DIALOGUE

ONTARIO PSYCHIATRIC ASSOCIATION

MARCH 2011

THE NEWSLETTER OF THE ONTARIO PSYCHIATRIC ASSOCIATION / UNE PUBLICATION DE L'ASSOCIATION DES PSYCHIATRES DE L'ONTARIO

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THANK YOU

to the outgoing OPA Council members

Dr. ANNE HENNESSY

&

Dr. ANDREW HOWLETT

For their outstanding contributions to the

ONTARIO PSYCHIATRIC ASSOCIATION

President's Message

Dr. Doron Almagor

I am privileged as President to once again address our membership in this *Dialogue* from the Ontario Psychiatric Association. The theme for this year's Presidency has been that of *Building a Community of Practice* and I am delighted to see that the pages of *Dialogue* are crowded with communications from both Council Members and our members-at-large, all working towards this purpose. As always, thanks are owed to many of the dedicated council members who work tirelessly and selflessly towards our common goals, only a few of whom I will mention by name in this report.

Dr. Patricia Cavanagh has been leading our Communications Committee, firstly bringing you this publication, but also working towards renewing our web site and planning a comprehensive and fresh electronic and social media strategy. Our web site has been much improved in form and functionality and you are now able to register online for upcoming events such as the 2011 Annual Conference. In the near future, Dr. Cavanagh and the members of the Communications Committee will be looking at ways in which the OPA can increase the communications between members and exploring at the ways in which this can be done within the context of social media.

Dr. Sonu Gaind's article on tariff updates describes important recent changes to the OHIP Schedule of Benefits. The rectification of relativity inequities that we have achieved, as Dr. Gaind notes, do not just address issues of compensation in of themselves, but fundamental issues in regards to the stigma associated with the mentally ill; underfunding of the mental health system is directly related to the undervaluation of our patients as people deserving care. Dr. Gaind's article also gives details as to new Conference and Physician-to-Physician Telephone Consultation codes. I believe that the importance and major implications to practice of these new codes have not yet been fully grasped by our profession, nor has knowledge about them been disseminated widely. These new codes have the potential of improving patient care significantly by helping psychiatrists communicate both amongst ourselves and with allied professionals.

These tariff changes could only have been achieved through many years of hard work and strategic cooperation between the Ontario Psychiatric Association, the OMA's Section on Psychiatry, and our bridging organization, the Coalition of Ontario Psychiatrists. One of key leverage points the OPA has is the sheer number of psychiatrists we represent. I am proud to report that we have made significant growth in our membership numbers and currently stand at 913 members, the highest membership level in the history of our organization. Our fortune lies in our future members and here too the news is good: at 212 we have more Members-in-Training than ever before. These numbers bode well for the future vibrancy of our organization.

That vibrancy of our association was in full display at our Annual Fall Psychotherapy Conference. Dr. Tina Chadda and the Psychotherapy Section of the OPA invited renowned author and psychotherapist Adam Phillips for a thoroughly engaging day of lecture and audience participation. Dr. Andrew Howlett writes in this issue about his own personal experience of the conference as a member-in-training, and I know his article will encourage those of you who don't know about this gem of a meeting to attend next year's psychotherapy conference.

Our Strong Council and Membership will continue to help us build a vital and dynamic organization

The next venue at which our membership can come together as a community will be our Annual Conference in Toronto on April 15th & 16th, 2011. I know that this year's meeting, featuring a keynote address by Dr. Mark Vonnegut, our award recipient, Margaret Trudeau, and an extensive program of world-class CME events, will be our most successful assembly yet. The conference's theme, "Engaging the Profession", will be helmed by our new incoming President, Dr. Alison Freeland. Dr. Freeland's theme expands on this year's focus on *Building a Community of Practice*. Her energy, skills, and experience, together with our strong council and membership, will continue to help us build a vital and dynamic organization that will help shape the landscape of mental health in the province for years to come.

I hope to see you all at the Annual Conference in Toronto on April 15th & 16th!▲

Doron Almagor, MD, FRCP(C)
President, Ontario Psychiatric Association

91st OPA Annual Conference

I hope you will join us for this year's Ontario Psychiatric Association Annual Conference, once again being held at the historic Le Méridien King Edward Hotel in Toronto. The theme of this year's annual conference is *Engaging the Profession*, and your Education Committee has prepared a remarkably strong academic programme for you to enjoy.

The conference will open with a keynote address, *"Is Diagnosis Useful? A Journey of Personal Experience, Societal Views and Medical Perceptions"* by Dr. Mark Vonnegut, a paediatrician in Massachusetts and son of iconic author Kurt Vonnegut. The programme includes a diverse range of sessions by renowned invited speakers, including Dr. Zindel Segal, Dr. Peter Selby, Dr. Claudio Soares, Drs. Elliott Lee & Alan Douglass, and Drs. Keith Connors, Doron Almagor & Russell Schachar. The remainder of the programme is equally exciting, including the awarding of the *T. A. Sweet Award* to Margaret Trudeau at the Friday night Gala Dinner.

You can find additional details in the conference brochure included with this issue of OPA *Dialogue*. If you have not already registered to attend, I encourage you to do so now and join us for what promises to be an excellent conference. Hope to see you in April!▲

K. Sonu Gaind, MD, FRCP(C)
Chair, OPA Education Committee

OPA 2011 Annual Conference: ENGAGING THE PROFESSION

Dr. Alison Freeland

Ontario's 1900 psychiatrists are a diverse group that provides specialized assessment and treatment in diverse settings to a wide range of mental illnesses affecting people across the lifespan. It is little wonder that we have been challenged to find a unified voice that represents our many interests and concerns at a provincial level. However, we are at a critical point where we must engage in the upcoming processes and decisions that are influencing the landscape in which we practice.

In December 2010, "Respect, Recovery, Resilience: Recommendations for Ontario's Mental Health and Addictions Strategy" was released. Although there are many commendable recommendations within this report that could positively influence provision of services in Ontario over the next ten years, there is a noticeable absence of the role of psychiatrists as being uniquely trained to provide treatment for those with mental illness and substance use disorders. We must take time to review these recommendations and advocate and educate both locally and provincially regarding our role as medical experts and clinical leaders on teams.

Next year the OMA will begin discussions to negotiate a new Physician Services Agreement with the Ministry of Health. We must remain current and informed regarding how these progress, as we will need to advocate for resources to support the wide range of psychiatric services necessary to ensure highest quality care for Ontario's residents.

Finally, a recent report developed by the MOHLTC and the OMA has identified that Ontario will be facing a shortage of psychiatrists that will steadily increase in most areas of the province through to 2030. Recruitment of medical graduates into psychiatry remains a priority issue requiring a clear demonstration of pride in our profession and leadership in the delivery of mental health and addictions care within the province of Ontario.▲

The OPA wants this year's conference to ignite the enthusiasm of Ontario's psychiatrists as leaders and advocates. Engaging the profession in becoming informed and active in shaping current and future mental health and addictions health care issues is the goal, and we look forward to seeing you at this year's 91st OPA Annual Conference!

Dr. Alison Freeland, MD, FRCP(C)
President-Elect, Ontario Psychiatric Association

The T. A. Sweet Award

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Margaret Trudeau

The *T. A. Sweet Award* is presented annually to an individual who has made a major contribution to the understanding of mental illness and its impact on individuals in society. The OPA is delighted to announce this year's recipient: **Margaret Trudeau,** *Celebrated Canadian and Mental Health Advocate.*

Margaret Trudeau became the youngest Prime Minister's wife in Canadian history, when she married Pierre Elliot Trudeau at the age of 22. She has led a rich and interesting life by raising five children and travelling the country and the world extensively.

Trudeau has authored three books, including her latest, *Changing My Mind*, which has topped the best selling charts. Margaret discusses with candour and insight the bi-polar condition she has struggled with all her life and shares her journey of recovery, acceptance and hope with the wish that others suffering will reach out and get the help they need.

For all her adult life, Trudeau has suffered from the debilitating effects of her bipolar condition. Now, after seeking medical treatment that has given her life balance and happiness, she advocates strongly on mental health issues, helping people overcome the stigma of mental illness that often prevents sufferers from getting help. Trudeau is working with The Royal Ottawa Hospital to raise funds for their new hospital and raise public awareness of mental health issues.

She now sits on the Executive Advisory Board of the UBC Mental Health Institute as a community advocate. She will further her knowledge of mental health issues and gain new insights into the diagnosis and treatment of some of the most challenging issues in modern medicine.

Today, Trudeau is the Honorary President of WaterCan, a charitable Canadian non-governmental agency dedicated to helping the poorest communities in developing countries build sustainable water supply and sanitation services. Their mission is to educate and raise public awareness of the essential nature of pure water. She has traveled three times to Africa with WaterCan and is very knowledgeable on water issues and the impending global water crisis.

Margaret Trudeau will be accepting OPA's *T. A. Sweet Award* at the Gala Dinner on April 15, 2011.▲

Update on SUBSPECIALTIES

Dr. Gary Chaimowitz

The Royal College of Physicians and Surgeons of Canada has officially approved three psychiatric Subspecialties. The process for the creation of Subspecialties dates back many years during which time leaders within the four Academies, Child and Adolescent Psychiatry, Geriatric Psychiatry, Consult/Liaison Psychiatry and Forensic Psychiatry, had advocated for the creation of Subspecialties. The four Academies have been the governing bodies of the incipient Subspecialties and meet regularly. They also form part of the Council of Academies with a strong presence at the Canadian Psychiatric Association.

Some years ago the four Academies applied to the Royal College for Subspecialty status. After some initial back and forth it was determined that Child and Adolescent Psychiatry, Geriatric Psychiatry and Forensic Psychiatry would go forward as Subspecialties. Selection of these subspecialties was based on RCPSC criteria, including documented societal need, an identified distinct body of knowledge, and an adequate level of national organization and infrastructure to support further development.

As can be imagined, the work that needed to go into the preparation of the application documents for the creation of Subspecialties was enormous. In essence, the same structures, documentation and supporting data required for any specialty needed to be marshalled for presentation to the Royal College. There were two parts to the application process and each Academy had their stalwarts working actively to get these documents together and presented.

In September of 2009 the Royal College granted formal Subspecialty status to the three Academies and the three Subspecialties were born.

That however was just the beginning of the next phase of work for the Academies. Working Groups were struck as per protocol of the Royal College and they began working on the formal documents that would form the basis of the Subspecialty training as to be implemented across the country.

The Royal College values its brand extremely highly and its educational processes are renowned and respected internationally. Hence the activities of the Subspecialty Working Groups as they moved forward were tied very closely to the expectations and demands of Royal College protocol.

Hence Working Groups have mandated regional representation, i.e. with five regional members, and a chair and vice-chair. The initial tasks of the working group were to put together the core documents such as the Standards of Accreditation, Objectives of Training, the FITER, and the STR that would form the standards for the Subspecialties.

Committees met and documents were produced and submitted for review. They received feedback from College educators and, once rewritten, the final documents were submitted to the Royal College for final approval.

The process from here on is as follows. Once the specialty training documents are approved, the Subspecialties are in essence "live" with that information readily available. Programs across the country may then apply to the RCPSC Specialty Committee to get approval that they may run their Subspecialty programs.

At the time that they go "live" as well the Working Group then becomes the formal Specialty Committee of the Subspecialty and deals with matters related to the Specialty.

Once these documents have been completed, Royal College Specialty Committees for each subspecialty will maintain standards, accredit training programs and liaise with national specialty societies (CACAP, CAPL and CAGP). Each new subspecialty will function as an autonomous discipline, accredited to RCPSC standards separately from currently established training programs in Psychiatry. All candidates must be certified in their primary specialty in order to write the RCPSC subspecialty examinations.

In order to get a program up and running, the University programs will need to review the criteria, make an application and indicate that it is able to meet the published criteria. There will be a review at that point. Once approved, residents are able to begin in the programs.

The real test comes not at the application but will come when the programs get accredited. It is important that the various Subspecialty programs are sufficiently resourced that they are able to meet the criteria indicated. An unfavourable accreditation would set back the program for some years.

There are some other interesting issues worth considering. One is the relationship between the Subspecialty and Psychiatry. Each Subspecialty can be seen as an independent "Specialty" with its own Program Director and resources. Although it does not report to the Postgraduate Director of Psychiatry, that relationship is going to be a close and hopefully collaborative one.

Important issues are ensuring that in each province government funds the development of Subspecialties and makes PGY6 years available. This is rolling out unevenly across the country and may in fact be a limiting factor for certain Subspecialties.

Areas of great interest have been what would happen to currently practicing subspecialty psychiatrists. A practice eligibility route (PER) is being developed, giving practicing psychiatrists in the areas of subspecialties the ability to have their training acknowledged so that they would be grandfathered to *write* the exam. No one will be able to avoid the exam but it is anticipated that most practicing subspecialists should be able to be accredited to write the exam in the first few years.

Each new subspecialty will function as an autonomous discipline, accredited to RCPSC standards separately from currently established training programs in Psychiatry.

The Specialty Committee members and the Examination Board for the various subspecialties will be precluded from writing the exams for five years beyond the time that they have completed their work on those committees. Given that some of the smaller subspecialties will have many of its key members on those two committees, that would create a fairly large deficit in what would ultimately be exam-certified specialists. The Royal College has created a category of Founder to recognize those individuals. Founders will eventually need to write the exam and their Founder status will then fall away.

The Examination Board will be a product of the Specialty committees. It is anticipated that the first examinations would be ready to be written in the Fall of 2012, i.e. after the first batch of Fellows conceivably will have finished in July of 2012.

Clearly each of the Academies (CACAP, CAPL and CAGP) is going to want to ensure that its current members are apprised of the Practice Eligibility Route as soon as that becomes available.

This is an exciting time for the Subspecialties. There are certainly going to be interesting political, economic and service delivery consequences to the creation of the three Subspecialties, hopefully all positive.▲

Dr. Gary Chaimowitz, MD, FRCP(C)
President, Canadian Academy of Psychiatry and the Law
OPA Council Member

The Coalition of Ontario Psychiatrists, OPA and OMA Section on Psychiatry – ROLES AND HISTORY

Dr. K. Sonu Gaind

There are nearly 1,900 psychiatrists in Ontario. On a provincial level, we are represented by three groups, the Ontario Psychiatric Association (OPA), Ontario Medical Association Section on Psychiatry (OMA Section), and the Coalition of Ontario Psychiatrists (Coalition). It is important for Ontario psychiatrists to be aware of the roles of these different organizations and how they work in concert to advocate for psychiatrists and our patients.

