Needs List for ENT

I.

Need Statement:

A safer way to **drill the mastoid bone** in patients with chronic ear diseases in order to **avoid dural or sinus plate destruction**.

Brief Description of the Need:

A large number of patients have ear discharge through a perforated eardrum due to a diseased mastoid bone (bony prominence behind the ear). In these patients, surgical management is the definitive care. During the surgery, drilling of the mastoid bone is performed in order to remove the source of the disease. Since the bone is abnormal, its consistency and appearance is abnormal and this makes it difficult to differentiate normal structures (facial nerve, semi-circular canals, dural and sinus plates) from the diseased bone, hence leading to injuries to these normal structures while drilling the bone. This leads to complications such as paralysis of one side of the face, dizziness in the post-operative period and injury to the brain tissue respectively.

Treatment Gap Today:

Medical line of management and lifestyle changes are usually tried for a few months (3 – 6 months), however if the recovery is poor, a surgical intervention is the only curative solution for middle ear disease. There are drilling systems that provide irrigation and keep the field of vision clear and also sometimes alert or auto-stop when they are in contact with anything but bone. However, since the diseased bone has a lot of abnormal soft tissue embedded within the bone, these drills are difficult to use in such conditions. Image guided techniques are available but are expensive and require training & infrastructure. Training for surgeons is the current approach taken to address the need.

Solution Guidance (Suggestion):

A solution that can enable an existing drilling system to prevent injury to these important structures while performing the surgery.

II.

Need Statement:

An easier way to **accurately assess functional OSA** in order to improve patient compliance to treatment protocols.

Brief Description of the Need:

Obstructive Sleep Apnoea (OSA) is a condition in which the upper airway collapses during sleep (Tongue/uvula falls back into the oropharynx blocking the airway). Due to this the patient may get up from sleep 20-30 times due to breathlessness. This is called as an apnoeic attack. Due to OSA patients do not get sufficient oxygenation to the brain and patients feel sleepy through out the day often falling asleep while working or driving. There is accumulating evidence that OSA is being considered as an independent risk factor for hypertension, glucose intolerance / diabetes mellitus, cardiovascular diseases and stroke, leading to increased cardio-metabolic morbidity and mortality. The common clinical presenting symptoms are heavy snoring, witnessed apnoeas and daytime hypersomnolence (excessive sleepiness), which would help to identify the affected individuals.

Treatment Gap Today:

Before offering surgical or medical management, it is important to assess the degree of OSA during sleep, therefore necessitating assessment of vital parameters during sleep. This requires being hooked on to multiple probes and monitoring instruments at the hospital or at home. This test costs INR 5 -8000 for the patient and the overnight assessment reduces compliance to undergo the evaluation. This delays the definitive management and leads to worsening of patient morbidity. Nasal valves, CPAP (continuous positive airway pressure) machines, surgeries (creating space in nasal airway, reducing tongue mass, stiffening the palate etc.), and weight loss regimes. All have not shown to be effective in long-term management of OSA.

Solution Guidance (Suggestion):

A solution that makes the overnight assessment comfortable and more affordable to the patient.

III.

Need Statement:

A more effective way to **prevent apnoeic attacks** in patients suffering from OSA during their sleep at home in order to prevent complications due to hypoxic brain injury.

Brief Description of the Need:

Obstructive Sleep Apnoeia (OSA) is characterized by frequent episodes of upper airway collapse during sleep, causing recurrent arousals, intermittent hypoxaemia (reduced oxygen in blood), sleep fragmentation and poor sleep quality. There is accumulating evidence that OSA in India is being considered as an independent risk factor for hypertension, glucose intolerance / diabetes mellitus, cardiovascular diseases and stroke, leading to increased cardio metabolic morbidity and mortality. In India these diseases are already very prevalent due to causes independent of OSA and hence patients have very poor insights into the correlation between OSA and the development of these chronic diseases. This considerably reduces their compliance to the management options available today. The common clinical presenting symptoms are heavy snoring, witnessed apnoeas and daytime hypersomnolence (excessive sleepiness), which would help to identify the affected individuals. Many of these have lead to road traffic accidents and poor work performance in addition to the stressful living conditions in developing countries.

