Achieving Consensus in the Management of Intrahepatic Cholestasis in Pregnancy: A Delphi Study

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Abstract

The incidence of intrahepatic cholestasis (ICP) in pregnancy, a liver condition, is increasing, suggesting a greater awareness of the disease. While this condition is an annoyance for a mother, typically causing intense itchiness of the hands and soles of the feet, she will return to normal after delivery. However, this condition has the potential to cause premature delivery, fetal distress and fetal death, so appropriate management is very important. Currently, guidelines available in North America conflict with guidelines in the United Kingdom. The purpose of this research is to establish evidence-based, current practice guidelines for managing cholestasis in pregnancy within a local context. A modified Delphi technique will be utilized with the goal of achieving consensus among local obstetricians about the management of ICP. It is anticipated that two rounds of questionnaires will be disseminated to the group. The content of the questionnaires and the resulting guideline, will take into consideration the unique health care environment and resources in one northeastern Ontario community.

Keywords: Intrahepatic Cholestasis in Pregnancy (ICP), E-Delphi, Consensus

Résumé

La fréquence de cholestase intrahépatique pendant la grossesse, une affection hépatique, augmente, ce qui suggère une plus grande prise de conscience de la maladie. Bien que cette condition soit un ennui pour une mère, causant habituellement intenses démangeaisons des mains et la plante des pieds, elle va revenir à la normale après l'accouchement. Cependant, cette condition a le potentiel de causer l'accouchement prématuré, la détresse fœtale et la mort fœtale, ainsi, une gestion appropriée est très importante. Les lignes directrices disponibles en Amérique du Nord s'opposent aux lignes directrices du Royaume-Uni. Cette recherche a pour objet d'établir des lignes directrices fondées sur des données factuelles pour gérer la cholestase pendant la grossesse dans un contexte local. Une technique Delphi modifiée sera utilisée dans le but de parvenir à un consensus parmi les obstétriciens locaux sur la gestion du CIG. Il est prévu que deux séries de questionnaires seront diffusées au groupe. Le contenu des questionnaires et des lignes directrices qui en découlent prendront en considération l'environnement médical et les ressources dans une communauté du nord-est de l’Ontario.

Mots-clés: Cholestase intra-hépatique pendant la grossesse (CIP), E-Delphi, Consensus
In the movement toward evidence-based practice health care providers will use clinical expertise and best available medicine to achieve the best patient outcomes (Sackett, Rosenberg, Gray, Haynes, & Richard, 1996). Hence, clinical practice guidelines are often derived from the integration of clinical experience, quality clinical research and patient values, through the use of systematic reviews and meta-analysis (Masic, Miokovic, & Muhamedagic, 2008). Despite the importance of use of evidence in practice, a great number of clinical situations do not have comprehensive evidence or clinical guidelines. For conditions where there are no clinical guidelines and scant evidence to support practice decisions, it is essential that there is a common understanding among local care providers when considering diagnosis, treatment and overall management of disease processes. Development of an agreement among a group of health care providers for care pathways ensures that the most up to date evidence is shared and integrated into practice. In circumstances where a variety of health care providers are involved in the management of a condition, it is optimal that all providers are aware of the best evidence and approach to be taken within their circles of care. It is particularly important that those who share the care of the patient are fully aware of the agreed upon approach so that patients will be better informed about the conditions and the evidence based rationale for the delivery of care.

One clinical issue for which there is no clear guideline is the diagnosis, monitoring and treatment of intrahepatic cholestasis in pregnancy (ICP). This liver condition, which presents most often in the third trimester have devastating effects on the fetus, including fetal death (Ozkan, Ceylan, & Yildirim, 2015). The incidence of ICP ranges from 1 case in 1000 to 1 in 10,000 deliveries throughout North America, Asia and Australia (Reyes, 2008). There is limited data specifically about prevalence of ICP in Canada. The most up to date sources indicates that ICP occurs in 10 per 10,000 pregnancies. However, this data was collected between 1963-1976 showing that the data about the incidence of ICP are quite out dated (Lammert, Marschall, Glantz & Matern, 2000).

Despite the seriousness of the condition, there is very little research evidence to guide practice. Often care of pregnant patients in low risk obstetrics is multidisciplinary. This proves to be quite satisfactory where patients are seen by a combination of general practitioners, midwives and/or obstetricians (Kidd, Avery, Duggan, & McPhail, 2013). However, each provider is independent in how ICP is managed. The need for a comprehensive algorithm based on the best available peer reviewed evidence supported by all practitioners is important in the optimal care of pregnant women and their unborn babies.

