

*The inaugural Digital Diabetes Congress, just a hop, skip, and a jump from our San Francisco HQ was an intimate gathering of over 100 very passionate digital health advocates. Read on for our take on the top highlights from the two-day Congress.*

### **Top Eight Highlights**

1. In a confidence-inspiring talk, Onduo CEO Dr. Josh Riff shared an update on what the ~\$500 million Sanofi/Verily joint venture are working on: "A management platform that brings together the right solution at the right time for the right patient. We don't have to own all of it, and we are looking for partnerships. Niche one-off solutions will fatigue payers, annoy providers, and add burden to the consumer." He also discussed his views on digital health in an aquatic-themed presentation - there were some great one-liners in this one that we show below.

2. IDEO's Dennis Boyle, Abbott's Joel Goldsmith, Impekable's Mr. Pek Pongpaet, and The Doctor Weighs In's Dr. Patricia Salber discussed strategies to engage and delight patients. Digital products can't just be safe and effective - devices must be "engineered to perform, designed to delight," according to Mr. Goldsmith (who was instrumental in helping to design FreeStyle Libre). We loved his other comment that products should deliver "all the value with virtually no interaction." Added Mr. Boyle, "There is no excuse for bad design ... but there is plenty of it." We'd love to see IDEO involved in more design of products in diabetes.

3. Both days saw ample debate and commentary on: (i) What outcomes matter; and (ii) How should information about outcomes be obtained? Factions formed in both cases: For outcomes, some were in favor of "engagement," while others pushed for health and payment outcomes. They are related, of course. In the data collection debate, some pushed for real-world results, while others demanded RCTs - the latter seems so "old world" in so many ways. The studies are important, but to what extent do they reflect the "real life" in which all patients live?

4. Sansum's Dr. David Kerr posed one of the most provocative questions of the meeting: How should the world of diabetes be segmented beyond type 1 and type 2 diabetes? Responses varied from "down to the individual" (n=1) to "it's impossible to tell a priori," and everywhere in between. We like the cohort idea.

5. We were glad to hear conversation in a panel turn to the prospect of technology in the care of vulnerable and underserved populations. UCSF's Dr. Courtney Lyles was the superstar of this discussion, raising unresolved issues related to tailoring of technology to these groups: We think about generalizability too late in the development process, and members of vulnerable populations may not be using smartphones with as much skill as other populations.

6. In a panel on pathways to regulatory approval, FDA's highly-respected Dr. Courtney Lias reiterated the Agency's platform-agnostic viewpoint when it comes to bringing software to market and wished for an ecosystem of compatible, interchangeable pieces (i.e., pumps, CGM sensors) that could be assembled into systems.

7. Stanford's Dr. Korey Hood, Lark CEO Ms. Julia Hu, Canary Health CMO Dr. Neal Kaufman, and OneDrop VP of Health & Behavioral Informatics Dr. Chandra Osborn discussed barriers and pull factors relating to adherence to digital health devices and interventions.

8. We heard significant enthusiasm for smart pens that can capture insulin doses passively - far more mentions and excitement, in fact, than for closed-loop systems. This shouldn't be a surprise to anyone, given the upside.

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## Top Eight Highlights

### 1. ONDUO CEO DR. JOSH RIFF GIVES MORE INFO ON PRODUCT, TALKS DIGITAL HEALTH

**In a confidence-inspiring talk, Onduo CEO Dr. Josh Riff shared an update on what the ~\$500 million Sanofi/Verily joint venture are working on:** "A management platform that brings together the right solution at the right time for the right patient. We don't have to own all of it, and we are looking for partnerships. Niche one-off solutions will fatigue payers, annoy providers, and add burden to the consumer." In that sense, Onduo would be a curator and integrator of existing devices, software (insulin dose titration?), and information to ensure that patients are receiving the best tools for the treatment of their disease - using population data in conjunction with personal information to optimize therapy for comorbidities, lifestyle, preferences, disease progression, etc. On top of this platform, Dr. Riff reiterated that the company aims to eradicate the "dinosaur" of PMPM (per-member, per-month) payment in favor of shared savings, risk-based models, and bundled payments. Still, he acknowledged that many questions remain about Onduo, and that many haven't been answered: "There's nothing out there, sort of on purpose." The whole undertaking is very ambitious, and we are eager to see what the team has to offer a year from now. For many in the diabetes community, this keynote was the first time hearing Dr. Riff speak publicly, and many feel that they now have a better understanding of his mission and views on digital health. At [ATTD](#), Onduo's Head of Product and Technology Mr. Andrew DiMichele said that the company will have a "product to show the world" in approximately one year; this timing was not commented on today.

- **According to Dr. Riff, we need to accelerate digital health adoption in order to hit the tipping point for growth, which will be followed by value.** He likened this scenario to retail consumption: Even though 95% of all retail purchase is still brick and mortar, the [market values](#) of behemoth retailers such as Best Buy, Target, JC Penney, and Sears have all plummeted in the last decade, while Amazon has grown a staggering 1,900% to \$352 billion in 2016 (over \$400 billion [today](#)). This is the tipping point for growth in online retail, and what is needed in digital health. Pointing to a [famous photo](#) comparing Vatican square during papal inaugurations in 2005 vs. 2013 (lit screens from tablets and smartphones recording the proceedings abound in the 2013 photo, where they were all but absent in the 2005 photo), Dr. Riff believes the population is ready. "The way we experience the world has completely changed, and studies show that two-thirds of people want to use digital health tools."
  - **In order to accelerate the rate of adoption to get to the tipping point of growth, digital health needs:** (i) The consumer-centric approach to be redefined, with a higher bar; (ii) Reimbursement, which is generally a product of real-world evidence and clinical trials showing outcomes (**he later called for everyone in the room to team up to gain access to digital reimbursement from CMS and all payers**); (iii) Seamless integration into providers' workflow to help them save time, save money, and even make money; and (iv) To stop selling to large employers and payers on engagement. He was particularly

passionate about this, concluding that "engagement is for Angry Birds; outcomes are for healthcare companies." (We don't disagree with this though we do prefer the word "engaged" to "compliant".)

