

developed countries; or a class of interventions, eg, physical therapy. Chris Silagy, an Australian general practitioner, has convened and coordinated the CC's primary health care field.

**Work still to be done**

The efforts of the CC have produced a new resource for physicians that achieves a high score on the usefulness equation. The information is portrayed in a manner that allows physicians to find POEMs and assess their likely impact. Validity issues are addressed by the methods laid out by the CC and by the assistance and structures provided for reviewers. However, as would be expected with any new venture, some faults and flaws still exist. In fact, the CC has been described by one of its key members as "an airplane that took off before its construction was completed."

This unstructured "work in progress" character shows in many ways. The database is still incomplete. While the number of reviews grows rapidly every quarter, there are still

many interventions, including many that are supported by good evidence, that are not included. The software used to search for reviews and view their contents is under continual redevelopment, leading to periodic changes of "look and feel."

Family physicians throughout the world are increasing their involvement in the CC as members of individual review groups, producers of reviews, or members of the primary care field. Their involvement, in collaboration with physicians from all specialties and with members of other disciplines, is leading to the rapid expansion of the CDSR and to its increasing usefulness as each quarterly update arrives. Those interested in becoming involved or simply in obtaining additional information should contact The Canadian Cochrane Centre, Health Information Research Unit, McMaster University Medical Centre, 1200 Main St W, Hamilton, ON L8N 3Z5, or visit the Cochrane webpage at <http://hiru.mcmaster.ca/cochrane>. ♦

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# The importance of being different

## Part 2: Transcending the mind-body fault line

Ian R. McWhinney, MD, CCFP

**Editor's note:** This editorial is an abbreviated version of the Pickles Lecture delivered at the Spring meeting of the Royal College of General Practitioners in Aberdeen, Scotland, in April 1996. The full version has been published in the *British Journal of General Practice* (1996;46:433-6).

In part 1,<sup>1</sup> I argued that defining our discipline in terms of relationships has consequences for our valuation of knowledge and our mode of thought, which I termed "organismic." Organismic thinking transcends the dualistic division between mind and body, which dominates modern medicine.

In their capacity for self-organization, learning, and self-transcendence, organisms behave in a way that is "mindful." This is not simply a mind "in the brain," but one that is immanent in the whole body. Every level of the organism – from the molecular upward – has a capacity for autonomous activity and for integrating its activity with the whole. Each level can transmit and receive coded messages that convey meaning. The immune system, long thought to be isolated, is connected reciprocally with the neuroendocrine systems through neural networks and circulating neurotransmitters. The immune system can learn from experience and can distinguish "self" from "not self."

Evidence shows that emotions can influence immune function, thus providing a physiologic link between life experience and the course and

outcome of illness.<sup>2</sup> Relationships act at this intermediate level of host resistance, not as causal agents for specific diseases.<sup>3</sup> Social isolation, for example, increases mortality from virtually all causes of death. The notion of a separate group of psychosomatic diseases is therefore obsolete. In any disease, social factors can be part of the causal web, and human relationships can be part of the healing process.

**Cognition and emotion**

The immanent mind knows the world through bodily feelings. The separation of thinking from feeling and the relegation of emotion to a limited role is being rendered untenable by cognitive science. Psychologists from Freud to Piaget have shown that thinking and feeling do not occur in isolation: emotion is necessary for cognition, especially for giving meaning to our experience. Neuroscience

now tells us that the connection is embodied in the structure and function of the brain.<sup>4</sup> Experiences that are significant to us are laid down as memory in our neural circuits, with the affective colouring that imbues them with meanings for us. The events of our lives are woven into a personal narrative that not only gives us our sense of self but enables us to interpret and give personal meaning to each new experience.<sup>5</sup>

The "body as machine" is replaced by a new metaphor – the embodied mind<sup>6</sup> – and our new language speaks of the mind-body or bi mind,<sup>7</sup> not the mind *and* the body. Our understanding comes from bodily experience of the world interpreted always in terms of our personal story. This approach takes very seriously the knowledge derived from experience. When applied to medicine it makes patients' experiences of illness an important aspect of medical knowledge. This is the domain of qualitative research: a natural field of inquiry for family medicine.

