

# Orientation for new teachers

## *Workshop on clinical teaching skills*

YVONNE STEINERT, PHD  
NORMA LAWN, RN  
RICHARD HANDFIELD-JONES, MD  
LOUISE NASMITH, MD  
DOMINIQUE LUSSIER, MD  
CHERYL LEVITT, MB, BCH

### SUMMARY

Since 1987, McGill University's Department of Family Medicine has invited new faculty to an orientation workshop. Workshop topics cover learning agreements and principles of adult learning, effective teaching methods, and feedback and evaluation. Workshop methods aim to promote active participation and experiential learning.

### RÉSUMÉ

Depuis 1987, le Département de médecine familiale de l'Université McGill invite ses nouveaux professeurs à participer à un atelier d'orientation. L'atelier permet de couvrir les contrats d'apprentissage et les principes de l'andragogie, l'efficacité des méthodes d'enseignement, la rétroaction et l'évaluation. Les méthodes utilisées dans cet atelier visent à promouvoir la participation active et l'apprentissage expérientiel.

*Can Fam Physician* 1995;41:79-85.

**N**EW TEACHERS OF FAMILY MEDICINE face many challenges. While they are keen to meet their new responsibilities, they are often poorly prepared to do so. Their teaching skills are frequently limited, as is their confidence. Indeed, few physicians have had specific training as teachers despite the years it has taken for them to become clinicians and researchers.<sup>1-3</sup>

To help teachers prepare for their teaching roles, the Department of Family Medicine at McGill University has developed a series of faculty development workshops, one of which is specifically designed to meet the needs and expectations of new teachers. This article describes the content and methods of this workshop and highlights its strengths and limitations. We hope that this description will help other departments plan and implement orientation programs for new faculty.

### Need for orientation programs

In 1985, Fleming and Bogdewic<sup>4</sup> surveyed American family medicine

**Dr Steinert, Ms Lawn, Dr Nasmith, Dr Lussier, and Dr Levitt** teach in the Department of Family Medicine at McGill University. **Dr Handfield-Jones** is now Director of Continuing Medical Education at the College of Family Physicians of Canada.

programs to determine the prevalence of orientation activities for new faculty. They found that less than a third of the departments surveyed had formal programs for new teachers. In addition, the content of available programs was frequently limited and did not form part of an integrated faculty development plan.

In 1985, Steinert and colleagues<sup>5</sup> surveyed faculty development activities in Canada and found that only six of the 16 departments of family medicine offered orientation programs for new faculty. Two of these programs were offered to all faculty, and four were designed for full-time faculty only. Most of these programs consisted of informal meetings tailored to individual needs, and none were part of an ongoing faculty development program. The situation remained the same in 1991.<sup>6</sup>

The challenges and problems encountered by new faculty have been well documented in the family medicine literature. In 1977, Stephens<sup>7</sup> described problems faced by new teachers as family medicine was emerging as a discipline. The same difficulties exist today. The most common apprehensions voiced by teachers include questions about their ability to do the job, fear of failure and anxiety about not having enough to teach, and concern that

academic medicine will not give the anticipated gratification or rewards.

Swee and colleagues<sup>8</sup> reported that new faculty members were concerned about being appropriate role models, developing teaching skills, and maintaining clinical competence. They also discussed the difficult transition from clinical practice to teaching and highlighted the value of preparing teachers for their roles.

New faculty are likely to be particularly anxious if they are just out of residency training with limited life experience. Hopkins and Green<sup>9</sup> examined some of the difficulties faced by recent graduates as they entered teaching roles. They reported that young faculty often suffer from a lack of "real world" experience, proximity in age to the residents, and being viewed as an extended chief resident. They also noted that recent graduates have difficulty balancing their own educational needs with those of residents and that they find faculty-resident interactions awkward.

Orientation programs for new employees seem to be used extensively in business and government to integrate people into every level of an organization.<sup>10-12</sup> Residency programs also make serious efforts to orient and integrate new residents through seminars, social activities, and mentorship programs.<sup>13-15</sup> Should orientation programs for new clinical teachers not also be considered? The need to confront the problems and concerns of new teachers has been poignantly addressed by Boice<sup>16</sup> and Worthington and Clay,<sup>17</sup> yet specific program descriptions are not readily available.