BACKGROUND

The OPA is the professional association for Ontario psychiatrists. Its governing body is OPA Council which consists of sixteen Council members elected by OPA members. Council members include the Past-President, President, President-Elect, Secretary, Treasurer, and eleven Councillors (of which two are Members-in-Training). The OMA Section on Psychiatry is the Section representing psychiatrists within the OMA. The Section Executive is elected by Section members and consists of the Past-Chair, Chair, Vice-Chair, Secretary, Chair of the Committee on Medical Practice and Tariff, Chair of the Scientific Program Committee, and seven Members-at-Large.

The Coalition was formed in the late 1990s as a partnership between the two organizations, the OPA and OMA Section on Psychiatry. The goal was to facilitate coordination and cooperation between these two bodies, and to allow psychiatrists to speak with a unified voice on common issues. Representatives from the OPA Council and OMA Section Executive worked together informally from 1996 until 1998, when a memorandum of agreement formally established the Coalition with its own bylaws and structure. The Directors of the Coalition are the President, Past-President, and President-Elect of the OPA, and the Chair, Past-Chair, and Vice-Chair of the OMA Section. Other representatives, including from the Association of General Hospital Psychiatric Services (AGHPS) and the OMA Section Medical Practice and Tariff Chair, participate as observer members.

FUNDING AND DUES

Each of these bodies receives funding in different ways. Funding for the OMA Section comes from OMA member dues, and given RAND in Ontario all psychiatrists are obligated to pay OMA dues. Funding for both the OPA and the Coalition is dependent upon voluntary dues. OPA dues are most commonly paid by OPA members at the time of renewal of their Canadian Psychiatric Association (CPA) membership (the CPA form includes a box for payment of OPA dues), though membership dues can also be paid directly to the OPA. Funding for the Coalition comes from psychiatrists contributing to the "OMA-OPA Coalition Action Fund" on their OMA membership renewal form. Both OPA and OMA-OPA Coalition Action Fund fees remain below $300 each.

Why should psychiatrists pay voluntary dues to the OPA and the Coalition when they are already paying OMA dues? Perhaps more fundamentally, you might even ask *"Why not have just one body, either the OMA Section on Psychiatry or the OPA, representing Ontario psychiatrists, rather than three?"*

ROLES

While all three of these organizations share certain goals, each also has its own unique roles and goals. The **OMA Section** is directly involved in negotiation issues and issues affecting psychiatrist remuneration in different practice models. Since agreements and funding are negotiated between the OMA and the Ministry of Health and Long-Term Care (MOHLTC) it is essential that the OMA Section on Psychiatry have a strong voice in representing psychiatrists at the OMA.

It is also essential that psychiatrists have a vibrant and autonomous professional association that supports psychiatrists and advocates for psychiatric patients on a broad range of issues. Promoting best practices, providing opportunities for member education and liaising with patient and mental health groups to improve mental health care are all functions of the **OPA** that extend beyond typical negotiation issues.

At the same time, the OPA and the OMA Section naturally share many common goals. The **Coalition** allows the OPA and OMA Section to coordinate efforts and pursue initiatives in these areas of overlap. Just as importantly, it provides funding separate from the flow through of OMA dues that the OMA Section is dependent on. This independent funding is used to support tariff and negotiations work; obtain legal advice, policy and lobbying support; facilitate communications on negotiations and other issues (this current mailing of *Dialogue* is being received by OPA non-members with financial support from the Coalition); and for other projects such as development of the Psychiatrist Billing Guide (the first such guide for psychiatrists in Canada, which was distributed in early 2005, with a revision planned for distribution to Coalition Action Fund contributors in the next year).

BENEFITS AND SUCCESSES

While it may initially seem confusing to have three different groups with some distinct goals and some shared objectives, in practice this arrangement has worked very well for psychiatrists in Ontario over the past decade. The OPA and the OMA Section have been able to maintain their autonomy and pursue their individual mandates, and the Coalition has been able to facilitate shared initiatives effectively. Rather than detracting from common goals with excessive redundancy or disparate voices, the evolution of these three groups working concurrently has allowed psychiatry to capitalize on the strengths of each and maximize effectiveness. On a personal note, I have worked with the OMA Section Executive, OPA Council, and the Coalition, and can attest to the benefits and flexibility of this arrangement.

It is also important for psychiatrists to appreciate the tangible benefits the above arrangement has led to, and the need to sustain efforts over time on many fronts to bring about significant change. For example, as you are aware the current OMA-MOHLTC Agreement allocates fully 50% of the OHIP fee increases to relativity. This is the first time in Ontario there has been such an explicit commitment to relativity in any such agreement. Psychiatry was instrumental in changing the previous longstanding policy of across-the-board fee increases (that simply magnified existing fee disparities) and forcing a focus on the issue of relativity, including introducing and passing an OMA policy setting motion at November 2001 OMA General Council that shifted future negotiations and allocations away from across-the-board increases: "That the OMA recognize that across-the-board fee increases to the Schedule of Benefits perpetuate existing fee inequities, and that fee increases must be allocated in a more equitable fashion." As a result of relativity, *psychiatry OHIP fees have increased cumulatively by approximately 16% over the past 2 years, which is double the general fee increase and nearly 4 times more than OHIP fee increases to sections not obtaining relativity increases.*

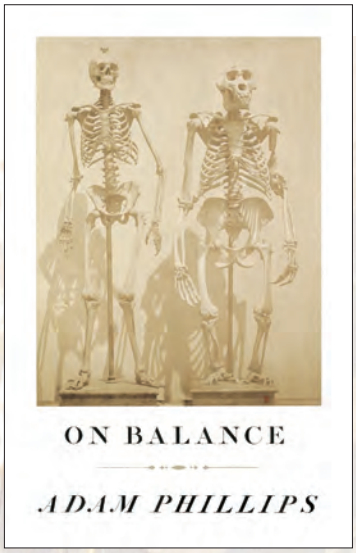
Even with our more recent successes, member engagement and participation is essential. You will recall the 2009 Coalition campaign to ensure that the value of specialist training be recognized in the new CANDI relativity model. Through member engagement, including hundreds of members responding to the Coalition letter writing campaign, we were able to change OMA policy and ensure that specialist training was appropriately recognized by the addition of a "Skills Acquisition Modifier", or SAM factor. As a direct result of this, psychiatry received an additional approximately $5 million in 2010 relativity allocations, and anticipate a similar additional amount in 2011 relativity allocations [*so a total of over $10 million additional ongoing annualized funding*] than we would have received without the SAM factor. Beyond increasing existing fees, this funding can also be used to improve how psychiatric services are delivered, including funding indirect services and other improvements.

Considering what is at stake, the less than $600 combined voluntary OPA and OMA-OPA Coalition Action Fund dues seem like a good investment.

Understanding the roles of the OPA, OMA Section on Psychiatry, and Coalition is important in appreciating the relevance of each organization to Ontario psychiatrists. It is also important to point out that ***all*** Ontario psychiatrists benefit from the work done by these groups. If you have supported your colleagues by contributing time and/or voluntary membership dues to the Coalition and OPA, thank you; if you have not, I hope you will consider adding your support to make these organizations even more effective at advocating for you, our colleagues and our patients.▲

K. Sonu Gaind, MD, FRCP(C)
Medical Practice and Tariff Chair,
Ontario Medical Association Section on Psychiatry
OPA Council Member

2010 Psychotherapy Section Fall Conference… enhances residency training



This psychotherapy conference was my first and I wasn't quite sure what to expect. I had been unable to attend the 2009 conference featuring Nancy McWilliams, a familiar name in our residency training. This year the invited guest was Adam Phillips, a prominent child psychoanalyst from the UK and a prolific writer appealing to both therapists and readers interested in the psychology of various aspects of human nature.

In any case, I was expecting Phillips to enlighten us with a few lectures on some of his published work and its application to psychotherapy or psychoanalysis. I imagined participants offering clinical material for reinterpretation by Phillips, and anticipated that the material would be processed and challenged by the attendees.

Instead, the conference began with Phillip's reading his unpublished essay, *On Frustration*. Others told me that this is not an unusual way for such conferences to begin and that I would likely find this essay published in his next book. His presentation was not limited to the names of Freud and Klein, but rather incorporated historical characters and references to broaden our understanding of the topic. Following the reading, the participants discussed his ideas and references to Shakespeare's *King Lear*. I listened and came to understand frustration as a relationship we have with ourselves, with objects and with others; the experience of something available but not yet achieved. Without frustration there would be no satisfaction; frustration leads to change.

The second phase was a "fire-side" interview with Phillips on his 2010 book, *On Balance*, conducted by the OPA Council member Tina Chadda, a psychiatrist and Chair of the Psychotherapy Section. Together they explored particular elements of the book in further detail. Since I had not read the book in advance I was unclear what I might gain out of this experience; however, much to my surprise, I was able to reflect on the interview and question period, finding opportunities to ask random questions and engage with Phillips. It was experiential learning — to sit amongst junior and senior psychotherapists and psychiatrists and explore these themes with the focus more on process rather than clinical material. This maintained a sophisticated dimension, enhancing the possibility of creating what Winnicott would call a transitional space in time, on this occasion, amongst peers.

Before coming to a close with final remarks by Pam Stewart, a psychiatrist and member of the OPA Psychotherapy Section Conference committee, a signed copy of *On Balance* was raffled off; however, this didn't stop those who didn't win from purchasing a book and requesting an autograph.

I continue to reflect on this experience and of course, having now read the book *On Balance* I have more questions for Adam Phillips. Having the opportunity to attend the 2010 Fall Conference adds to the joy of reading his work and pondering his ideas.

Andrew L. Howlett, MD
PGY-4
University of Toronto,
Department of Psychiatry
OPA Council Member

The Joint Task Force on Standards for Psychotherapy – *A History of Political Action*

If a person says, "It's not the money, it's the principle"…it's the money!
But if a politician says it, it is neither the principle or the money …it's the power!
— Anonymous

In previous articles I have dealt with the early days of the Ontario Neuro-Psychiatric Association, citing interesting anecdotes or personalities from that period. In this article I will look at the role of the OPA in establishing standards of practice and protecting the interests of psychiatrists in Ontario focusing on the *Joint OPA-OMA Section of Psychiatry Task Force on Standards for Psychotherapy*. That was established 20 years ago.

The Ontario Psychiatric Association has a proud history of leadership in professional standard setting over many years — usually driven by professional and clinical issues. The three professional organizations in Ontario had gradually evolved different roles. Clinical, educational and research issues were handled by the OPA. The professional standards of practice and ethics issues were referred to the College of Physicians and Surgeons of Ontario (CPSO). And the fee-setting and encounters with government were handled by the Ontario Medical Association (OMA). It was a convenient arrangement but as we shall see, did not always work out in the best interests of psychiatrists.

In the period of the 1980s and '90s, governments were very much concerned about problems in Medicare. The politicians and bureaucrats were concerned about escalating costs and what they perceived as too much power in the hands of hospitals and the medical profession. They became more involved in determining how physicians practiced and even what they could do and how much they could earn. These issues were very much the territory of the Ontario and Canadian Medical Associations and the OPA traditionally turned these issues over to the OMA Section of Psychiatry.

But the climate of debate changed dramatically in 1990. A case before the CPSO Discipline Committee concerned a complaint by a woman in psychotherapy who filed a complaint of sexual abuse against her GP. It concerned a form of psychotherapy her doctor called 'psychogenic bonding'. Apparently, the patient was expected to hug the therapist in a kneeling position while, as the complaint read, *"… (the physician) removed his trousers and was wearing nothing underneath."*

Unfortunately, the CPSO's Discipline Committee dismissed the complaint and justified this decision in its reports by saying that evidence had been presented that this was a recognized form of psychotherapy and further, the patient had returned for further sessions before lodging a complaint. Women's groups were outraged at the implication that the patient's return for further sessions suggested that she condoned the practice and therefore had no complaint. Psychiatrists were outraged that no psychiatrist had been called to testify to the Discipline Committee about this "therapy", which was by no means a practice that was respected or taught by the profession.

Medical practice quickly became a hot political issue. Ontario had just elected an NDP government under Premier Bob Rae. The newly appointed Minister of Health, Evelyn Gigantes was reputed to have called the Registrar of the CPSO demanding: *"Are you going to call the public enquiry or will I?"* The CPSO quickly set up the *"Task Force on the Sexual Abuse of Patients by Physicians"* that held public enquiries and reported in 1991 to the effect that sexual abuse of patients was totally unacceptable and could result, if proven, in permanent revocation of the Licence to Practice.

The spinoffs for Psychiatry were devastating. Even though the physician in question was not a psychiatrist but a general practitioner and the model of psychotherapy was not a recognized form, psychiatrists were being branded by some as abusers of their patients. In fact, and to the profession's shame, shortly after this, several prominent psychiatrists lost their licences for sexually abusing their patients.

The OMA was no help in this matter. GP psychotherapy — much of it untrained — was on the rise. In the previous years there had been a large increase in general physicians practicing psychotherapy to the point that in 1992, billings to OHIP for psychotherapy by general physicians equalled or exceeded billings by psychiatrists. General physicians dominated the discussion at all OMA Council meetings.

Pierre Beausejour was the President of OPA in 1990 and I followed him in 1991. We both agreed that this problem required a vigorous response by the OPA. After the CPSO 'Task Force' report came out in late 1991, we established the *OPA Task Force on Standards for Psychotherapy*. It was quickly endorsed by the OMA Section of Psychiatry and became the 'Joint Task Force' in 1992. The report of this Task Force was published in 1995 under the Chairmanship of Paul Cameron. Many members of the OPA Psychotherapy Section worked hard on this report and on the Book entitled *Standards and Guidelines for the Psychotherapies*, published by the U of T Press in 1998. This is an important example of the OPA's proactive response to pressing issues facing psychiatry and a part of our history that we must never forget.