I believe we are living through the final breakdown of the dualistic worldview – a situation with profound implications for us, as we turn to the fourth difference: *family medicine is the only major field that transcends the dualistic dissociation of mind and body.*

This dissociation runs through medicine like a geological fault. Most clinical disciplines lie on one side or the other: internal medicine, surgery, and pediatrics on one side; psychiatry, child psychiatry, and psychogeriatrics on the other. Separate taxonomies of disease lie on either side: textbooks of medicine and surgery on one, the *Diagnostic and Statistical Manual of Mental Disorders* on the other. We divide therapies into the physical and the psychological. In clinical practice, internists and surgeons do not normally explore the emotions, and psychiatrists do not examine the body. Because family medicine defines itself in terms of relationships, it cannot divide in this way.

**Treating the whole person**

Without this artificial barrier, the relationship between patient and doctor can develop through many encounters for all kinds of illness. In examining and attending to the body, we are also attending to the mind. Mental states are expressed in posture, movement, and muscle tone, and examining the body can trigger the expression of feeling. Body therapies can heal the mind; mental therapies can heal the body. Psychotherapy need not be separate from therapy for the body: indeed it is doubtful whether in family medicine we should call it "psychotherapy."

For most of us, I suspect it is a question of listening, supporting, reassuring, encouraging the expression of feelings, and reinterpreting perceptions that we call cognitive therapy. This is something we do for all patients, not only for those with "psychiatric" illness. The more we learn about the placebo effect, the more it appears to be the healing power of the doctor-patient relationship through symbolic acts and rituals.<sup>8</sup>

Because the effect is strengthened by each new experience of the relationship, it has a special importance for us in family medicine. Over time, the relationship with the doctor can become part of the patient's own narrative. One of the legacies of dualism is the clinical method we have inherited from the 19th century, a method that leaves it to psychiatrists to attend to the emotions. It is not surprising, therefore, that moves to reform our clinical method have come from family medicine.

**Patient-centred medicine**

The essence of the patient-centred method<sup>9</sup> is that the doctor attends to feelings, emotions, and moods, as well as categorizing the patient's illness. What does it mean to attend to a patient's feelings, emotions, and moods? Understanding the emotions is person-to-person, and we cannot attend to another person's emotions without attending to our own. The key

skill is attentive listening. To listen to a person with undivided attention is one of the greatest gifts we can bestow.<sup>10</sup> It is listening not only with our ears, but with all our faculties, especially with an open heart. We cannot do this if our eyes are on our "map," if we are thinking what to say next, or if we are consumed by our own negative emotions. If we can achieve this state of openness, we find that our responses to patients spring naturally from some inner source. Needleman<sup>10</sup> describes this attentive state as "nonegoistic, impersonal love," a love we call charity (to the Greeks *agapē*). It is not an emotion in the usual sense and does not depend on affection. The Good Samaritan did what was needed for the man he rescued, then went on his way. As physicians we can do likewise, whatever our discipline.

But for family physicians there is an additional dimension: the long-term relationship with patients, in the course of which affections grow. Of the four loves – affection, friendship, eros, and charity – C.S. Lewis<sup>11</sup> called affection the humblest and most widely diffused. When combined with charity, the warmth of affection must surely be a healing force, but it comes with a price, for the relationship between doctor and patient is subject to the same stresses and weaknesses as other human relationships. We see both love and hate, trust and mistrust, betrayal and forgiveness, irretrievable breakdown and survival of the relationship against all odds. Unacknowledged negative emotions, like fear, helplessness, anxiety, anger, and guilt, might be acted out by a doctor in avoidance, indifference, rejection, and even cruelty. Physicians' own needs for affection might be stronger than their ability to give it. It is the egoistic emotions, so destructive of human relationships, that prevent us from responding to suffering with our authentic feelings. The priest and the Levite "passed by on the other side," no doubt giving themselves very good reasons.

