

W. W. Rosser

The Role of the Family Physician in Smoking Cessation

SUMMARY

Two studies conducted at the Ottawa Civic Hospital Family Medicine Centre indicate that physicians are unlikely to help patients quit smoking merely by discussing cessation strategies; only highly motivated smokers who have made three to five attempts already are likely to stop smoking for a year or more. Each attempt helps the smoker to better understand the difficulties he must overcome in order to quit. A four-step program is suggested to help physicians address the problem of smoking. This program includes educating and informing the public about the dangers of smoking and second hand smoke; discussing the relationship between smoking and illness with smokers to encourage them to try quitting; low intensity intervention (e.g., support and encouragement and other simple strategies) to encourage smokers who aren't highly motivated to make an attempt to quit; and high intensity intervention (e.g., several group sessions) for patients who are highly motivated. (Can Fam Physician 1984; 30:160-167).

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DURING THE 1960s and 1970s, smoking was identified as the single largest cause of preventable illness in our society.^{1, 2} In the late 1970s, the University of Ottawa Department of Family Medicine Research Group decided to study the family physician's role in dealing with the problem of smoking, because of the problem's prevalence and physicians' frustration in dealing with intransigent smokers who were obviously harming themselves.

The literature in the late 1970s revealed many unsubstantiated state-

ments about the role physicians—particularly family physicians—should play in encouraging smoking cessation.^{1, 3-5} However, there was remarkably little research demonstrating practical and effective approaches for physicians to take.⁶⁻¹⁰

In 1978, a randomized trial by Michael Russell,¹¹ a psychiatrist at the Maudsley Hospital in London, England, demonstrated a significant difference in smoking cessation rates between groups of patients whose general practitioner told them at one office visit to stop smoking and a comparable control group. Russell projected that if all general practitioners in the U.K. carried out this strategy, there would be a significant decline in smoking, and a concurrent improvement in the health of the nation. This finding was reported in CANADIAN FAMILY PHYSICIAN and appropriate strategies for Canada were proposed.¹² Unfortunately, lifestyle issues that in-

SOMMAIRE

Deux enquêtes menées au Centre de médecine familiale du Ottawa Civic Hospital révèlent que les médecins n'aident vraisemblablement pas leurs patients à cesser de fumer en ne discutant que des stratégies de cessation; seuls les fumeurs très motivés ayant déjà fait de trois à cinq tentatives sont susceptibles de cesser de fumer pendant un an ou plus. Chaque tentative aide le fumeur à mieux comprendre les difficultés qu'il doit surmonter pour cesser de fumer. Un programme en quatre étapes est suggéré pour aider les médecins à s'attaquer au problème du tabagisme. Ce programme inclut l'éducation et l'information du public concernant les dangers du tabagisme et des effets du tabagisme sur les non-fumeurs; une discussion avec les fumeurs sur le lien entre le tabagisme et la maladie pour les encourager à cesser de fumer; une intervention de faible intensité (e.g. support et encouragement, et autres stratégies simples) dans le but de stimuler les fumeurs qui ne sont pas très motivés à tenter de cesser de fumer; et une intervention de forte intensité (e.g. plusieurs sessions de groupe) pour les patients qui sont hautement motivés.

volve cultural and societal factors are not always internationally transferable. Thus, a similar trial was conducted in Canada to determine the reproducibility of his findings.

Ottawa Civic Hospital Studies

The first study

The study was conducted at the Ottawa Civic Hospital Family Medicine Centre, a teaching practice with a registered practice population of about 13,500. Details of the practice's characteristics and methods of maintaining practice registration are described elsewhere.¹³

During a two month period, 2,000 consecutive visitors to the office were screened into a smoking and non-smoking group. Then 750 smokers were randomly allocated to four groups. Members of all four groups completed a questionnaire detailing the duration and characteristics of their

smoking habit. Their smoking behavior was assessed six months and one year later. The control group had no further intervention. Smokers in another group received one or two minutes of advice about smoking cessation from a physician during their visit. The third group received advice and a large red sticker that said 'Smoker' was placed on their chart. The last group received a brochure and advice to stop smoking.¹⁴

Results from the first test of the impact of physician interventions on 750 smokers showed that after one year, the control group had a cessation rate of 3.1%, those who received only physician advice and those who received physician advice and a 'smoker' sticker on their chart had a cessation rate of 3.1%, and those who received physician advice and a pamphlet had a cessation rate of 4.3%. The differences were not statistically significant. The failure to replicate Russell's findings stimulated a second more intensive study.