John C. Deadman, MD, DPsych, FRCP(C)
Archivist, Ontario Psychiatric Association

The OPA Questionnaire . . . with apologies to Proust*

OPA's Dialogue has developed this variation on the famous questionnaire, tailored to the Ontario Psychiatrist. Selections from different members' responses will be featured every issue.

Dr. PAUL MULZER

Dr. Mulzer is Sharon Mulzer's husband. He is Past President of the OPA and currently serves on the Advocacy and Education Committee. He practices in Concurrent Disorders (psychiatry and addiction medicine) in Thunder Bay, Ontario. He has been married for 25 years to the same damsel and has five rambunctious children. The children became alarmed when he suggested that he give up his day job and do full-time stand-up comedy. Critics!

What is your idea of perfect professional happiness?
I often feel that I'm asked to make soup from a nail and then management wants the nail back to fix the roof! Professional happiness would be adequately resourced services to meet the clinical needs.

What is your greatest fear?
To be irrelevant! I fear looking back and realizing that I have missed a golden opportunity.

What is the trait in yourself that you value most as a psychiatrist?
Inquisitiveness.

What is the trait in yourself that gives you the greatest challenge as a psychiatrist?
Impatience. Next?

What do you consider the most overrated virtue?
Quiet reflection. (Why don't some quiet people just admit they don't have an original idea?).

What is your greatest regret?
Not having trained at an exotic, obscure medical school.

What or who is the greatest love of your life?
That would have to be my wife who is dictating this as I type!

What is your current state of mind?
I'm in a state of mindfulness, fully savouring a juicy sultana raisin. At least I think it's a raisin! (You, of course, know that true sultana raisins hail from Turkey and you would not be confused by the Thompson seedless variety that is often substituted to the raisin-naïve).

What do you consider your greatest professional achievement?
Advocacy in its various forms for our First Nations' people and the chronically mentally ill.

What is your most treasured possession that you keep in your office?
A one year sobriety chip from a patient who got his addiction recovery back on track. He graduated from university four months later and is still sober and in graduate school.

Since my wife is still hovering my alternate answer is a glass jar which has the dried rose petals from her wedding bouquet. (True, and yes I saved and dried them myself. Tell me that's not romantic!).

What makes you the most unhappy about your work?
Exponential growth in administration with minimal growth in clinical resources.

What is your favorite occupation?
If I was not a psychiatrist I'd be a history professor, an archeologist in Israel or (if I went to that exotic, obscure medical school), a taxi driver in Toronto.

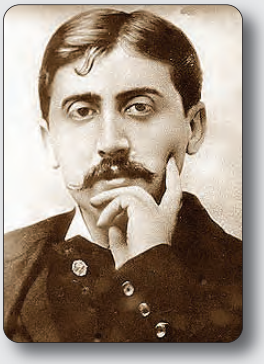
What do you most value in your colleagues?
Candor tempered with compassion.

Who are your favorite authors?
Dickinson, Goethe, Cervantes.

Who is your favorite hero of fiction?
Don Quixote.

Who are your psychiatric heroes in real life?
Far too many to mention by name and missing one would be regrettable. But my greatest hero who is not a physician is Lech Walesa.

How would you like to retire?
With a pulse.



*The **Proust Questionnaire*** *is a questionnaire about one's personality. Its name and modern popularity as a form of interview is owed to the responses given by the French writer Marcel Proust (1871-1922).*

Members' Corner

CONGRATULATIONS

Dr. GAIL BECK, an Ottawa west resident, has been honoured the *Order of Ontario* for her work with children and youth — and for championing the human papilloma virus (HPV) public immunization program.

Dr. Beck, a member of the OPA, is a child and adolescent psychiatrist who works at the Royal Ottawa Mental Health Centre.

The *Order of Ontario* was created in 1986 to… *"recognize Ontario residents who have achieved the highest level of individual excellence and achievement in any field."*▲

IN MEMORIAM
John Kenneth Clayton

JOHN CLAYTON died in Joseph Brant Memorial Hospital on the 2nd of December, 2010. He was 83. He had a long career in psychiatry and with the Executive of the Ontario Psychiatric Association, assuming the presidency in 1976.

He was born in Cut Knife, Saskatchewan in 1927, graduated in Medicine from Queen's and became a psychiatrist in the early 1950s. When I first met him in 1961 he was a Unit Director at the Ontario Hospital, Toronto (later the Queen Street Mental Health Centre). After that he was on staff at the Ontario Hospital, Hamilton and faculty of McMaster University. He later was a consultant to the Canadian Mental Health Association and to Health and Welfare Canada. He had been retired for some years, living in Waterdown with his partner, Ralph Atyeo who was another physician retired from Obstetrics and Gynaecology.

Last year, Ralph was in palliative care at the Joseph Brant Hospital. John visited him daily. He suffered a massive stroke and died at the hospital on the same day that Ralph also passed away. A memorial service for them both was held at Christ Church Cathedral in Hamilton on January 22nd, 2011.▲

John C. Deadman, MD, DPsych, FRCP(C)
Archivist, Ontario Psychiatric Association

Follow us on …

Dr. K. Sonu Gaind

October 2010 Changes

October 2010 saw significant changes to psychiatry codes in the OHIP Schedule of Benefits. You will recall that the last OMA-MOHLTC [Ministry of Health and Long-Term Care] agreement provided for an overall 3% increase to the Schedule of Benefits. Based on our successful efforts to address long-standing relativity inequities, as in 2009 psychiatry once again received a significantly higher allocation, this time of just over 6% in October 2010 [consisting of 1.5% 'across the board' to all sections, plus a 4.5% relativity allocation]. The majority of this allocation was distributed to make relativity corrections and led to increases of approximately 5.2% for most time-based K-codes, and between approximately 4-15% for other existing psychiatric care codes including consultations, hospital assessment codes, and group therapy codes.

In addition, psychiatry obtained several **significant new codes**, as follows:

Special Psychiatric Consultation, A/C/W190 - $285

This new code may be billed when providing consultations in outpatient (A190), inpatient (C190) or long-term care (W190) settings if a minimum of 75 minutes of direct contact is spent with the patient. Being a consultation code, all the elements of a normal consultation must be met. Unlike most consultations, since there is a minimum time requirement, it is important you record the start and stop times in the patient's medical record. As we all know, complex psychiatric patients often require lengthy consultations for appropriate assessment and management, this code will be especially helpful in providing consultations to such patients.

Conference Codes, K701 [mental health out-patient, $27.50/unit], K702 [bariatric out-patient, $27.50/unit], K704 [paediatric out-patient, $27.50/unit], K121 [hospital in-patient, $29.15/unit]

These new codes support patient case conferences between the psychiatrist and other health professionals. The psychiatrist may participate in person, via videoconference or telephone, and a record of all conference participants must be made in the patient's medical record. The case conference must be pre-scheduled, and there must be at least 2 other professionals attending the conference [for K121 and K702, 2 other physicians or regulated health professionals; for K701, 2 other physicians, regulated health professionals, or MOHLTC Mental Health agency personnel; for K704, 2 other physicians, regulated health professionals, education professionals, or personnel employed by an accredited centre of Children's Mental Health Ontario]. Please also refer to the guidelines starting on page A21 of the OHIP Schedule of Benefits [included for reference] for rule details on the charting and other requirements of these codes.

These conference codes are time-based with units of 10 minutes each, requiring a minimum of 10 minutes to bill the first unit, and subsequently the major part thereof for each following unit (i.e. 10 minutes = 1 unit, 16 minutes = 2 units, 26 minutes = 3 units, etc.). The out-patient codes K701, K702, K704 are all $27.50 per unit, in-patient K121 is $29.15 per unit. The case conference codes have the following limits: maximum of 4 services per patient per physician per 12 month period (i.e. maximum of 4 case conferences per patient per physician for a 12 month period), and maximum of 8 units per physician per patient per day (i.e. maximum of 80 minute case conference per patient per physician for each case conference). If multiple patients are discussed during a case conference, separate times reflecting discussion of each individual must be recorded for each patient and billed accordingly (i.e. no 'double-dipping' of billing the same time for different patients). If multiple physicians are attending, each may bill for their time accordingly. Keep in mind that for adult out-patients (18 years or older), K701 should be used; for out-patients less than 18 years old, K704 [the paediatric code] should be used (for geriatric patients, psychiatrists should still use the K701 mental health code, *not* the K703 geriatric code). It should be noted that while all physicians may access the K121 in-patient case conference code, out-patient conference codes are restricted to a much smaller group of physicians. For out-patients only psychiatrists may bill K701, and only psychiatrists and paediatricians may bill K704.

Physician to Physician Telephone Consultation, K730 (referring MD, $27.50) and K731 (consultant MD, $35.50)

These new codes provide for remuneration to both physicians when one physician (the referring physician) requests the opinion of another physician (the consultant physician) who is "competent to give advice…because of the complexity, seriousness, or obscurity of the case." The physicians must spend a minimum of 10 minutes on the phone discussing the patient, each physician submitting a claim must record the patient's name and health number, start/stop times, name of the referring and consultant physicians, reason for the consultation, and the opinion and recommendations of the consultant physician. The minimum 10 minute time does not need to be continuous (though does need to be on the same day). Only 1 service is billable per patient per physician per day (i.e. these are not *per unit time* codes like the case conference codes). If the

physician is on duty in an emergency department or hospital urgent care clinic, K734 (referring) and K735 (consultant) should be billed instead [the rates are the same as K730 and K731]. Note that family physicians and specialists can be either the "referring" and/or "consultant" physician. Please refer to the guidelines starting on page A27 of the OHIP Schedule of Benefits [included for reference] for complete billing rules.

For those of you planning to attend the upcoming OPA Annual Conference in April, please note that there will be a Billing Guidelines workshop reviewing appropriate use of new and existing codes and billing optimization.

Flow Through Payments

As you will recall, psychiatrists in various non-fee-for-service arrangements were also eligible for flow through increases in the last agreement. While some of the initial payments should have now been received (e.g. the initial 3% 'top-up'), the Section is aware that there are continued delays in psychiatrists receiving their entitled monies in a timely way. We have been informed that many of the delayed flow through payments should be made in February (2011!), and are continuing to monitor this issue with the OMA.

More Than Just $$$

Over the past 2 years alone, psychiatrists across Ontario have seen significant increases in psychiatric OHIP fees. Psychiatry's combined allocation for 2009 and 2010 has led to an approximately 16% increase in psychiatric fees, compared to an increase of 4% for sections not receiving any relativity increases. ***While these gains are clearly significant monetarily, their true relevance extends beyond the narrow consideration of psychiatrists simply "making more".*** Such increases are necessary to correct the longstanding relativity inequities that have plagued psychiatric services, inequities that at their core reflect a devaluation of psychiatric patients and mental illness. It is encouraging that we are finally seeing some relativity corrections, which help to properly value psychiatric care, help recruitment and retention, and improve patient care.

It is equally important to recognize that these gains would not have been achieved without the active engagement of psychiatrists across Ontario. As one example, you may recall the member engagement campaign the Coalition of Ontario Psychiatrists, OPA, and OMA Section on Psychiatry orchestrated to ensure the revised relativity formula, CANDI, appropriately valued specialist training. The success of this campaign led to the inclusion of the Skills Acquisition Modifier (SAM) acknowledging the value of specialist training, which would otherwise not have been part of CANDI. As a direct result of this, psychiatry's relativity allocation in 2010 was a full 50% higher than had been projected without SAM, or 4.5% instead of 3%. On a provincial psychiatry OHIP budget of over $300 million, this additional 1.5% alone led to approximately $5 million additional ongoing annualized funding to psychiatric services; and the SAM factor will continue to impact future relativity calculations similarly. Psychiatric services in Ontario would not have received this money without the help of you and your colleagues in this Coalition campaign.

Finally, beyond even relativity corrections and increased fees, increased allocations for psychiatric services have funded improvements in how patient care can be delivered. The Section has been advocating for years for indirect and collaborative care codes for psychiatric patients, and the importance of encouraging and acknowledging care of complex and intense psychiatric patients, and has made numerous submissions for such codes to be included in the OHIP Schedule of Benefits. The new conference codes, telephone codes and special psychiatric consultation code, now available broadly across Ontario through the fee-for-service system, are all steps towards providing psychiatrists with the tools we need to properly treat our patients.

Thank you to all who have helped make these gains possible, and I encourage all of you to continue to support the work of the OPA, OMA Section on Psychiatry and Coalition of Ontario Psychiatrists to improve the professional lives of psychiatrists and the care of our patients.▲

K. Sonu Gaind, MD, FRCP(C)
Medical Practice and Tariff Chair,
Ontario Medical Association Section on Psychiatry
Chair, Canadian Psychiatric Association
Standing Committee on Economics

CONSULTATIONS AND VISITS

FAMILY PRACTICE & PRACTICE IN GENERAL (00)

CASE CONFERENCES

PREAMBLE

Definition/Required elements of service:

Where the conditions set out in this *Schedule* are met, a case conference is an insured service despite paragraph 6 of s. 24(1) of Regulation 552. A case conference is a pre-scheduled meeting, conducted for the purpose of discussing and directing the management of an individual patient. A

a. may by conducted by personal attendance, videoconference or by telephone (or any combination thereof), and

b. must involve at least 2 other participants who meet the eligible participant requirements as indicated in the specific listed case conference services.

[Commentary:
Case conferences for educational purposes such as rounds, journal club, group learning sessions, or continuing professional development, or any meeting where the conference is not for the purpose of discussing and directing the management of an individual patient is not a case conference.]

For case conferences where the time unit is defined in 10 minute increments, the following payment rules and medical record requirements are applicable, except in circumstances where these requirements are modified for specific listed case conference services, as indicated.

[Commentary:
Long-Term Care/Community Care Access Centre (CCAC) Case Conference – K124 has 20 minute time units. See page A26.]

Case conferences are time based services calculated in time units of 10 minute increments. In calculating time unit(s), the minimum time required is based upon consecutive time spent participating in the case conference as follows:

# Units	Minimum time
1 unit	10 minutes
2 units	16 minutes
3 units	26 minutes
4 units	36 minutes
5 units	46 minutes
6 units	56 minutes
7 units	66 minutes [1h 6m]
8 units	76 minutes [1h 16m]

Payment rules:

1. A case conference is *only eligible for payment* if the physician is actively participating in the case conference, and the physician's participation is evident in the record.

