"Acute Otitis Media in Children: An Indian Pediatricians' Perspective on its Diagnosis and Management (OMICIP Study)"

SPONSOR:
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LIST OF ABBREVIATIONS:

AOM: Acute Otitis Media

TABLE OF CONTENTS:

BACKGROUND AND INTRODUCTION:

Acute otitis media (AOM) is the second most commonly diagnosed condition in the pediatric emergency department following upper respiratory infections. It can occur at any age, but is most commonly seen in children aged 6 to 24 months. Around 80% of all children will experience otitis media during their lifetime, and between 80% and 90% of all children will have otitis media with an effusion before school age.[1] OM is highly prevalent worldwide and is the main cause of hearing impairment in developing countries.[2] A recent Indian study has shown overall prevalence of otitis media in the first 2 years of life was 29% and the maximum incidence occurred in the second half of the first year of life and at the age of 8 years it was reduced to 14%.[3]

Treatment of otitis media is directly related to its subtype of otitis media. The objective of treatment is to control pain and to treat the infectious process with antibiotics. Non-steroidal anti-inflammatory drugs (NSAIDs) can be used to achieve pain control. Many opinions have been expressed regarding which drugs are best for first- and second-line therapy or whether antibiotics should be prescribed in all patients with AOM. [4]

OBJECTIVES:

The objective of OMICIP Study is to understand the latest practice trends of the Indian pediatricians in the diagnosis and management of acute otitis media (AOM) in children.

SURVEY RATIONALE:

Data on true burden of AOM in office practice, its risk factors, offending pathogens diagnosis, selection of antibiotics and symptomatic therapies in Indian children are limited. This questionnaire-based survey is designed to understand the current landscape in disease trends, its diagnosis and management in India.

DESIGN & SURVEY POPULATION:

Overview:

It is a questionnaire-based e-survey to gain insights on the prevalence, diagnosis and management of AOM in Indian children from the practicing pediatricians.

Survey Flow Chart:

The e-survey will be available to the doctors (delegates) on a dedicated conference registration link; survey will feature on the link post-registration till the day of conference.

The doctor will be prompted digitally to first read through the survey protocol.

Thereafter, the doctor will gain access to the doctor e-consent and e-survey questionnaire. Subsequently, he/she will be requested to agree/ disagree to provide his consent and fill the e-survey questionnaire, accordingly.

On receiving all the completed e-survey questionnaire results, post conference, the Project Lead from the Medical Affairs team will check the documents and send it to an external agency for data entry and statistical analysis.

After receiving the required data analysis, the Project Lead from the Medical Affairs team will prepare the survey report.

The information from the survey may be further used for publication purpose.

Survey Population:

In this survey about 200 – 750 general pediatricians from India will participate.

Inclusion Criteria:

General pediatricians who will complete the questionnaire would be taken for analysis.

Exclusion Criteria:

Pediatricians not registering as delegates in a conference will not be included in the survey.

DURATION:

The duration for the survey is 20 minutes on any day, starting from 01st September and ending on 26th September 2021.

EVALUABLE VARIABLES:

- Understand the epidemiology of AOM in routine practice of pediatricians
- Understand diagnostic/ investigation modalities and pediatricians' choice of antibiotics for management of AOM

SAFETY REPORTING:

Not applicable as survey will evaluate the opinion of the doctors.

DATA MANAGEMENT AND STATISTICAL METHODS:

Data Management Plan

A data management plan will be prepared with designing database, data entry process which will be thereafter followed by cleaning database.

Statistical Methods

All the pediatricians who will completely fill the questionnaire will be included for analysis. Statistical analysis will be used to analyze the survey questionnaire data and results will be presented using frequency and percentages.

DOCTOR CONSENT & ETHICAL REVIEW:

Doctor consent will be obtained from the doctor prior to filling of the survey questionnaire.

An EC approval is not applicable for this survey, since patient data is not being captured.

PUBLICATION POLICY:

The survey data may be used for the purpose of publication and/or presentation in conference.

REFERENCES:

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PROTOCOL SIGNATURE PAGE:

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