

Assessing Oral Feeding Readiness Through Neonatal Salivary Analysis Q and A

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1. Could the presenter give a quick refresher on what p values are significant?
 - a. We consider a p value of < 0.05 as statistically significant. This threshold translates into a less than a 5% probability that the results we are seeing are due to chance alone.

2. Thinking of cost and availability to local hospitals, how likely do you think hospitals are to have access to this technology and how costly would this be to families as they are involved in treatment/therapy options? Many of our local hospitals barely have access to skilled feeding therapists as it is. Is this something that could realistically be accessible to guide best therapy practices?
 - a. If and when a salivary diagnostic platform is approved for use in the neonate, the goal would be to provide a rapid return of result (45 minutes or less) at a price point of $< \$50$. Most platforms could be performed in a central hospital lab with CLIA certification.

3. When do you recommend modified swallow study? What gestation?
 - a. I often refer to my speech pathologist colleagues for guidance regarding the need and timing for a modified swallow study. In my experience, this test is only performed in infants > 35 weeks corrected age.

4. Is this gene analysis going to be available for facilities to use?
 - a. Our hope is to one day have the platform commercialized for use worldwide. However, due diligence must be done to ensure the platform's accuracy and regulatory guidelines must be followed. It may take in excess of 5-10 years before that goal is achieved.

5. When should olfactory stimulation be implemented?
 - a. Our limited data from our pilot study suggests that olfactory stimulation initiated < 31 weeks' gestation has the most positive effect on oral feeding maturation. (Davidson et al, 2019, Breastfeeding Medicine)

6. Are your neonatal therapists using this research to assist with therapy interventions? If so, how is that driving therapy?
 - a. As the diagnostic platforms remain 'research only' at this current time, our neonatal therapists do not use salivary readouts to inform care. However, they are excited about the opportunity to integrate this research into practice and frequently request that I enroll a subject into our ongoing trials.

7. Do you believe it may be gene expression issues that affect full term infants with dysphagia without other issues?
 - a. I believe that it is very possible that either gene expression (RNA level) or gene variants (DNA level) may result in an infants' inability to feed at term. I believe we are likely underdiagnosing these infants in the NICU.

8. How common is it for a hospital to have a place to have these studies completed? Are labs like these already based in hospitals and just not being utilized in this way?
 - a. The vast majority of hospitals in the US have CLIA certified laboratories on site, as these are frequently required to run even routine testing on patients. Thus, once a diagnostic platform is approved, our goal would be to have it universally applicable across the country.

9. For the study on diabetic vs non-diabetic mothers, are you controlling for different levels of mother's control over her diabetes? Like mothers with A1C over 7 versus under 7?
 - a. We record maternal A1C levels for appropriate comparisons, along with other confounding conditions such as maternal obesity.