Treatment Gap Today:

Nasal valves, CPAP (continuous positive airway pressure) machines, surgeries (creating space in nasal airway, reducing tongue mass, stiffening the palate etc), weight loss regimes. All have not shown to be effective in long-term management of OSA. Most of this is also because of the poor patient compliance towards long-term solutions.

Solution Guidance (Suggestion):

A solution that effectively prevents apnoeic attacks in patients in an affordable manner.

IV.

Need Statement:

An effective way to **reduce the constant ringing sensation** perceived without any external stimulus in patients with tinnitus.

Brief Description of the Need:

Tinnitus is a condition where there is a sensation of sound (usually continuous ringing) perceived by an individual in the absence of an external sound source. The exact cause for tinnitus is still unclear but it is believed the perception of sound is because of internal damage to the auditory nerve. Many clinicians believe there is no permanent cure for tinnitus even today. Patients face extreme distress because of the constant noise that affects their social life, sleep and occupational functioning. Many develop pervasive low mood, anxiety and constant irritability. Tinnitus may persist for many years or for the rest of one's life.

Treatment Gap Today:

Existing solutions are noise masking devices, hearing aids, medications and tinnitus retraining therapies. These are either expensive or ineffective as solutions.

Solution Guidance (Suggestion):

A solution that can generate sound in the opposite phase/frequency of the tinnitus so as to cancel the noise and relieve the symptoms of tinnitus would be useful. As an alternative, a low cost white noise generator in a small wearable or insertable (into the ear canal) device which helps mask the tinnitus and allows patients to sleep without being distracted by tinnitus.

V.

Need Statement:

An effective way to **open the eustachian tube** in order to restore normal hearing in patients with eustachian tube dysfunction.

Brief Description of the Need:

The eustachian tube (ET) connects the middle ear to the nasopharynx (area behind the nasal cavity) and often gets blocked by mucous plugs or due to swelling present during ear infections. The eustachian tube is important to equalize the pressure between the middle ear and the nasopharynx. However when it is blocked, it creates a negative pressure within the middle ear and causes retraction of the eardrum, causing ear blockage and pain. This often persists for many days and sometimes even months creating chronic distress and discomfort to the patients.

Treatment Gap Today:

ET dysfunction is usually treated by prescribing some mucolytics (mucous dissolving agents), decongestants and exercises such as Valsalva/ Toynbee that help in equalizing middle ear pressure. In severe cases the eustachian tube is catheterized with another tube and air is insufflated to clear the blockage. This sometimes creates injury within the tube, which heals by reducing the lumen diameter and worsening the dysfunction.

Solution Guidance (Suggestion):

An office procedure where ET can be dilated and cleaned without damaging the inner lining of the tube.

VI.

Need Statement:

A safer way to **introduce the tracheostomy tube** into the tracheal stoma after it has been incised in order to **prevent entry into a false passage** and resulting hypoxic brain injury.

Brief Description of the Need:

A tracheotomy is a procedure where a "C" shaped tube is inserted into the trachea by making a hole through the neck in situations when an endotracheal intubation is not possible or not required. Since this surgery involves creating an incision in the neck and inserting the tracheostomy tube through a small opening, there is a chance for the tube to be inserted into a false passage other than the trachea. This occurs more in emergency situations or in cases where patients have a short neck or an enlarged thyroid gland. Insertion of the tracheostomy tube in a false passage can lead to hypoxic brain injury and death due to lack of a secure airway.

Treatment Gap Today:

To prevent this problem, sometimes various flaps are created over the trachea to prevent a false passage insertion. This increases procedure time and involves larger portion of the trachea being cut/removed.

Solution Guidance (Suggestion):

A solution that helps an existing tracheostomy tube to enter the trachea accurately and can provide immediate feedback of being in the correct passage.