### Orientation workshop

Our orientation workshop, a 2-day event held specifically for new teachers, focuses on the clinical teaching skills most commonly encountered in family medicine. Although attendance is not mandatory, new faculty members are strongly encouraged to attend, and the department subsidizes part of the workshop fees. *Table 1* outlines the

main goals of the workshop, which has been held eight times to date.

Most of the workshop is conducted in small groups with an emphasis on experiential learning. Although short lectures are frequently used to introduce particular topics or modules, didactic teaching is limited. Much of the learning occurs through small group discussions, analyses of videotaped teaching sessions, and role playing. We strongly believe that adult learners prefer to learn by doing, and we rely heavily on principles of microteaching<sup>18</sup> and adult learning.<sup>19,20</sup>

To facilitate active participation and interaction among group members, each workshop is limited to 18 participants. To date, most of the 140 teachers who have participated in these workshops have come from the McGill Department of Family Medicine. About 15% have come from other programs. Of the McGill teachers, 40% have come from urban teaching centres, 20% from urban community practices, and 25% from rural settings. Although most of the participants have been physicians, nurses, psychologists, and social workers have also attended.

All the workshops are led by members of the department's Faculty Development Committee, several of whom have specific training and expertise in educational methods and faculty development. All the committee members are practising clinicians: physicians, nurses, or psychologists. Part-time secretarial assistance is available for workshop administration. Experienced faculty members are invited as guest facilitators so that participants can benefit from their clinical and educational expertise.

### Workshop modules

**Orientation of new faculty: problems and possible solutions.** This session focuses on the concerns and problems commonly encountered by new faculty. "What do we have to teach?" and "How do we prepare our practices for teaching?" are two of the most frequently expressed concerns.

**Table 1. Workshop goals**

- To help new teachers address their most common teaching problems
- To introduce participants to the principles of adult learning and to the value of learning agreements
- To highlight the strengths and limitations of different clinical teaching methods
- To give participants an opportunity to critically appraise their own clinical teaching skills
- To describe the basic principles of effective feedback and evaluation, and give participants an opportunity to practise their own feedback skills

The session aims to address participants' problems, to reassure them that they are not alone with their difficulties and to demonstrate, through role modeling, how to work with medical students and residents. Most importantly, this session sets the stage for the next 2 days by assessing the needs and expectations of participants.

**Assessing learner needs.** Defining learners' needs and expectations is an important challenge in clinical teaching. This session introduces participants to the idea of learning agreements, sometimes called educational contracts,<sup>21</sup> and gives teachers an opportunity to practise negotiating such agreements through role playing. In our experience, learning agreements can be particularly useful for community preceptorships, rural rotations, and time spent in the family medicine unit. They can also be used creatively in many other situations, including daily encounters with patients.

**Principles of adult learning.** Organizers of teaching workshops for physicians often wonder how much theory should be presented. This issue is critical in this module. We believe that one of the most important theoretical concepts for clinical teachers is that of adult learning.<sup>19,20</sup> Not respecting principles of adult learning is, perhaps, one of the more serious downfalls of medical education and one of the greatest sources of dissatisfaction for medical students, residents, and teachers alike.

Instead of lecturing participants on theories of adult learning, we briefly review the most important principles (eg, adults are independent and need to know the importance of the subject in order to learn; adults often resist the student role; much of adult learning is relearning rather than new learning), and try to model them throughout the workshop. We also talk about different learning and teaching styles. Participants have an opportunity to complete a Learning Style Inventory,<sup>22</sup>

and we discuss matching teaching methods to learning styles.

**Overview of teaching methods: matching methods to needs.** This session, perhaps the most challenging and rewarding for workshop leaders, tries to sensitize participants to the strengths and weaknesses of different clinical teaching methods and to give participants an opportunity to practise their teaching skills with feedback from the group.

