PREDICT Paediatric Research in Emergency Departments International Collaborative

Study Progress, Communication & Study Fatigue

PCCRG Paediatric Critical Care Research Group

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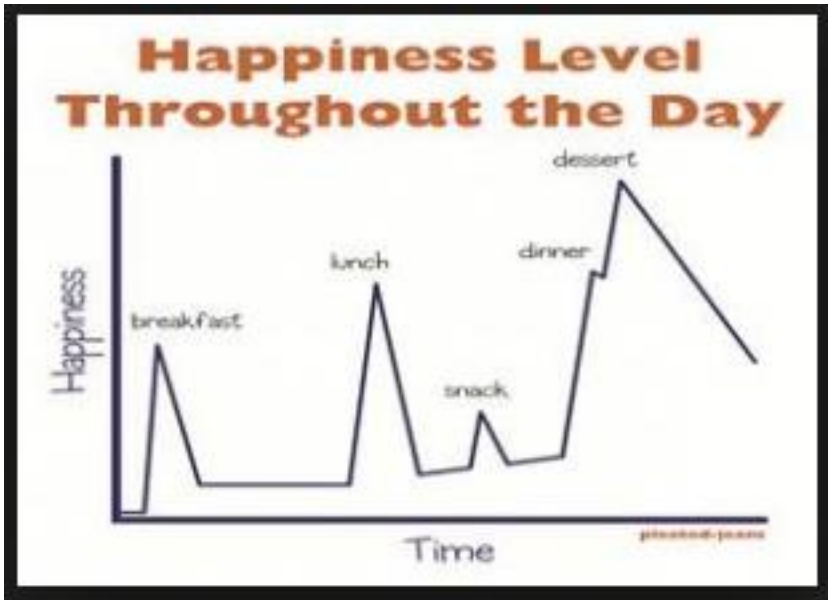
Study performance

Monitoring progress and quality to maintain research performance at a high standard

How to maintain/monitor?

- Utilise meetings to communicate changes in protocol
- Allow all team members to have input
- Observe and discuss team workload…
  How are they coping?
  Is there adequate staff?
  Equipment?



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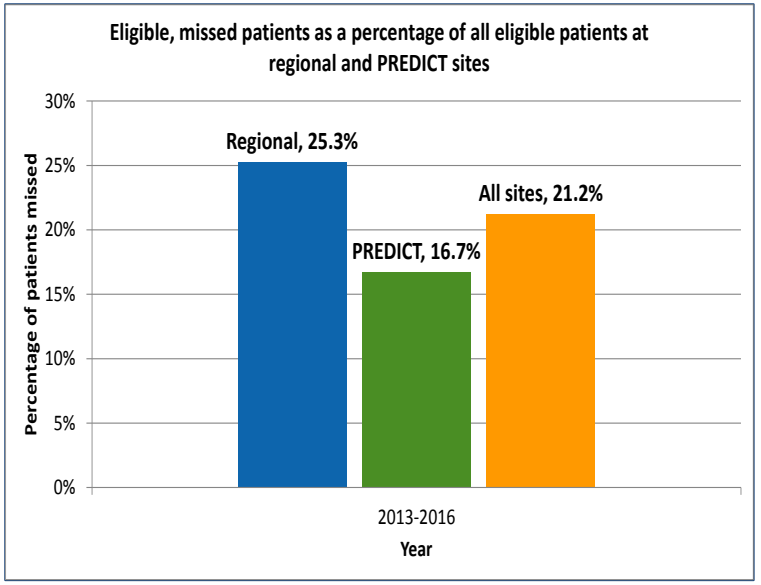
Monitoring study progress and quality

Communicate/Review regularly in all aspects (face-to-face/electronic)

- Study milestones (individual/group – newsletters)
- Recruitment accrual
- Protocol deviations
- Educational needs (Champions)
- Data collection
- Stock & Equipment
- Issues & Concerns
- SAEs and AEs



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Challenges with studies

- Non-adherence to protocol
- Difficulties with equipment/Drug
- Limited access to equipment/drug
- Limited access to supplies
- Lack of educated staff (new staff turn over/agency etc)
- Bureaucracy – Ethics/Governance

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Monitoring study progress and quality

- If study not performing well, determine the root cause and seek advice
  - Principal Investigator
  - Nurse Educator/s
  - Other medical/nursing staff
- If progress reports/screening logs taking longer or less/no communication – follow up
- Seek expertise from peers or relevant specialists eg. Statistician, research office
- Consider if issue needs to be referred to steering committee.
- Document your actions in emails or start an issues log.