This project arose from an observation that in the target community in previous years there were no reports of ICP, but in the in the latter part of 2015 to mid 2016 where there was more than 10 cases of ICP. This was approximately (0.875%) of all pregnancies, amongst the practices of six obstetricians working in a small North Eastern Ontario community (Local Hospital Data Entry, 2015-2016) derived from average birthrates. The mechanism for the increase in the diagnosis of ICP in this local area is not known. However, according to Ghosh and Chaudhuri (2013) in geographical locations such as Chile and Bolivia there is an increasing incidence of ICP, suggesting a greater awareness of the disease and potentially a reason for the increase in diagnosis in the local community. Each obstetrician managed the care of ICP differently and communicated different directives to shared care providers. The increased incidence along with the inconsistent management was the impetus for working toward a consensus in the approach to the management of this condition.

The final product of this project is to develop consensus for an algorithm for the management of ICP among obstetricians in a mid-sized community in North Eastern Ontario. It
is anticipated that the final algorithm will reflect best evidence as well as the unique challenges in the local health care environment. Dissemination of the guideline among all providers who care for women during pregnancy in the community will help to ensure a common understanding of the approach to the condition. It is anticipated that the consensus document will ensure that patients are better informed about the condition and rationale for treatment options are available to all health care providers.

Intrahepatic Cholestasis in Pregnancy

**Etiology, Pathogenesis and Clinical Presentation of ICP**

ICP remains a complex, multifactorial aetiology, noting environmental, genetic, hormonal and dietary influences (Gabzdyl & Schlaenger, 2015). The pathogenesis is as complex. Hepatocytes are responsible for making bile acid and the secretion of the bile from the liver to the gall bladder occurs in the bile-secretory unit made up of a canalicular network (Boyer, 2013). It is thought that cytotoxic bile acids will accumulate when this pump malfunctions (Gabzdyl & Schlaenger, 2015). It is the delay in bile emptying into the gallbladder from the high levels of estrogen and progesterone during pregnancy that cause an accumulation of bile salts into maternal circulation resulting in biliary stasis (Gabzdyl & Schlaeger, 2015). According to Lammert et al. (2010) research is questioning if there is a defect in the proteins that are responsible for the elimination of biliary excretion or if there is a problem with the transport mechanism. Saleh and Abdo (2007) concur suggesting symptoms occur when the malfunctioning transporter become overwhelmed by the high level of sex hormones during the pregnancy.

The onset of disease can present in the second or third trimester, however diagnosis is most often identified in the third trimester (Bull et al., 2015). Presentation is manifested by intense pruritus of the hands and soles of the feet with no associated visible rash, along with elevated biochemical markers (Diken, Usta, & Nasssar, 2014) that normalize after delivery (Bruce & Watson, 2007). In some circumstances pruritus can progress to the entire body (Ghosh & Chaudhuri, 2013; Lee & Brady, 2009). The intensity can be distressing and severe with the symptoms being worse at night causing sleep deprivation and in some cases suicidal thoughts (Ghosh & Chaudhuri, 2013). The cause of pruritus in ICP is not known but it is surmised that the deposition of bile salts in the nerve endings of the skin is responsible (Saleh & Abdo, 2007). Jaundice is rare but some women may develop a decrease in fat absorption leading to vitamin K deficiency thereby increasing the risk of postpartum hemorrhage (Lee & Brady, 2009) and intrapartum hemorrhage without adequate supplementation of vitamin K (Saleh & Abdo, 2007).

**Diagnosis**

Elevated fasting bile acids and normal or elevated liver function tests are the common biomarkers used in the diagnosis of ICP and are considered sufficient to diagnose disease (Kenyon & Girling, 2011). Other causes for pruritus and abnormal liver enzymes need to be explored and ruled out before the diagnosis of ICP can be made (Clinical Guidelines Obstetrics and Midwifery, 2016; Gurung et al., 2013; Kenyon & Girling, 2011; Lindor & Lee, 2016).