## EDITORIALS

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We can attend to a patient's feelings and emotions only if we know our own, but self-knowledge is neglected in medical education, perhaps because the path to this knowledge is so long and hard. Egoistic emotions often come disguised as virtues, and we all have a great capacity for self-deception. But there are pathways to this knowledge, and medical education could find a place for them. Could medicine become a self-reflective discipline? The idea might seem preposterous. Yet, I think it must if we are to be healers as well as competent technologists.

By living in a world of abstractions and neglecting our own emotional development, we erect an invisible barrier between ourselves and our patients. We protect ourselves by growing a hard shell that makes openness difficult, and our patients interpret this as cold indifference or rejection. One writer has recently referred to our profession's "stunted emotions."<sup>12</sup> Even psychiatry is not a model of self-reflectiveness. As Bettelheim<sup>13</sup> and Needleman<sup>10</sup> have noted, psychiatry has directed its attention more to *other peoples'* emotions. Rather than turn our attention inward, we are driven by our culture to put our faith in new abstractions like systems theory, not seeing that, however useful they might be as maps, they can come between us and our patients.

### Ideal therapeutic setting: family medicine

The four differences I have described are all of a piece. Giving primacy to long-term relationships directs our attention to the particulars of illness; the complexity of illness in the context of relationships makes it difficult for us to think in mechanistic and dualistic terms. But we have hardly begun to see the advantages of our position. Transcending the "fault line" should make family medicine the ideal therapeutic setting for the many disorders that, like chronic pain, do not fit neatly on one side or the other. The more we

learn about the effect of supportive relationships on cancer and other chronic diseases, the more redundant the fault line becomes.<sup>14,15</sup>

To realize our potential, however, we have other work to do. Thinking in the way I have described might be natural for us, but it is still difficult, for we are all, to some extent, prisoners of an unreformed clinical method and the language of linear causation and mind-body dualism. The fault line runs through the affect-denying clinical method that dominates the modern medical school. Not until this is reformed will emotions and relationships have the place in medicine they deserve.

Finally, to become self-reflective, medicine will have to go through a huge cultural change. In these changes family medicine is already some distance along the path. The importance of being different is that we can lead the way. ♣

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comme producteurs d'articles de synthèse ou participants dans le domaine des soins de première ligne. Grâce à cette implication et à la collaboration de toutes les spécialités et des autres disciplines, la banque de données connaît une expansion rapide et chaque mise à jour trimestrielle accroît son utilité.

Si vous êtes intéressé à vous impliquer ou simplement à obtenir des renseignements supplémentaires, veuillez communiquer avec le Canadian Cochrane Center, Health Information Research Unit, McMaster University Medical Center, 1200 Main St W, Hamilton, ON L8N 3Z5, ou visitez la page web Cochrane à l'adresse suivante : <http://hiru.mcmaster.ca/cochrane>. ♣

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## L'importance d'être différent

### 2<sup>e</sup> partie : Transcender la démarcation corps-esprit

Ian R. McWhinney, MD, CCMF

**Note du rédacteur :** Cet éditorial est une version abrégée de l'allocution prononcée dans le cadre de la Pickles Lecture lors de la rencontre printanière du Royal College of General Practitioners à Aberdeen, Écosse, tenue en avril 1996. La version intégrale a été publiée dans le *British Journal of General Practice* (1996;46:433-6).

Dans la première partie de cet article<sup>1</sup>, j'ai soutenu que le fait de définir notre discipline en termes de relations avait des répercussions sur notre appréciation de la connaissance et de notre mode de pensée que j'ai qualifié « d'organiciste ». La pensée organiciste transcende la division dualiste entre le corps et l'esprit qui domine la médecine moderne.

