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Exposition of problem
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Acute respiratory tract infection (ARI) is the leading cause of morbidity and mortality throughout the world particularly in developing countries (Selwyn, 1990). The majority of severe infections are due to lower respiratory tract infections (LRTI). Viral pathogens account for 30-40% of ARI cases where human respiratory syncytial virus (HRSV) is the most frequently identified pathogen, especially among infants and young children (Huq et al., 1990; John et al., 1991).

The WHO global programme for vaccine and immunization has stressed the need for extensive surveillance of HRSV in developing countries to better understand the epidemiology of HRSV. Surveillance is also required to estimate the burden of HRSV disease, which will assist health officials and immunization programme managers in the future, when introduction of HRSV vaccine will be considered in the immunization programme. Excluding influenza, HRSV is of highest priority for vaccine development because of common occurrence of virus in infants and children and potential severity of disease.

Surveillance of HRSV requires laboratory confirmation as symptoms and signs of respiratory illness lack the specificity. For the rapid detection of HRSV, serological methods are used less frequently. Earlier reports indicate the use of MAbs for the rapid detection of HRSV from clinical specimens (Bell et al., 1983; Kim et al., 1983). Conventional tube culture (Arens et al., 1986), immunofluoresence (IF) (Gardner and McQuillin, 1968), enzyme linked immunosorbenent assay (ELISA or EIA) (Todd et al., 1995) and reverse transcription polymerase chain reaction (RT-PCR) (Paton et al., 1992) are some of the techniques that can be used for the direct detection of viral antigen or viral genome but these techniques have some disadvantages:

- Diagnosis of HRSV can be made by demonstration of four-fold rise in antibody between acute and convalescent phase serum sample of the patient with ARI. But children 4-9 month of age possess maternal antibodies may complicate the data during surveillance or mislead the diagnosis.
- Tube culture technique is not rapid technique because HRSV is very labile and it is very difficult to recover the virus from culture. It takes several days to weeks for isolation and identification of the HRSV.
The sensitivity of PCR is much greater than that of cell culture or IF and it also permits subgroup classification of HRSV strains but it is very expensive and needs well-equipped laboratories.

Presently, imported commercial assays such as EIA kit (Directigen, USA) and IF kit (Chemicon Inc. USA) are available for the rapid detection of HRSV from clinical specimens. But these kits are expensive, and require a cold chain during transportation. In India, indigenous reagents for the rapid detection of HRSV are currently unavailable and there is an urgent need to develop such reagents. Hence,

2.1 The objective of the study was

- Preparation and characterization of monoclonal antibodies (MAbs) against an Indian strain of HRSV isolated at NIV, Pune.
- Standardization of NIV MAb based IF and ELISA tests employing nasopharyngeal aspirates (NPA) from children with acute respiratory infection attending OPD and admitted to KEM Hospital, Pune. These will include specimens positive and negative for HRSV as determined by commercially available Chemicon IF Kit.
- Evaluation of NIV IF test and NIV ELISA by comparing with Chemicon IF kit as ‘gold standard’.

2.2 The advantages of these reagents are

- They will serve as substitute for costly imported reagents and therefore make HRSV diagnosis always more widely available to health care providers.
- A rapid diagnostic test positive for the HRSV will provide etiologic confirmation of the respiratory disease and unnecessary antibiotic treatment will be curtailed and will allow immediate antiviral treatment with ribavirin in seriously ill infants or patients with underlying cardiopulmonary diseases.
- Early detection of HRSV will also help in the applying control measures for HRSV disease, as nosocomial infections with HRSV are known.
- These tests will be useful in the study of HRSV epidemiology.
- HRSV MAbs will also be useful in the antigenic analysis of HRSV strains.