Bile acid levels are strongly correlated with adverse pregnancy outcomes (Geenes et al., 2014; Brouwers et al., 2015). Maternal outcomes are benign, however, ICP can result in preterm labour, meconium staining, fetal distress and fetal demise (Ozkan et al., 2015) with the greatest to the fetus identified after 37 weeks (Bull et al., 2015).
The severity of a case of ICP is defined according to the level of bile acids. ICP is classified as mild with bile acid values of 10-39 umol/L and severe when bile acid values are greater than or equal to 40 umol/L (Glantz, Marschall, and Mattsson, 2004). Generally it is accepted that bile acids greater than or equal to 10 umol/L is indicative of diagnosis of ICP eliminating other liver diseases (Brouwers et al., 2015). Further levels of bile acids are proportionately correlated with severity (Brouwers et al., 2015). Once bile acids reach levels greater than 40 umol/L there is an increase in stillbirth risk (Geenes et al., 2014).

**Pharmacological Treatment of ICP**

The Cochrane Review by Gurung, Stokes, Middleton, Hague, & Thorton (2013) examined interventions for treatment of intrahepatic cholestasis in pregnancy and concluded that the treatment of ICP with ursodoxycholic acid (UDCA) presents no adverse fetal effects and is substantiated as being the best intervention for relief of maternal symptoms and decreasing bile acid levels. The Cochrane Review found that there was support for UDCA for the relief of maternal pruritus (Gurung et al., 2013; Saleh & Abd, 2007) and restoring bile acids to a normal state (Saleh & Abd, 2007), by increasing the biliary secretion that lowers the toxic bile salts, bilirubin (Gabzdyl & Schlaenger, 2015) and liver enzymes in maternal blood (Ozkan et al., 2015). This is further substantiated by a meta-analysis including non-randomized studies conducted by Grand’Maison et al. (2014). UDCA was associated with less preterm births and neonatal intensive care admissions and therefore the recommended treatment for ICP (Grand’Maison et al., 2014).

The exact mechanism of UDCA is unknown but it is responsible for restoring the maternal-placental bile transport (Pusl & Beurs, 2007). Ursodoxycholic acid is thought to increase excretion of bile acids and bilirubin, protect cholangiocytes and protect liver cells from cell death (Gabzdyl & Schlaenger, 2015). The UDCA’s effect on bile acid levels are of utmost importance in that the severity of disease is associated with the rising of bile acid levels (Gurung et al., 2013). It is the high level of bile acids that are thought to be the mechanisms causing adverse perinatal outcomes and testing of bile acids is advised for surveillance (Geenes et al., 2014).

**Additional Considerations in Management of ICP**

Fetal surveillance, dosing of UDCA, and timing of delivery seem to be a common discussion of debate in the literature and practice (Clinical Guidelines Obstetrics and Midwifery, 2016; Gurung et al., 2013; Kenyon & Girling, 2011; Lindor & Lee, 2016;). Elevated bile acids and its potential adverse effects on the fetus create some controversy regarding the timing of delivery (Gabzdyl & Schlaenger, 2015; Gurung et al., 2013) as does recommendations for fetal surveillance (Gabzdyl & Schlaenger, 2015). Aggressive elective timing of delivery between 34-37 weeks gestation is a consideration once bile acids approach values greater than 100 umol/L however, with moderately elevated bile acids (40-99 umol/L) delivery prior to 37 weeks is not justified given the lower incidence of complications (Brouwers et al., 2015). Kenyon and Girling (2011) identified that UDCA was effective only in lowering bile acid salts if the levels were greater than 40 umol/L. According to Brouwers et al. (2015) there is a causal relationship between bile acid levels and adverse fetal outcomes. However, it is unclear if the lowered bile acids produced by the drug intervention has any effect on fetal outcome, therefore delivery is recommended at or greater than 37 weeks, especially in women with more severe biochemical
abnormalities (Kenyon & Girling, 2011). Findings, by Geenes et al. (2014) suggest delivery from 37 weeks gestation once the bile acids were greater than or equal to 40 \text{umol/L}, in an effort to decrease the risk of stillborn, noting that increasing bile acids are associated with an increased risk of fetal adverse effects. The probability of perinatal compromise to the fetus was not appreciated until bile acid levels were greater than 40 \text{umol/L} in a study that was done by Glantz et al. (2004) supporting the above findings.