We quickly enumerate the teaching methods we most commonly use, highlighting the fact that there is no single recipe for success: different methods have different advantages in different situations. We show two videotaped doctor-patient interviews and ask participants to identify learners' problems and to decide which teaching method they would use to address an identified problem. Participants then prepare a short teaching exercise. Teaching materials (eg, transparencies, construction paper, wool) are provided, and 15 minutes is allowed for preparation. Participants can teach any topic to one or more learners for no more than 3 minutes. (Three minutes teaching is sufficient because most of the learning occurs during the ensuing feedback and discussion.) In past workshops, most participants have chosen to teach a nonmedical procedural skill, such as tying a shoelace or baking a cake. This session emphasizes the need to observe principles of adult learning, to assess the needs and expectations of learners, to establish mutual objectives for the teaching session, to question effectively, to provide relevant and helpful information, to give constructive feedback, to focus on one skill at a time, and to demonstrate respect for learners.

**What makes a good teacher?** The first day ends with a discussion of what makes a good teacher. We ask participants to think of the best and worst teachers they have ever had, and then we generate a list of characteristics of good teachers. We believe that encouraging

participants to identify the attributes of their clinical teachers helps them to recognize their own strengths and weaknesses. We also compare our list with studies that have examined characteristics of effective teachers as perceived by residents and faculty.<sup>23,24</sup>

**Supervision by case discussion.**

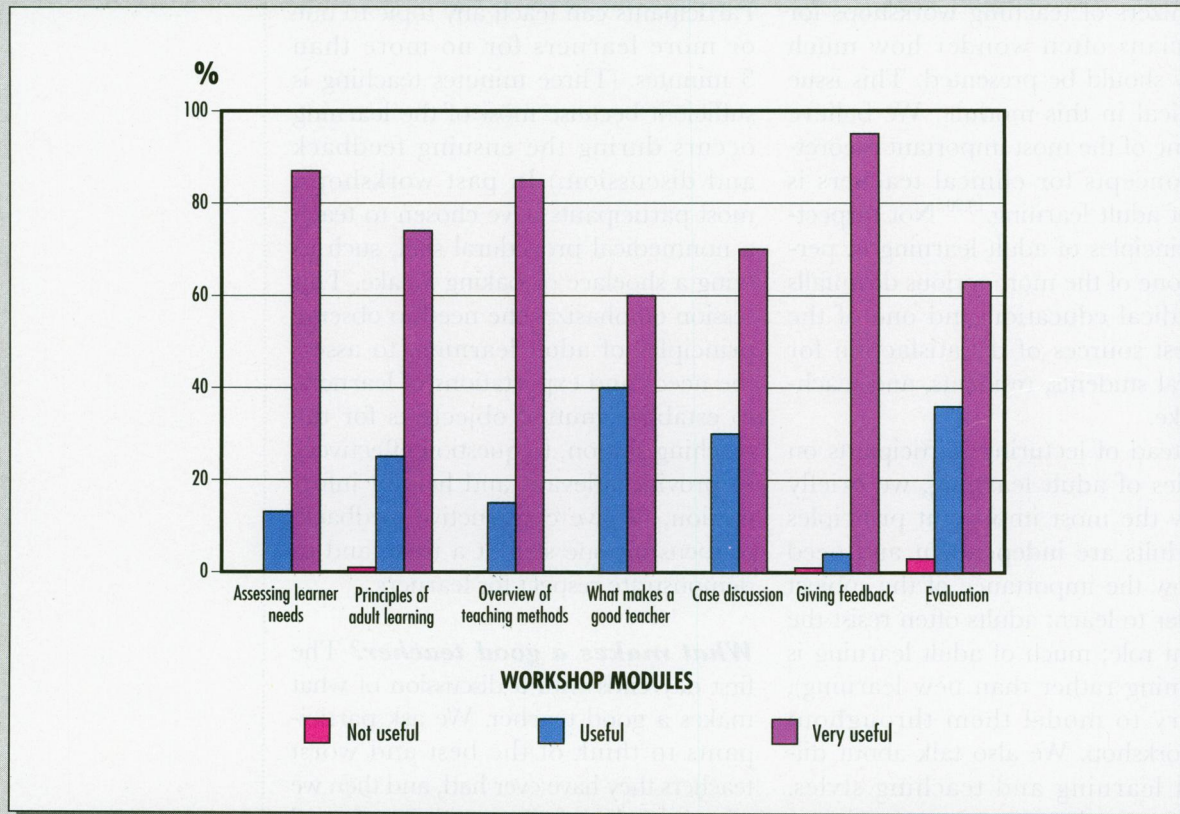
Because supervision by case discussion is one of the most common teaching methods used in clinical settings, we devote an entire session to the topic. This module highlights some of the important principles of case presentations (eg, the need to define clear objectives, the importance of dealing with learners' needs) and describes some of the main teaching skills that can make this method effective (eg, questioning, summarizing, providing feedback).