The second study

Over 3,000 smokers who came to the Family Medicine Centre over a one year period were asked if they wished to stop smoking and invited to participate in a trial of smoking cessation methods. About 1,000 people expressed a desire to participate and took home a package of questionnaires and self addressed, stamped envelopes. The questionnaires included information about smokers' habits, assessment of motivation to stop, assessment of psychological benefits and questions about smoking history.

Only about 200 questionnaires were returned to the office. Another 180 patients had to be recruited from community physicians' offices. The 380 smokers who returned questionnaires were randomly assigned to one of four groups. The control group completed follow up questionnaires and smoking diaries six months and one year after the questionnaire. The physician intervention group were given a special appointment with their physician to discuss their smoking and to receive "The Helping Smokers Quit Kit",²³ developed by the American Cancer Institute as a self-help program for smoking cessation. The third group participated in six group sessions using a program developed by the British Columbia Lung Association called

"Operation Kick-It".²⁴ Groups of ten to 15 patients were led by a public health nurse or a health educator for six 90 minute sessions followed by a 'booster' session. This program was chosen because it required few resources and thus could be organized in most communities in Canada. The fourth group was exposed to eight behavior modification sessions delivered by two clinicians with masters degrees in psychology.

Each of the three intervention groups received a battery of questionnaires and completed a smoking diary immediately after the program and six and twelve months later. Preliminary results include all of the six month and about 60% of the one year questionnaires. A variety of statistical tests were applied to analyze the data.¹⁵

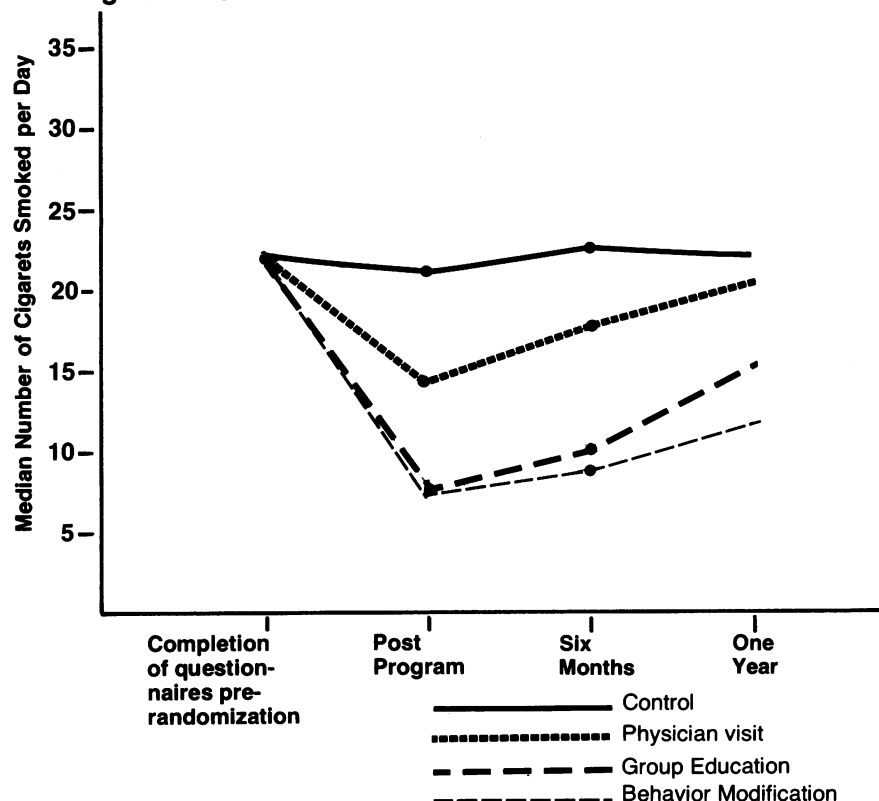
Immediately post-program, there was a substantial decrease in the number of cigarettes smoked per day in all members of the intervention groups (65-75%) compared to those in the control group (see Figures 1 and 2). However, at six months follow up, all three experimental groups began to approach the control smoking rate; at 12 months, there were insignificant differences between the physician intervention groups and the control group.