There are additional clinical guidelines of ICP provided by Clinical Guidelines Obstetrics and Midwifery (2016) by the Department of Health and Western Australia but they do not identify how these were formulated. According to these clinical guidelines, timing of delivery at 37-38 weeks is based on literature dating back to 2008-2010 (Clinical Guidelines Obstetrics and Midwifery, 2016). There are no recommendations for fetal surveillance and it is left to the discretion of the obstetrician (Clinical Guidelines Obstetrics and Midwifery, 2016). UDCA is the recommended medication of choice but the dosing is not provided (Clinical Guidelines Obstetrics and Midwifery, 2016).

Presently, the American College of Obstetricians and Gynecologists (ACOG) and Society of Obstetricians and Gynecologists of Canada (SOGC) do not have guidelines for managing ICP. Lindor and Lee (2016) and Kenyon and Girling (2011) do provide guidelines for management of care for the obstetrical patient who presents with ICP. Interestingly all guidelines compiled by Kenyon and Girling (2011) were challenged by authors Prusova, Churcher, Tyler and Lokugamage (2014) revealing that the majority of their guideline recommendations do not reflect high quality evidence.

**Shared Care Model**

In the northern community where this research will take place shared care models exist between the local obstetricians and nurse practitioners, physicians, and midwives. Most often, if ICP is suspected, it is the obstetricians that will initiate the initial work up. However, if ICP is suspected while in the care of a shared care provider the algorithm provided through this research will enable the physician, nurse practitioner or midwife to select the blood work that needs to be performed prior to the referral appointment. This will expedite the diagnosis and provide a more timely intervention, therefore minimizing risk. A clear consensus would be very beneficial due to local practice limitations associated with blood test results. If bile acid blood samples are drawn as a hospital inpatient, there is zero cost to the patient and the sample is sent to a large urban center whereby the results are available in 5 days. Conversely, if bile acid samples are drawn in an outpatient private laboratory there is a cost of forty dollars to the patient and the results can take up to 7-10 days. These limitations that also exists in the literature (Lindor & Lee, 2016) make it very challenging to make clinical decisions based on bile acid results and clinical presentation.

**Purpose**

The purpose of this paper is to assist a group of obstetricians to develop local consensus in the management of ICP in a North Eastern community. Although the maternal implications are distressing and dismissal of the potential implications due to severe disease are rare in presentation, it is the prevention of adverse fetal outcomes that drives this project to review the literature and establish an evidence-based guideline for the management of ICP.
The Delphi Technique

According to Kitson & Strauss (2010) high quality guidelines and systematic reviews are produced by research-based evidence. Prior to initiation of practice change or implementing strategies to improve quality care, assessment of current practice needs to be assessed (Kitson & Strauss, 2010). Evidence based is defined as integrating clinical expertise with the best available clinical evidence from systematic research (Sackett et al., 1996). The Delphi technique provides a way to look at current practice integrate it with current evidence and make change or create guidelines that are supported with knowledge, experience and evidence based medicine (Wu, Viswanathan & Ivy, 2011). The Delphi technique is a method of research whereby data is collected by a group of experts, to achieve consensus (Hsu & Sandford, 2007). The Delphi technique is highly effective in achieving consensus for a variety of topics, and it has been used in educational and healthcare settings, forecasting disease patterns, establishing consensus or in creating clinical guidelines (Thangaratinam & Redman, 2005). The Delphi technique has the advantage of organizing and structuring communication as experts offer individual opinions that require uniformity and consensus (Powell, 2003). Further, it aids in the synthesis of concepts, knowledge and evidence and integrates into the practice (Hollowell & Gambatese, 2010). This technique is further supported when evidence of management is lacking on topics of complexity, allowing for structured expert exchange of collected data via multiple questionnaires so that consensus building can be achieved (Hsu & Sandford, 2007).

During the time when the Delphi technique was developed, Dalkey and Helmer (1963) outlined distinct advantages of this technique over conventional round table gatherings such as: avoidance of confrontation, anonymity, coercion or being swayed by popular opinion. The anonymity component further displaces the risk of hierarchical professional status intimidation and unproductive discussions (Thangaratinam & Redman, 2005). The Delphi technique is an indirect, anonymous, iterative process aimed at achieving consensus among experts when guidelines or consensus is lacking (Hsu & Sandford, 2007) and when one is trying to achieve agreement on the use of available guidelines (Thangaratinam & Redman, 2005).