We show videotapes of case presentations to participants and ask them to comment. We also address common problems encountered in supervision

by case discussion, such as ensuring continuity of care, ensuring patient welfare, modifying skills through second-hand information, and dealing with residents' deficiencies.<sup>25</sup>

**Giving feedback.** Giving feedback is one of the most difficult challenges for clinical teachers, especially at the beginning of their teaching careers. As a result, this is probably one of our most popular sessions. We begin by showing a videotape of a teacher interviewing a patient. The group is then asked to give feedback to the interviewer and to comment on the feedback process. In this way we generate a list of characteristics of effective feedback.<sup>26</sup> A common problem in giving feedback is that teachers quickly tell learners how they perceive strengths and weaknesses without soliciting the learners' perceptions. Following group discussion on principles of giving feedback, we break into small groups so that each participant

Figure 1. Participant feedback 1987 to 1993



can practise giving and receiving feedback during role-playing exercises.

**Evaluation.** This module aims to generate useful ways of avoiding problems often encountered when evaluating medical students and residents. By reviewing several available evaluation forms, participants are led to consider certain questions: What problems do you encounter in evaluating medical students and residents? What do you need to know in order to carry out an effective evaluation? Who should do the evaluation? How do you communicate your information to learners? What is the value of daily feedback in the evaluation process? How do you implement an effective evaluation system in your own setting? By highlighting the importance of learning agreements, feedback, and documentation, this session aims to make the evaluation process as pragmatic and useful as possible.

**Back to reality: from workshop to workplace.** Participants often leave a workshop keen to try new ideas. Then, back in their daily routines, they forget much of what they intended to do differently. This final module aims to help group members devise strategies for maintaining their enthusiasm and for bringing about change in their home environments. We ask participants to summarize what they have learned in the workshop and to comment on the tips they have received. We also ask them to describe how they will take this new information back to their own settings and how they will maintain their interest and enthusiasm.

### Workshop evaluation

About 140 clinical teachers have participated in the orientation workshop during the last 7 years. Outcome, however, is difficult to assess. Are teachers more competent after they participate in these sessions? Are they able to apply what they have learned? Will their newly gained competence translate into improved performance? The problem of evaluating the effectiveness

of faculty development activities has been well documented.<sup>27-29</sup> Ideally, we would observe teachers in their own settings before the workshop and then 6 months and 1 year afterward. Unfortunately, we do not have the resources to do that. Instead, we rely on verbal feedback and a written evaluation form completed at the end of the workshop.

**Feedback.** Feedback on these workshops has been highly favourable. All of the participants have indicated that workshop objectives were met, and that they would recommend this workshop to their colleagues. Their comments have also underscored the value of experiential learning, participants' active involvement in the workshop, and the practical focus of the concepts under discussion. *Figure 1* summarizes participants' feedback on the workshop modules.

Comments from participants and some of their colleagues following the workshop suggest that certain changes have, indeed, taken place. They report a more regular use of learning contracts, improved feedback, a more comprehensive understanding of evaluation, and a renewed enthusiasm for teaching. Future research projects could validate these anecdotal comments and observations. Although several studies have looked at the long-term impact of faculty development workshops on teaching behaviour,<sup>30-32</sup> to our knowledge no studies have looked at orientation programs in particular.

**Universality of teaching.** Participant feedback has also highlighted the universality of teaching. Although these workshops were designed for family medicine faculty in particular, teachers from other medical specialties have participated for a variety of reasons and have commented that the workshop content is relevant to them as well. Workshop modules have also been modified and adapted to other cultures and work environments, including those in Costa Rica and Israel, with good results.

**Future challenges.** We think a 2-day workshop is an excellent method for initiating an orientation program for new faculty. It is limited, however, in that it does not allow for follow up, reinforcement of new skills, or discussion of teaching problems as they arise.

