CASLPM
THE COLLEGE OF AUDIOLOGISTS AND SPEECH-LANGUAGE PATHOLOGISTS OF MANITOBA

Obtaining Informed Consent for Invasive Procedures Guidelines for Speech-Language Pathologists

Introduction

These guidelines provide guidance to speech-language pathologists in Manitoba on obtaining informed consent for procedures considered invasive in the scope of speech-language pathology:

- TEP Prosthesis Change
- Fibreoptic (Flexible) Endoscopic Evaluation of Swallowing (FEES)
- Insufflation Testing for Laryngectomy
- Saline Installations

Standard

College of Audiologists and Speech-Language Pathologists of Manitoba (CASLPM) registrants ensure that they obtain appropriate consent in accordance with CASLPM Standards of Practice, guidelines, ethical standards, and applicable legislation. These procedures involve physical entry into the body or body cavity, typically by inserting an instrument, device or substance and carry potential risks.

Demonstrating the Standard

Registrants will ensure that consent for any invasive procedure is:

- Informed – The patient (or their legal substitute decision-maker) understands the nature, benefits, risks, and alternatives of the procedure.
- Voluntary – The patient is not coerced and is free to withdraw consent at any time.
- Specific – Consent must apply to the particular procedure being proposed.
- Capable – The patient must have the capacity to understand and make decisions regarding their care.

Consent may be verbal or written but must always be documented.

Procedure Specific Information

TEP prosthesis change involves removal of existing prosthesis and insertion of a new prosthesis in tracheoesophageal puncture. The TEP prosthesis is a small one-way valve that fits between the trachea and esophagus. This valve allows a person to redirect air for voicing after a total laryngectomy surgery and prevents food/liquid entering the airway.

Consent Considerations:

- Describe the purpose of the TEP voice prosthesis change including its role in supporting alaryngeal voice production and management of leakage through or around the prosthesis.
- Informs the client of the expected steps of the procedure, potential sensations (e.g. discomfort), common risks such as coughing, minor bleeding and aspiration of esophageal contents.
- Explain if there will be use of a topical anesthetic during the procedure (e.g. lidocaine spray).

- Discuss alternatives including variety of voice prothesis options available, deferring procedure, resizing of TEP and referral for surgical review as indicated.
- Discuss risks of declining TEP change including ongoing leakage, aspiration risk and reduced vocal function.
- Confirm that client has had opportunities to ask questions and understands the information in order to provide consent.
- Document the client's consent and relevant information in the clinical record.

Fiberoptic (Flexible) Endoscopic Swallowing (FEES) involves the passing of a small flexible scope with a camera on the end into the nose to the back of the throat allowing the structures of the throat to be viewed during swallowing.

Consent Considerations:

- Describe the procedure and its purpose.
- Explain the application of topical anesthetic into the nose, if applicable.
- Inform the patient of potential risks (e.g. discomfort, nosebleed, laryngospasm or feeling faint, aspiration of food/liquid).
- Confirm the client has had opportunities to ask questions and understands the information in order to provide consent.
- Document the client's consent and relevant history in the clinical record.

Insufflation testing for laryngectomy involves assessing the vibratory potential of the pharyngoesophageal (PE) segment. The purpose of this assessment is to determine candidacy for tracheoesophageal speech and to evaluate suitability for secondary TEP voice prosthesis placement. It may also be used to assist in troubleshooting voice or voice-prosthesis related concerns.

Consent Considerations:

- Describe the procedure and its purpose.
- Inform the client of potential risks (e.g. gagging or coughing, mucosal irritation, spasm of the pharyngeal constrictor muscles, skin irritation).
- Explain the use of topical anesthetics through the nose to minimize discomfort, as applicable.
- Discuss available alternatives (e.g. electrolarynx speech, esophageal speech).
- Confirm the client has had opportunities to ask questions and understands the information in order to provide consent.
- Document the client's consent and relevant information in the clinical record.

Saline installations involves the delivery of a saline bolus directly into the trachea through the stoma in a laryngectomy patient to assist in pulmonary clearance.

Consent Considerations:

- Describe the procedure and its purpose.
- Inform the client of potential risks (e.g. coughing, breathlessness).

- Discuss available alternatives (e.g. use of humidifier, wearing various filters on tracheostoma, nebulizers, cold pot).
- Confirm the client has had opportunities to ask questions and understands the information in order to provide consent.
- Document the client's consent and relevant history in the clinical record.

Other Special Considerations

Pediatric or Dependent Adults

- Consent must be obtained from the parent, guardian, or substitute decision-maker.

Emergency Situations

- In true emergencies where consent cannot be obtained and the procedure is necessary to prevent serious harm, action may be taken under implied consent. Such situations are rare in Speech-Language Pathology.

Language and Cultural Sensitivity

- Use interpreters when required to ensure comprehension.
- Be mindful of cultural attitudes toward touch or body-related procedures.

When to Re-obtain Consent

- If the client's condition or understanding changes.
- If a significant amount of time has passed since the last procedure.
- If the procedure is different in scope or method from previous ones.
- If new risks emerge.

Documentation

Speech-language pathologists must document the following in the client record:

- That informed consent was obtained.
- The key risks/benefits discussed.
- That a procedure was performed and the findings.

Example of documentation entry:

Informed consent was obtained prior to the procedure. The clinician explained the purpose and nature of the proposed invasive procedure and informed the client of the anticipated benefits. Key risks were discussed, including potential discomfort, coughing, minor bleeding, airway irritation, aspiration risk, or other procedure-specific complications, as well as reasonable alternatives and the option to decline or defer the procedure. The client was provided the opportunity to ask questions, which were addressed, and demonstrated understanding. The clinician confirmed the client's voluntary consent to proceed. The client tolerated the procedure well.