

KEYNOTE



Harish Nair - RESCEU coordinator

RSV- what do we know and what more needs to be done?

The last couple of decades have witnessed a substantial decline in global child pneumonia mortality. This is largely a result of improved living standards, better access to care and introduction of vaccines against leading bacterial causes of pneumonia (namely *Streptococcus pneumoniae* and *Haemophilus influenzae* type b). It is expected that with the increase in coverage against the bacterial causes of pneumonia, the proportional contribution of viral aetiologies to child pneumonia will increase. The Respiratory Viral Epidemiology Research Group at the University of Edinburgh developed the first estimates of global disease burden due to RSV and influenza in young children. We recently published the updated estimates for RSV disease burden in children younger than five years in 2015. These estimates indicate that globally in 2015, 33.1 million episodes of RSV-ALRI resulted in about 3.2 million hospital admissions and between 59,600 - 118,200 deaths in under five children. The burden is disproportionately higher in children younger than six months (about 44% hospitalisations and 46% of in-hospital deaths). In the last seven years, there has been an unprecedented activity to develop an RSV vaccine. Several strategies (maternal and paediatric vaccines; long half-life monoclonal antibodies) are being pursued for paediatric immunisation. Simultaneously, vaccines are being developed for protecting the elderly - another high-risk group.

Our current and previous work has highlighted the scale of the problem and helped inform policy both at WHO and also for funding agencies. However, substantial gaps still remain. Our overall child RSV mortality estimates are based on relatively few data and therefore have large uncertainties. Age specific mortality estimates by narrower age bands (which are important for informing target age groups for vaccination) are not available. There are no estimates for RSV related recurrent wheeze and asthma in childhood - a substantial burden on the healthcare system and an important driver to inform vaccine policies. Additionally, there are no reliable global or regional estimates of the cost of illness related to RSV. Even in well-resourced settings like Europe, the evidence base

(primary care consultations, hospitalisation and mortality) to inform vaccine policy are not available. Similarly, there are no global or regional estimates for RSV related morbidity and mortality in the elderly. Hitherto, the majority of the RSV -related research was funded by the Bill and Melinda Gates Foundation. Now, the EU and EFPIA through the Innovative Medicines Initiative, have made substantial investments in RSV research. Over the next five years, RESCEU will work with other research groups and agencies like WHO to address several of these gaps not only for Europe but also globally.



RESCEU Let's include!

After careful preparation and spending considerable amounts of time behind computers working hard to get the clinical studies in place, the moment is finally there: the first RESCEU inclusions in the clinical studies are a fact!

With already over 150 participants included in the infant cohort study and over 350 recruited in the older adult study at the moment of writing, we are off to a good start! Due to great dedication, every site involved is on track to start or has already started including the first participants.

The infant cohort study, a birth cohort study with the aim of including 10,000 term born infants, is designed to determine the burden of RSV disease in term born infants. With the milestone of including its first participant in July, this study has officially started. At the moment ethics approval is almost in place at all sites involved and inclusion has already started in the Netherlands and Spain. All sites plan to be operational and start including in September.

The adult cohort study, a burden of RSV disease study in approximately a 1000 older adults is off to a start as well. With ethics approval obtained at all sites, recruitment of participants has started. Altogether, approximately 350 participants are recruited so far and the first baseline visits are already completed.

The COPD study is a burden of RSV disease study in 500 adults with COPD. UMCG has IRB approval and started with recruitment and baseline visits. Imperial will make use of their existing COPD cohort. The RESCEU study protocol has been submitted to the Ethics Committee.

Last but not least, the infant case-control study, which will start at the beginning of the RSV season in October, is currently under review at the local ethic committees at all sites. All involved sites are working hard to start including from the start of the season.

With all clinical studies on the way, we are all very curious on what this upcoming season will bring. So brace yourself, winter is coming!

First set of RESCEU deliverables completed and submitted to IMI

Since the RESCEU project started in January this year significant progress has been made in all workpackages. The teams are actively working towards achieving the goals of the respective workpackages and of the project as a whole. The first set of deliverables has been timely completed and submitted to IMI.

D4.1 - First study subject approvals package - all clinical studies	WP4	Public	Completed
D6.1 - Ethics policy handbook	WP6	Public	Completed
D4.2 - Data management system	WP4	Public	Completed
D4.3 - Ethical approval at all sites- all clinical studies	WP4	Public	Some approvals in progress
D5.1 - "Virtual biobank" of archived samples and metadata established	WP5	Public	Completed
D6.2 - Project Handbook	WP6		Completed
D6.3 - Data and knowledge management plan	WP6	Public	Completed
D6.4 - Communication Plan, including project branding and policies	WP6	Public	Completed

Public deliverables - which is the vast majority- have been published in the RESCEU website and can be consulted by everyone interested in the project's development. More than 250 people are at present actively involved in the project, comprising Consortium partners, affiliated partners and advisors. The RESCEU team is committed and working to complete a successful first year of the project.

Upcoming major RSV/respiratory meetings

SVVW CONFERENCE 2017 - 4TH RESVINET MEETING

We are delighted to announce the RSV Vaccines For The World conference 2017 which is organized by ReSViNET. The goal of the conference is to bring together the scientific data and expertise (mainly focusing on vaccine developments) and connecting the stakeholders involved in RSV research e.g. scientists, physicians, pharmaceutical companies, regulators and representatives from governmental bodies. Researchers and physicians from all over the world are invited to join the discussions and share their knowledge. Specifically, scientists and physicians from low- and middle-income countries (LMICs) and young researchers are being encouraged and supported to participate in this meeting. This year, the conference will be held on 29 November-01 December in Malaga, Spain

For more information about attending and/or sponsorship possibilities please contact Mrs. Leyla Kragten-Tabatabaie via info@resvinet.org.

List of recent RSV papers

September

Karron RA, Black RE. Determining the burden of respiratory syncytial virus disease: the known and the unknown. Lancet.;390(10098):917-918.

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