Analysis of all patients who were successful in quitting identified a number of demographic and social characteristics of successful quitters. There were remarkably few characteristics that consistently related to success at post-program and to outcomes at six month follow up. Immediately following the three interventions, married and employed people showed the highest rates of quitting, while at six months follow up this trend was no longer significant.

There was no correlation between success in quitting, years of smoking or even the number of cigarettes smoked when the patient entered the program. The most consistent finding was that the more often someone in any of the four groups had tried to stop smoking in the past, the more likely he was to successfully quit.

Figure 3 illustrates associations between smoking rates at the beginning of the trial and selected social demographic and attitudinal variables for all participants. Different trends in the relationship between social demographic variables and rates of smoking cessation are evident between the different interventions. For example, the age and duration of smoking history had a negative association with age and

Fig. 1. Number of cigarettes smoked by participants before and after the smoking cessation trial



smoking rates immediately post-program, and at six months for the physician intervention and health education group, but the opposite was seen in the behavior modification and control groups. Younger smokers responded best to doctor and health educator, whereas those who reduced or stopped smoking with behavioral modification, or with no assistance (i.e., those in the control group) tended to be older and had smoked longer.

When attitudinal and psychological questions were considered, there were only two significant predictors of successful outcome for the control group. They were self confidence and experience with smoking cessation programs in the past.

When a physician led the intervention, few variables were associated with success. They included degree of self confidence, duration of smoking, and satisfaction with the program. Details of the results for the group health education and behavior modification groups are described elsewhere.¹⁵

Implications For Family Physicians

There are several theoretical explanations for why simple discussions by family physicians about smoking ces-

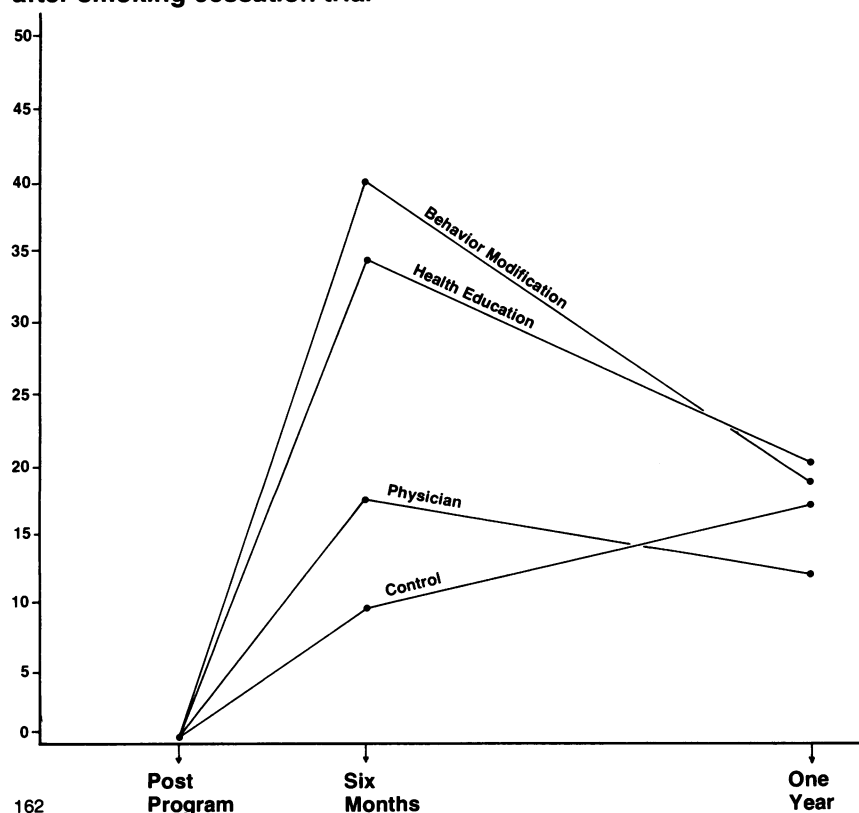
sation are unlikely to be successful. Information and education are only the first of several steps required to change a person's beliefs so that he is prepared to make a fundamental lifestyle modification (see Figure 3).¹⁶ Other more elaborate and intensive interventions have not been successful in promoting lifestyle change, so it would be surprising if simple office interventions *did* have an impact.¹⁷

Those who smoke 20 or more cigarettes a day and who decide to stop, must overcome an addiction, the psychological barriers of change in daily lifestyle, and a deeply ingrained habit. The smoker must learn to deal with multiple cues or signals that are associated with taking a break for relaxation with a cigaret. Most smokers associate cigarettes with completing meals, drinking coffee or talking on the telephone. Strategies must be developed to overcome the desire for cigarettes at these times.

