IMPAAACT 2013
Helpful Hints

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Helpful Hints: Visits

- Prepare paperwork, NW kits, and blood draw kits ahead of time
  - We purchase gallon sized zip lock bags
  - We include the snack and book/toy
- Schedule families who may know each other at the same time
  - They liked having lunch together
  - This helped with retention to the large number of visits
- Morning visits
  - Timing of sending specimens to be processed worked better for our site
  - Children are often in better spirits in the AM
Helpful Hints: Participant

- Provide fruit snacks or animal crackers (based on age of child) right after the nasal wash
- Provide a prize like a small board book and a sticker
  - Families liked the books
- Older kids
  - Complete the visit fast
  - Hide the nasal wash supplies & gown and prep until just prior to the nasal wash
  - These kids had a harder time with nasal wash, but often recovered quickly

Some of the items for the visit kit
Helpful Hints: Participant

- Compensate at a higher rate for participants who came to clinic vs doing a home visit- (per your IRB standards)
  - Justified because it takes the families longer to come in and transportation costs
  - This was helpful as we had nearly all of our patients coming to clinic
    - Saves a lot of time for our staff
Helpful Hints: Participant

- Provide transportation to the clinic for visits
- Provide meals
- Provide routine well child visits with study visits (when appropriate)
- Obtain routine blood draws with study visit blood draws when possible
- Provide flu shots at the end of the time period when allowed, and if indicated at a regular study visit if able
- Provide immunizations if needed and then hold on enrollment until they are eligible, if able
Helpful Hints: Lab

- Devise a plan with pharmacy and the lab to maintain the blinding of the study
- Staff may be normally involved in shipping specimens from the pharmacy to the lab – in this case they cannot be involved with this part; it may unblind the study
Helpful Hints: Lab

- Pre-printing
  - LDMS labels (day of visit)
  - Label printer (prior to day of visit)
  - Including the study visit day # on specimen label
- Bring extra VTM to the visit
- Label SD notes with the study week and study visit day
- Prepare an EMR (Epic) template for your study notes
  - Our site has one that can be shared if you use EPIC
Helpful Hints: CRF Completion

- Follow directions on the CRF for how to accurately reflect the visit date and week/day when you are doing an in clinic visit on a date when there should be a telephone visit.
  - 2013 MOP Appendix VIII is a useful guide
- Use a flow sheet to keep track of signs and symptoms that can be carried over from visit to visit.
  - If this is not in an EMR then be sure to sign and date it at each visit
- Don’t wait to reconcile signs and symptoms until several weeks into the study.
  - Daily or weekly review to be sure the S/S and dates match up and are resolved as needed
  - This can be confusing when you see a well child on a Monday morning and they develop rhinorrhea on that Monday night.
  - The symptom needs to have a start date of that Monday even though they did not have the symptom at that Monday visit.
Helpful Hints: Source Documentation

- We list all important info in our note which is a dot phrase in our EMR.
- We use a chart to clarify whether a symptom or Diagnosis is:
  - Reportable on a CRF
  - Is related to Study TX
  - The grade
  - Why is meets or does not meet the solicited AE criteria
Helpful Hints: Source Documentation

- We use a drop down menu for labs so it's clear if we sent an adventitious assay or antibodies or simply a nasal wash.
- We cross check these charts with our CRFs weekly for consistency.
- If getting outside records and you think the records are not complete, be sure to request the completed records as soon as possible.
- Sometimes a second pair of eyes on a set of records can see things the first pair of eyes missed.
Medically Attended Events During RSV Surveillance Season

- A child has a fever, symptoms of a URI, LRI or an OM
  - It is medically attended if
    - The child sees a medical provider for it
    - The parent contacts a medical provider and the provider provides *prescription* medications

- A child has other symptoms (ie GI symptoms)
  - It is medically attended if
    - The child presents with symptoms of a URI, LRI or OM and is provided prescription medication for those symptoms
Thank You!

Questions?

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CHIP Pool Party for study Participants

Source: IMPAACT Field Representative, Emily Barr, CPNP, CNM, MSN 2017