Although several faculty development models could be considered,<sup>17</sup> we have tried to deal with the workshop's limitations by sponsoring a series of seminars and "booster" sessions for workshop participants. Booster sessions are held 6 to 8 months after the workshop, and participants are encouraged to bring their teaching problems for discussion and review. In many ways, the outcome of these booster sessions is more powerful than the workshops themselves. We focus on the teachers' individual problems, try to find solutions pertinent to their own teaching sessions, and aim to arrange for unit-based follow up.

Some of the teaching methods used in this workshop could be presented in separate sessions. Participants have frequently requested sessions on how to use videotape in teaching or how to conduct role playing more effectively. We have tried to accommodate these requests by devising a seminar series for ongoing faculty development. With additional resources, we might also consider developing a 1-week seminar<sup>33</sup> on effective teaching methods or a 1-year course<sup>3</sup> on teaching and learning.

New teachers of family medicine need to understand clearly their new roles and responsibilities. An orientation workshop, such as the one described here, forms an important part of their introduction to teaching and learning. ■

#### Acknowledgments

We thank the clinical teachers who participated in our workshop for their input into developing the workshop modules. We also acknowledge Dr M.W.L. Davis, former Chairman of the Department of Family Medicine, for his support of the workshops.

**Correspondence to:** Dr Y. Steinert, Herzl Family Practice Center, Sir Mortimer B. Davis Jewish General Hospital, 5757 Legare St, Montreal, QC, H3T 1Z6

#### References

1. Bates GW. Faculty development: a continuing process. *J Med Educ* 1988;63:490.
2. Cantrell T. How do medical school staff learn to teach? *Lancet* 1973;2:724-7.
3. Desmarchais JE, Jean P, Delorme P. Basic training in medical pedagogy: a one year program for medical faculty. *Can Med Assoc J* 1990;142:734-9.
4. Fleming MF, Bogdewic S. Faculty orientation within departments of family medicine. *Fam Med* 1985;17:48-9.
5. Steinert Y, Levitt C, Lawn NR. Faculty development in Canada: a national survey of family medicine departments. *Can Fam Physician* 1988;34:2163-6.
6. Steinert Y. Faculty development in family medicine. A reassessment. *Can Fam Physician* 1993;39:1917-22.
7. Stephens G. On becoming a teacher of family medicine. *J Fam Pract* 1977;4:325-7.
8. Sweet DE, Winter RO, Hammond BL. Testing a model of career development. *Fam Med* 1989;21:350-4.
9. Hopkins JR, Green WM. Family practice residency graduates as faculty members. *J Fam Pract* 1978;6:823-6.
10. Holland J. *Handbook of modern personnel administration*. New York: McGraw Hill, 1972:23-33.
11. Hollman RW. Let's not forget about new employee orientation. *Pers J* 1976;244-50.
12. Wanous JP. *Organizational entry: recruitment, selection, orientation and socializing of newcomers*. Reading, Mass: Addison-Wesley, 1992.
13. Burr BD. The first-year family practice resident: an identity crisis. *J Fam Pract* 1975; 2:111-4.
14. Weiner PS. A social discussion group for first-year residents. *J Med Educ* 1984;59:137-9.
15. Brashear DB. Support groups and other supportive efforts in residency programs. *J Med Educ* 1987;62:418-24.
16. Boice R. *The new faculty member*. San Francisco: Jossey Bass, 1992.
17. Worthington RC, Clay MC. Components of effective faculty orientation. *Fam Med* 1993; 25:437-40.
18. Allen D, Ryan K. *Microteaching*. Don Mills, Ont: Addison Wesley, 1969.