Par leur capacité d'auto-organisation, d'apprentissage et d'autotranscendance, les organismes se comportent de façon « réfléchie ». La présence de la pensée n'est pas limitée au « cerveau », mais elle est immanente à la nature même de l'être, c'est-à-dire qu'on la retrouve dans chacune de ses composantes. À partir du stade moléculaire, toutes les composantes de l'organisme sont capables d'activité autonome et d'intégration de cette activité à l'ensemble de l'organisme. Chaque composante peut transmettre et recevoir des messages codés qui ont une signification. Le système immunitaire, longtemps considéré comme une entité séparée, est raccordé par des connexions bidirectionnelles aux divers systèmes neuroendocriniens grâce aux réseaux de neurones et de neurotransmetteurs circulants. Le système immunitaire possède la capacité d'apprendre par expérience et peut faire la distinction entre le « moi » et le « non-moi ».

La science nous apprend que les émotions influencent la fonction immunitaire, établissant ainsi un lien physiologique entre le vécu et l'évolution et le pronostic de la maladie<sup>2</sup>. Les relations agissent à ce niveau intermédiaire de la résistance de l'hôte et non pas comme agents étiologiques de certaines maladies spécifiques<sup>3</sup>. L'isolement social, par exemple, est un facteur qui augmente les taux de mortalité de presque toutes les causes de décès. La notion d'un groupe distinct de maladies psychosomatiques est donc désuète. Quelle que soit la maladie, les facteurs sociaux peuvent faire partie de la multiplicité des causes, tout comme les relations humaines peuvent faire partie du processus de guérison.

### La cognition et l'émotion

La pensée immanente (intégrée à la nature de l'être) apprend à connaître le monde en utilisant les sensations corporelles. Séparer la pensée des sentiments et reléguer l'émotion à un rôle limité deviennent des arguments insoutenables devant la science de la cognition. Depuis Freud jusqu'à Piaget, les psychologues ont prouvé que la pensée et les sentiments ne sont pas des événements isolés ; l'émotion est un élément essentiel de la cognition surtout lorsqu'il faut donner un sens à notre expérience. Les sciences neurologiques nous apprennent que cette connexion fait partie intégrante de la structure et de la physiologie du cerveau<sup>4</sup>. Les expériences considérées significatives par chacun de nous sont classées dans la mémoire de nos circuits neuronaux, y compris la coloration affective individuelle qui leur donne un sens. Les événements vécus contribuent à tisser notre histoire personnelle qui définit non seulement notre sens du moi mais qui nous rend capable d'interpréter et de donner une signification personnelle à chacune de nos expériences nouvelles<sup>5</sup>.

La notion voulant que le « corps est une machine » est remplacée par une nouvelle métaphore : « la pensée

incarnée»<sup>6</sup>. Ce nouveau langage parle de corps-esprit ou de biopensée<sup>7</sup>, et non pas de pensée *et* de corps. Notre compréhension provient de l'expérience corporelle du monde que nous interprétons toujours à la lumière de notre histoire personnelle. Cette approche prend en très sérieuse considération les connaissances acquises par l'expérience. Transposée à la médecine, l'expérience personnelle de la maladie vécue par les patients constitue un élément important des connaissances médicales. Nous voici dans le domaine de la recherche qualitative, un domaine naturel de recherche pour la médecine familiale.