The democratic structured process of the Delphi technique has the ability to develop agreement among diverse groups (Powell, 2003) that may otherwise not be able to gather due to time or distance, enabling rapid responses from experts in their perspective areas of expertise (Yousuf, 2007). In this regard, his technique has been successful in producing guidelines or seeking agreement in the area of obstetrics and gynaecology (Thangaratinam & Redman, 2005). Wu et al., (2011) developed a conceptual framework inclusion of a multidisciplinary team in the field of obstetrics and gynaecology. The technique was instrumental and successful in the goal of consensus by allowing respondents to revisit and revise responses based on previous answers (Wu et al., 2011). The authors considered the process complete with the achievement of consensus (2011).

It is recommended that if the Delphi technique is used qualitative and quantitative measures be employed and the findings interpreted to enhance thinking, practice or theory (Hasson & Keeney, 2011). The advantage of the Delphi technique is the simplicity of data gathering, anonymity, controlled feedback and the elimination of advanced analysis due to the design and implementation (Yousuf, 2007).

Utilization of a questionnaire is a common and acceptable modification to the Delphi technique (Hsu & Sandford, 2007). In this process a series of questionnaires are presented to an expert panel and the feedback obtained allows the panel to consider opinions of other
participants and encourages the panellists to reconsider previous views and modify original thinking (Hsu & Sandford, 2007). The facilitator provides an anonymous summary and reasoning after each round and when there is limited change between rounds, the process will be completed and the final round will be based on averaging the answers (Yousuf, 2007). Interactions between the members is facilitated by the researcher, who presents feedback in a controlled process (Yousuf, 2007).

A modification to the Delphi technique is an electronic Delphi technique or e-delphi technique that was utilized by Avery et al. (2005) to achieve consensus on safety features in computer systems. The technique was deemed successful in that they were able achieve consensus with a multidisciplinary expert panel with a high response rate from the respondents (Avery et al., 2005). Also the use of e-mail for circulating questionnaires is now more common than the traditional postal system, but the risk of lengthy return time of questionnaires still remain, considering round 2 can take as long as 30 days (McMillan, King & Tully, 2016). Modification of the Delphi technique as seen with Dean, Barber and Schachter (2000) added a variation in which the second questionnaire only included information that the first questionnaire failed to reach consensus. Detailed literature reviews followed by questionnaires along with face-to-face interactions are other modification to the Delphi technique (McMillan et al., 2016). A variation of the Delphi technique will be utilized in this project to identify and establish consensus on clinical guidelines for the management of ICP among obstetricians working in a community in North Eastern Ontario.

**Theoretical Framework**

The knowledge to action framework (KTA) will guide the acquisition and dissemination of information gathered using the Delphi technique. The framework is set up in 2 cycles, knowledge acquisition and action (Graham et al., 2006). The knowledge acquisition takes place in many fields such as inquiry, synthesis and use of tools, such as guidelines (Graham et al., 2006). The authors Graham et al. (2006) describe action as a means of disseminating the information in the way of planning and executing change (2006). It is fitting in that as information and knowledge is acquired during the rounds of questionnaires in the Delphi technique, it becomes clear to the participants what the most valid and evidence based information should be and this will guide the practice (Graham et al., 2006). The KTA framework can be complex and challenging as the exchange of knowledge between the stakeholders is striving for consensus of terms and definitions, and in this particular study it takes it one step further to seek consensus in diagnosis and management of intrahepatic cholestasis in pregnancy. The resulting synthesis of this knowledge will result in an action that will guide and alter practice. The stakeholders must be engaged in the process of KTA and knowledge translation into practice in order for a practice change to occur (Graham et al., 2006).

**Methodology**

This project is a Delphi technique modification. It will consist of 2 questionnaires, a review of the literature and an algorithm all sent by e-mail. This first questionnaire will serve the purpose of acquiring information of current practice and the application to the existing evidence. This questionnaire serves as a baseline of how each obstetrician practices and how they have utilized the current literature. It asks the obstetricians general questions about their practice with ICP including diagnostic tests used, list of differential diagnosis and tests to rule out other liver
diseases, treatment options and dosages, follow up blood work, ongoing fetal surveillance, timing of delivery and post-partum follow up. There is opportunity in this step, for the participants to provide feedback and a rationale for their answers. From this any themes or need for clarification will be used in the second questionnaire (Okoli & Pawlowski, 2004).

