

REG NEWS: NOV/DEC 2014

REG's Autumnal Activities in Asia-Pacific

In November, 2,500 healthcare professionals from over 50 countries travelled to Bali for the 2014 Asia Pacific Society of Respirology (APSR) Annual Congress. REG was involved in a number of events over the three days.

Real-Life Session

REG collaborators David Price, Rupert Jones and Omar Usmani delivered a fantastically well-received session on *The Evolving Role of Real Life Research in Respiratory Medicine*. Following a similar format to the ERS session in September, the speakers reviewed the differences and complementary features of RCTs and real-life studies; considered the types of evidence that are currently available and offered guidance as to how databases can be harnessed to conduct for quality research purposes. Our thanks to David, Rupert and Omar for their really excellent presentations.

Collaborators' & Supporters' Meeting

We held an REG Collaborators & Supporters' meeting at APSR, our first (of many) to take place outside Europe and North America. The meeting brought together existing and potential collaborators & supporters from Singapore, China, the Philippines and Europe and we were also delighted to see and welcome Ron Tomlins, President of the International Primary Care Respiratory Group (IPCRG) among the delegates. The meeting was an opportunity to

raise awareness among the wider APSR delegates of REG's work and to grow our collaborator list from the region as well as to learn (from attending clinicians and researchers) more about the respiratory data sources and opportunities within Asia-Pacific. Among the discussions, it was established that:

- **Singapore:** is in the process of developing a national clinical database. In addition, the Singapore Women's and Children's Hospital already has a longitudinal paediatric database that could be used for research purposes.
- **Australia:** Although there is currently no national database, the majority of practices do use electronic medical records and it was suggested that there could be research opportunities available through working with selected larger practices.
- **China:** The Centre for Disease Control and Prevention (CDC) are looking into conducting a pilot with a view to centralising the collection of hospital data. Drawing expertise from REG and its experience in working with quality databases around the world will help inform the development of a China robust clinical database will have potential to offer valuable research data.
- **Japan:** secondary care (including prescribing) data is collected in Japan, but not primary care data. It is also of note that hospital usage in Japan may differ significantly from that of other countries (e.g. USA, UK) as they often



admit patients for respite care rather than because of acute / life-threatening symptoms.

- **Philippines:** data collection systems and criteria are unique to each clinic. There are growing pressures from the Department of Health in the Philippines to report national data (disease prevalence, drug use, etc) but that there is currently a lack of "know-how" as to how to collect community-based data.
- **Uganda:** is setting up an asthma and COPD cohort.

A recurrent challenge reported by meeting attendees was that of publishing their real-life research. David's advice on publication was to focus the research around a question that *cannot be answered in any way other way*, i.e. avoid "competing" with RCTs and, instead, focus on complementing them.

(APSR highlights continued on p3)



Left: signage outside the REG collaborators' meeting; **Right:** Delegates awaiting the first ever Asia-Pacific REG collaborators meeting

REG 2015: Winter Summit

Winter Summit Programme available online

With the REG Winter Summit now just over a month away, the REG team have been busy confirming speakers, reviewing abstracts and planning the programme.

The theme for the 2015 Winter Summit is "Maximising the Yield" and the programme includes plenary talks on methods for "maximising the yield" as well as thematic sessions that will explore different data sources and opportunities around the world (within EMEA and The Americas). There will also be an interactive workshop on designing the ideal database and a plenary talk providing guidance and recommendations for getting real-life evidence published in peer review journals.

The thematic abstract sessions held across the two days will share some of the latest data on risk prediction, management and diagnosis, adherence and device effectiveness and technique in the real world.

Excitingly, a number of real-life device studies designed to evaluate patients inhalation technique, handling skills, ease (and maintenance) of technique mastery are reaching key milestones around the time of the summit. We

think these may offer a great platform for launching some PR and media outreach activities in the new year with the aim of broadening awareness of the organisation and starting to really build REG's profile as a leader in real-world research and as a group that is increasingly important from a policy and regulatory perspective.

For Council Members and REG Working Group Members, the programme also details a full schedule of Working Group Meetings. These are predominantly taking place on Thursday the 22nd, ahead of the main body of the programme, but there are also a number of breakfast meetings planned for the Friday and Saturday mornings to make maximum use of the time we have together.

The draft, indicative programme is now available on the REG Website (www.efficacyevaluation.org>> Summits & Events>> Winter Summit>> Programme). Please note, as the final

speakers are still being confirmed and late breaking abstracts are being accepted **up to the 5th of January**, small elements of the draft programme may be subject to change. A Final programme will be published online on January 12th.

REG 2015 WINTER SUMMIT

DATABASES AND REGISTRIES
AROUND THE WORLD:
Maximising the Yield

PROGRAMME

22ND - 24TH JANUARY 2015

HILTON HOTEL, WEENA 10, 3012 CM ROTTERDAM, NETHERLANDS

THE MEETING HAS BEEN ORGANISED BY THE
RESPIRATORY EFFECTIVENESS GROUP



And when the hard work is over...here are trip advisor's top 5 Rotterdam Sights

1 ROTTERDAM CENTRAAL STATION (340 reviews)

The city's central station seems to steal the top spot ... apparently for its functionality and interesting architecture. I'm sure the city has more to offer!