Although the physician can motivate an individual to consider cessation by being supportive and giving advice, considerable personal commitment and effort by the smoker is necessary to overcome the barriers to successful quitting.

If appropriate trials of physician counselling and advice have not

Fig. 2
Percentages of participants who stopped smoking after smoking cessation trial



PRESS-O-TEST AVAILABLE AT:

British Columbia

All Woodwards Store Pharmacies
Baker Health Care Products
Ste. 214, 8400 Main St., Vancouver
The Bay Pharmacy
Main Store, Vancouver
The Bay Pharmacy
Main Store, Victoria

Alberta

All Woodwards Store Pharmacies
Value Drug Marts
Standard Medical Supply
3435 9th St. S.E., Calgary
Saveco Store Dispensary
10736 Jasper Ave., Edmonton

Saskatchewan

Eaton's Pharmacy
Saskatoon
Schaan Health Care Products
2342 Hanselman Ave.,
Box 6050, Saskatoon

Manitoba

Northland Health Care Products
Limited
104 King Edward St. E., Winnipeg

Ontario

Medical Mart Supplies
1224 Dundas St. E., Mississauga
Starkman Surgical Supply
1243 Bathurst St., Toronto
Medicine Shoppe Ltd.
2917 Bloor St. W., Toronto
Boots Drug Stores
(all locations, available upon request)
G.A. Ingram Company (Canada) Ltd.
(all locations)
Golden Mile Pharmacy
690 Tecumseh Rd. E., Windsor

Quebec

Pharmacies Universelles
(all locations, available upon request)
Pharm-Escomptes Jean Coutu
(all locations, available upon request)

Maritimes

Lawton Health Care Centre
7071 Bayers Rd., Halifax
(available upon request)
MacQuarrie's Drug Mart
Truro Centre, Truro
Archibald Green Pharmacy
541 Prince St., Truro
Acadia Drug Mart
404 St. George St., Moncton

demonstrated clinically significant success in achieving smoking cessation, what role should family physicians play in promoting smoking cessation?

Family physicians should consider an approach that will benefit their entire practice population. Most smokers are aware that smoking is harmful to health. Even adolescents entering high school have a high level of awareness.² Ninety percent of the smokers in the Ottawa Civic Hospital Family Medicine Centre study were aware that smoking is harmful to health, but only 70% stated they wished to stop (see Figure 3). Thus, 30% of smokers in our survey did not have adequate information or motivation to attempt smoking cessation.

Seventy percent of smokers wished to stop and 60% had already tried to quit at least once. Using a single attempt as a sincere indication of a desire to stop, 60% of smokers want to quit but only 3% are successful during one year. From the information obtained in both studies, the 60% of smokers who have tried to stop once require several years and three to five attempts before prolonged (at least one year) cessation occurs. During each unsuccessful attempt, the smoker learns more about the lifestyle changes required and the pleasures that must be sacrificed to achieve cessation. Presumably, the pleasurable effects of smoking outweigh the perceived benefits of cessation until the smoker has learned to overcome the drawbacks or some event so alarms him that his motivation is great enough to outweigh the hardships involved.

Although we approached 3,000 smokers, only 1,000 agreed to participate in the second Ottawa Civic Hospital Study. Only 200 actually joined the study, of whom only ten to 15 in each of four groups actually succeeded in quitting.

Based on our work, you can expect about 3% of smokers in your practice to stop smoking in any given year. If the average family practice has approximately 1,800 patients, of whom about 600 smoke, then about 18-25 patients will successfully stop each year.

Proposed Four-Step Program

In developing a program for physicians to deal with the problem of smoking, it is necessary to have knowledge of the efficacy of cessation programs on smoking patients, to effi-

ciently use scarce resources, and to offer physicians and other health care workers a better understanding of the process involved in smoking cessation. This can reduce their level of frustration in dealing with a problem to which only 3% of patients are likely to respond to each year.

