulted in less time off work (or time on claim) for patients treated in these centres; patients may even be receiving longer treatment than they would have before Bill 164.

The *Toronto Star* (Jan. 2, 1996) reported that a local organization was encouraging doctors to join a venture to share the cost of setting up a rehabilitation centre. The physicians would refer patients to the clinic, and the operator and physician-investors would split the profits. The *Star* said physicians would expect a return on investment in the range of 185% per year.

It is clear that these clinics create a conflict of interest that results in much higher costs to the insurance industry and ultimately to everyone buying auto insurance. Can anything be done about this?

I believe that the medical profession should take a firm stand against self-referral clinics. Section 45 of the

CMA Code of Ethics states that an ethical physician "will avoid any personal profit motive in ordering drugs, appliances or diagnostic procedures from any facility in which the physician has a financial interest."

In the US this problem has been solved by legislation, which states in part: "A physician may not refer Medicare or Medicaid patients to a facility where the physician has either an ownership interest or a financial relationship." It is worth noting that physicians can own these facilities in the US;^{2,3} however, if they refer patients to them the insurer, either Medicare or Medicaid, will not pay.

If the College of Physicians and Surgeons or the government doesn't legislate against these practices, what can the insurance industry do? First,

it should demand that a certain standard of care is met. This could be done by having all facilities that bill the insurance industry meet certain standards that could be set and overseen by an impartial expert in the field, such as experts from a rehabilitation hospital.

Second, the industry should set fees that are reasonable and pay only according to this schedule.

Third, the industry should provide clients with a list of preferred providers — centres that demonstrate excellence in rehabilitation and involve no conflict of interest.

Shaw summed up the extremes to which conflict of interest can lead this way: "I cannot knock my shins severely without forcing on some surgeon the 'difficult question': Could I not make better use of a

pocketful of guineas than this man is making of his leg?"

If we get rid of conflict of interest in rehabilitation medicine physicians will not be faced with this sort of difficult decision, and we will all be better for it.

References

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CYTOTEC® (misoprostol) 100 µg / 200 µg

THERAPEUTIC CLASSIFICATION Mucosal Protective Agent

INDICATIONS CYTOTEC (misoprostol) is indicated for the prevention of NSAID-induced gastric ulcers. Patients at high risk of developing NSAID-induced complications and who may require protection include: • Patients with a previous history of ulcer disease or a significant gastrointestinal event. • Patients over 60 years of age. • Patients judged to be at risk because of general poor health, severe concomitant medical disease, or patients who are poor surgical risks. • Patients disabled by joint symptoms (e.g., HAQ Disability Index Score >1.5) or those with severe systemic manifestations of arthritis. • Patients taking other drugs known to damage or exacerbate damage to the gastrointestinal tract such as corticosteroids or anticoagulants. • Patients taking a high dosage or multiple NSAIDs, including those available Over-The-Counter. The risk of NSAID-induced complications may be highest in the first three months of NSAID therapy. CYTOTEC is also indicated for the treatment of NSAID-induced gastric ulcers (defined as ≥ 0.3 cm in diameter) and for the treatment of duodenal ulcers.

CONTRAINDICATIONS Known sensitivity to prostaglandins, prostaglandin analogues, or excipients (microcrystalline and hydroxypropyl methylcellulose, sodium starch glycolate and hydrogenated castor oil). Contraindicated in pregnancy. (See CLINICAL PHARMACOLOGY.) Women should be advised not to become pregnant while taking CYTOTEC (misoprostol). If pregnancy is suspected, use of the product should be discontinued.

WARNINGS Women of childbearing potential should employ adequate contraception (i.e., oral contraceptives or intrauterine devices) while receiving CYTOTEC (misoprostol). (See CONTRAINDICATIONS.) **Nursing Mothers:** It is unlikely that CYTOTEC is excreted in human milk since it is rapidly metabolized throughout the body. However, it is not known if the active metabolite (misoprostol acid) is excreted in human milk. Therefore, CYTOTEC should not be administered to nursing mothers because the potential excretion of misoprostol acid could cause significant diarrhea in nursing infants. **Pediatric Use:** Safety and effectiveness in patients below the age of 18 have not been established.