2. A case conference is *only eligible for payment* in circumstances where there is a minimum of 10 minutes of patient related discussion.

3. A case conference is *only eligible for payment* if the case conference is pre-scheduled.

4. Any other insured service rendered during a case conference is *not eligible for payment*.

CONSULTATIONS AND VISITS

FAMILY PRACTICE & PRACTICE IN GENERAL (00)

5. A case conference is *not eligible for payment* in circumstances where the required participants necessary to meet the minimum requirements of the case conference service receive remuneration, in whole or in part, from the physician claiming the service.
6. The case conference is *not eligible for payment* to a physician who receives payment, other than by fee-for-service under this *Schedule*, for the preparation and/or participation in the case conference.
7. Where payment for a case conference is an included element of another service, services defined as case conferences are *not eligible for payment*.

[Commentary:

1. Chronic dialysis team fees are all-inclusive benefits for professional aspects of managing chronic dialysis and includes all related case conferences (see page J30).
2. "Payment, other than by fee-for-service" includes compensation where the physician receives remuneration under a salary, primary care, stipend, APP or AFP model.]

Medical record requirements:

A case conference is *only eligible for payment* where the case conference record includes all of the following elements:

1. identification of the patient;
2. start and stop time of the discussion regarding the patient;
3. identification of the eligible participants, and
4. the outcome or decision of the case conference.

[Commentary:

1. In circumstances where more than one patient is discussed at a case conference, claims for case conference may be submitted for each patient provided that the case conference requirements for each patient have been fulfilled.
2. One common medical record in the patient's chart for the case conference signed or initialled by all physician participants (including listing the time the service commenced and terminated and individual attendance times for each participant if different) would satisfy the medical record requirements for billing purposes.]

CONSULTATIONS AND VISITS

FAMILY PRACTICE & PRACTICE IN GENERAL (00)

Hospital in-patient case conference

In addition to the definitions, required elements, payment rules, medical record requirements in the Preamble - Case conferences, a hospital in-patient case conference is participation by a physician and at least 2 other participants that *may include* physicians and/or regulated health professionals regarding a hospital in-patient.

K121 Hospital in-patient case conference .....per unit 29.15

Payment rules:

1. K121 is eligible for payment for a case conference regarding a hospital in-patient at an acute care hospital, chronic care hospital, or rehabilitation hospital. K121 is *not eligible for payment* for a resident in a long term care institution.
2. K121 is limited to a maximum of 4 services per patient, per physician, per *12 month period*.
3. A maximum of 8 units of K121 are payable per physician, per patient, per *day*.
4. K121 is *not eligible for payment* for radiation treatment planning services listed in the Radiation Oncology section of this *Schedule*.
5. Services described in the team care in teaching units section of this *Schedule* are *not eligible for payment* as K121.

[Commentary:

1. For case conferences regarding out-patients, see K700, K701, K702, K703, and K704 for applicable services.
2. For case conferences regarding an in-patient in a long term care institution, see K124.]

Palliative care out-patient case conference

In addition to the definitions, required elements, payment rules, medical record requirements in the Preamble - Case conferences, a *palliative care* out-patient case conference is participation by a physician and at least 2 other participants that *may include* physicians and/or regulated health professionals regarding a *palliative care* out-patient.

K700 Palliative care out-patient case conference .....per unit 27.50

Payment rules:

1. K700 is *only eligible for payment* for case conference services regarding a *palliative care* out-patient.
2. No other case conference or telephone consultation service is eligible for payment with K700 for the same patient on the same *day*.
3. K700 is limited to a maximum of 4 services per patient, per physician, per *12 month period*.
4. A maximum of 8 units of K700 are payable per physician, per patient, per *day*.
5. K700 is *not eligible for payment* for radiation treatment planning services listed in the Radiation Oncology section of this *Schedule*.

[Commentary:

1. For definitions related to *palliative care*, see General Definitions in the General Preamble of the *Schedule*.
2. For case conferences regarding an in-patient in an acute care hospital, chronic care hospital, or rehabilitation hospital, see K121.
3. For case conferences regarding an in-patient in a long term care institution, see K124.]

CONSULTATIONS AND VISITS

FAMILY PRACTICE & PRACTICE IN GENERAL (00)

Paediatric out-patient case conference

In addition to the definitions, required elements, payment rules, medical record requirements in the Preamble - Case conferences, a paediatric out-patient case conference is participation by a physician with at least 2 other participants that *may include* physicians, regulated health professionals, education professionals, and/or personnel employed by an accredited centre of Children's Mental Health Ontario, regarding an out-patient less than 18 years of age.

K704 Paediatric out-patient case conference.....per unit 27.50

Payment rules:

1. No other case conference or telephone consultation service is eligible for payment with K704 for the same patient on the same *day*.
2. K704 is limited to a maximum of 4 services per patient, per physician, per *12 month period*.
3. A maximum of 8 units of K704 are payable per physician, per patient, per *day*.
4. K704 is *only eligible for payment* to physicians in the following specialties: Paediatrics (26) and Psychiatry (19).

[Commentary:

1. For case conferences regarding an in-patient in an acute care hospital, chronic care hospital, or rehabilitation hospital, see K121.
2. For case conferences regarding an in-patient in a long term care institution, see K124.
3. For a list of mental health centres accredited by Children's Mental Health Ontario, see the following link: http://www.kidsmentalhealth.ca/about_us/memberslist.php.]

Mental health out-patient case conference

In addition to the definitions, required elements, payment rules, medical record requirements in the Preamble - Case conferences, a mental health out-patient case conference is participation by a physician with at least 2 other participants that *may include* physicians, regulated health professionals, and/or personnel employed by a mental health community agency funded by the Ontario Ministry of Health and Long-Term Care, regarding an *adult* out-patient.

K701 Mental health out-patient case conference .....per unit 27.50

Payment rules:

1. No other case conference or telephone consultation service is eligible for payment with K701 for the same patient on the same *day*.
2. K701 is limited to a maximum of 4 services per patient, per physician, per *12 month period*.
3. A maximum of 8 units of K701 are payable per physician, per patient, per *day*.
4. K701 is *only eligible for payment* to physicians in the following specialties: Psychiatry (19).

[Commentary:

1. For case conferences regarding an out-patient aged less than 18 years of age, see K704.
2. For case conferences regarding an in-patient in an acute care hospital, chronic care hospital, or rehabilitation hospital, see K121.
3. For case conferences regarding an in-patient in a long term care institution, see K124.]

CONSULTATIONS AND VISITS

FAMILY PRACTICE & PRACTICE IN GENERAL (00)

Bariatric out-patient case conference

In addition to the definitions, required elements, payment rules, medical record requirements in the Preamble - Case conferences, bariatric out-patient case conference is participation by a physician with at least 2 other participants that are working at a Bariatric Regional Assessment and Treatment Centre (RATC) and *may include* physicians and/or regulated health professionals regarding an out-patient registered with a Bariatric RATC for the purpose of pre-operative evaluation and/or post-operative follow-up medical care.

K702 Bariatric out-patient case conference.....per unit 27.50

Payment rules:

1. K702 is *only eligible for payment* when rendered for a patient registered in a Bariatric RATC.
2. K702 is *only eligible for payment* for physicians identified to the ministry as working in a Bariatric RATC.
3. No other case conference or telephone consultation service is eligible for payment with K702 for the same patient on the same *day*.
4. K702 is limited to a maximum of 4 services per patient, per physician per *12 month period*.
5. A maximum of 8 units of K702 are payable per physician, per patient, per *day*.

[Commentary:

1. For the definition of a Bariatric RATC, see Definitions in the General Preamble.
2. For case conferences regarding an in-patient in an acute care hospital, chronic care hospital, or rehabilitation hospital, see K121.
3. For case conferences regarding an in-patient in a long term care institution, see K124.]

Geriatric out-patient case conference

In addition to the definitions, required elements, payment rules, medical record requirements in the Preamble - Case conferences, geriatric out-patient case conference is participation by a physician with at least 2 other participants that *may include* physicians and/or regulated health professionals regarding an out-patient who is at least 65 years of age or, a patient less than 65 years of age who has dementia.

K703 Geriatric out-patient case conference .....per unit 27.50

Payment rules:

1. K703 is *not eligible for payment* with any other case conference or telephone consultation service for the same patient on the same *day*.
2. K703 is limited to a maximum of 4 services per patient, per physician, per *12 month period*.
3. A maximum of 8 units of K703 are payable per physician, per patient, per *day*.
4. K703 is *only eligible for payment* to a physician in the following specialties: Geriatrics (07).

[Commentary:

1. For case conferences regarding an in-patient in an acute care hospital, chronic care hospital or rehabilitation hospital, see K121.
2. For case conferences regarding an in-patient in a long term care institution, see K124.]

CONSULTATIONS AND VISITS

FAMILY PRACTICE & PRACTICE IN GENERAL (00)

PHYSICIAN TO PHYSICIAN TELEPHONE CONSULTATION

Physician to physician telephone consultation is a service where the referring physician, in light of his/her professional knowledge of the patient, requests the opinion of another physician (the "consultant physician") by telephone who is competent to give advice in the particular field because of the complexity, seriousness, or obscurity of the case.

This service is *only eligible for payment* if the consultant physician has provided an opinion and/or recommendations for patient treatment and/or management.

For the purpose of this service, "relevant data" include family/patient history, history of the presenting complaint, laboratory and diagnostic tests, where indicated and feasible in the circumstances.

Note:
The Definition/Required elements of service and payment rules for consultations in the General Preamble are not applicable to physician to physician telephone consultations.

Definition/Required elements of service – Referring physician

The referring physician initiates the telephone consultation with the intention of continuing the care, treatment and management of the patient.

In addition to the Constituent and Common Elements of Insured Services described in the General Preamble of this *Schedule*, this service includes the transmission of relevant data to the consultant physician and all other services rendered by the referring physician to obtain the advice of the consultant physician.

Note:
This service is eligible for payment in addition to visits or other services provided to the same patient on the same *day* by the same referring physician.

Definition/Required elements of service – Consultant physician

This service includes all services rendered by the consultant physician to provide opinion/advice/recommendations on patient care, treatment and management to the referring physician. The consultant physician is required to review all relevant data provided by the referring physician.

K730	Physician to physician telephone consultation - Referring physician	27.50
K731	Physician to physician telephone consultation - Consultant physician	35.50

Physician on duty in an emergency department or a hospital urgent care clinic

K734	Physician to physician telephone consultation - Referring physician	27.50
K735	Physician to physician telephone consultation - Consultant physician	35.50

[Commentary:
Referring and consultant physicians participating in physician to physician telephone consultations while on duty in an emergency department or a hospital urgent care clinic should submit claims using K734 and K735. K730 and K731 should not be claimed in these circumstances.]

CONSULTATIONS AND VISITS

FAMILY PRACTICE & PRACTICE IN GENERAL (00)

Payment rules:

1. A maximum of one K730 or K734 service is eligible for payment per patient per *day*.

2. A maximum of one K731 or K735 service is eligible for payment per patient per *day*.

3. This service is *only eligible for payment* for a physician to physician telephone consultation service:

- **a.** that includes a minimum of 10 minutes of patient-related discussion for any given patient
- **b.** where the referring physician and consultant physician are physically present in Ontario at the time of the service

4. This service is *not eligible for payment* to either the referring and consultant physicians in the following circumstances:

- **a.** when the purpose of the telephone discussion is to arrange for transfer of the patient's care to any physician;
- **b.** when rendered in whole or in part to arrange for a face to face or telemedicine consultation or procedure, including an expedited face to face or telemedicine consultation or procedure;
- **c.** when rendered in whole or in part to arrange for diagnostic investigations;
- **d.** when rendered primarily to discuss results of diagnostic investigations; or
- **e.** when a face-to-face or telemedicine consultation is rendered by the consultant physician on the same *day* or *day* following the telephone consultation for the same patient.

5. This service is *not eligible for payment* where a physician receives compensation, other than by fee-for-service under this *Schedule*, for participation in the telephone consultation.

Medical record requirements:

Physician to physician telephone consultation is *only eligible for payment* where the following elements are included in the medical record for a physician who submits a claim for the service:

1. patient's name and health number;

2. start and stop times of the discussion;

3. name of the referring and consultant physicians;

4. reason for the consultation; and

5. the opinion and recommendations of the consultant physician.

Claims submission instructions:

K731 and K735 are *only eligible for payment* if the consultant physician includes the referring physician's billing number with the claim.

[Commentary:

1. In calculating the minimum time requirement, time does not need to be continuous. In circumstances where a physician to physician telephone consultation service with the consultant physician on the same *day* is not continuous, the total time represents the cumulative time of all telephone consultations with the same physicians on that *day* pertaining to the same patient.

2. "Payment, other than by fee-for-service" includes compensation where the physician receives remuneration under a salary, primary care, stipend, APP or AFP model.]

Once Daily
Seroquel XR®
quetiapine

Prescribing Summary

Patient Selection Criteria

Therapeutic classification: Antipsychotic/Antidepressant agent

INDICATIONS AND CLINICAL USE

Adults: SEROQUEL XR® (quetiapine fumarate extended-release) is indicated for the symptomatic relief of major depressive disorder (MDD) when currently available approved antidepressant drugs have failed either due to lack of efficacy and/or lack of tolerability. While there is no evidence that the efficacy of SEROQUEL XR is superior to other antidepressants, it provides a treatment option for patients who have failed on previous antidepressant treatments. Clinicians must take into account the safety concerns associated with antipsychotic drugs, a class of drugs to which SEROQUEL XR belongs. Safety concerns of this class include: weight gain, hyperlipidemia, hyperglycaemia, tardive dyskinesia and neuroleptic malignant syndrome (see WARNINGS AND PRECAUTIONS). SEROQUEL XR should only be prescribed in patients with MDD by clinicians who are aware of the importance and are experienced in the early detection and management of the above-mentioned safety issues associated with this class. Long-term safety of SEROQUEL XR in MDD has not been systematically evaluated. Thus, the physician who elects to use SEROQUEL XR in the treatment of MDD should use SEROQUEL XR for the shortest time that is clinically indicated. When lengthier treatment is indicated, the physician must periodically re-evaluate the long-term usefulness of the drug for the individual patient keeping in mind the long-term risks (see SUPPLEMENTAL PRODUCT INFORMATION). ***Geriatrics (>65 years of age):*** SEROQUEL XR is not indicated in elderly patients with dementia (See Serious Warnings and Precautions box and Special Populations). ***Pediatrics (<18 years of age):*** The safety and efficacy of SEROQUEL XR in children under the age of 18 years have not been established.