Step 1: Education and information

Physicians should be encouraged to communicate to the community, to schools and to politicians, in order to improve public awareness of the health problems created by smoking—especially second hand smoke. Every physician should display in his office pamphlets and posters focusing on the adverse effects of cigarettes. The fact should be emphasized to patients that nearly 30,000 Canadians die each year as a direct result of smoking.¹⁸ No patient should leave the office without being exposed to material emphasizing the adverse effects of second hand smoke. Physicians should take the lead in supporting legislative changes restricting smoking in public, in the work place and in health care facilities.¹⁹ Physicians should increase their support of the many volunteer agencies promoting non smoking. If every physician reading this article asked his or her school board, municipal and provincial politicians what steps are being taken to decrease and restrict smoking, then the powerful tobacco

industry would have significant opposition. Federal politicians should be asked why cigarettes are the only completely unregulated substance people can put in their mouths. Cigarettes contain some substances so toxic that any measurable level in the air is unacceptable by federal regulations. Because it is so difficult to get people to stop smoking, the most significant gains will be made by preventing young people from starting the habit and by supporting the concept of a 'smokeless generation'.²⁰

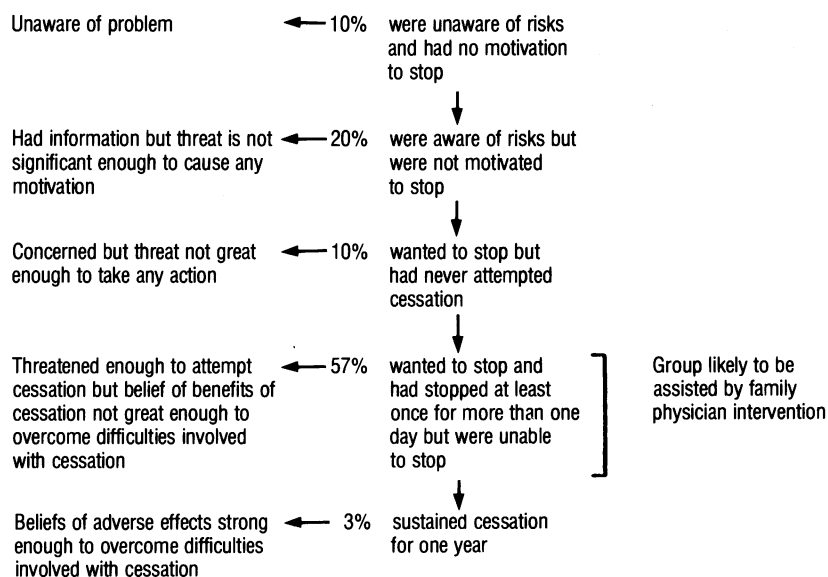
Step 2: Individual motivation

Every patient visiting a primary care physician should be screened for smoking. If he smokes, a red sticker denoting him as a smoker, non smoker or former smoker should be placed on his chart. This reminds both patient and physician at every visit about smoking and health. If patients are pregnant, request birth control pills, or have any smoking related illness, the physician should make the patient directly aware of the relationship between smoking and illness as a method of motivating him to quit. There is some evidence that intervention at critical times (e.g., when a close relative has died of a smoking-related disease) in a patient's life may increase motivation to quit.²¹

Step 3: Low intensity intervention

Because 60% of the patients in the Ottawa Civic Hospital Family Medi-

Fig. 3. The beliefs and actions of 751 smokers surveyed at the Ottawa Civic Hospital Family Medicine Centre, September to November 1979 and resurveyed four months and one year later*



* On the first survey, 751 of 2,004 patients making visits to the office regularly smoked more than ten cigarettes a day.

cine Centre practice had attempted to stop smoking at least once, those who are motivated to attempt cessation represent the largest percentage of smokers. Any patient from this group who says he would like to stop should be assessed to find out how likely he is to succeed.

Patients may be asked how many previous attempts they have made, and how long they managed to quit for. Then the physician can assess how motivated they are to stop; for instance, he might ask them if they are prepared to attend evening sessions. Patients who are not highly motivated, who have never tried to quit or who have quit only once or twice for short periods, should be supported and encouraged with self-help booklets, nicotine gum or other simple strategies that require a minimal time and energy commitment from the physician. A smoking diary is a particularly useful way for a smoker to learn about the problems of cessation.