2.5 mg, 5 mg and 10 mg

19. Knowles MS. *The adult learner: a neglected species*. Houston: Gulf Publishing, 1990.
20. Merriam S, Caffarella RS. *Learning in adulthood*. San Francisco: Jossey Bass, 1991.
21. Pratt D, Magill M. Educational contracts: a basis for effective clinical teaching. *J Med Educ* 1983;58:462-6.
22. Kolb DA. *Learning style inventory*. Boston: McBer, 1985.
23. Irby DM, Ramsey PG, Gillmore GM, Schaad D. Characteristics of effective clinical teachers of ambulatory care medicine. *Acad Med* 1991;66:54-5.
24. Gjerde CL, Coble RJ. Resident and faculty perceptions of effective clinical teaching in family practice. *J Fam Pract* 1982;14:323-7.
25. Edwards JC, Brannan JR, Burgess L, Plauche WC, Marier RL. Case presentation format and clinical reasoning: a strategy for teaching medical students. *Med Teach* 1987;9:285-92.
26. Ende J. Feedback in clinical medical education. *JAMA* 1983;50:777-81.
27. Hitchcock MA, Stritter FT, Bland CJ. Faculty development in the health professions: conclusions and recommendations. *Med Teach* 1993;14:295-309.
28. Eble KE, McKeachie WJ. *Improving undergraduate education through faculty development*. San Francisco: Jossey Bass, 1985.
29. Stritter FT. Faculty development and evaluation. In: McGuire CH, Foley RP, Gorr A, Richards RW, editors. *Handbook of health professions education*. San Francisco: Jossey Bass, 1983:357-60.
30. Hitchcock MA, Anderson WA, Stritter FT, Bland CJ. Profiles of family practice faculty development graduates 1978-1985. *Fam Med* 1988;20:33-8.
31. Sheets KJ, Henry RC. Evaluation of a faculty development program for family physicians. *Med Teach* 1988;10:75-83.
32. McGaghie WC, Bogdewic S, Reid A, Arndt J, Stritter F, Frey J. Outcome of a faculty development fellowship in family medicine. *Fam Med* 1990;22:196-200.
33. Craig JL. Teacher training for medical faculty and residents. *Can Med Assoc J* 1988;139:949-52.

• • •

**Antihypertensive Agent/Dihydropyridine Calcium Channel Blocker**

**INDICATIONS AND CLINICAL USE**

PLENDIL® (felodipine) is indicated in the treatment of mild to moderate essential hypertension. PLENDIL should normally be used in those patients in whom treatment with a diuretic or a beta-blocker was found ineffective or has been associated with unacceptable adverse effects.

PLENDIL can be tried as an initial agent in those patients in whom the use of diuretics and/or beta-blockers is contraindicated or in patients with medical conditions in which these drugs frequently cause serious adverse effects.

Combination of PLENDIL with a thiazide diuretic or a beta-blocker has been found to be compatible and showed an additive anti-hypertensive effect. Safety and efficacy of concurrent use of PLENDIL with other antihypertensive agents has not been established.

**CONTRAINDICATIONS**

PLENDIL (felodipine) is contraindicated in:

- 1) Patients with a known hypersensitivity to felodipine or other dihydropyridines.
- 2) In women of childbearing potential, in pregnancy, and during lactation. Fetal malformations and adverse effects on pregnancy have been reported in animals.

**Teratogenic Effects.** Studies in pregnant rabbits administered doses of 0.46, 1.2, 2.3 and 4.6 mg/kg/day (from 0.4 to 4 times the maximum recommended human dose on a mg/m<sup>2</sup> basis) showed digital anomalies consisting of reduction in size and degree of ossification of the terminal phalanges in the fetuses. The frequency and severity of the changes appeared dose-related and were noted even at the lowest dose. These changes have been shown to occur with other members of the dihydropyridine class. Similar fetal anomalies were not observed in rats given felodipine.

In a teratology study in cynomolgus monkeys, no reduction in the size of the terminal phalanges was observed but an abnormal position of the distal phalanges was noted in about 40 percent of the fetuses.

**Non-teratogenic Effects.** In a study on fertility and general reproductive performance in rats, prolongation of parturition with difficult labour and an increased frequency of fetal and early postnatal deaths were observed in the groups treated with doses of 9.6 mg/kg/day and above.

Significant enlargement of the mammary glands in excess of the normal enlargement for pregnant rabbits was found with doses greater than or equal to 1.2 mg/kg/day. This effect occurred only in pregnant rabbits and regressed during lactation. Similar changes in the mammary glands were not observed in rats or monkeys.

**WARNINGS**

**Congestive Heart Failure.** The safety and efficacy of PLENDIL (felodipine) in patients with heart failure has not been established. Caution should, therefore, be exercised when using PLENDIL in hypertensive patients with compromised ventricular function, particularly in combination with a beta-blocker. Acute hemodynamic studies in a small number of patients with New York Heart Association Class II or III heart failure treated with felodipine have not demonstrated negative inotropic effects.