SEROQUEL XR is also indicated for the management of the manifestations of schizophrenia, as monotherapy for the acute management of manic episodes associated with bipolar disorder and as monotherapy for the acute management of depressive episodes associated with bipolar I and bipolar II disorder. Please consult the Product Monograph for complete prescribing information.

CONTRAINDICATIONS

SEROQUEL XR (quetiapine fumarate extended-release) is contraindicated in patients with a known hypersensitivity to this medication or any of its ingredients.

Special Populations

Pregnant Women: Patients should be advised to notify their physician if they become pregnant or intend to become pregnant during treatment with SEROQUEL XR. The safety and efficacy of SEROQUEL XR during human pregnancy have not been established. Therefore, SEROQUEL XR should only be used during pregnancy if the expected benefits justify the potential risks. ***Nursing Women:*** The degree to which quetiapine is excreted into human milk is unknown. Women who are breast-feeding should therefore be advised to avoid breast-feeding while taking SEROQUEL XR. ***Pediatrics (<18 years of age):*** The safety and efficacy of SEROQUEL XR in children under the age of 18 years have not been established. ***Geriatrics (≥65 years of age):*** The number of patients 65 years of age or over exposed to SEROQUEL XR during clinical trials was limited (n=68). When compared to younger patients the mean plasma clearance of quetiapine was reduced by 30% to 50% in elderly subjects. In addition, as this population has more frequent hepatic, renal, central nervous system, and cardiovascular dysfunctions, and more frequent use of concomitant medication, caution should be exercised with the use of SEROQUEL XR in the elderly patient (see ADMINISTRATION). In a clinical trial that evaluated non-demented elderly patients (aged 66 to 89 years) with MDD, the tolerability of SEROQUEL XR once daily was comparable to that seen in adults (aged 18-65 years) other than the incidence of extrapyramidal symptoms (see WARNINGS AND PRECAUTIONS, Neurologic, Tardive Dyskinesia [TD] and Extrapyramidal Symptoms [EPS]). **Use in Geriatric Patients with Dementia: Overall Mortality: Elderly patients with dementia treated with atypical antipsychotic drugs showed increased mortality compared to placebo in a meta-analysis of 13 controlled trials of various atypical antipsychotic drugs. In two placebo-controlled trials with oral SEROQUEL in this population, the incidence of mortality was 5.5% for SEROQUEL-treated patients compared to 3.2% for placebo-treated patients. SEROQUEL XR is not indicated in elderly patients with dementia.** ***Cerebrovascular adverse events:*** An increased risk of cerebrovascular adverse events has been seen in the dementia population with some atypical antipsychotics. The mechanism for this increased risk is not known. There is insufficient data with quetiapine to know if there is an increased risk of cerebrovascular events associated with quetiapine. An increased risk, however, cannot be excluded. SEROQUEL XR is not indicated in patients with dementia. ***Vascular disease:*** SEROQUEL XR should be used with caution in patients with risk factors for stroke or with a history of stroke. ***Dysphagia:*** Esophageal dysmotility and aspiration have been associated with antipsychotic drug use. Aspiration pneumonia is a common cause of morbidity and mortality in elderly patients, in particular those with advanced Alzheimer's dementia. SEROQUEL XR and other antipsychotic drugs should be used cautiously in patients at risk for aspiration pneumonia (see WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS).

Safety Information

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Increased Mortality in Elderly Patients with Dementia

Elderly patients with dementia treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. Analyses of thirteen placebo-controlled trials with various atypical antipsychotics (modal duration of 10 weeks) in these patients showed a mean 1.6-fold increase in death rate in the drug-related patients. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature.

General: ***Body Temperature Regulation:*** Disruption of the body's ability to reduce core body temperature has been attributed to antipsychotic agents. Appropriate care is advised when prescribing SEROQUEL XR (quetiapine fumarate extended-release) for patients who will be experiencing conditions which may contribute to an elevation of core temperature, e.g., exercising strenuously, exposure to extreme heat, receiving concomitant medication with anticholinergic activity or being subject to dehydration. ***Acute Withdrawal (Discontinuation) Symptoms:*** Acute discontinuation symptoms such as insomnia, nausea, headache, diarrhea, vomiting, dizziness and irritability have been described after abrupt cessation of antipsychotic drugs including SEROQUEL XR. Gradual withdrawal over a period of at least one to two weeks is advisable. Symptoms usually resolved after 1 week post-discontinuation. **Cardiovascular:** ***Hypotension and Syncope:*** As with other drugs that have high α_1-adrenergic receptor blocking activity, SEROQUEL XR may induce orthostatic hypotension, dizziness and sometimes syncope, especially during the initial dose-titration period. These events may lead to falls. In placebo-controlled SEROQUEL XR trials, there was little difference in the adverse reaction reporting rate of syncope in patients treated with SEROQUEL XR (0.5%, 11/2388) compared to patients on placebo (0.3%, 4/1267). Syncope was reported in 1% (35/4083) of patients treated with SEROQUEL (quetiapine, immediate-release formulation), compared with 0.3% (3/1006) on placebo and 0.4% (2/527) on active control drugs. SEROQUEL XR should be used with caution in patients with known cardiovascular disease (e.g., history of myocardial infarction or ischemic heart disease, heart failure or conduction abnormalities), cerebrovascular disease or other conditions predisposing to hypotension (e.g., dehydration, hypovolemia and treatment with antihypertensive medications) (see OVERDOSAGE). ***Cholesterol and Triglyceride Elevations:*** Very common (≥10%) cases of elevations in serum triglyceride levels (≥2.258 mmol/L on at least one occasion) and decreases in HDL cholesterol (<1.025 mmol/L males; <1.282 mmol/L females at any time) have been observed during treatment with quetiapine in clinical trials (see ADVERSE REACTIONS). Lipid changes should be managed as clinically appropriate. In 6-week MDD monotherapy clinical trials, SEROQUEL XR-treated patients had increases from baseline in mean triglycerides of 8%, compared to a mean decrease of 1% for placebo-treated patients. In the same trials, both SEROQUEL XR- and placebo-treated patients had decreases from baseline in mean cholesterol of 1% and 3%, respectively. In a longer-term randomized withdrawal MDD trial, patients who completed at least 158 days of SEROQUEL XR treatment (n=196) showed mean increases from baseline in triglycerides of approximately 5% and mean decreases from baseline in cholesterol of approximately 4%. ***QT Prolongation:*** In clinical trials, quetiapine was not associated with a persistent increase in absolute QT intervals. However, in post-marketing experience, there were cases reported of QT prolongation with overdose (see OVERDOSAGE). As with other antipsychotics, caution should be exercised when quetiapine is prescribed in patients with cardiovascular disease or family history of QT prolongation. Also caution should be exercised when quetiapine is prescribed either with medicines known to increase QT interval or with concomitant neuroleptics, especially for patients with increased risk of QT prolongation, i.e., the elderly, patients with congenital long QT syndrome, congestive heart failure, heart hypertrophy, hypokalemia or hypomagnesemia (see DRUG INTERACTIONS). **Endocrine and Metabolism:** ***Hyperglycaemia:*** As with some other antipsychotics, hyperglycaemia and diabetes mellitus (including exacerbation of pre-existing diabetes, diabetic ketoacidosis and diabetic coma including some fatal cases) in the aggregate have been reported rarely (≥0.01% - <0.1%) during the use of quetiapine in post-marketing experience, sometimes in patients with no reported history of hyperglycaemia (see ADVERSE REACTIONS, Post-Market Adverse Drug Reactions). Blood glucose increases to hyperglycemic levels (fasting blood glucose ≥7.0 mmol/L or a nonfasting blood glucose ≥11.1 mmol/L on at least one occasion) have been observed commonly (≥1% - <10%) with quetiapine in clinical trials. Occasional reports of diabetes have also been observed in clinical trials with quetiapine (see ADVERSE REACTIONS, Abnormal Hematologic and Clinical Chemistry Findings). Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in

patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycaemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment-emergent hyperglycaemia-related adverse events in patients treated with the atypical antipsychotics. Precise risk estimates for hyperglycaemia-related adverse events in patients treated with atypical antipsychotics are not available. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycaemia including polydipsia, polyuria, polyphagia and weakness. Patients who develop symptoms of hyperglycaemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycaemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. ***Hyperprolactinemia:*** During clinical trials with quetiapine, elevation in prolactin levels occurred in 3.6% (158/4416) of patients treated with quetiapine compared to 2.6% (51/1968) on placebo (see ADVERSE REACTIONS). Increased prolactin levels with quetiapine were observed in rat studies. As is common with compounds which stimulate prolactin release, the administration of quetiapine resulted in an increase in the incidence of mammary neoplasms in rats. The physiological differences between rats and humans with regard to prolactin make the clinical significance of these findings unclear. To date, neither clinical nor epidemiological studies have shown an association between chronic administration of drugs that stimulate prolactin release, and mammary tumourigenesis. Tissue culture experiments, however, indicate that approximately one third of human breast cancers are prolactin dependent *in vitro*; a factor of potential importance if prescription of these drugs is contemplated in a patient with previously detected breast cancer. Possible manifestations associated with elevated prolactin levels are amenorrhea, galactorrhea and menorrhagia. In the multiple fixed-dose schizophrenia clinical trial there were no differences in prolactin levels at study completion for SEROQUEL, across the recommended dose range, and placebo. ***Hypothyroidism:*** In SEROQUEL XR clinical trials, 0.2% (4/1755) of patients on SEROQUEL XR compared to 0% (0/796) on placebo experienced decreased free thyroxine and 2.7% (46/1716) on SEROQUEL XR compared to 1.4% (11/785) on placebo experienced increased TSH; however, no patients experienced a combination of clinically significant decreased free thyroxine and increased TSH. In clinical trials, on average SEROQUEL was associated with about a 20% mean reduction in thyroxine levels (both total and free). Forty-two percent of SEROQUEL-treated patients showed at least a 30% reduction in total T_4 and 7% showed at least a 50% reduction. Maximum reduction of thyroxine levels generally occurred during the first two to four weeks of treatment with SEROQUEL. These reductions were maintained without adaptation or progression during longer-term treatment. Decreases in T_4 were not associated with systematic changes in TSH or clinical signs or symptoms of hypothyroidism. Approximately 0.4% (12/2595) of patients treated with SEROQUEL experienced persistent increases in TSH, and 0.25% of patients were treated with thyroid replacement. ***Weight Gain:*** In 6-week placebo-controlled MDD acute monotherapy clinical trials, for patients treated with SEROQUEL XR mean weight gain was 0.87 kg (n=1149) compared to 0.31 kg (n=648) in patients treated with placebo. In a longer-term randomized withdrawal MDD trial, patients who completed at least 158 days of SEROQUEL XR treatment (n=196), mean weight gain for patients in SEROQUEL XR 50, 150 and 300 mg/day groups was 1.0 kg, 2.5 kg and 3.0 kg, respectively. In these same patients the percentage of patients experiencing a weight increase of ≥7% by 158 days in SEROQUEL XR 50, 150 and 300 mg/day groups was 13%, 24% and 33%, respectively. Based on the cumulative acute placebo-controlled clinical trial database, weight gain (based on ≥7% increase in body weight from baseline) was reported in 9.6% in quetiapine-treated patients and 3.8% in placebo-treated patients, which occurs predominantly during the early weeks of treatment in adults. **Gastrointestinal:** ***Antiemetic Effect:*** Consistent with its dopamine antagonist effects, SEROQUEL XR may have an antiemetic effect. Such an effect may mask signs of toxicity due to overdosage of other drugs, or may mask symptoms of disease such as brain tumour or intestinal obstruction. **Dysphagia and Aspiration Pneumonia:** Dysphagia and aspiration have been reported with quetiapine. Although a causal relationship with aspiration pneumonia has not been established, SEROQUEL XR should be used with caution in patients at risk for aspiration pneumonia (see WARNINGS AND PRECAUTIONS, Special Populations and ADVERSE REACTIONS). **Hematologic:** ***Neutropenia:*** Severe neutropenia (<0.5 x 10^9/L) has been uncommonly reported in quetiapine clinical trials. There was no apparent dose relationship. Possible risk factors for leucopenia and/or neutropenia include pre-existing low white cell count (WBC) and history of drug-induced leucopenia and/or neutropenia. SEROQUEL XR should be discontinued in patients with a neutrophil count <1.0 x 10^9/L. These patients should be observed for signs and symptoms of infection and neutrophil counts followed (until they exceed 1.5 x 10^9/L) (see ADVERSE REACTIONS, Abnormal Hematologic and Clinical Chemistry Findings and Post-Market Adverse Drug Reactions). **Hepatic:** ***Hepatic Impairment:*** Decreased clearance of SEROQUEL was observed in patients with mild hepatic impairment (see ACTION AND CLINICAL PHARMACOLOGY, Special Populations and Conditions). No pharmacokinetic data are available for quetiapine in patients with moderate or severe hepatic impairment. However, should clinical judgement deem treatment with SEROQUEL XR necessary, the drug should be used with great caution in patients with moderate or severe hepatic impairment (see ADMINISTRATION). ***Transaminase Elevations:*** Asymptomatic, transient and reversible elevations in serum transaminases (primarily ALT) associated with SEROQUEL XR have been reported. The proportions of patients with transaminase elevations of >3 times the upper limits of the normal reference range in a pool of placebo-controlled trials were approximately 1% for both SEROQUEL XR and placebo. During premarketing clinical trials, therapy with SEROQUEL was associated with elevation of hepatic transaminases, primarily ALT. Precautions should be exercised when using SEROQUEL XR in patients with pre-existing hepatic disorders, in patients who are being treated with potentially hepatotoxic drugs, or if treatment-emergent signs or symptoms of hepatic impairment appear. For patients who have known or suspected abnormal hepatic function prior to starting SEROQUEL XR, standard clinical assessment, including measurement of transaminase levels, is recommended. Periodic clinical reassessment with transaminase levels is recommended for such patients, as well as for patients who develop any signs and symptoms suggestive of a new onset liver disorder during SEROQUEL XR therapy. **Neurologic:** ***Neuroleptic malignant syndrome (NMS):*** Neuroleptic malignant syndrome is a potentially fatal symptom complex that has been reported in association with antipsychotic drugs, including SEROQUEL XR. The clinical manifestations of NMS are hyperthermia, muscle rigidity, altered mental status and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis) and acute renal failure. In arriving at a diagnosis, it is important to identify cases where the clinical presentation includes both serious medical illness (e.g., pneumonia, systemic infection, etc.) and untreated or inadequately treated extrapyramidal signs and symptoms. Other important considerations in the differential diagnosis include central anticholinergic toxicity, heat stroke, drug fever and primary central nervous system pathology. The management of NMS should include immediate discontinuation of antipsychotic drugs, including SEROQUEL XR, and other drugs not essential to concurrent therapy; intensive symptomatic treatment and medical monitoring; and treatment of any concomitant serious medical problems for which specific treatments are available. There is no general agreement about specific pharmacological treatment regimens for uncomplicated NMS. If a patient requires antipsychotic drug treatment after recovery from NMS, the potential reintroduction of drug therapy should be carefully considered. The patient should be carefully monitored since recurrences of NMS have been reported. ***Tardive Dyskinesia (TD) and Extrapyramidal Symptoms (EPS):*** Tardive dyskinesia is a syndrome of potentially irreversible, involuntary, dyskinetic movements that may develop in patients treated with antipsychotic drugs including quetiapine. Although the prevalence of the syndrome appears to be highest among the elderly, especially elderly women, it is impossible to rely upon estimates to predict which patients are likely to develop the syndrome. In placebo-controlled clinical trials for schizophrenia and bipolar mania the incidence of EPS was no different from that of placebo across the recommended therapeutic dose range. It has been hypothesized that agents with a lower EPS liability may also have a lower liability to produce TD. This relationship predicts that quetiapine should have less potential than typical antipsychotic agents to induce TD in schizophrenia and bipolar mania patients. In short-term, placebo-controlled clinical trials for bipolar depression and major depressive disorder, the incidence of EPS was higher in quetiapine treated patients than in placebo treated patients. See ADVERSE REACTIONS. The risk of developing TD and the likelihood that it will become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic drugs administered to the patient increase. However, the syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses. There is no known treatment for established cases of TD, although the syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn. Antipsychotic treatment, itself, however, may suppress (or partially suppress) the signs and symptoms of the syndrome and thereby may possibly mask the underlying process. The effect that symptomatic suppression has upon the long-term course of the syndrome is unknown. Given these considerations, SEROQUEL XR should be prescribed in a manner that is most likely to minimize the occurrence of TD. Chronic antipsychotic treatment should generally be reserved for patients who appear to suffer from a chronic illness that is known to respond to antipsychotic drugs, and for whom alternative, equally effective, but potentially less harmful treatments are not available or appropriate. In patients who do require chronic treatment, the smallest dose and the shortest duration of treatment producing a satisfactory clinical response should be sought. The need for continued treatment should be reassessed periodically. If signs and symptoms of TD appear in a patient on SEROQUEL XR, dose reduction or drug discontinuation should be considered. Some patients may require treatment with SEROQUEL XR despite the presence of the syndrome. The symptoms of TD can worsen or even arise after discontinuation of treatment (see ADVERSE REACTIONS). ***Seizures:*** In controlled clinical trials with SEROQUEL XR, there was no difference in the incidence of seizures in patients treated with SEROQUEL XR (0.04%, 1/2388) or placebo (0.2%, 3/1267). Nevertheless, as with other antipsychotics, caution is recommended when treating patients with a history of seizures or with conditions associated with a lowered seizure threshold (see ADVERSE REACTIONS). ***Potential Effect on Cognitive and Motor Performance:*** Somnolence was a very commonly reported adverse event in patients treated with SEROQUEL XR, especially during the initial dose-titration period. Since SEROQUEL XR may cause sedation and impair motor skill, patients should be cautioned about performing activities requiring mental alertness, such as operating a motor vehicle or hazardous machinery, until they are reasonably certain that therapy with SEROQUEL XR does not affect them adversely. Somnolence may lead to falls. **Ophthalmologic:** ***Cataracts:*** **The development of cataracts was observed in association with quetiapine treatment in chronic dog studies at 4 times the recommended human dose. Lens changes have also been observed in patients during long-term SEROQUEL treatment but a causal relationship to SEROQUEL use has not been established. The possibility of lenticular changes during long-term use of SEROQUEL XR in man thus can not be excluded at this time. Eye examinations (e.g., slit lamp exam) prior to or shortly after initiation of treatment with SEROQUEL XR and at 6-month intervals thereafter, are recommended. If clinically significant lens changes associated with SEROQUEL XR use are observed, discontinuation of SEROQUEL XR should be considered.**