Je suis d'avis que nous vivons présentement l'étape finale de l'effondrement de la vision dualiste du monde, situation qui aura des implications marquantes sur la médecine familiale et qui nous ouvre la porte de la quatrième différence : *la médecine familiale est le seul domaine important qui transcende la dissociation dualiste du corps et de l'esprit.*

Cette dissociation traverse la médecine comme une faille géologique. La plupart des disciplines cliniques se retrouvent d'un côté ou de l'autre : la médecine interne, la chirurgie et la pédiatrie d'un côté ; la psychiatrie, la psychiatrie infantile et la psychogériatrie de l'autre. Chaque côté dispose de sa propre taxonomie ; d'une part, les volumes de référence de la médecine et de la chirurgie ; d'autre part le *Manuel diagnostique et statistique des troubles mentaux*. Cette division touche également les thérapies : d'un côté, les thérapies physiques et, de l'autre, les thérapies psychologiques. En pratique clinique, il est normal que les internistes et les chirurgiens n'explorent pas les émotions et que les psychiatres n'examinent pas le corps. On ne peut diviser de cette façon la médecine familiale puisqu'elle se définit en termes de relations.

### Traiter la globalité de la personne

Lorsqu'on enlève cette barrière artificielle, la relation entre le médecin et le

patient peut se développer lors des multiples rencontres, quelle que soit la raison de consultation. Tout en examinant et en prenant soin du corps, nous nous préoccupons également de l'esprit. Les états d'esprit s'expriment par la posture, le mouvement et le tonus musculaire ; l'examen du corps peut déclencher l'expression d'un sentiment. Les traitements physiques peuvent guérir l'esprit et les thérapies mentales peuvent guérir le corps. Il n'est pas nécessaire d'établir une démarcation entre la psychothérapie et les thérapies corporelles. De fait, pourquoi parlons-nous de « psychothérapie » en médecine familiale ?

Pour la plupart d'entre nous, je soupçonne que c'est une question d'écouter, de soutenir, de rassurer, d'encourager l'expression des sentiments et d'établir une nouvelle interprétation des perceptions à laquelle nous avons donné le nom de thérapie cognitive. Nous appliquons cette façon de faire à tous nos patients et non pas seulement aux problèmes « psychiatriques ». Plus nous en apprenons sur la notion de l'effet placebo, plus il semble que cet effet soit rattaché au pouvoir de guérison de la relation patient-médecin par des gestes et des rituels symboliques<sup>8</sup>.

À cause de l'effet de renforcement que procure chaque nouvelle expérience vécue dans la relation, elle revêt une importance spéciale pour nous, médecins de famille. Avec le temps, la relation avec le médecin peut faire partie de l'histoire personnelle du patient. L'un des héritages de ce dualisme, c'est la méthode clinique que nous avons héritée du 19<sup>e</sup> siècle, une méthode qui laisse aux psychiatres le champ des émotions. Il ne faut donc pas se surprendre que la médecine familiale soit à l'origine des mouvements visant à réformer notre méthode clinique.

### Médecine centrée sur le patient

Dans son essence, la méthode centrée sur le patient<sup>9</sup> implique que le médecin s'occupe des sentiments, des émotions

et des humeurs en même temps qu'il précise le diagnostic qui sous-tend les problèmes du patient. Que signifie s'occuper des sentiments, des émotions et des humeurs d'un patient ? La compréhension des émotions relève de la relation interpersonnelle et il est impossible de s'occuper des émotions d'une autre personne sans s'occuper des nôtres. L'écoute attentive en est la qualité principale. Être capable d'écouter une personne sans se laisser distraire constitue l'un des plus grands dons qui soient donnés à quelqu'un<sup>10</sup>. C'est une écoute qui implique non seulement nos oreilles mais toutes nos facultés et, surtout, une ouverture du cœur. Nous ne pouvons pas y parvenir si nous sommes trop centrés sur nous-mêmes, si nous réfléchissons à la prochaine question ou si nous sommes envahis par nos propres émotions négatives. Lorsqu'on peut atteindre cette qualité d'ouverture, nous constatons que nos réponses aux patients surgissent naturellement d'une source interne. Needleman<sup>10</sup> décrit cet état d'attention comme un type « d'amour dépourvu d'égoïsme et impersonnel », un amour que nous appelons charité (du grec *agapè*). Ce n'est pas une émotion dans son sens habituel et elle ne repose pas sur l'affection. Le bon Samaritain a répondu aux besoins de l'homme qu'il a secouru, puis il a poursuivi son chemin. Comme médecins, nous pouvons faire la même chose, quelle que soit notre discipline.