2 ROTTERDAM ZOO (661 reviews)

The Zoo combines collections of historical and very rare collections of birds and animals. The reviews are more compelling than for Centraal Station, and include: "might be one of the best zoos in the world".

3 ERASMUM BRIDGE (498 reviews)

Sometimes referred to as the "elegant swan of Rotterdam," the Erasmus Bridge is considered to be an architectural work of art. Shaped like a harp, it stretches high over Rotterdam's harbour (the largest harbour in Europe... surely that has to be worth checking out in its own right?).

4 MUSEUM BOIJAMS VAN BEUNINGEN (98 reviews)

Pairs famous works by Van Gogh and Rembrandt with contemporary works and exhibits. Some reviewers

event rank it at the same level as some of the more famous Dutch museums, e.g. Rijksmuseum, Kroller-Müller, van Gogh.

5 ARBORETUM TROMPENBURG (63 reviews)

If you're in need of a quiet corner, but in the fresh air, after a couple of days in REG sessions, this arboretum features lovely gardens, outdoor seating and a wide variety of plants. It claims to have over 750 species of Hosta (which our research tells us is a leafy plant, often known as a plantain lily).

New Supporters!

We are delighted to announce that Aerocrine, Cipla, Boehringer Ingelheim and Mundipharma Pte Ltd have all now confirmed their support of REG in 2015. A full list of REG's supporters is detailed to the right.



MEDA

TEVA

AstraZeneca



NOVARTIS



Boehringer
Ingelheim

Cipla

OPTIMUM
PATIENT CARE

Aerocrine

REG 2015: Winter Summit

REG's Autumnal Activities in Asia-Pacific (continued...)

Next Steps

REG's (i) Database and (ii) Validation & Standardisation of Coding Working Groups will carry forward these discussions by examining and mapping core database variables, considering both clinical and research utility. The groups will stratify disease-specific variable lists:

- **Minimum Criteria:** data that all practitioners should capture;
- **Optimal Criteria:** those that

would allow clinical diagnosis to be demonstrated, e.g. for COPD: spirometry, symptom score (CAT, MRC), exacerbations, blood eosinophil count;

- **Ideal Criteria:** more detailed data, such as CT scans, sputum, etc.
- If standard data collection criteria could be agreed across countries, and embedded across different health systems, it could be extremely powerful.

Workshop Accreditation

Real-life research and tools for carrying out database studies were also the subject of an educational workshop at the APSR, run by the Respiratory Research Alliance (REA). The materials from the workshop have since been submitted to the REG Accreditation Committee for retrospective approval – the first of many accreditation requests we anticipate for the Committee.

Funding update for the 2014 short-listed study ideas

The Sept/Oct REG Newsletter announced the 2014 studies (proposed by REG collaborators and supporters) that have been short listed by the REG Research Review Committee for REG support.

REG "Support" may be in the form of direct funding from REG, through our own core research budget. Alternatively, REG's role may be one of sourcing appropriate funding from one, or multiple external funding organisa-

tions (commercial and/or academic). The source of the funding, as well as the focus of the research topic will dictate whether it will proceed as:

- 1. An REG Study:** funded through REG's core research budget;
- 2. An REG Collaboration:** a non-commercial study conducted by REG via a grant from a sole supporter.
- 3. A Commercial Research Study:** a product-specific study funded by ≥ 1

REG supporter. Commercial studies will not be carried out by REG, but will be acknowledged to be addressing a research need identified by REG collaborators.

The potential sources of funding identified so far, and progress made to date to secure that funding, are summarised below, by study. We'll continue to provide updates over the coming weeks/months as funding is secured.