Psychiatric: ***Suicide/Suicidal Thoughts or Clinical Worsening:*** Depressive episodes are associated with an increased risk of suicidal thoughts, self-harm and suicide (suicide-related events). This risk persists until significant remission of depression occurs. As improvement may not occur during the first few weeks or more of treatment, patients should be closely monitored until such improvement occurs. It is general clinical experience that the risk of suicide may increase in the early stages of recovery. Patients with a history of suicide-related events are also known to be at a greater risk of suicidal thoughts or suicide attempts, and should receive careful monitoring during treatment. In short-term placebo-controlled clinical trials across all indications and ages, the incidence of suicide-related events (suicidal thoughts, self-harm and suicide) was 0.9% for both quetiapine (61/6270) and for placebo (27/3047). In MDD acute clinical trials, the incidence of treatment-emergent suicidal ideation or suicide attempt was 0.7% in SEROQUEL XR-treated patients and 0.7% in placebo-treated patients. In a longer-term randomized withdrawal study in patients with MDD, the incidence during randomized treatment was 0.3% for SEROQUEL XR and 0.5% for placebo. **Renal:** There is little experience with SEROQUEL XR in patients with renal impairment, except in a low (subclinical) single-dose study with SEROQUEL. SEROQUEL XR should thus be used with caution in patients with known renal impairment, especially during the initial dosing period (see ADMINISTRATION).

ADVERSE REACTIONS

Commonly Observed Adverse Events in Short-Term Placebo-Controlled Clinical Trials:

The most commonly observed adverse events associated with the use of SEROQUEL XR (incidence of at least 5%, and an incidence at least 5% higher than that observed with placebo) during acute monotherapy with SEROQUEL XR were dry mouth, sedation, somnolence, dizziness and fatigue.

Adverse Events Associated With Discontinuation in Short-Term Placebo-Controlled Clinical Trials:

In placebo-controlled monotherapy MDD trials, 14.3% of patients on SEROQUEL XR discontinued due to adverse events compared to 4.5% on placebo. In a placebo-controlled monotherapy trial in elderly patients with MDD, 9.6% of patients on SEROQUEL XR discontinued due to adverse events compared to 4.1% on placebo.

To report adverse events:
AstraZeneca Canada Inc.
1004 Middlegate Road
Mississauga, Ontario
L4Y 1M4
www.astrazeneca.ca
T 1-800-433-0733
F 1-800-267-5743

DRUG INTERACTIONS

Drug-Drug Interactions: Given the primary central nervous system effects of quetiapine, SEROQUEL XR should be used with caution in combination with other centrally acting drugs. Caution should be exercised when quetiapine is used concomitantly with drugs known to cause electrolyte imbalance or to increase QT interval (see WARNINGS AND PRECAUTIONS, Cardiovascular).

Administration

SEROQUEL XR (quetiapine fumarate extended-release) tablets should be swallowed whole and not split, chewed or crushed. SEROQUEL XR can be administered with or without food. SEROQUEL XR should be administered once daily, generally in the evening (see INDICATIONS AND CLINICAL USE). Usual Dose: The titration rate, based on the clinical trials, is shown in the table below.

	Day 1	Day 2	Day 3
Once-daily dosing	50 mg	50 mg	150 mg

The usual target dose is 150 mg. Some patients may respond to doses as low as 50 mg/day and, where clinically indicated, dose may be increased to 300 mg/day after Day 4. In clinical trials, doses between 50-300 mg/day were shown to be efficacious; however, the incidence of certain adverse events increased with dose. In MDD, the safety of doses above 300 mg/day has not been evaluated. Some of the safety concerns associated with SEROQUEL XR and this class of agents (i.e., antipsychotics) may be dose-related. The SEROQUEL XR dose should thus be periodically reassessed to achieve and maintain the lowest effective dose. Furthermore, as the long-term safety of SEROQUEL XR in MDD has not been systematically evaluated, the physician who elects to use SEROQUEL XR in the treatment of MDD should use SEROQUEL XR for the shortest time that is clinically indicated. When long-term treatment is believed to be indicated, the physician must periodically re-evaluate the long-term usefulness of the drug for the individual patient keeping in mind the long-term risks. ***Switching Patients From SEROQUEL Tablets to SEROQUEL XR Tablets:*** For more convenient dosing, patients who are currently being treated with divided doses of SEROQUEL (quetiapine, immediate-release formulation) may be switched to SEROQUEL XR at the equivalent total daily dose taken once daily. Individual dosage adjustments may be necessary. ***Switching Patients From Other Antidepressants:*** For many antidepressants a gradual taper is recommended prior to complete discontinuation of the drug (physicians should refer to the approved Product Monograph of the specific antidepressant). There are no systematically collected data to address switching patients from other antidepressants to SEROQUEL XR. Generally there should be no need for a wash-out period between stopping an antidepressant and starting SEROQUEL XR. The physician may elect to initiate SEROQUEL XR treatment while tapering the antidepressant; however, patients may experience additive side effects during the overlap period. **Dosing Considerations in Special Populations:** ***Elderly:*** As with other antipsychotics, SEROQUEL XR should be used with caution in the elderly, especially during the initial dosing period. The rate of dose titration of SEROQUEL XR may need to be slower, and the daily therapeutic target dose lower, than that used in younger patients. In clinical trials, 68 patients, 65 years of age or over, were treated with SEROQUEL XR. Given the limited experience with SEROQUEL XR in the elderly, and the higher incidence of concomitant illness and concomitant medication in this population, SEROQUEL XR should be used with caution. The mean plasma clearance of SEROQUEL was reduced by 30% to 50% in elderly subjects when compared to younger patients. Elderly patients should be started on the lowest available dose (i.e., 50 mg/day) of SEROQUEL XR. The dose can be increased in increments of 50 mg/day to an effective dose, depending on the clinical response and tolerance of the individual patient. In elderly patients with MDD, initial dosing should begin at 50 mg on Days 1-3, the dose can be increased to 100 mg on Day 4, and 150 mg on Day 8. ***Hepatic Impairment:*** Quetiapine is extensively metabolized by the liver. Therefore, SEROQUEL XR should be used with caution in patients with mild hepatic impairment, especially during the initial dosing period. Patients with mild hepatic impairment should be started on the lowest available dose (i.e., 50 mg/day) of SEROQUEL XR. The dose should be increased daily in increments of 50 mg/day to an effective dose, depending on the clinical response and tolerance in the individual patient. No pharmacokinetic data are available for quetiapine in patients with moderate to severe hepatic impairment. However, should clinical judgement deem treatment with SEROQUEL XR necessary, the drug should be used with great caution in patients with moderate or severe hepatic impairment (see WARNINGS AND PRECAUTIONS, Hepatic). ***Renal Impairment:*** As clinical experience is lacking, caution is advised (see WARNINGS AND PRECAUTIONS, Renal). **Missed Dose:** SEROQUEL XR should be taken at the same time each day. If a previous day's dose has been missed, administration should be resumed the next day at the normal administration time. **Dosage Forms and Packaging:** SEROQUEL XR (quetiapine fumarate extended-release) is available as film-coated tablets containing quetiapine fumarate equivalent to 50, 150, 200, 300 or 400 mg of quetiapine free base as follows: 50 mg quetiapine tablets are peach coloured, capsule-shaped, biconvex, intagliated with "XR 50" on one side and plain on the other, available in high-density polyethylene (HDPE) bottles of 60 tablets. 150 mg quetiapine tablets are white, capsule-shaped, biconvex, intagliated with "XR 150" on one side and plain on the other, available in HDPE bottles of 60 tablets. 200 mg quetiapine tablets are yellow, capsule-shaped, biconvex, intagliated with "XR 200" on one side and plain on the other, available in HDPE bottles of 60 tablets. 300 mg quetiapine tablets are pale yellow, capsule-shaped, biconvex, intagliated with "XR 300" on one side and plain on the other, available in HDPE bottles of 60 tablets. 400 mg quetiapine tablets are white, capsule-shaped, biconvex, intagliated with "XR 400" on one side and plain on the other, available in HDPE bottles of 60 tablets. SEROQUEL XR is available in 5 strengths containing 50, 150, 200, 300 or 400 mg quetiapine per tablet (as quetiapine fumarate). The core of the tablet contains the excipients hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose and sodium citrate. The coating of the tablet contains hydroxypropyl methylcellulose, polyethylene glycol 400, red ferric oxide (50 mg tablets), titanium dioxide and yellow ferric oxide (50, 200 and 300 mg tablets).

SUPPLEMENTAL PRODUCT INFORMATION

Adverse Reactions

The stated frequencies of adverse events represent the proportion of individuals who experienced, at least once, a treatment-emergent adverse event of the type listed. An event was considered treatment-emergent if it occurred for the first time or worsened while receiving therapy following baseline evaluation. **Clinical Trial Adverse Drug Reactions:** The prescriber should be aware that the figures in the tables and tabulations cannot be used to predict the incidence of side effects in the course of usual medical practice where patient characteristics and other factors differ from those that prevailed in the clinical trials. Similarly, the cited frequencies cannot be compared with figures obtained from other clinical investigations involving different treatments, uses and investigators. The figures cited, however, do provide the prescribing physician with some basis for estimating the relative contribution of drug and nondrug factors to the side effect incidence in the populations studied.