**Hypotension, Myocardial Ischemia.** PLENDIL may, occasionally, precipitate symptomatic hypotension and rarely syncope. It may lead to reflex tachycardia which, particularly in patients with severe obstructive coronary artery disease, may result in myocardial ischemia. Careful monitoring of blood pressure during the initial administration and titration of felodipine is recommended. Care should be taken to avoid hypotension especially in patients with a history of cerebrovascular insufficiency, and in those taking medications known to lower blood pressure.

**Beta-Blocker Withdrawal.** PLENDIL gives no protection against the dangers of abrupt beta-blocker withdrawal; any such withdrawal should be a gradual reduction of the dose of beta-blockers.

**Outflow Obstruction.** PLENDIL should be used with caution in the presence of fixed left ventricular outflow obstruction.

**PRECAUTIONS**

**Peripheral Edema.** Mild to moderate peripheral edema was the most common adverse event in the clinical trials. The incidence of peripheral edema was dose-dependent. Frequency of peripheral edema ranged from about 10 percent in patients under 50 years of age taking 5 mg daily to about 30 percent in those over 60 years of age taking 20 mg daily. This adverse effect generally occurs within 2-3 weeks of the initiation of treatment. Care should be taken to differentiate this peripheral edema from the effects of increasing left ventricular dysfunction.

**Use in Elderly Patients or in Patients with Impaired Liver Function.** Patients over 65 years of age as well as patients with impaired liver function may have elevated plasma concentrations of felodipine and, therefore, may require lower doses of PLENDIL. These patients should have their blood pressure monitored closely during the initial administration and dosage adjustment of PLENDIL, and should rarely require doses above 10 mg per day. (See Pharmacokinetics and DOSAGE AND ADMINISTRATION.)

**Gingival Hyperplasia.** PLENDIL can induce gingival enlargement in patients with pronounced gingivitis and parodontitis. However, such changes may be reversed by measures of good oral hygiene and mechanical debridement of the teeth.

**Pregnancy and Lactation.** See CONTRAINDICATIONS.

**Use in Children.** PLENDIL is not recommended in children since the safety and efficacy in children have not been established.

**Drug Interactions.** *Beta-Adrenoceptor Blocking Agents:* A pharmacokinetic study of felodipine in conjunction with metoprolol demon-

strated no significant effects on the pharmacokinetics of felodipine. The AUC and C<sub>max</sub> of metoprolol, however, were increased approximately 31 and 36 percent, respectively. In controlled clinical trials, however, beta-blockers including metoprolol were concurrently administered with felodipine and were well tolerated.

*Cimetidine:* In healthy volunteers pharmacokinetic studies showed an approximately 50 percent increase in the area under the plasma concentration time curve (AUC) as well as the C<sub>max</sub> of felodipine when given concomitantly with cimetidine. It is anticipated that a clinically significant interaction may occur in some hypertensive patients. Therefore, it is recommended that low doses of PLENDIL be used when given concomitantly with cimetidine.

*Digoxin:* When given concomitantly with felodipine as conventional tablets the peak plasma concentration of digoxin was significantly increased. With the extended release formulation of felodipine there was no significant change in peak plasma levels or AUC of digoxin.

*Phenytoin, carbamazepine and phenobarbital:* In a pharmacokinetic study maximum plasma concentrations of felodipine were considerably lower in epileptic patients on long term anticonvulsant therapy (phenytoin, carbamazepine, phenobarbital) than in healthy volunteers. The mean area under the felodipine plasma concentration-time curve was also reduced in epileptic patients to approximately 6% of that observed in healthy volunteers. Since a clinically significant interaction may be anticipated, alternative antihypertensive therapy should be considered in these patients.

**Other Concomitant Therapy:** In healthy subjects there were no clinically significant interactions when felodipine was given concomitantly with indomethacin or spironolactone.

**ADVERSE REACTIONS**

In 1102 patients treated with felodipine, either alone or in combination with other antihypertensive agents, adverse events were reported in 52% of patients and caused discontinuation of therapy in 9%. The most common adverse events (incidence of at least 1%) were: peripheral edema (21.3%), headache (14.9%), feeling of warmth/flush (13.2%), dizziness/vertigo (4.6%), fatigue (2.4%), palpitation (1.6%), extrasystoles (1.5%), nausea (1.5%), pain (1.5%), paraesthesia (1.2%), chest pain (1.1%).

