Dental Implant Safety Workgroup Meeting
Minutes
July 26, 2018

MEMBERS PRESENT:	Gary Underhill, D.M.D., Co-Chair Julie Ann Smith, D.D.S., M.D., M.C.R., Co-Chair Todd Beck, D.M.D., OBD Board Member Paul Kleinstub, D.D.S., M.S., OBD Chief Investigator & Dental Director Daniel E. Blickenstaff, D.D.S., M.S.c., OBD Investigator James Katancik, D.D.S. - OHSU School of Dentistry designee S. Shane Samy, D.M.D. – ODA designee Normund K. Auzins, D.D.S. – ODA designee Cyrus B. Javadi, D.D.S. – Board Appointed Duy Anh Tran, D.M.D. – Board Appointed Russell A. Lieblick, D.M.D. – Board Appointed Donald Nimz, D.M.D. – Board Appointed
STAFF PRESENT:	Stephen Prisby, Executive Director Teresa Haynes, Office Manager Ingrid Nye, Examination & Licensing Manager
OTHERS PRESENT:	Chip Dunn, OBD Board Member
VISITORS PRESENT:	Jen Lewis-Goff, ODA; Richard Zeider, D.M.D.; Jim Delgado, D.M.D.; James A. Miller, D.M.D.; Tad Hodgert, D.M.D.; Nathan Tanner, D.M.D.; Duane T. Starr, D.M.D.

The meeting was called to order by Dr. Underhill at 6:30 p.m. Dr. Underhill welcomed everyone and requested that those present introduce themselves.

Workgroup Members reviewed the minutes from the May 17, 2018 Dental Implant Safety Workgroup Meeting. Dr. Beck moved and Dr. Javadi seconded to approve the minutes as presented. The motion was approved unanimously.

The Workgroup reviewed and discussed a sample consent form for dental implants from DBIC.

The Workgroup reviewed and discussed a letter from Dr. Richard Zeider. Dr. Zeider's email advocated for minimal restriction and regulation of implant placement by practitioners licensed by the OBD. Dr. Zeider expressed concerned about a "minefield of bureaucracy" stifling a learning environment based on trial and error.

The Workgroup reviewed and discussed a letter from Dr. Tad Hodgert. Dr. Hodgert's email stated that inadequate or nonexistent education and/or supervised practice, along with deceptive marketing strategies, contribute significantly to the frequency of implant failure. The letter called into question which party should ultimately be held responsible for "maintaining-optimizing" the health of an implant. Dr. Hodgert believes that educators in the field of implant dentistry should be approved by qualified organizations outside the OBD, or by a panel of specially selected individuals who are adequately qualified to determine the competence of an educator. Dentists wishing to place implants should complete an educational course approved by this panel or by an outside organization, and also demonstrate competency by passing an examination.

The Workgroup reviewed and discussed recommendations proposed by Dr. Gary Underhill, which are reproduced here in full:

In order to place and restore dental implants in Oregon, the license must complete the following:

1) XX *hours of CE in the placement and restoration of dental implants. These CE hours must be a clinical hands on training course(s). These courses must be accredited by AGD PACE or ADA CERP.*
2) XX *Dental Implants must be placed per year.*
3) *A special consent form for Dental Implants, similar to the one suggested by DBIC, must be signed by the patient and included in the patient record.*

Dr. Underhill announced that he had changed his mind in regards to a requirement for a certain number of implants to be placed per year, and struck that item from his recommendations.

The Workgroup reviewed a communication from Dr. S. Shane Samy in which he retracted his previous recommendation and submitted revised recommendations. Dr. Samy recommends that the OBD's protocols be changed "when there is a complaint filed and / or if the licensee is audited for an implant related procedure then the licensee will be required to submit documentation for implant education that is comprehensive and in a continuum format (single topic, short courses will not qualify), if the licensee does not have this qualification then the licensee will have limitations placed on their license to practice dentistry until he / she completes a ___X ____ amount of CE hours to satisfy the above".

The Workgroup discussed and reviewed recommendations proposed by Dr. Russell A. Lieblick, which are reproduced here in full:

Considering all discussions at the previous meetings, I recommend the following:

1) *There should be a transparent informed consent process with language, specified by the board, informing patients that a general dentist is not a surgeon and if the patient would like to have their surgical procedure completed by a surgical specialist, they have that option.*
2) *A minimum of 100 dental implants should be restored prior to any surgical placement.*
3) *A minimum of 30 implants should be placed with proctored mentorship.*
4) *A minimum currency of 30 implants per year should be placed to maintain competency.*
5) *Subjecting patients to procedures that are not required for training purposes is unacceptable.*
6) *Placing multiple brands of implants in a single "case" is unacceptable. This does not include rerestoration of older implants or re-using implants already placed in another practice.*
7) *Informing a patient that they are not an implant candidate without specialist consultation is below the standard of care.*

The Workgroup discussed and reviewed recommendations proposed by Dr. Donald Nimz, which are reproduced in full:

I agree with the following recommendations.