Table 1: Adverse Events Reported for at Least 1% of SEROQUEL XR-Treated Subjects (Doses Ranging From 50 to 300 mg/day) and for a Higher Percentage of SEROQUEL XR-Treated Subjects Than Subjects Who Received Placebo in Short-Term, Placebo-Controlled MDD Monotherapy Phase III Trials

Body System and MedDRA Term[a,b]	Percentage of Subjects With Adverse Events*	
	SEROQUEL XR (n=1149)	Placebo (n=648)
General disorders and administration site conditions		
Fatigue	7	2
Irritability	4	3
Nervous system disorders		
Sedation	28	4
Somnolence	24	7
Dizziness	14	8
Disturbance in attention	2	<1
Hypersomnia	2	<1
Lethargy	2	1
Gastrointestinal system disorders		
Dry mouth	35	8
Constipation	8	4
Vomiting	3	1
Dyspepsia	4	3
Metabolic and nutritional disorders		
Increased appetite	5	3
Weight increased	3	<1
Musculoskeletal and connective tissue disorders		
Back pain	3	2

Body System and MedDRA Term[a,b]	Percentage of Subjects With Adverse Events*	
	SEROQUEL XR (n=1149)	Placebo (n=648)
Myalgia	3	2
Musculoskeletal stiffness	2	1
Psychiatric disorders		
Abnormal dreams	2	1
Respiratory disorders		
Nasal congestion	2	1
Special senses		
Vision blurred	3	2

* Events for which SEROQUEL XR incidence was equal to or less than placebo are not listed in the table. Table reports percentage rounded to the nearest integer.

a Patients with multiple events falling under the same preferred term are counted only once in that term.

b The following adverse events occurred in 1% of patients treated with SEROQUEL XR compared to <1% in placebo: chills, dysarthria, dysgeusia, sluggishness, akathisia, dizziness postural, tachycardia, restless legs syndrome, gastroesophageal reflux disease, pharyngolaryngeal pain and restlessness.

Table 2: Dose-Related Adverse Events in ≥1% of Patients Treated With SEROQUEL XR (Doses 50, 150 and 300 mg/day) Where the Incidence of the Adverse Events in Patients Treated With SEROQUEL XR 150 mg and/or 300 mg was Greater Than the Incidence in SEROQUEL XR 50 mg and Placebo-Treated Patients in Short-Term Fixed-Dose, Placebo-Controlled MDD Monotherapy Phase III Trials

Body System and MedDRA Term[a]	Percentage of Subjects With Adverse Events*			
	Placebo (n=338)	SEROQUEL XR 50 mg (n=181)	SEROQUEL XR 150 mg (n=328)	SEROQUEL XR 300 mg (n=331)
General disorders and administration site conditions				
Pain	0	1	1	2
Chills	0	1	0	2
Nervous system disorders				
Sedation	6	27	37	34
Somnolence	9	18	22	28
Dizziness	8	9	13	15
Dysarthria	0	1	1	3
Body System and MedDRA Term[a]	**Percentage of Subjects With Adverse Events***			
	Placebo (n=338)	SEROQUEL XR 50 mg (n=181)	SEROQUEL XR 150 mg (n=328)	SEROQUEL XR 300 mg (n=331)
Disturbance in attention	0	1	2	2
Hypoaesthesia	1	0	1	2
Akathisia	1	0	2	1
Lethargy	1	2	3	1
Paraesthesia	1	1	2	1
Hypersomnia	0	1	2	1
Gastrointestinal system disorders				
Dry mouth	9	22	36	40
Constipation	4	7	7	9
Nausea	8	8	12	9
Vomiting	2	2	4	5
Dyspepsia	3	2	5	4
Gastroesophageal reflux disease	0	0	1	2
Abdominal distension	1	0	0	2
Abdominal pain	1	1	2	1
Cardiovascular disorders				
Tachycardia	0	1	2	1
Metabolic and nutritional disorders				
Increased appetite	3	4	5	4
Weight increased	1	1	2	3
Musculoskeletal and connective tissue disorders				
Back pain	2	2	5	5
Arthralgia	2	2	3	3
Myalgia	2	4	5	3
Muscle tightness	1	1	0	2
Psychiatric disorders				
Anxiety	2	1	2	3
Abnormal dreams	3	2	4	2
Restlessness	0	0	1	2
Nightmare	1	1	1	2
Infections and infestations				
Nasopharyngitis	3	2	4	3
Gastroenteritis	0	1	2	1
Respiratory disorders				
Nasal congestion	2	1	2	3
Sinus congestion	1	1	2	2
Dyspnoea	1	1	1	2
Epistaxis	0	1	0	2
Nasal dryness	0	0	1	1
Special senses				
Vision blurred	1	2	3	5

* Events for which SEROQUEL XR incidence was equal to or less than placebo are not listed in the table.

a Patients with multiple events falling under the same preferred term are counted only once in that term.

Table 3: Adverse Events Reported for at Least 1% of SEROQUEL XR-Treated Subjects (Doses Ranging From 50 to 300 mg/day) and for a Higher Percentage of SEROQUEL XR-Treated Subjects Than Subjects Who Received Placebo in a Short-Term, Placebo-Controlled Elderly MDD Monotherapy Phase III Trial

Body System and MedDRA Term[a,b]	Percentage of Subjects With Adverse Events*	
	SEROQUEL XR (n=166)	Placebo (n=172)
General disorders and administration site conditions		
Fatigue	8	3
Asthenia	4	1
Nervous system disorders		
Somnolence	33	8
Headache	19	14
Dizziness	18	15
Sedation	5	1
Dysgeusia	2	1
Balance disorder	2	1
Dizziness postural	2	1
Akathisia	2	1
Gastrointestinal disorders		
Dry mouth	20	10
Constipation	5	2
Abdominal pain upper	3	2
Dyspepsia	2	1
Cardiovascular system disorders		
Hypotension	2	0
Metabolic and nutritional disorders		
Weight increased	5	4
Weight decreased	2	1
Musculoskeletal and connective tissue disorders		
Back pain	2	1
Extrapyramidal disorder	4	1
Body System and MedDRA Term[a,b]	**Percentage of Subjects With Adverse Events***	
	SEROQUEL XR (n=166)	Placebo (n=172)
Pain in extremity	2	1
Respiratory disorders		
Nasal congestion	2	0

* Events for which SEROQUEL XR incidence was equal to or less than placebo are not listed in the table. Table reports percentage rounded to the nearest integer.

a Patients with multiple events falling under the same preferred term are counted only once in that term.

b The following adverse events occurred in 1% of patients treated with SEROQUEL XR compared to <1% in placebo: hypersomnia, restless legs syndrome, joint sprain, muscular weakness, pharyngolaryngeal pain and vision blurred.

Other Adverse Events: ***Weight Gain:*** In placebo-controlled MDD acute monotherapy clinical trials, for patients treated with SEROQUEL XR mean weight gain was 0.87 kg (n=1149) compared to 0.31 kg (n=648) in patients treated with placebo. In a longer-term randomized withdrawal MDD trial, patients who completed at least 158 days of SEROQUEL XR treatment (n=196), mean weight gain for patients in SEROQUEL XR 50, 150 and 300 mg/day groups was 1.0 kg, 2.5 kg and 3.0 kg, respectively. In these same patients the percentage of patients experiencing a weight increase of ≥7% by 158 days in SEROQUEL XR 50, 150 and 300 mg/day groups was 13%, 24% and 33%, respectively (see WARNINGS AND PRECAUTIONS). Based on the cumulative acute placebo-controlled clinical trial database, weight gain (based on ≥7% increase in body weight from baseline) was reported in 9.6% in quetiapine-treated patients and 3.8% in placebo-treated patients, which occurs predominantly during the early weeks of treatment in adults (see WARNINGS AND PRECAUTIONS). ***Seizures:*** There have been uncommon reports (≥0.1% - <1%) of seizures in patients administered quetiapine, although the frequency was no greater than that observed in patients administered placebo in controlled clinical trials (see WARNINGS AND PRECAUTIONS, Neurologic). ***Restless Legs Syndrome:*** There have been uncommon cases of restless legs syndrome in patients administered quetiapine. ***Priapism:*** There have been rare reports (≥0.01% - <0.1%) of priapism in patients administered quetiapine. ***Somnolence:*** Somnolence may occur, usually during the first 2 weeks of treatment, which generally resolves with the continued administration of SEROQUEL XR. ***Neuroleptic Malignant Syndrome:*** As with other antipsychotics, rare cases of neuroleptic malignant syndrome have been reported in patients treated with quetiapine (see WARNINGS AND PRECAUTIONS, Neurologic). ***Vital Signs:*** As with other antipsychotics with α_1-adrenergic blocking activity, SEROQUEL XR may induce postural hypotension, associated with dizziness, tachycardia and, in some patients, syncope, especially during the initial dose-titration period (see WARNINGS AND PRECAUTIONS, Cardiovascular). SEROQUEL was associated with a mean baseline to endpoint increase in heart rate of 3.9 beats per minute, compared to 1.6 beats per minute among placebo-treated patients. ***Peripheral Edema:*** As with other antipsychotics, common cases (≥1% - <10%) of peripheral edema have been reported in patients treated with quetiapine. ***Mild Asthenia:*** As with other antipsychotic agents, common cases of mild asthenia have been reported in patients treated with quetiapine. ***Rhinitis:*** There have been common reports of rhinitis in patients administered quetiapine. ***Hypersensitivity:*** Uncommon cases of hypersensitivity including angioedema have been reported. ***ECG Changes:*** In MDD monotherapy trials, 0.2% of SEROQUEL XR patients, and no placebo patients, had tachycardia (>120 bpm) at any time during the trials. SEROQUEL XR was associated with a mean increase in heart rate, assessed by ECG, of 7 beats per minute compared to a mean decrease of 1 beat per minute for placebo. This is consistent with the rates of SEROQUEL. This slight tendency to tachycardia may be related to the potential of SEROQUEL XR for inducing orthostatic changes (see WARNINGS AND PRECAUTIONS, Cardiovascular). ***Tardive Dyskinesia:*** There have been uncommon cases of tardive dyskinesia reported in patients administered quetiapine (see WARNINGS AND PRECAUTIONS, Neurologic). ***Extrapyramidal Symptoms (EPS):*** In short-term placebo-controlled monotherapy clinical trials in MDD, the aggregated incidence of EPS was 5.4% for SEROQUEL XR and 3.2% for placebo. In a short-term placebo-controlled monotherapy trial in elderly patients with MDD, the aggregated incidence of EPS was 9.0% for SEROQUEL XR and 2.3% for placebo. In long-term studies of schizophrenia, bipolar disorder and MDD, the aggregated exposure-adjusted incidence of treatment-emergent EPS was similar between quetiapine and placebo (see WARNINGS AND PRECAUTIONS, Neurologic). ***Dysphagia:*** There have been uncommon cases of dysphagia in patients administered quetiapine (see WARNINGS AND PRECAUTIONS, Gastrointestinal and Special Populations). ***Dysarthria:*** There have been common cases of dysarthria in patients administered quetiapine. ***Acute Withdrawal (Discontinuation) Symptoms:*** In acute placebo-controlled monotherapy clinical trials, which evaluated discontinuation symptoms, the aggregated incidence of discontinuation symptoms after abrupt cessation was 12.1% for quetiapine and 6.7% for placebo. The aggregated incidence of the individual adverse events (e.g., insomnia, nausea, headache, diarrhea, vomiting, dizziness and irritability) did not exceed 5.3% in any treatment group and usually resolved 1 week after discontinuation. ***Abnormal Dreams and Nightmares:*** There have been common cases of abnormal dreams and nightmares in patients administered quetiapine. ***Suicide-Related Events:*** In these trials of patients with MDD the incidence of suicide-related events was 2.1% (3/144) for quetiapine and 1.3% (1/75) for placebo in patients 18-24 and 0.6% (11/1798) for quetiapine and 0.7% for placebo (7/1054) in patients ≥25 years of age. ***Irritability:*** There have been common cases of irritability in patients administered quetiapine. ***Increased Appetite:*** There have been common cases of increased appetite in patients administered quetiapine. ***Abnormal Hematologic and Clinical Chemistry Findings:*** As with other antipsychotics, common cases of leucopenia and/or neutropenia have been observed in patients administered quetiapine. Uncommon cases of eosinophilia and thrombocytopenia (platelet count decreased, ≤100 x 10^9/L on at least one occasion) have been observed. Based on clinical trial adverse event reports not associated with neuroleptic malignant syndrome, rare cases of elevations in blood creatine phosphokinase have been reported in patients administered quetiapine. Common cases of elevations in serum prolactin levels have been observed (>20 µg/L in males and >30 µg/L in females) (see WARNINGS AND PRECAUTIONS, Hyperprolactinemia). In three-arm SEROQUEL XR placebo-controlled monotherapy clinical trials, among patients with a baseline neutrophil count ≥1.5 x 10^9/L, the incidence of at least one occurrence of neutrophil count <1.5 x 10^9/L was 1.5% in patients treated with SEROQUEL XR and 1.5% for SEROQUEL, compared to 0.8% in placebo-treated patients. In all placebo-controlled monotherapy clinical trials among patients with a baseline neutrophil count ≥1.5 x 10^9/L, the incidence of at least one occurrence of