| LEAD AUTHOR | STUDY IDEA | FUNDING STATUS |
|--------------|--|---|
| Grigg J | Asthma Management in the under 5s | |
| Murray C | Is the addition of oral antibiotics with oral corticosteroids in an acute asthma exacerbation of benefit in terms of time to next unscheduled GP visit with asthma; time to next oral corticosteroid prescription and use of SABA of the following 6 months? Is any effect seen antibiotic class specific? | Prioritised for REG Core funding. Investigators have been (or will be) asked to develop a study budget to inform level of grant award |
| Lisspers K | UNLOCK study: are pharmacological RCTs relevant to real-life asthma populations? | Prioritised for funding; data provision only |
| Kern E | Outpatient factors predictive of emergency department use and hospitalizations among patients with COPD | |
| Turner S | Are Patient Characteristics Predictive of Response to Step Up Treatment in Children with Asthma? | Prioritised for REG Core funding pending 2015 budget. |
| Monteagudo M | Incidence of Cardiovascular Disease in Newly Diagnosed COPD Patients in Primary Care | Funding opportunities still under consideration |
| Stallberg B | UNLOCK Study: the prevalence of comorbidities in COPD patients and their impact on the quality of life and COPD symptoms in primary care patients | Prioritised for funding; data provision only |
| Williams S | Developing a validated claims-based algorithm for severe COPD | Funding opportunities still under consideration |
| Kern E | Using Medicare Claims Data to Determine the Effect of Pulmonary Rehabilitation and CT Phenotypes on the Occurrence and Cost of Severe Exacerbations of COPD | |
| Ryan D | Development, Validation and Evaluation of a Short form of EXACT (Exacerbations of Chronic Pulmonary Disease Tool) Questionnaire for Clinical Use and Self-(tele) Monitoring | Potential funding interest from current REG supporter. Proposals requested to confirm potential support. |
| Budmann S | Evaluation of fractional exhaled nitric oxide for predicting response to inhaled corticosteroids for patients with non-specific respiratory symptoms | Potential funding interest from current REG supporter. |
| Price D | A New Methodology for Assessing Mastery and Maintenance of Dry Powder Inhaler Technique in Adults with Asthma | Potential funding interest from current REG supporter. |
| Campbell J | Development of a Longitudinal Asthma Treatment Step Algorithm and Association with Asthma Outcomes | |
| van Ganse E | Ratios in Hospitalized Asthma Patients (RHAP) | Potential funding interest from current REG supporter. Proposals requested to confirm potential support. |
| Papi A | Triple Therapy in COPD | |
| Freeman D | Future COPD risk: Red Flags Identifiable from Routine Care Data | |

Other news...

Natural History Museum Annual Science Lecture



The Museum's Dippy – the Diplodocus

On the 4th of December, Sir Paul Maxime Nurse, English geneticist, Nobel Prize Winner, President of the Royal Society and Chief Executive and Director of the Francis Crick Institute gave the Annual Evening Science Lecture at London's Natural History Museum.

Rather than speaking about genetics and cell biology, his own specialty, he chose to speak on: **Science as Revolution**, a more general topic that lent itself well to the wide cross-section of attendees (some budding geneticists and working scientists, others more interested in a chance to visit the museum after hours and see the museum's Diplodocus, illuminated in the great hall; see picture).

Sir Nurse took his listeners on a whistle-stop tour of the history of science, from early man who monitored regular patterns in nature and erected stone circles, to the modern day physicists identifying new particles in their subterranean labs at CERN.

The repeated theme was how, throughout history, scientific methodologies of observation, hypothesis generation, consensus and scrutiny have been at the core of all significant social changes, be that changing attitudes to the shape of the world and its position within the universe to gene sequencing, genetics and genetically modified crops.

ERS Hot Topic

In late November / Early December REG responded to a late call for proposals for the 2015 ERS Congress. With much of the programme already decided, the ERS Scientific Committee are looking to fill their remaining few slots with Hot Topic proposals. So... in collaboration with Nicolas Roche, Guy Brusselle, Jerry Krishnan and Jon Campbell we've submitted a hot topic session proposal entitled: **Real-world asthma comparative effectiveness research (CER), where are we now?** If successful, the session will report how the work of the REG Taskforce has responded to numerous international and society calls for action to define appropriate methodologies for CER, featuring methods standards, a framework for how to evaluate this evidence, and examples for how this evidence might be best integrated into clinical guidelines. We should find out whether we've been successful in Feb/March.

Among the ideas he put forward was that there are many **false tensions** in science. The example he used was the apparent antagonism between Holism and Reductionism. Whatever Reductionists propose, he pointed out, must ultimately be tested in a holistic setting, which creates a necessary partnership between the two ideologies.

This brings to mind the false antagonism between real-life research and RCTs. As Sir Nurse said of Holism and Reductionism, the two are not sworn enemies, rather mutually reinforcing approaches to scientific evaluation of the world around, and the medical interventions available, to us.

The REG framework (published last year in *Lancet Respiratory Medicine*) that enables all types of studies to be viewed within a two-dimensional framework (bounded by patient selection on one axis and ecology of care on the other) was a first step to viewing different approaches to the evaluation of therapeutic interventions within a common "space" and understanding the relative linkages between them. Next year, REG's Quality Standards Taskforce will build provide tools to help interpret different types of evidence in a more integrated, holistic way.

Horizon 2020 bid

At the Inaugural REG Summit in June earlier this year, the final session on the Saturday evening considered how new Apps, Wearables and innovative technologies bring with them new opportunities for medical management (and research). It also touched on some of the ethical, moral and philosophical implications that new technologies bring in terms of storage and use of people's increasing digital footprint. The motivation for the session was mileage in putting together a bid for a Horizon 2020 technology and innovate grant to fund a joint respond to both the challenges and opportunities of emerging respiratory technologies.

After a few months "on ice", plans around this idea were reinvigorated in November by a very apt Horizon2020 call for proposals. Bid ideas are still embryonic, but more news will follow early in the new year.

Seasons Greetings!

As the REG staff will be taking their Christmas / New Year break shortly, we wanted to take the opportunity to thank you for all your support of REG in 2014 and to wish you a very happy festive/new year break. We look forward to more fun and exciting challenges with you all in 2015.

Please note, Hendrix (pictured) is Alison's dog. He was not harmed in the taking of this photograph (just slightly humiliated)!