1) Minimum of 40 hours of continuing education in implant placement, and restoration. With a minimum of 15 of these hours being hands on and or clinical.

2) Per my recommendation at one of our very first meetings. To restore a minimum of 30 dental implants placed by a certified dentist.

3) A grandfather clause allowing a general dentist who as placed over 50 implants competently, and successfully, and completed over 100 hours of dental implant education.

4) A minimum of 12 hours education every two years, with four hours of being specifically on risk management in relation to dental implants.

Workgroup Members were given the opportunity to express their thoughts about the materials that were being discussed throughout the duration of the meeting.

Key Discussion Points

- The OBD should potentially change their rules to require written consent form (to be signed by the patient and kept in the patient's chart) prior to implant surgery. Workgroup Members expressed different preferences for the level of detail that shouldbe prescribed by the Workgroup or by the Board for this form. Dr. Katancik suggested that the Workgroup instruct the Board to change the rules "requiring written informed consent forms for all hard or soft tissue surgical procedures including the placement of implants." There were differing opinions on the feasibility and necessity of requiring written informed consent for all hard or soft tissue surgical procedures.
- Potential educational prerequisites for licensees wishing to provide dental implant restoration and/or placement/surgery.
    - It was generally agreed that licensees who have successfully placed many implants should be "grandfathered in" and exempted from these requirements.
    - There was also discussion of certain specialists, or individuals who had completed certain specialty programs, being exempted from additional education.
    - The suggestions from previous meetings about requiring a licensee to restore a certain number of implants prior to being permitted to place implants (while still requiring specific education requirements) were once again discussed.
- Setting aside initial education/training for the moment, the Workgroup discussed "maintenance CE" to be required at each renewal cycle. In particular:
    - It was generally agreed that a requirement for a certain number of implants to be placed per year would be burdensome and difficult to enforce; that suggestion was discarded by several of the Workgroup Members who had previously suggested or supported the idea.
    - There was general support for the suggestion that implant-related maintenance CE should be required of all licensees, even those who do not place implants, as implants are increasingly prevalent in the patient population and will likely be encountered by the vast majority of licensees in the days to come.
    - There was a great deal of discussion on exactly how specific the CE rules should be.
- Changing patient perceptions of implant placement. The public perception (encouraged by manufacturers with financial motivation) is that implants are easy to place and carry minimal risk of failure/poor outcomes. However, this is not necessarily borne out by the facts and the success or failure of implant placement can depend not just on dentist competence but also on the suitability of an individual patient candidate. Board Members and Staff reported that the large volume of complaints related to poor implant outcomes and implant failures signaled a serious problem, one which the Workgroup was created to address.
- There was a suggestion that possibly the ODA could develop guidelines for implant placement that might go beyond what it is possible for the OBD to do (Workgroup Members clarified that the OBD can make rule changes, but doesn't typically provide guidelines).
- A review of OAR 818-012-0010(1) & (2) Unacceptable Patient Care – demonstrated how the Board of Dentistry has rules in place addressing treatment being provided and that alternative treatment and seeking consultation for better and safer treatment options is defined for Licensees. It is unacceptable patient care to provide treatment which exposes a patient to risk of harm when equivalent or better treatment with less risk to the patient is available.

- Discussion took place on how the current rules could be (or are being) enforced and how they might be improved to give the Board "teeth" to go after the bad actors. There was discussion on the level of success the Board has experienced in the past with correcting bad behavior with disciplinary actions such as consent orders.
- Once again the following issues were specifically cited as contributing to the large volume of implant failure and/or complaints regarding poor implant outcomes:
    - "Cutting corners" such as using substandard materials, mixing different manufacturers, purchasing a large volume of implant materials and then using those even if they are not the best suited for the case, etc.
    - Patently unethical actions, such as pursuit of financial gain at the expense of a patient's well-being.
    - Poor clinical judgment.
    - Inadequate or nonexistent education and training.
    - Inadequate or nonexistent communication with patients who experience problems with implants that have already been placed (infection, bad placement, etc.), and/or implant failure. Patients are sometimes not even made aware that a serious problem with the implant (such as a persistent months-long infection) is abnormal.
    - Failure to appropriately refer patients to licensees "who have special skills, knowledge, and experience" in placing implants "whenever the welfare of a patient would be safeguarded or advanced" by doing so (reference OAR 818-012-0010).
- There was discussion of the current OBD requirements for licensees wishing to administer anesthesia, and for other specialized or "risky" dental procedures such as endodontic procedures, Botox, etc. Workgroup Members stated that Oregon has been very fortunate to avoid "bad outcomes" in anesthesia that have plagued other state, and suggested that Oregon's relatively strict requirements for anesthesia permit holders have averted some of the poor outcomes that have gained a great deal of negative media attention in other states.
- Several Workgroup Members restated the goal of the Workgroup: to "elevate the culture" surrounding implant dentistry, and "create a higher standard" for the profession of dentistry in Oregon.