Dans le cas des médecins de famille, nous ajoutons une autre dimension : la relation à long terme avec nos patients, et c'est dans ce contexte que l'affection grandit. Selon C. S. Lewis<sup>11</sup>, parmi les quatre types d'amour (affection, amitié, *eros* et charité), c'est l'affection qui est la plus modeste et la plus répandue. Combinée à la charité, la chaleur que dégage l'affection doit sûrement contribuer aux pouvoirs de la guérison. Mais il y a un prix à payer puisque la relation entre un médecin et son patient est soumise aux mêmes tensions et aux mêmes faiblesses auxquelles sont confrontées toutes les

autres relations humaines. Nous constatons, contre toute attente, la présence d'amour et de haine, de confiance et de non-confiance, de pardon et de trahison, de rupture irrécupérable et de survie. Des émotions négatives non reconnues comme la crainte, le sentiment d'impuissance, l'anxiété, la colère et la culpabilité peuvent être exprimées par le médecin sous forme de réaction d'évitement, d'indifférence, de rejet et même de cruauté. Il se peut que les besoins personnels du médecin en termes d'affection soient plus importants que sa capacité d'en donner. Ce sont les émotions égoïstes, tellement destructrices pour les relations humaines, qui nous empêchent de réagir à la souffrance par des sentiments véritables. Le prêtre et le lévite « ont traversé de l'autre côté du chemin » en se donnant sûrement d'excellentes raisons.

Nous ne pouvons être à l'écoute des sentiments et des émotions que si nous connaissons nos propres sentiments et émotions. La formation médicale néglige la connaissance de soi, peut-être parce que l'apprentissage de cette connaissance est long et difficile. Les émotions égoïstes revêtent souvent la forme de vertus et nous avons tous une grande capacité à nous décevoir nous-mêmes. Mais il existe des chemins qui mènent à cette connaissance, et l'éducation médicale devrait leur définir une place. Se pourrait-il que la médecine devienne une discipline capable de réfléchir sur elle-même ? L'idée peut sembler absurde. À mon avis, il faudra y parvenir si nous voulons être à la fois des guérisseurs et des techniciens compétents.

En vivant dans un monde d'abstractions et en négligeant notre propre développement émotif, nous érigeons une barrière invisible entre nous et nos patients. Nous nous protégeons en durcissant une carapace qui ne présente pas d'ouverture, ce que nos patients interprètent comme une indifférence froide ou un rejet. Un auteur a récemment fait référence

à la « fausse émotivité » de notre profession<sup>12</sup>. La psychiatrie non plus n'est pas un modèle de réflexion sur elle-même. Comme le soulignent Bettelheim<sup>13</sup> et Needleman<sup>10</sup>, l'attention de la psychiatrie s'est portée sur les émotions *des autres*. Plutôt que de s'attarder à l'introspection, notre culture nous entraîne à croire en de nouvelles abstractions comme la théorie des systèmes, en oubliant que malgré leur utilité possible comme repères, elles peuvent s'interposer entre nos patients et nous.

### La médecine familiale : un contexte thérapeutique idéal

Les quatre différences que j'ai décrites font toutes partie du même ensemble. Le fait d'accorder la primauté aux relations à long terme concentre notre attention sur les particularités de la maladie. Dans un contexte relationnel, la complexité de la maladie nous incite à ne pas penser en termes dualiste et mécaniste. Nous commençons à peine à percevoir les avantages de notre position. Le fait de transcender la ligne de démarcation de la « faille » devrait permettre à la médecine familiale de devenir le contexte idéal pour les nombreux troubles qui, à l'instar de la douleur chronique, n'ont pas de place définie, ni d'un côté ni de l'autre. Plus nos connaissances progressent concernant les effets de la relation de soutien sur le cancer et les autres maladies chroniques, plus cette ligne de démarcation devient redondante<sup>14,15</sup>.

