To summarize, temporomandibular disorders (TMDs) are complex multi-etiological conditions that can include orofacial pain within the orofacial complex where the biopsychosocial model must be respected in the framework and hierarchy of treatment modalities . A true multidisciplinary professional approach is appropriate and required with exhaustion of patient self help measures, conservative, reversible, non-harm causing treatment prior to escalation to potentially irreversible methods. All treatment must also show clinical efficacy and cost effectiveness that above all provides optimal patient management and protection.

To consider expansion of the scope of practice of the GP dentist to include Neuromodulator administration as a therapeutic modality for TMD, must not be taken lightly by the CDSS . As a regulatory/public protection body, the burden of proof for support must be overwhelmingly in favour of the proposal, unquestionably and undeniably.

The question "Does Botox therapy, overall, meet the standard of care for management of TMD?" is imperative to establish. If we cannot, unequivocally, establish this, then how will we rule on the standard of care for practice when the CDSS will have to judge/rule on GP care? Standard of Care is established by the extent of support within current, non-biased, peer reviewed, evidence based literature for any treatment modality. For the current situation, this has been conducted , reviewed and demonstrated by this committee.

The committee's overall conclusion is that the current standard of care does not support Therapeutic Botox (Neuromodulator) administration by a Saskatchewan GP dentist as a treatment modality for TMDisorder, and that (unequivocal ?) support for the proposed expanded scope of practice of Botox therapy as a therapeutic modality of treatment for TMD does not exist within the current literature.

Neuromodulator Administration use for facial esthetics sees support by the literature. "The cosmetic use of BTX is becoming ever more common in the treatment of facial rhytides, where there is strong evidence to show its effectiveness against a placebo, without severe complications " (BDJ, Systemic Review….Vol 226, No9 page 668). As judged by this committee , scope of practice for the GP dentist can be expanded to include this and one can refer to the Standards of Care available within the CDSS Bylaws and Act. As a therapeutic modality for TM Disorder , neuromodulator use by the GP dentist is not allowed, although this is can be revisited subsequently as literature becomes available with further proper research, study, and conclusions.

Regarding Neuromodulator Therapy for TMD, let us consider the following as directly related to lack of support for Botox administration for therapeutic use and the literature to support the parameters covered.

1) It is imperative to have an intimate understanding of orofacial pain, as TMD can mimic other orofacial pain conditions (RCDSO p2, col2, line5), and with Neuromodulator Therapy treating TMD symptomatically for pain reduction only (American Academy of Orofacial Pain/Orofacial Pain 2018 page ?) , and the potential of a possible misdiagnosis, the administration of Botox has the potential to cause irreparable harm to our patient with not only the continual delivering of unnecessary treatment (CADTH page4, key findings, paragraph 3, and US National Academies TMD, page 198, section 5-21 paragraph5), but the cost associated with it as well (CADTH, page 9 last paragraph, BT for TMD and AAOP/Orofacial Pain 2018, page ? and BDJ ,Systemic Review of Botulinin Toxin in Management of patients with TMD ,Vol 226, No 9, May 2019 page 671) . Our leading ethical guideline is to cause no harm; this would violate it. (RCDSO article p2, col2, paragraph 4 and US National Academies 5-1, page 178)

2) Repeated Botox delivery for TMD, considering the possibility of a misdiagnosed TMD and the continual symptomatic management of pain, may result in a masked/undiagnosed serious pain presenting condition such as, but not limited to ," the neuralgias, CNS tumours, peripheral tumours, vascular headaches, tension-type headaches, dentoalveolar disease, sinus disease, ear disease, salivary gland disease, psychiatric/psychological disorders." (RCDSO page 2, Introduction, Col 2, Paragraph 3) To even attempt to diagnose the majority of these conditions, the diagnostics are not within the realm of the GP dentist with tests indicated such as MRI scans, CT scans, amongst others (RCDSO page 5, special investigations, column 2 paragraph 3). Allowing GP dentists to treat TMD with pain-masking Botox may prevent the diagnosis and treatment of other serious medical conditions - once again, a violation of ethics with the potential to cause harm. (RCDSO see item 1)

3) Due to the psychosocial nature of TMD's, patients that have presented to their "Botox GP", unfortunately, unmanageable signs and symptoms. Patients that are exhaustively "treated" by the GP, with the promise of a "cure" or the promise of pain relief by repeated neuromodulator therapy, are not being correctly managed by the GP dentist. In fact, this potential "long term failure" of treatment by the GP makes management at the referral specialist level even more of a challenge, sometimes even impossible. These continued attempts at treating TMD with only symptomatic relief can potentially bring irreparable harm onto our patients. In fact Schiffman tells us "the longer the pain persists, greater the potential for emergence and amplification of cognitive, psychosocial and behavioural risk factors with resultant enhanced pain sensitivity and reduced probability of success from standard treatments." (Schiffman, Diagnostic Criteria for TMDs, Journal of Oral & Facial Pain and Headache, Vol 28, Number 1, 2014, page 7)

4) Current peer-reviewed, evidence based literature does not support Botox as being part of the regular armamentarium within GP therapeutic modality of treatment for TMD.