Dr. Katancik left the meeting at 8:20 p.m.

Dr. Julie Ann Smith offered a summary from her notes of the proposed "action items" from the Workgroup:

- Require a written informed consent form for dental implant placement. The level of detail that should be included in such a form was not yet agreed upon.
- Develop the educational requirements/prerequisites for dentists who wish to place implants.
- Develop a plan for "grandfathering in" licensees with a great deal of experience and success placing and restoring dental implants.
- Require a certain amount of CE pertaining to dental implants be required of licensees practicing implant dentistry for each renewal cycle.
- Determine whether <u>all</u> licensed dentists will be required to complete a certain amount of CE pertaining to dental implants each renewal cycle.
- Communicate with the Oregon Dental Association regarding developing a set of specific "guidelines" for Oregon licensed dentists practicing implant dentistry.

Later in the meeting, Dr. Julie Ann Smith added this additional point to her summary:

- Develop a requirement for how important information related to the implant (such as type/

manufacturer) is properly documented and provided to the patient.

Comments from individual audience members:

- Dr. Nathan Tanner mentioned more than one course he had completed in implants. Dr. Tanner opined that the courses that contained more mentorship and allowed students and instructors to "rub shoulders" were more effective training programs than those that were larger and more impersonal. Dr. Tanner suggested that good judgment can be learned in a "great course" and he further stressed the importance of mentorship and access to proctors in developing that good judgment that is so critical to the success of implant dentistry practice.
- Dr. James Miller commented on the practice of placing "mini-implants" and/or temporary implants that are not suited or intended for long-term use. Dr. Miller mentioned that he had been told that denturists are placing and restoring dentures on these "mini-implants"; Dr. Beck clarified that the OBD does not have jurisdiction over denturists. Dr. Miller went on to speculate on the possibility of dental therapists placing implants in the future; it should be noted that the OBD does not currently license dental therapists. Dr. Miller stated his support for a suggestion that had been made in previous Workgroup discussion that would require certain types of imaging to be completed prior to placing an implant. Dr. Miller also commented generally on the complexity of implant dentistry, and how a particular case that may appear quite simple may eventually prove to be extremely complicated and/or difficult.
- Dr. Tad Hodgert expressed concern that "everybody is trying to make it too complicated" and pointed out that dental students have, by virtue of successfully completing dental school and clinical examinations, demonstrated their ability to learn and retain information. Dr. Hodgert once again stressed that implant dentistry is "a piece of treatment that is more complex" and stressed the appropriateness of, and the need for, proper and comprehensive education to be completed prior to dentists placing implants. Dr. Hodgert stated that with some of the more advanced elements of implant dentistry, even the completion of 80 hours of education wouldn't necessarily guarantee competence.
- Dr. Duane Starr stated that he had been considering the phrase "educate not litigate" in the context of implant dentistry. Dr. Starr agreed with other speakers who had stated that implant dentistry is extraordinarily complex, and suggested that the Workgroup (and by extension, the Board) consider what role they could play in education. Finally, Dr. Starr also mentioned that the prices for CT scanners are coming down; imaging that some licensees may have once found prohibitively expensive to implement is becoming more and more accessible as time passes.

The OBD's Executive Director, Stephen Prisby, outlined the next steps for the Workgroup. Board Staff will compile all of the information that has been presented at the Workgroup meetings and share it with the Workgroup Members for review. The ultimate goal, according to Mr. Prisby, is to have a specific set of recommendations ready for the Board to review at their meeting on December 14, 2018. The October Board meeting will only have six of ten Board Members in attendance, that is why he suggested that the full Board review this Workgroup's recommendations at its December Board meeting when all ten should be in attendance.

Dr. Auzins moved and Dr. Javadi seconded that the Workgroup direct Board Staff to prepare the recommendations summarized above for presentation to the Board at the December 14, 2018 Board Meeting. The motion passed unanimously.

Both Dr. Underhill and Dr. Smith thanked everyone for their participation and contributions to the Workgroup.

The meeting was adjourned at 9:00 p.m.