Welcome to the first issue of the CARRA Registry Newsletter! This newsletter was created to keep families informed of all the latest happenings in the CARRA Registry, STOP-JIA and FROST studies. Please contact us at DCRI-Carra_Registry@dm.duke.edu to suggest topics or information you would like to see in future newsletters.

THE CARRA REGISTRY

What is the CARRA Registry?
The CARRA Registry is a database of information about children and young adults with pediatric-onset rheumatic diseases such as juvenile idiopathic arthritis (JIA) and lupus. The CARRA Registry allows children from all over North America share their identity protected information including clinical outcomes, patient reported outcomes, and blood sample collection that is then shared with researchers to better understand pediatric rheumatic diseases. By documenting a patient’s clinical course of action and drug treatment plan over time, future doctors and families can make more informed decisions on what treatment is safest and would work best for each child upon diagnoses. Right now, only JIA and lupus patients are being enrolled, and only those who are receiving their care from one of 60+ CARRA Registry sites. Other pediatric rheumatic diseases, such as dermatomyositis and scleroderma will be added later this year.

DID YOU KNOW? The CARRA Registry was created to monitor the long-term safety of the medications used in pediatric rheumatic conditions. Long term safety was voted by JIA and JDM families as their #1 research priority in a recent survey.

Why was the CARRA Registry created?
The registry was created to monitor the long term safety of the medications used to treat pediatric rheumatic diseases. A recent survey of parents listed understanding long term safety of medications as their #1 priority. But the registry does so much more: It also collects large amounts of information on thousands of patients, their treatments, side effects and quality of life, so you will be able to make more informed decisions about your/your child’s health. The goal is to have all the information you need to choose the safest treatment for your desired outcome.

What have we learned so far?*
3,725 patients with JIA have enrolled from 60 different sites across the US and Canada
- 70% of patients are female
- The average age at enrollment is 12 years
- All different types of JIA patients have been enrolled, but more than 60% have ever had at least 5 involved joints
- Approximately 50% of patients currently take methotrexate
- Approximately 50% of patients currently take a biologic medication
138 lupus patients have been enrolled so far

If you would like more information on the CARRA Registry or updates on Registry progress, please visit here: https://carragroup.org/carra-registry-updates. *as of January 2018
STOP-JIA

What is it? STOP-JIA (Start Time Optimization of Biologic Therapy in Polyarticular JIA) is a CARRA Registry research project that will answer a critical question for patients and their families: **When is the best time to begin biologic medications to achieve the best possible outcomes?** In this study, patients with polyarticular JIA, their families and doctors will discuss and choose one of 3 treatment plans which differ in the timing of when biologics are started. For more information on STOP-JIA please visit the STOP JIA page on the CARRA Website: https://carragroup.org/about-stop-jia.

FROST

What is it? FROST (First Line Options for SJIA Treatment) is another CARRA Registry research project that **compares the four most common treatments for new-onset Systemic JIA (sJIA):** Steroid medications, Methotrexate, IL-1 blocker (such as Kineret® or Ilaris®), and an IL-6 blocker (such as Actemra®), because we don’t know which one(s) work best. In FROST, systemic JIA patients, their families and doctors will discuss and select one of these commonly used treatments. They will get regular checkups to see how they are doing, and answer questions about how they are feeling at the doctor’s office and at home through an app. For more information on FROST, please visit the FROST page on the CARRA website:

Blood Samples

Why are blood samples being collected? Blood samples are being collected for some of the registry studies. The reason is that researchers are trying to answer some important questions about JIA using these samples, such as understanding why some children respond to one medication but not as well to others, and one day being able to predict how well children will respond to which medications.
Insurance FAQs

1. **Does my child’s care require a referral?**
   Your insurance may require a referral to the office for a specialist, especially if the physician is a Pediatric Rheumatologist who may be out of network.
   Your health plan may require you to get a referral as a part of the benefit coverage — not getting a referral when you need one could lead to a) benefit coverage not being available b) your benefit may be limited or considerably reduced c) you may be subject to higher cost sharing d) you may end up having to go through an administrative appeal process to get the coverage.
   It is important for you to know the requirements of your Health Plan and make sure that you (or your physician on your behalf) follow them.