Il nous reste encore du travail à accomplir avant d'actualiser notre potentiel. Cette façon de penser pourrait être dans la nature de la médecine familiale mais nous éprouvons encore des difficultés parce que nous sommes, jusqu'à un certain point, prisonniers d'une méthode clinique non réformée et d'un langage qui s'exprime en termes de causalité linéaire et de dualisme corps-esprit. Cette ligne de démarcation de la faille se retrouve à tous les niveaux de la méthode clinique dépourvue d'affect

qui domine la formation médicale moderne. Tant que cette réforme n'aura pas lieu, les émotions et les relations n'auront pas la place qu'elles méritent en médecine.

Finalement, si elle veut réfléchir sur elle-même, la médecine doit passer par une transformation culturelle profonde. La médecine familiale a déjà parcouru un bout de chemin dans cette voie de changement. L'importance d'être différent, c'est que nous pouvons tracer la voie. ♣

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### Références

1. L'importance d'être différent. 1<sup>re</sup> partie : Transcender le statut marginal de la médecine familiale [éditorial]. *Can Fam Physician* 1997;43:193-5 (Eng), 203-5 (Fr).
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2.5 mg, 5 mg and 10 mg

**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 antihypertensive 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 ischaemia. 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 demonstrated 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. **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. **Enzyme Inhibitors.** **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. **Erythromycin:** Concomitant treatment with erythromycin has been shown to cause an increase in felodipine plasma levels. **Enzyme Inducers.** **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. **Interaction with Grapefruit Juice:** Published data show that through inhibition of cytochrome P-450, flavonoids present in grapefruit juice increase the plasma levels of felodipine, and thus can augment its pharmacodynamic effects (see ACTION AND CLINICAL PHARMACOLOGY). Therefore, the administration of felodipine with grapefruit juice should be avoided.




**ADVERSE REACTIONS** In 1,102 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%), paresthesia (1.2%), chest pain (1.1%). Most of the adverse events were of mild to moderate severity, and, with the exception of peripheral edema, transient. Incidence (%) of peripheral edema, headache and feeling of warmth/flush reported in clinical trials (some patients were randomized to dose, others were dose titrated).

	5 mg (n=342)	10 mg (n=638)	20 mg (n=425)	TOTAL (n=1102)
Peripheral oedema	8.2	15.5	25.2	21.4
Headache	8.8	14.6	9.6	14.9
Feeling of warmth/flush	7.0	12.4	10.11	13.2

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. **Musculoskeletal:** arthralgia, myalgia. **Respiratory:** cough, dyspnea. **Genitourinary:** impotence, dysuria, frequent urination. **Others:** abnormal vision, anemia, substernal chest pain, asthenia, generalized edema, periorbital edema, facial edema, change in weight, chills, hypersensitivity reactions (e.g. urticaria, angioedema). **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.

**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. **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.

**AVAILABILITY** PLENDIL tablets are extended release, film-coated tablets, containing felodipine in strengths of 2.5 mg, 5 mg and 10 mg.

PLENDIL 2.5 mg Tablet: A yellow, circular, biconvex film-coated tablet, engraved  on one side and 2.5 on the other. PLENDIL 5 mg Tablet: A pink, circular, biconvex film-coated tablet, engraved  on one side. PLENDIL 10 mg Tablet: A red-brown, circular, biconvex film-coated tablet, engraved  on one side.

Each tablet strength is available in blister packages (30's) and in 10 x 10 unit dose blister packages.

NOTE: These extended release tablets must not be divided, crushed or chewed.

Full Product Monograph available on request.

PLENDIL® is a registered trademark of Astra Pharma Inc., Mississauga, Ontario L4Y 1M4.

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