During the phase of low intensity intervention, the patient may unsuccessfully attempt to quit smoking two or three times. Each failed attempt should be treated as a success; the patient is moving one step closer to permanent cessation.

Step 4: High intensity intervention

Patients who have quit several times, have not smoked for several weeks, and who are highly motivated, are more likely to benefit from high intensity programs involving several group sessions. Structured programs of six or eight sessions are likely to yield the best results. Any program to

which physicians refer patients should be evaluated by an appropriate trial and have demonstrated significant results. Unfortunately, most currently used programs have not been properly evaluated.

Discussion

Successful smoking cessation is a more difficult and prolonged process than most family physicians previously believed. With an improved understanding of the process, both they and their patients can have more reasonable expectations. This should result in more appropriate physician reactions to patients' failed attempts, and less physician frustration. The family physician's role should be that of educator, motivator and facilitator, and he should expect only 15-25 successes annually in his practice.

Family physicians are well suited for the role of educator and facilitator because they usually know the patient well, and have had repeated contact with him over the years.

Smoking cessation requires significant behavioral change, and it can occur only when the patient understands what is involved and persists. He must be motivated enough to learn how to deal with his cravings and the loss of a significant part of his life.

The fact that in our study, only ten percent of smokers invited to participate in a serious smoking cessation program registered and only five to ten percent of these highly motivated individuals were successful for one year, confirms that only modest improvements over the three percent spontane-

ous cessation rate can be expected in the population.

Perhaps in future, societal pressure will influence smokers and make smoking socially unacceptable, so that young people no longer feel that smoking is 'adult' behavior. However, as long as smoking advertising is permitted this change is unlikely. Although family physicians should educate their smoking patients, the greatest gains are likely to be made by supporting efforts to restrict smoking and to make it socially unacceptable. Physicians should pressure school boards to use the latest and most effective anti-smoking programs in schools, and write to municipal, provincial and federal politicians. The Minister of Health and Welfare's suggestion to increase tax on cigarettes so they would cost 30% more should be strongly supported by the medical community as an effective method of reducing smoking.²²

Principles that are involved in getting patients to stop smoking are similar to those involved in getting patients to lose weight, decrease drinking, or make other significant lifestyle changes. More studies are required so that the role of family physicians in lifestyle changes can be better defined. ●

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(Panadol, a leading analgesic/antipyretic in Saudi Arabia and more than 70 countries, is now available in Canada.)

PANADOL*

Acetaminophen tablets in 325 mg and 500 mg strengths.

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THEO-DUR



ACTION: Theophylline is a xanthine structurally related to theobromine and caffeine. As with other xanthine derivatives, the precise mechanism of action of theophylline has not been determined. Theophylline stimulates central nervous system and skeletal muscles, stimulates cardiac muscle, relaxes certain smooth muscles including those of the bronchi, produces diuresis, and causes an increase in gastric secretion.

Theo-Dur tablets are sustained-release tablets which produce peak blood levels between 5-8 hours after dosing in adults, and between 4-6 hours after dosing in children 6 years of age and older. Once the steady state level has been reached, the therapeutic blood levels persist for 12 hours in most adult patients.

INDICATIONS AND CLINICAL USES: Theo-Dur tablets are indicated for the symptomatic treatment of reversible bronchospasm associated with asthma, chronic bronchitis, emphysema and related bronchospastic disorders.

CONTRAINDICATIONS: Theo-Dur is contraindicated in patients with:

• hypersensitivity to theophylline or xanthine derivatives; • peptic ulcer; • coronary artery disease (when, in the physician's judgement, myocardial stimulation might prove harmful).

WARNINGS: The margin of safety above the therapeutic dose is small. The use of Theo-Dur tablets in children under the age of six years is not recommended as a dose schedule in this age group has not been established.

PRECAUTIONS: Marked differences in serum levels may be seen in patients receiving the same theophylline dose. This may be explained by differences between patients in the rate of metabolism. Dosage regimens should therefore be individualized.

Ideally serum theophylline levels should be monitored in all patients and a theophylline half-life calculated which would enable doses and dosing regimens to be tailored to each patient to maintain a therapeutic level, to ensure optimal clinical response and to avoid toxicity.