2. **My pharmacy is unable to fill my child’s medication(s). Why?**
   Many insurance companies require prior authorization for biologic and injectable medications such as Enbrel, Humira and some high cost oral medications. They may also require the medication be shipped to you via a specialty pharmacy. Also, your pharmacy may be out of network for your insurance. Your pharmacist and your insurance company should be able to tell you why, and if the medication(s) needs to be filled elsewhere, like a mail-order pharmacy, and if the medication needs a prior authorization. Medications may need pre-authorization due to formulary status, being an injectable drug, or seeking exception due to multiple reasons.

3. **What can a parent do to assist the process?**
   Always keep your insurance information updated with your physician office and pharmacy.
   Always keep in mind that when you go through a benefit renewal, even if you did not change the plan, the process to access your benefits may have changed.
   Know that you may need a new authorization due to a multitude of reasons — most common being; if you change physicians, pharmacy or health plan. Or in some cases when your health plan changes their specialty pharmacy.
   Contact your insurance company. Inquire if the medication needs a prior authorization and if it needs to be filled by a specialty pharmacy.
   Keep in touch with your pharmacy regarding the status of the prescription.
   Call your doctor’s office if a prior authorization is needed or if the prescription needs to be sent to a different pharmacy. Ask your doctor/nurse if the medication has a copay assistance program. Many drug manufacturers offer programs to ensure the patient is able to receive medication.

4. **What types of resources does a health plan provide to help us?**
   Contact your insurance company and/or your Human Resources at your employer. They may offer a Case Management nurse, Care Coordination resources from a Pharmacy Benefit Management company and/or Patient Navigators from your employer.
Anne Dennos
Anne is the lead project coordinator for the CARRA Registry and has worked as part of registry operations team for the last two years. She has a background in public health and epidemiology and currently works on several large scale registries in her role with the Duke Clinical Research Institute in Durham, North Carolina. Her team is responsible for working with registry sites and managing the data collected from patients enrolled in the registry. In her free time, Anne enjoys traveling and all types of baking—a hobby generally appreciated by her friends and family.

Uday Deshmukh
Uday U. Deshmukh, MD, MPH, is HealthHelp’s Chief Medical Officer. In this role, he leads all medical management and clinical quality-related activities as well as medical policy and technology assessment. He is also an adjunct assistant professor of internal medicine at the University of Central Florida College of Medicine. Prior to HealthHelp, he has served as physician executive in Florida Blue, Cigna. He has been active in county and state medical organizations and several healthcare advisory panels, including the STOP-JIA stakeholder panel. Deshmukh received an MD from Delhi University and an MPH from Johns Hopkins Bloomberg School of Public Health.

Notes From a Parent Who Has Been There
The time of diagnosis can be a very overwhelming one, as are the following months and sometimes years. When my daughter was diagnosed four years ago, I wanted nothing more than to talk to a parent who had been through this same journey. I have spent lots of time in the past years mentoring newly diagnosed families and just being a soft place for people to call/email/text to vent knowing that I understand. The registry, STOP-JIA and FROST study team is comprised of many “experienced” parents and young adults diagnosed with JIA when they were children, and we would like to make ourselves available to you. If you are looking for that type of support and someone to talk to, please feel free to reach out to either myself, Vincent Del Gaizo or Kate Murphy.

Melanie Kohlheim - melaniejaprojects@gmail.com - (765) 532-6843 (parent)
Vincent Del Gaizo - vdelgaizo@comcast.net - (908)-303-9037 (parent)
Kate Murphy - katherinelinnea@gmail.com - (760) 470-0077 (young adult patient)

CARRA is grateful for ongoing financial support from the Arthritis Foundation which helps make the CARRA Registry possible. For a complete listing of all CARRA Registry supporters visit www.carragroup.org