ISSUES LOG:
Date of issue:

What is the issue?

Your actions
Outcome

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Communication

Use:

- alternative electronic avenues within your facility (eg. Sharepoint/TeachQ)
- short brief handover times (eg. brain bolus, short grand rounds)
- Different visual notices (noticeboards in obvious places)
- other methods – clinical handover form (completed data)

PARIS High Flow Newsletter

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snapshot only	Screened to date	Enrolled to date
	~5400 of which ~700 eligible	635

From Chief Investigator, Andreas Schibler

NEWSLETTER 1

To all the very motivated and great research teams in our local regional centres and our seven PREDICT (Paediatric Research in Emergency Departments International Collaborative) groups across Australia and New Zealand, we are now almost two years into enrolment of the PARIS High Flow Trial. It has been a busy two years setting up 17 centres across the two countries, and commencing the trial in all of these centres.

This is one of the largest paediatric trials of [illegible] work and effort that has gone into establish[illegible] centre has not gone unnoticed by both [illegible] search team. The great enthusiasm and [illegible] wards this study has been overwhelming an[illegible] kful to each and every one of the nursing and [illegible] members involved; whether this be in the logistics, o[illegible]ation, and education for the study, or the bedside care and management of the enrolled patients. We are travelling very well with recruitment numbers and are feeling confident of reaching the target of 1400 enrolled patients by the end of 2016.

This year I have presented at various international and national conferences in Japan, Korea, UK, Switzerland, USA, Hong Kong and Australia. The word is out! Clinicians across the globe know that we are doing this very large and very important study, which will inform not only your own local clinical practice but also the clinical practice of bronchiolitis infants around the world. People that I have spoken with are extremely eager for the results of the study, so it's important that we continue to adhere correctly to protocol, and not escalate care too soon, as it may not be needed.

As we roll into spring/summer, enjoy the quieter season particularly for our Victorian, ACT and New Zealand colleagues prior to getting ready for next year's bronchiolitis season! Thank you all for your work with this monster trial!

Andreas

In this newsletter:

Study site locations

Contact us

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PARIS High Flow Newsletter

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Merry Christmas

From Chief Investigator, Andreas Schibler

NEWSLETTER 2

The year 2015 is coming to a close, and it has been an incredibly busy one for all 17 centres now recruiting to the trial. The work and efforts you put in each and every day have not gone unnoticed by the central research team in Bris[illegible]ur sincerest thank you's to everyone for the incredible work you do; ensuring [illegible]n data that will provide clear scientific outcomes. We recognise that t[illegible]e who go the extra mile at each centre, answering staff queries, [illegible]ial recruitments, and ensuring study protocol adherence. Thank y[illegible]RIS HF Trial flag for all. We are currently ahead of projected r[illegible] that is almost unheard of, and is only possible with your support.

All centres have been recruiting since November 2015, and although the quieter summer season is now upon us, infants who meet the three inclusion criteria (diagnosed bronchiolitis, less than 12 months corrected age, and with an oxygen requirement) are still coming through our emergency department doors and being admitted to the paediatric wards. Please continue to enrol these eligible infants into the study.

Congratulations to all as we have now passed the half way mark of enrolments. It is common for study fatigue to set in at this time period and I ask all medical and nursing staff to encourage each other to keep up the good work. It is important to continue to observe for eligible patients in your departments and wards. Your hospital has agreed to support and take part in this study until all 1400 enrolments are complete. We recognise that high flow therapy has been present in many centres in Australia and New Zealand for several years, and after greater exposure to high flow we tend to think and believe this therapy works and would prefer having patients on high flow, hence avoid recruitment. We are now in a crucial phase of the study and it is very important that this effect does not creep in, particularly during the low recruitment period over summer. I encourage you to adhere to the study protocol and recruit as many eligible patients as possible, until all 1400 patients are enrolled. Ongoing education will continue to occur at all centres throughout summer and into 2016.