The incidence of toxicity increases at serum theophylline levels greater than 15 µg/ml and levels above 20 µg/ml are usually quite toxic in most patients (adults). High serum levels may be seen in some patients receiving doses considered to be conventional. The possibility of overdose should therefore not be considered with large doses only. Overdosage of theophylline may cause peripheral vascular collapse.

Careful monitoring of serum levels is particularly advisable in patients with hepatic dysfunction since theophylline metabolism may be impaired, resulting in toxic levels.

Theophylline should also be used with caution in elderly patients, and patients with severe hypoxemia, uncompensated cardiac failure, cor pulmonale, or hyperthyroidism.

Theophylline may also worsen pre-existing arrhythmias.

Caution should be exercised when theophylline is used concurrently with sympathomimetic amines, since the incidence and severity of adverse reactions may be increased. The concurrent administration of other theophylline derivatives along with Theo-Dur is not recommended.

In the interpretation of biochemistry tests, it should be remembered that theophylline may cause an elevation of urine catecholamines and plasma free fatty acids.

Usage In Pregnancy: Theophylline crosses the placental barrier and also passes freely into breast milk, where concentrations are similar to plasma levels. Safe use in pregnancy has not been established relative to possible adverse effects on fetal development, but neither have adverse effects on fetal development been established. Therefore, use of theophylline in pregnant women should be balanced against the risk of uncontrolled asthma.

DRUG INTERACTION: Cimetidine, erythromycin, influenza vaccine and propranolol may increase the effect of theophylline by decreasing theophylline clearance.

Smoking may decrease theophylline effect by increasing clearance.

Acidifying agents, by increasing urinary excretion of weak bases such as xanthines, may inhibit theophylline action. Alkalinizing agents, by decreasing urinary excretion, may potentiate theophylline action.

The actions of thiazide diuretics and digitalis glycosides may be potentiated by xanthine derivatives such as theophylline.

The effects of coumarin anticoagulants may be antagonized by methylxanthine-induced increases of prothrombin and fibrinogen.

Theophylline has been shown to increase the ratio of clearance of lithium/creatinine and may thus decrease serum lithium to ineffective levels. Xanthines may antagonize the antihypertensive action of allopurinol; the uncoupling action of probenecid may also be antagonized.

Xanthines have been shown to be nephrotoxic with prolonged use at high dosage. Coincident toxicity should therefore be borne in mind when other potentially nephrotoxic drugs are administered concurrently.

Combined use of several xanthines, or the concurrent use of sympathomimetics, may cause excessive CNS stimulation.

ADVERSE REACTIONS: The most common adverse reactions are nausea, vomiting, epigastric pain, headache and tremor. These are usually early signs of toxicity; however, with high doses, ventricular arrhythmias or seizures may be the first signs to appear. Adverse reactions reported with theophylline preparations include: 1. Gastrointestinal: nausea, vomiting, epigastric pain, hematemesis, diarrhea, anorexia, reactivation of peptic ulcer, intestinal bleeding. 2. Central nervous system: headaches, irritability, restlessness, insomnia, hyperactivity, reflex hyperexcitability, muscle twitching, clonic and tonic generalized convulsions. 3. Cardiovascular: palpitation, tachycardia, extrasystoles, flushing, hypotension, circulatory failure, life-threatening ventricular arrhythmias. 4. Respiratory: tachypnea. 5. Renal: albuminuria, diuresis and hematuria. 6. Others: hyperglycemia and inappropriate ADH syndrome.

SYMPTOMS AND TREATMENT OF OVERDOSAGE:

Symptomatology:

1. Insomnia, restlessness, mild excitement or irritability, and rapid pulse, are early symptoms, which may progress to mild delirium. 2. Sensory disturbances such as tinnitus or flashes of light are common. Anorexia, nausea and vomiting are frequently early observations of theophylline overdosage. 3. Fever, diuresis, dehydration and extreme thirst may be seen. Severe poisoning results in bloody, syrup-like "coffee-ground" vomitus, tremors, tonic extensor spasm interrupted by clonic convulsions, extrasystoles, quickened respiration, stupor and finally coma. Cardiovascular disorders and respiratory collapse, leading to shock, cyanosis and death follow gross overdosages.