The second questionnaire is dependent upon the analysis of the first questionnaire. This questionnaire will be used to obtain further clarification of practice and how it compares to the evidence and seeks clarification and refines practice when consensus is far apart. It also allows the respondents to provide rationale for their answers. According to Hsu and Sandford (2007) the feedback process allows for the participants to reassess previous thoughts and allow opinions to be modified or changed based on new findings.

It is anticipated that first questionnaire will be analyzed against the evidence, adjusted and presented in the form of an algorithm for the management of ICP. An algorithm will act as a consolidated list of answers from the first questionnaire and will be formulated based on majority practice and reflective of current evidence. Evidence and rationale based on current literature for management of ICP, will be sent with the second questionnaire along with the algorithm to demonstrate where the evidence is in relation to how each individual practices. This serves to inform and educate the respondent group (Hsu & Sandford, 2007).

If another round of questionnaires is needed for further clarification this will be instituted until consensus is achieved (Okoli & Pawlowski, 2004). The summary or in this case the algorithm, allows an opportunity to apply new information developed by previous iterations (Hsu & Sandford, 2007). If consensus is not achieved another round will ensue.

Evidence will be shared amongst the obstetricians via e-mail as per their request along with rationale for the final algorithm. An invitation for an in-person meeting where there can be an opportunity to discuss and revise the algorithm as a group will be offered and sent as an invitation email.

**Ethical Application**

The Research Ethics Boards of the North Eastern Ontario hospital and community agency as well as Laurentian University in Sudbury, ON reviewed the submission of this study.

**Sample**

Participants will consist of a group of 7 local obstetricians with minimum 10 years experience, who currently practice in a setting with a approximately 1000 births a year and having at least managed 5 cases of ICP in their practice. The consensus for the appropriate number of participants selected to participate in a Delphi study is not defined in the literature (Hsu & Sanford, 2007). The obstetricians will participate in at least one of possibly two rounds of questionnaires, knowing that further iterations are possible until agreement is achieved. Hsu and Sandford (2007), note that continuous iteration may occur until consensus is achieved.

The primary researcher, a nurse practitioner (NP) will serve as the facilitator. An email will be sent to the obstetricians inviting them to participate with a URL link to the online survey, which will serve as consent.
Analysis

The NP and the research mentor, who will look for common trends and outliers, will perform analysis of the responses for each round of the Delphi process. Both quantitative analysis, through counts and percentages of ‘like’ responses and qualitative analysis through review of the narrative responses of the participants, will be conducted. Knowledge gaps, learning needs and lack of evidence-based interventions of the participants will also be identified.

Conclusion

The purpose of this research is to establish a consensus evidence-based practice guideline for managing ICP in a northern Ontario community. The process affirmed the need for ongoing research in regards to classification of mild vs. severe intrahepatic cholestasis, maternal and fetal surveillance, timing of delivery, effective dosing of UDCA and the role if any in decreasing adverse perinatal outcomes. Evidence based research for antepartum guidelines in the management of ICP remain to prevent perinatal complications to one of the most common liver related disorder in pregnancy.

At the completion of the Delphi process an algorithm will be produced to guide the practices so that definitions and expectations are similar. The guideline produced will involve an integrated process of best evidence and clinical expertise and will aid in the management of ICP. The literature provides varying management advice and the algorithm is an attempt to synthesize the evidence and allow for independent practice preferences concerning diagnosis, treatment, maternal/fetal surveillance, timing of delivery and post-partum follow up. It is imperative to keep in mind that guidelines are only applicable to individual patients whose clinical presentation and patient choice are congruent, as guidelines do not replace clinical judgement and individualized care (Sacket et. al, 1996).

These clinical guidelines will be shared with the clinicians that produced them via e-mail and the final consensus will be shared with the participants in an informal gathering as per requested by this group, where there is opportunity to discuss the final algorithm and make changes if in agreement. The final guideline will also be shared with physicians, nurse practitioner and midwives in the community who care for the prenatal patients. There is also potential for the guideline that is developed in this process to be shared with the other groups of health care providers in the province.

The acceptance and success of the Delphi technique in the development of consensus for practice guidelines in a local setting are worth evaluation. If the process is effective, it may serve as a foundation for the development of guidelines or consensus for other conditions for which the evidence is scant and/or there is no clear path for clinical management.

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