It has been a pleasure working with you this year, and my team and I would like to wish you all a very happy and safe Christmas, and all the very best in New Year. We look forward to working with you all in 2016, and hope to complete all enrolments by end of the year.

Merry Christmas and best wishes,

Andreas and the team (Donna, Lee, Geraldine, Greta, Luregn and Trang)

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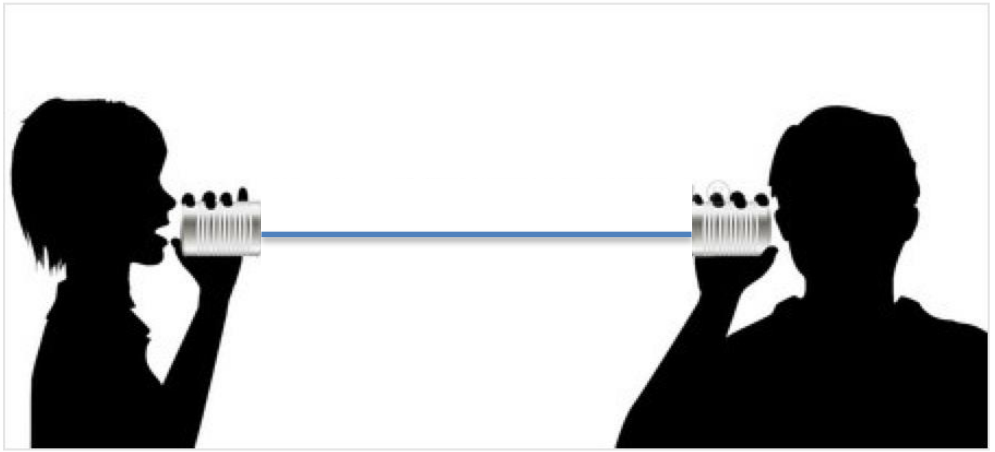
Innovative communication methods

- Educational tools via video (Vimeo) if specific and short (eg. protocol)
- Use of iPad with consenting
- Use of wider audience education tools (Documentaries)
- Relevant apps



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Remember…

Without your respondents you don't have a trial…

Look after them and keep them informed, interested and up to date on progess.

Acknowledge the individuals and the team

Reflect on the progress and job well done!

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Tired?

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STUDY TIRED?

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Study Fatigue

* Tired * Bored * Disinterested

Definition Respondent Fatigue -> tendency for respondents in a research project to lose interest if the study takes a great length of time to complete

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Overcoming Study Fatigue

Keep the study alive!

- Face-to-face walk around reminders
- Brief outline of why the study is important -> OUTCOMES
- Australia and NZ are leading the way with research in this field
- Refresher education (short and brief)
- Show progress data to keep motivation
- Remember Anniversary dates

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Keep the study fun!

Remember the outcome and potential benefits!

Make the team feel inclusive!

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General Issues and Challenges of Multicentre Research

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- Communication
- Different processes and procedures at each site
- RA cover
- Data handling- identifying information
- Training of staff

Positives of Multi-Centre Research - ConSEPT

- Patient sample representative
- Quicker recruitment
- Access to funding
- Networking and team approach

Challenges of Multi Centre Trials- ConSEPT

- Multiple ethics Committee's
- Multiple research office's
- Data interpretation
- Recruitment and protocol compliance
- Distance
- Site differences

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Resources

- PREDICT website public resources (links to MCRI/RCH)

http://www.predict.org.au/research-information/research-resources/

- PREDICT website members - http://www.predict.org.au/research-information/site-staff-login/
- CTN submissions

https://www.tga.gov.au/getting-started-online-ctn-form

https://www.tga.gov.au/using-online-ctn-form

Resources

- Monitoring and Reporting responsibilities

https://www.health.qld.gov.au/ohmr/documents/regu/nma_monitor_tables.pdf

https://www.health.qld.gov.au/ohmr/html/regu/mutual_accept.asp

https://www.health.qld.gov.au/ohmr/documents/regu/nma_mon_framework.pdf

http://hrep.nhmrc.gov.au/_uploads/files/Framework_for_Monitoring.pdf

- WA (PMH) HREC - http://www.pmh.health.wa.gov.au/development/resources/eth