PRECAUTIONS **Selection of Patients:** Caution should be used when using symptomatology as the sole diagnostic and follow-up procedure, since CYTOTEC (misoprostol) has not been shown to have an effect on gastrointestinal pain or discomfort. Before treatment is undertaken, a positive diagnosis of duodenal ulcer or NSAID-induced gastric ulcer should be made. The general health of the patient should be considered. Misoprostol is rapidly metabolized by most body tissues to inactive metabolites. Nevertheless, caution should be exercised when patients have impairment of renal or hepatic function. (See CLINICAL PHARMACOLOGY: Pharmacokinetics.) **Diarrhea:** Rare instances of profound diarrhea leading to severe dehydration have been reported. Patients with an underlying condition such as irritable bowel disease, or those in whom dehydration, were it to occur, would be dangerous, should be monitored carefully if CYTOTEC is prescribed. **Use in Elderly or Renally Impaired: Considerations for Dosage Adjustment:** In subjects over 64 years of age or those who are renally impaired the pharmacokinetics may be affected, but not to a clinically significant degree. (See DOSAGE AND ADMINISTRATION.) No routine dosage adjustment is recommended in older patients or those patients with renal impairment. Dosage may need to be reduced if the usual dose is not tolerated. In patients with renal failure, a starting dose in the low range (100 µg QID) is recommended. **Drug Interactions:** The serum protein binding of misoprostol acid (the active metabolite of misoprostol) was not affected by: indomethacin, ranitidine, digoxin, phenylbutazone, warfarin, diazepam, methyldopa, propranolol, triamterene, cimetidine, acetaminophen, ibuprofen, chlorpromazine, and hydrochlorothiazide. Salicylic acid (300 µg/mL) lowered the protein binding of misoprostol from 84% to 52%; this is not considered clinically significant since the binding of misoprostol acid is not extensive and its elimination half-life is very short. In laboratory studies, misoprostol has shown no significant effect on the cytochrome P450-linked hepatic mixed function oxidase system, and therefore should not affect the metabolism of theophylline, warfarin, benzodiazepines or other drugs normally metabolized by this system. No drug interactions attributable to misoprostol have been observed to date. (See CLINICAL PHARMACOLOGY.) Some prostaglandins and prostaglandin analogues have the capacity to produce hypotension through peripheral vasodilation. The results of clinical trials to date indicate that CYTOTEC has not produced hypotension at dosages effective in promoting the healing of ulcers. Nevertheless, CYTOTEC should be used with caution in the presence of disease states where hypotension might precipitate severe complications, e.g., cerebral vascular disease or coronary artery disease. Epileptic seizures have been reported with prostaglandins and prostaglandin analogues administered by routes other than oral. Therefore, misoprostol tablets should be used in known epileptics only when their epilepsy is adequately controlled and then only when expected benefits outweigh potential risks. Symptomatic responses to CYTOTEC do not preclude the presence of gastric malignancy.

ADVERSE REACTIONS **Gastrointestinal:** In subjects receiving CYTOTEC (misoprostol) 400 or 800 µg daily in clinical trials, the most frequent gastrointestinal adverse events were diarrhea, abdominal pain and flatulence. The average incidences of these events were 11.4%, 6.8% and 2.9%, respectively. In clinical trials using a dosage regimen of 400 µg bid, the incidence of diarrhea was 12.6%. The events were usually transient and mild to moderate in severity. Diarrhea, when it

occurred, usually developed early in the course of therapy, was self limiting and required discontinuation of CYTOTEC in less than 2% of the patients. The incidence of diarrhea can be minimized by adjusting the dose of CYTOTEC, by administering after food, and by avoiding co-administration of CYTOTEC with magnesium-containing antacids. **Gynecological:** Women who received CYTOTEC during clinical trials reported the following gynecological disorders: spotting (0.7%), cramps (0.6%), hypermenorrhea (0.5%), menstrual disorder (0.3%) and dysmenorrhea (0.1%). **Elderly:** There were no significant differences in the safety profile of CYTOTEC in approximately 500 ulcer patients who were 65 years of age or older, compared with younger patients. Confusion has been reported in a small number of patients in our post marketing surveillance of CYTOTEC. **Incidence greater than 1%:** In clinical trials, the following adverse reactions were reported by more than 1% of the subjects receiving CYTOTEC and may be causally related to the drug: nausea (3.2%), headache (2.4%), dyspepsia (2.0%), vomiting (1.3%) and constipation (1.1%). However, there were no clinically significant differences between the incidences of these events for CYTOTEC and placebo.

DOSAGE AND ADMINISTRATION **Treatment and Prevention of NSAID-Induced Gastric Ulcers:** The recommended adult oral dosage of CYTOTEC (misoprostol) for the prevention and treatment of NSAID-induced gastric ulcer is 400 to 800 µg a day in divided doses. NSAIDs should be taken according to the schedule prescribed by the physician. When appropriate, CYTOTEC and NSAIDs are to be taken simultaneously. CYTOTEC should be taken after food. **Duodenal Ulcer:** The recommended adult oral dosage of CYTOTEC (misoprostol) for duodenal ulcer is 800 µg per day for 4 weeks in two or four equally divided doses (i.e., 200 µg qid or 400 µg bid). The last dose should be taken at bedtime with food. Antacids (aluminum based) may be used as needed for relief of pain. Treatment should be continued for a total of 4 weeks unless healing in less time has been documented by endoscopic examination. In the small number of patients who may not have fully healed after 4 weeks, therapy with CYTOTEC may be continued for a further 4 weeks. **Use in Elderly and Renally Impaired: Consideration for Dosage Adjustment:** Pharmacokinetic studies in patients with varying degrees of renal impairment showed an approximate doubling of $T_{1/2}$, C_{max} and AUC compared to normals. There was no clear correlation between degree of impairment and AUC. In subjects over 64 year of age the pharmacokinetics may be affected. In both patient groups the pharmacokinetic changes are not clinically significant. No routine dosage adjustment is recommended in older patients or those patients with renal impairment. Dosage may need to be reduced if the usual dose is not tolerated. In patients with renal failure, a starting dose in the low range (100 µg QID) is recommended.

AVAILABILITY CYTOTEC (misoprostol) 200 µg tablets are white to off-white, scored, hexagonal with SEARLE 1461 engraved on one side available in bottles of 120 and 500 tablets. CYTOTEC 100 µg tablets are white to off-white, round tablets with SEARLE engraved on one side and CYTOTEC on the other available in bottles of 100 tablets.

Store below 30°C (86°F).

Pharmacist: Dispense with Patient Insert.

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Oakville, Ontario
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SEARLE

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