In addition, the following events were reported with an incidence of less than 1 percent (Adverse Events that were Judged Serious are in Bold Face): **Cardiovascular:** angina pectoris, myocardial infarction, atrial fibrillation, arrhythmia, abnormal ECG, AV block, bundle branch block, postural hypotension, syncope, tachycardia, bradycardia. **Central & Peripheral Nervous System:** brain stem disorder, tremor, abnormal gait, anxiety, depression, insomnia, nervousness, somnolence, agitation, apathy, increased appetite, impaired concentration, confusion, emotional lability, hallucination, sleep disorder, malaise. **Gastrointestinal:** abnormal hepatic function, cholestatic hepatitis, abdominal pain, vomiting, constipation, diarrhea, dyspepsia, dysphagia, flatulence, gingivitis, gum hyperplasia, gingival bleeding, dry mouth, salivary gland enlargement. **Dermatologic:** photosensitivity reaction, erythema nodosum, eczema, pruritus, rash, increased sweating. **Musculo-skeletal:** arthralgia, myalgia. **Respiratory:** cough, dyspnea. **Genito-urinary:** impotence, dysuria, frequent urination. **Others:** abnormal vision, anemia, substernal chest pain, asthenia, generalized edema, periorbital edema, facial edema, change in weight, chills.

**Laboratory tests:** For the following laboratory values statistically significant decreases were observed; bilirubin, red blood count, hemoglobin, and urate. Statistically significant increases were found in erythrocyte sedimentation rate and thrombocyte count. None of these changes were considered to be of clinical significance. In addition, the following abnormal blood chemistry results were reported: hypokalemia, hyperkalemia, hyponatremia.

**DOSAGE AND ADMINISTRATION**

PLENDIL should be swallowed whole and not crushed or chewed.

The dose should be adjusted individually according to patient response.

The recommended initial dose is 5 mg once daily. The 2.5 mg tablet is available for dose titration purposes. The usual maintenance dosage range is 5-10 mg once daily. Dose adjustment, if necessary, should be done at intervals of not less than two weeks. The maximum recommended daily dose is 20 mg once a day. In clinical trials 20 mg once daily showed an increased blood pressure response but also a large increase in the rate of peripheral edema and other vasodilatory adverse events (see ADVERSE REACTIONS). Modification of the recommended dosage is usually not required in patients with renal impairment. Plendil tablets are extended release, film-coated tablets, containing felodipine in strengths of 2.5 mg, 5 mg and 10 mg.

**Use in the Elderly or in Patients with Impaired Liver Function.** Patients over 65 years of age or patients with impaired liver function, may have elevated plasma concentrations of felodipine (see PRECAUTIONS). In these patients an initial treatment of 2.5 mg daily should be considered. In general, doses above 10 mg should not be considered in these patients.

Product monograph available on request.

1. Gradman AH. *Am Heart J* 1992; 123: (1): 273-8. 2. Ljung B. *J Cardiovasc Pharmacol* 1990; 15 (Suppl 4): S11-6. 3. Fariello R, et al. *Am J Hyper* 1991; 4: 27-33. 4. Brandtbonbrener M, et al. *Circulation* 1965; XII: 557-66. 5. Culling W, et al. *Br Heart J* 1984; 52: 431-4.
6. Koenig W. On behalf of the Multicentre Study Group. *Drug Invest* 1993; 5(4): 200-5. 7. Hosie J, et al. *J Drug Development* 1992; 5(3): 129-36. 8. Plendil (felodipine) Product Monograph. 9. Leidholm H, Melander A. *J Cardiovasc Pharmacol* 1989; 14: 109-13.
10. Franssens KT, et al. *Clin Trials J* 1990; 27(3): 187-94.
11. Lorimer AR, Pringle SD. *J Cardiovasc Pharmacol* 1990; 15 (Suppl 4): S85-S89. 12. Manufacturers' Price Lists, O.D.B. 1993. 13. Lund-Johansen P. *J Cardiovasc Pharmacol* 1989; 14 (Suppl 10): S7-S13.



**ASTRA**

Astra Pharma Inc., Mississauga, Ontario L4Y 1M4