neutrophil count <1.5 x 10^9/L was 1.72% in patients treated with SEROQUEL, compared to 0.73% in placebo-treated patients. In clinical trials conducted prior to a protocol amendment for discontinuation of patients with treatment-emergent neutrophil count <1.0 x 10^9/L, among patients with a baseline neutrophil count ≥1.5 x 10^9/L, the incidence of at least one occurrence of neutrophil count <0.5 x 10^9/L was 0.21% in patients treated with SEROQUEL and 0% in placebo-treated patients and the incidence ≥0.5 - <1.0 x 10^9/L was 0.75% in patients treated with SEROQUEL and 0.11% in placebo-treated patients (see WARNINGS AND PRECAUTIONS, Hematologic). Common cases of asymptomatic elevations in serum transaminases (AST, ALT) or uncommon cases of γ-GT levels have been observed in some patients administered quetiapine. These elevations were usually reversible on continued quetiapine treatment (see WARNINGS AND PRECAUTIONS, Hepatic). SEROQUEL treatment was associated with small dose-related decreases in thyroid hormone levels, particularly total T_4 and free T_4. The reduction in total and free T_4 was maximal within the first 2 to 4 weeks of quetiapine treatment, with no further reduction during long-term treatment. There was no evidence of clinically significant changes in TSH concentration over time. In nearly all cases, cessation of quetiapine treatment was associated with a reversal of the effects on total and free T_4, irrespective of the duration of treatment. Smaller decreases in total T_3 and reverse T_3 were seen only at higher doses. Levels of TBG were unchanged and in general reciprocal increases in TSH were not observed and there was no indication that SEROQUEL causes clinically relevant hypothyroidism (see WARNINGS AND PRECAUTIONS, Endocrine and Metabolism). ***Hyperglycaemia:*** Blood glucose increases to hyperglycemic levels (fasting blood glucose ≥7.0 mmol/L or a nonfasting blood glucose ≥11.1 mmol/L on at least one occasion) have been observed commonly (≥1% - <10%) with quetiapine in clinical trials. In short-term (12 weeks duration or less) placebo-controlled clinical trials (3342 treated with quetiapine and 1490 treated with placebo), the percent of patients who had a fasting blood glucose ≥7.0 mmol/L or a nonfasting blood glucose ≥11.1 mmol/L was 3.5% for quetiapine and 2.1% for placebo. In a 24-week trial (active-controlled, 115 patients treated with SEROQUEL) designed to evaluate glycemic status with oral glucose tolerance testing of all patients, at Week 24 the incidence of a treatment-emergent post-glucose challenge glucose level ≥11.1 mmol/L was 1.7% and the incidence of a fasting treatment-emergent blood glucose level ≥7.0 mmol/L was 2.6% (see WARNINGS AND PRECAUTIONS, Endocrine and Metabolism). ***Cholesterol and Triglyceride Elevations:*** Very common (≥10%) cases of elevations in serum triglyceride levels (≥2.258 mmol/L on at least one occasion), and elevations in total cholesterol (predominantly LDL cholesterol) (≥6.2064 mmol/L on at least one occasion), and decreases in HDL cholesterol (<1.025 mmol/L males; <1.282 mmol/L females at any time) have been observed during treatment with quetiapine in clinical trials (see WARNINGS AND PRECAUTIONS, Cardiovascular). Lipid changes should be managed as clinically appropriate. In one 24-week clinical trial, where LDL cholesterol was directly measured as opposed to calculated, there was a slight mean increase in total cholesterol in patients administered SEROQUEL, which was driven by increases in LDL cholesterol. The mean LDL level increased at Week 24 by 10% in patients administered SEROQUEL, which was statistically significant. The total cholesterol/HDL ratio did not change significantly during therapy with SEROQUEL. Furthermore, triglycerides did not increase significantly nor did HDL cholesterol decrease during therapy (see WARNINGS AND PRECAUTIONS, Cardiovascular). ***Post-Market Adverse Drug Reactions:*** During post-marketing experience, leucopenia and/or neutropenia have been reported during SEROQUEL treatment. Resolution of leucopenia and/or neutropenia has followed cessation of therapy with SEROQUEL. Possible risk factors for leucopenia and/or neutropenia include pre-existing low white cell count and history of drug-induced leucopenia and/or neutropenia (see WARNINGS AND PRECAUTIONS, Hematologic). As with some other antipsychotics, hyperglycaemia and diabetes mellitus (including exacerbation of pre-existing diabetes, diabetic ketoacidosis and diabetic coma including some fatal cases) in the aggregate have been reported rarely (≥0.01% - <0.1%) during the use of SEROQUEL, sometimes in patients with no reported history of hyperglycaemia (see WARNINGS AND PRECAUTIONS, Endocrine and Metabolism). Anaphylactic reactions have been reported very rarely in post-marketing reports, including a case with a fatal outcome, possibly related to SEROQUEL treatment. The reporting rate of anaphylaxis associated with SEROQUEL use, which is generally accepted to be an underestimate due to underreporting, does not exceed the background incidence rate estimates. Estimates of the background incidence rate (all cause) of severe life-threatening anaphylaxis in the general population range between 80 and 210 cases per million person-years, and the incidence rate of drug-induced anaphylaxis is reported to be 16 cases per million person-years. In addition, the all-cause fatal anaphylaxis rate is reported to be one case per million person-years while the drug-induced fatal anaphylaxis is estimated to be 0.3 cases per million person-years. If a patient develops anaphylaxis after treatment with SEROQUEL XR, the drug should be discontinued and an alternative treatment started. Based on post-marketing reports, galactorrhea has been reported rarely.

Drug Interactions

Drug-Drug Interactions: The Effect of SEROQUEL XR on Other Drugs: ***Alcohol:*** SEROQUEL (quetiapine, immediate-release formulation) potentiated the cognitive and motor effects of alcohol in a clinical trial in subjects with psychotic disorders. Alcoholic beverages should be avoided while taking SEROQUEL XR. ***Antihypertensive Agents:*** Because of its potential for inducing hypotension, SEROQUEL XR may enhance the effects of certain antihypertensive agents. ***Levodopa and Dopamine Agonists:*** As it exhibits *in vitro* dopamine antagonism, SEROQUEL XR may antagonize the effects of levodopa and dopamine agonists. ***Lithium:*** The single dose pharmacokinetics of lithium were not altered when coadministered with SEROQUEL. ***Antipyrine:*** SEROQUEL did not induce the hepatic enzyme systems involved in the metabolism of antipyrine. ***Lorazepam:*** SEROQUEL did not affect the single-dose pharmacokinetics of lorazepam. ***Divalproex:*** Coadministration of SEROQUEL (150 mg bid) and divalproex (500 mg bid) increased the mean oral clearance and the mean maximum plasma concentration of total valproic acid (administered as divalproex) by 11%. These changes were not clinically relevant. **The Effect of Other Drugs on SEROQUEL XR:** ***Hepatic Enzyme Inducers:*** Concomitant use of SEROQUEL XR with hepatic enzyme inducers such as carbamazepine may substantially decrease systemic exposure to quetiapine. In a multiple-dose trial in patients to assess the pharmacokinetics of SEROQUEL given before and during treatment with carbamazepine (a known hepatic enzyme inducer), coadministration of carbamazepine significantly increased the clearance of quetiapine. This increase in clearance reduced systemic quetiapine exposure (as measured by AUC) to an average of 13% of the exposure during administration of quetiapine alone, although a greater effect was seen in some patients. As a consequence of this interaction, lower plasma concentrations can occur, and hence, in each patient, consideration for a higher dose of SEROQUEL XR, depending on clinical response, should be considered. It should be noted that the recommended maximum daily dose of SEROQUEL XR is 800 mg/day and continued treatment at higher doses should only be considered as a result of careful consideration of the benefit risk assessment for an individual patient. Coadministration of SEROQUEL and another microsomal enzyme inducer, phenytoin, caused five-fold increases in the clearance of quetiapine. Increased doses of SEROQUEL XR may be required to maintain control of psychotic symptoms in patients coadministered SEROQUEL XR and phenytoin and other hepatic enzyme inducers (e.g., barbiturates, rifampicin, etc.). The dose of SEROQUEL XR may need to be reduced if phenytoin or carbamazepine or other hepatic enzyme inducers are withdrawn and replaced with a non-inducer (e.g., sodium valproate). ***CYP 3A4 inhibitors:*** CYP 3A4 is the primary enzyme responsible for cytochrome P450-mediated metabolism of quetiapine. Thus, coadministration of compounds (such as ketoconazole, erythromycin, clarithromycin, diltiazem, verapamil or nefazodone), which inhibit CYP 3A4, may increase the concentration of SEROQUEL XR. In a multiple-dose trial in healthy volunteers to assess the pharmacokinetics of SEROQUEL given before and during treatment with ketoconazole, coadministration of ketoconazole resulted in an increase in mean C_{ss} and AUC of quetiapine of 235% and 522%, respectively, with a corresponding decrease in mean oral clearance of 84%. The mean half-life of quetiapine increased from 2.6 to 6.8 hours, but the mean t_{max} was unchanged. Due to the potential for an interaction of a similar magnitude in a clinical setting, the dosage of SEROQUEL XR should be reduced during concomitant use of quetiapine and potent CYP 3A4 inhibitors (such as azole antifungals, macrolide antibiotics and protease inhibitors). Special consideration should be given in elderly and debilitated patients. The risk-benefit ratio needs to be considered on an individual basis in all patients. ***Divalproex:*** Coadministration of SEROQUEL (150 mg bid) and divalproex (500 mg bid) increased the mean maximum plasma concentration of quetiapine by 17% without changing the mean oral clearance. ***Cimetidine:*** In a clinical study examining the pharmacokinetics of SEROQUEL following coadministration with cimetidine (a non-specific P450 enzyme inhibitor), no clinically significant interaction was observed. ***Thioridazine:*** Coadministration of thioridazine (200 mg bid) with SEROQUEL (300 mg bid) increased the clearance of SEROQUEL by 65%. ***Fluoxetine, Imipramine, Haloperidol and Risperidone:*** Fluoxetine (60 mg daily), imipramine (75 mg bid), haloperidol (7.5 mg bid) and risperidone (3 mg bid) did not significantly alter the steady state pharmacokinetics of SEROQUEL. ***In patients taking the following antidepressants:*** amitriptyline, bupropion, citalopram, duloxetine, escitalopram, fluoxetine, paroxetine, sertraline and venlafaxine, addition of SEROQUEL XR (150 mg or 300 mg/day; for up to 4 weeks) did not appear to have a consistent overall effect on the trough or pre-dose plasma concentrations of the antidepressant. **Drug-Food Interactions:** SEROQUEL XR can be taken with or without food. **Drug-Herb Interactions:** Interactions with herbal products have not been established. **Drug-Laboratory Interactions:** Interactions with laboratory tests have not been established.

Overdosage

For management of suspected drug overdose, contact your regional Poison Control Centre.

Experience: ***Clinical Trials:*** One death has been reported in a clinical trial following an overdose of 13,600 mg of quetiapine alone; however, survival has also been reported in acute overdoses of up to 30,000 mg of quetiapine. Most patients who overdosed reported no adverse events or recovered fully from the reported events. ***Post-Marketing:*** In post-marketing experience, there were cases reported of QT prolongation with overdose. Patients with pre-existing severe cardiovascular disease may be at an increased risk of the effects of overdose (see WARNINGS AND PRECAUTIONS, Cardiovascular, Hypotension and Syncope). ***Symptoms:*** In general, reported signs and symptoms were those resulting from an exaggeration of the drug's known pharmacological effects (e.g., drowsiness and sedation, tachycardia and hypotension). ***Treatment:*** There is no specific antidote to quetiapine. In cases of severe intoxication, the possibility of multiple drug involvement should be considered, and intensive care procedures are recommended, including establishing and maintaining a patent airway, ensuring adequate oxygenation and ventilation, and monitoring and support of the cardiovascular system. Close medical supervision and monitoring should be continued until the patient recovers.

AstraZeneca

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This Prescribing Summary provides you with the most current information at the time of printing. For the most current information, the full Product Monograph prepared for health professionals can be found at www.astrazeneca.ca.

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SEROQUEL XR (quetiapine fumarate extended-release) is indicated for the symptomatic relief of major depressive disorder (MDD) when currently available approved antidepressant drugs have failed either due to lack of efficacy and/or lack of tolerability.

While there is no evidence that the efficacy of SEROQUEL XR is superior to other antidepressants, it provides a treatment option for patients who have failed on previous antidepressant treatments. Clinicians must take into account the safety concerns associated with antipsychotic drugs, a class of drugs to which SEROQUEL XR belongs. Safety concerns of this class include: weight gain, hyperlipidemia, hyperglycaemia, tardive dyskinesia and neuroleptic malignant syndrome (see WARNINGS AND PRECAUTIONS). SEROQUEL XR should only be prescribed in patients with MDD by clinicians who are aware of the importance and are experienced in the early detection and management of the above-mentioned safety issues associated with this class.

Long-term safety of SEROQUEL XR in MDD has not been systematically evaluated. Thus, the physician who elects to use SEROQUEL XR in the treatment of MDD should use SEROQUEL XR for the shortest time that is clinically indicated. When lengthier treatment is indicated, the physician must periodically re-evaluate the long-term usefulness of the drug for the individual patient keeping in mind the long-term risks.

SEROQUEL XR is also indicated for the management of the manifestations of schizophrenia, as monotherapy for the acute management of manic episodes associated with bipolar disorder and as monotherapy for the acute management of depressive episodes associated with bipolar I and bipolar II disorder. Please consult the Product Monograph for complete prescribing information.

SEROQUEL XR (quetiapine fumarate extended-release) is contraindicated in patients with a known hypersensitivity to this medication or any of its ingredients.

During acute MDD therapy with SEROQUEL XR, the most commonly observed adverse events associated with the use of SEROQUEL XR (incidence of at least 5% and an incidence at least 5% higher than that observed with placebo) were as follows: *Adults:* dry mouth (35%), sedation (28%), somnolence (24%), dizziness (14%) and fatigue (7%). *Elderly:* somnolence (33%), dry mouth (20%), headache (19%) and fatigue (8%).

Increases in blood glucose and hyperglycaemia, and occasional reports of diabetes have been observed in clinical trials.

Eye examinations are recommended prior to, or shortly after, initiation of treatment and at 6-month intervals thereafter. Caution should be used in the elderly and those with known hepatic and renal impairment.

Serious Warnings and Precautions

Increased Mortality in Elderly Patients With Dementia

Elderly patients with dementia treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. Analyses of thirteen placebo-controlled trials with various atypical antipsychotics (modal duration of 10 weeks) in these patients showed a mean 1.6-fold increase in death rate in the drug-related patients. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature.

Please consult the Product Monograph for warnings, precautions and adverse events.

Reference: 1. SEROQUEL XR® Product Monograph. AstraZeneca Canada Inc. February 17, 2010.

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