A) The British Dental Journal states “Botox does not have a role in tackling the underlying aetiology of TMD or bruxism (somatoform disorder, a mental/behaviour disorder) but only in the potential outcomes (for example, pain…) Primary conservative options…should clearly be exhausted first before BTX is considered.” (BDJ, Review of Botox in Mgmt. of pts with TMD and bruxism, Vol 226 No 9 May 10, 2019 page 672)

B) The US National Academies TM Disorder Priorities for Research and Care 2020 (Section 5-21 page 198, paragraph 5) states there is “inconclusive evidence concerning effectiveness of botulinum toxin (botox) for myofascial pain in the head and neck muscles”.

C) The Canadian Agency for Drugs and Technologies in Health, which recommends to policy makers, based on current literature review, to make well informed decisions to improve quality of health care services, states that it has no confidence “in the efficacy (clinical effectiveness) of botulinum toxin (Botox) for treating TMD”, that there is “no evidence to support cost effectiveness of Botox in TMD,” that the clinical utility for Botox in TMD has “significant uncertainty” , and that “botulinum toxin (Botox) treatment for TMD is an invasive procedure with risk inherent in its administration” and potential risks of harm, needs to be studied further.” In summary, this review found no benefit to botulinum toxin over placebo nor over primary conservative therapy. (CADTH Botulinum Toxin for TMDisorder 2020, pgs4 and 9)

D) The British Journal of Oral and Maxillofacial Surgery states that the “consensus on the therapeutic benefit of BTX in the management of myofascial TMD is lacking.” (BJOMFS Review of Botox in Management of TM Disorders, February 2020, Abstract summary)

E) The American Academy of Orofacial Pain concludes that there was “insufficient evidence to determine whether or not this medication is effective due to the lack of an adequate number and poor quality of the clinic trials” and that there is “insufficient evidence for botulinum use” because of “lack of standardized outcome measurements, treatment modalities, and follow-up”. (Orofacial Pain: guidelines for assessment, diagnosis, and management, Sixth Edition 2018)

5) Many studies cite the potential harm that Botox may cause to patients that has not yet been studied properly.
    A) CADTH report states that “Botox treatment for TMD is invasive with inherent risks and potential harm risks that need to be studied further.”(page 4, key findings, paragraph3)
    B) The BDJ warns of potential/possible side effects such as but not limited to “chewing discomfort, dry mouth, swallowing problems, facial paralysis”. (BDJ 2019 Review of Botox in Mgmt of pts with TMD and bruxism, page 671)
    C) US National Academies cites a study that found “loss of bone strength with repeated Botox use and TMJ Association issued caution to individuals with TMD pursuing treatment with Botox” (US National Academies TMDisorder, Bond E et al, Section 5-21 pg 198 paragraph 5)
    D) Clinical Oral Investigations (2019) 23:3411-3421, BT type A applications for masticatory myofascial pain and trigeminal neuralgia:what is the evidence regarding adverse effects?, states that “it is recommended that future studies aim to assess the safety and possible adverse effects of multiples applications or high doses of this treatment.”

6) Studies have also cited the significant recurrent financial costs that have to be incurred by patients receiving Botox therapy whilst the ineffectivess of this modality of therapy as a treatment for TMD is often mentioned in the literature. The lack of cost effectiveness of Botox as a therapeutic modality of TMD treatment evidence can be found in the CADTH report and in the BDJ review paper (page 671) as well as the Cranio article , citing multiple injections visits resulting in increasing patient costs, mentioned below in #7

7) Some studies have cited no statistical difference noted between Botox injections vs placebo/saline injections in the outcome of TMD treatment. Evidence can be found in the CADTH summary (page 8), and Cranio 27:1, 46-53 BT, Lidocaine, and Dry-Needling Injections in Patients with Myofascial Pain and Headaches states “lidocaine could be adopted as a substance of choice.”

8) There was a general consensus in the literature that further study is required for therapeutic neuromodulator use in TMD treatment with possible reassessment indicated once these studies have been completed and available for review.
    A) The BJOMFS states that further studies on the therapeutic benefit of BTX is needed with “larger sample sizes, minimal biases, and longer followup periods.”