Treatment:

A. If potential oral overdose is established and seizure has not occurred: 1. Induce vomiting. 2. Administer a cathartic (this is particularly important when a sustained-release preparation has been taken). 3. Administer activated charcoal.
B. If patient is having a seizure: 1. Establish an airway. 2. Administer oxygen. 3. Treat the seizure with intravenous diazepam, 0.1 to 0.3 mg/kg up to a total dose of 10 mg. 4. Monitor vital signs, maintain blood pressure and provide adequate hydration.
C. Post-Seizure Coma: 1. Maintain airway and oxygenation. 2. If a result of oral medication, follow above recommendations to prevent absorption of drug, but intubation and lavage will have to be performed instead of inducing emesis, and the cathartic and charcoal will need to be introduced via a large bore gastric lavage tube. 3. Continue to provide full supportive care and adequate hydration while waiting for drug to be metabolized. In general, the drug is metabolized sufficiently rapidly so as not to warrant consideration of dialysis. However, charcoal or resin hemoperfusion should be considered if serum level monitoring indicates dose-dependent kinetics.

DOSEAGE AND ADMINISTRATION: Therapeutic serum levels are generally considered to be between 10 and 20 µg/ml. Due to variable rates of elimination, there is patient-to-patient variation in dosage needed to achieve a therapeutic serum level. Because of the variation from patient to patient, the variation within the same patient, and the relatively narrow therapeutic range, dosage should be individualized. Monitoring of serum theophylline concentrations is also extremely important, especially in the initial stages of therapy (see PRECAUTIONS).

It is preferable to monitor peak concentrations rather than trough concentrations. Therefore, blood samples should be drawn 4-8 hours after Theo-Dur dosing. It should be ascertained that all doses have been taken for 60 hours prior to blood sampling. Depending on the sensitivity of the assay method used, dietary xanthines may interfere with assay results.

If a dosage increase is not tolerated, dosage should be reduced to the previously tolerated level. Do not attempt to maintain a dosage which is not tolerated or which produces serum concentrations above the therapeutic range.

Theo-Dur tablets should not be chewed or crushed, but may be halved.

Adult Dose: The usual initial adult dose is 200-300 mg every 12 hours. This dose may be increased by 50-100 mg every 12 hours at 3 day intervals until a satisfactory response is obtained or toxic effects appear.

Dosage adjustments should be based upon serum theophylline concentration and/or upon the patient's clinical response. However, doses of 400 mg every 12 hours or higher should not be given unless serum theophylline concentration can be monitored. It should not be necessary to exceed a daily dose of 18 mg/kg in adult patients. Even with serum level monitoring, this dose may lead to side effects because of day-to-day variations in blood levels within individual patients.

Children's Dose: The usual initial dose for children (age 6-12 years) is 6 mg/kg given every 12 hours (12 mg/kg/day).

If the desired response is not obtained after 3 days, and there are no adverse effects, dosage may be increased to 8 mg/kg every 12 hours (16 mg/kg/day). This dose should be considered the maximum unless serum theophylline concentrations can be monitored to guide further dose increases.

If serum concentrations are monitored, and there are no adverse effects, the dosage may be increased by 2-3 mg/kg/day at intervals of not less than 3 days, until the desired response is obtained, or until side effects appear. It should not be necessary to exceed a daily dose of 24 mg/kg to obtain an adequate response in children. Even with serum theophylline concentration monitoring, this dose (24 mg/kg/day) may lead to side effects because of day-to-day variations of blood levels within individual patients.

Dividing the daily dosage into 3 doses administered at 8 hour intervals may be indicated if symptoms repeatedly occur at the end of 12 hour dosing intervals.

AVAILABILITY: Theo-Dur formulated as sustained-action tablets contains anhydrous theophylline with no colour additives.

Theo-Dur is available in three strengths: 100 mg, 200 mg and 300 mg.

Theo-Dur 100 mg: White, round, biconvex tablets, engraved "KEY" on one side and scored in the transverse direction on the opposite side.

Theo-Dur 200 mg: White, flat, elliptical tablets with bevelled edges and engraved "THEO-DUR"-200 on one side and scored in the transverse direction on the opposite side.

Theo-Dur 300 mg: White, biconvex, staff-shaped tablets with parallel sides and rounded ends engraved "THEO-DUR"-300 on one side and scored in the transverse direction on the opposite side.