(BJOMFS Review of Botox in Management of TM Disorders February 2020 Abstract summary)

B) The CADTH reiterates that potential harm risks need to be studied further (Conclusions page 9).
C) The BDJ states that current literature justifies that "further investigation" is needed (Conclusion, page 671)
D) The Journal of Dental Research states that the effectiveness of Botox in TMD requires further high quality studies that are "evidence based, well designed, and with low risk bias" before they provide approval for useage of Botox in therapeutic TMD management. (JDR, 98(13) Botox Type A in Dental Medicine 2019, Conclusion, page 1456)
E) The US National Academies states that "current data is limited and of poor quality" thereby, at this time, providing inconclusive evidence on the effectivenss of Botox in TMD therapeutic management. (US National Academies TMD, Section 5-21, page 198 Botox)
F) The International Journal of Oral Maxillofacial Surgery 2015; 44:1018-1026, Botulinum toxin therapy for tmd: a systematic review of randomized controlled trials (Chen, Chiu, Chen, Chuang) states that " no consensus could be reached on the therapeutic benefits of BTX on TMDs and that a more rigorous design of randomized clinical trials….should be carried out in future studies."

9) A comprehensive survey of recognized Association and US Federal Agencies summary on TMD management do not mention Botox therapy as a treatment modality and the general conclusions reached by the US National Academies on TMD also do not recognize Botox as a therapeutic modality. (Section 5-31 pages 208-209 and Section 5-35 page 212)

10) Presented to CDSS Council as current published literature advocating therapeutic Botox management in TMDisorder does not meet the scientific guidelines for "non-biased, peer reviewd, evidence based" literature that widely applicable protocol/guidelines that expose the public to proposed new treatment protocol , can be based upon from an efficacy, cost effectiveness, and patient protection perspective.

To review the articles submitted to the CDSS for support of Botox as a therapeutic modality in the treatment of TMDisorder

2003 Chikhani – This article is in French, but the abstract makes contradicting statements, ie "one single session is curative in 2/3 of patients" -- cannot be curative as the toxin effects are temporary and need recurrent injections every 6 months to maintain the clinical effects.

2017 Peng – This is not a scientific study at all, it is an anecdotal incidence of complications over a certain time period in a private practice of a cosmetic

dermatologist. Relevance to dentistry is unclear. More of an opinion/guideline from 1 person.

2012 Long et al – A literature search is not a sufficient level of evidence to implement clinical guidelines. Within their search there was only 2 Randomized Clinical Trials that were identified with "high quality research". However, neither of them identified comparison to the current standard of care.

2015 Azam et al – A review article is again not a very high level of evidence to base clinical guidelines on. it is only a summary of an individuals findings on the topic.

2007 Ihde et al -- Although a systematic review is considered to have a high level of evidence compared to the other types of studies, in this case it is not sufficient to change clinical standards of care. The study implicitly states the need for more Randomized Controlled Trials to establish clinical guidelines for the therapeutic use of botox. This is a key point as the strength in the level of evidence should be based on blinded randomized controlled trials with statistical power to prove the therapeutic use of botox is superior to the current standard of care.

11) The use of Botox in TMD treatment by Dental Specialists I believe needs to be assessed as well, to gauge the use of this modality of treatment for those who truly see and diagnose TMD as a referral based/Private Practice specialty. I believe the consensus from those consulted is that use of Botox in the therapeutic management of TMD is "last resort" and minimally, if at all, utilized for the management of TMD. Botox Therapy by the GP for TMD is not a cure for the disease entity, just a temporary bandaid that can be removed and reapplied several times within a circle of pain management that will do more harm than good, so why would we place this as a generally available armamentarium for the Saskatchewan GP dentist ?
Toxins, June 15, 2020 in Efficacy and Safety of BT Type A on Persistent Myofascial Pain: A Randomized Clnical Trial states that "due to its dose-dependent adverse events, its efficacy and development of adverse events ratio should be assessed, and that conservative treatments should be the first option for MFP."

12) The most recent literature release on TMD, US National Academies…TMD:Priorities for research and care reiterates, reclassifies, the complex nature of TMD, the evolving treatment scheme for TMD, in fact, Charles Greene, a guru in TMD summarizes quite adequately…"Recent research demonstrates that TMD's are complex multi-system disorders, which points to the need for a different patient-centred, interprofessional approach to TMD research and treatment. Therefore, traditional dental-centric approaches to research and treatment of TMD's must be modernized to align with insights gained from new scientific discoveries." (CDA essentials Volume 8 Issue 5 2021)

Conclusion….

In summary, the committee at this time does not recommend an expansion of the scope of practice of GP's in Saskatchewan to utilize Botox for the therapeutic management of TMD. The committee recommends that this can be revisited/reviewed and reassessed in the future as more literature becomes available. The committee does not object to the expansion of the scope of practice of GP's in Saskatchewan for Botox use in the "Facial Esthetics" (non therapeutic) aspect of patient care. (??)