- **Dr. Riff emphasized the need for human-human interaction in healthcare.** While Onduo will employ AI, he knows that it can't ignore good service, the value of "looking someone in the eye, especially when they are most fragile."
- **"When I think about diabetes, I think about the iceberg," said Dr. Riff, "and I came to Onduo because I know the iceberg too well."** As a physician, Dr. Riff knew the tip of the iceberg - DKA and hypoglycemia, which patients presented with in the ER. Still, he knew that the underside of diabetes is complications and comorbidities, which make care all the more complicated. Later, while working with payers at WellPoint and Optum, he developed an understanding of the cost of diabetes - the middle section of the iceberg - he realized that this truly could be a disease that bankrupts the country if left unchecked. Finally, as Target's Chief Medical Director, he saw the deepest section of the iceberg, what diabetes does to people and a community; namely, the productivity loss and absenteeism, in addition to the effect on loved ones. The entire iceberg inspired him to work at Onduo, and puts the company's mission into perspective.
  - **Dr. Riff went on to note that, at Onduo, there is no longer an iceberg, but one fragmented ice field.** There is a whole ice flow in the way, coupled with treacherous waters. Indeed, revamping service models and the diabetes management ecosystem will require charting some uncharted territory.

**Dr. David Klonoff (Diabetes Technology Society, Foster City, CA): So the patients will be using multiple solutions?**

Dr. Riff: Yes, depending on patients' needs. There is a hierarchy starting with understanding, and then optimizing. What do you optimize first? **The key here, is to really be a population health company.** We need many solutions for many people, no one size fits all.

**Q: How will Onduo do all this, integrate with provider and patients' life, and make it so we're not thinking about healthcare all the time, the payment. How are you going to make it all fit together?**

Dr. Riff: Consumers will tell you they don't want diabetes, and they want to forget diabetes. "And don't remind me I have diabetes with texts," etc. How do you take as much of the friction out of the daily disease? **We need a stepwise approach of bringing solutions to market, partnering with companies that will help calculate insulin doses and eliminate finger pricks, all the way to helping deliver insulin.** The average primary care doctor doesn't see diabetes as a burden. If we could fill in the gaps for the doctor, we'd be doing them a service.

**Dr. David Kerr (William Sansum Diabetes Center, Santa Barbara, CA): It struck me that as a clinician, we increasingly don't see people that have only diabetes, but also atherosclerosis, other impairments. At Onduo, are you dealing with multiple comorbidities at this point?**

Dr. Riff: **If you're a purist in digital health, you will fail. We will learn how to treat patients differently for depression, or heart disease, and through machine learning, may find insights to help us take care of the patient.**

**2. THE USER EXPERIENCE BAR FOR DIGITAL HEALTH: "ENGINEERED TO PERFORM, DESIGNED TO DELIGHT" - ABBOTT'S JOEL GOLDSMITH**

**IDEO's Mr. Dennis Boyle, Abbott's Mr. Joel Goldsmith, Impekable's Mr. Pek Pongpaet, and The Doctor Weighs In's Dr. Patricia Salber discussed strategies to engage and even delight people with diabetes.** While the panelists agreed that the outcomes of digital products were the most important metric of success, they also concurred that it wasn't enough for digital products to just be safe and effective. Digital medical devices represent the intersection between medicine and consumer devices (e.g., smartphones), and therefore, must be - in the words of Mr. Goldsmith - **"engineered to perform, designed to**

delight." (Mr. Goldsmith was instrumental in helping to design FreeStyle Libre, so he definitely know what he is talking about!) Mr. Goldsmith also noted that **products should deliver "all the value with virtually no interaction,"** a lofty but necessary goal, given that patients using digital technologies ultimately want to think less about their diabetes. Mr. Pongpaet warned against "microachievements" that alert the user multiple times a day, which feels like a "teacher with a ruler."

- **To produce great user experiences, Mr. Boyle emphasized the need to involve patients directly in the design process. Using Lilly's IDEO-designed Trulicity pen as an example,** he proposed "listening relentlessly to what users need" by asking patients to test incomplete prototypes ("sacrificial prototypes") and including them in the design. Along those lines, the panelists also said that designers often miss flaws in their own products, and that bringing in "red teams" to play devil's advocate may prevent bias.
- **One of the challenges facing digital products is the inherent latency due to the long regulatory process and fast pace of technological advances.** Although Mr. Goldsmith acknowledged that this "problem probably cannot be solved," he argued that there is a silver lining to the delay in launching products. During the testing period, designers can alter their product design in accordance to the trends in the market, incorporating sustainable strategies and removing short-term trends. That said, it is getting more difficult to launch great devices - the bar rises every day, and the pace of iteration in software far outpaces the iteration in hardware. That's a tough trend for device companies to deal with.
- **Quotable quotes popped up everywhere in this panel - we've selected our top four:**
  - **"I started using a phrase, which was, 'engineered-to-perform, designed to delight,'** and that second half, at least within the diabetes world, wasn't a focus point, which was surprising because the devices that are being used to manage and treat the disease have a degree of intimacy that is unlike anything else, but share the same attributes as consumer products that we expect a lot of. So, why should we expect anything else when it comes to products that may be lifesaving medical devices?" - Mr. Goldsmith
  - **"We call it taking the friction out of the experience.** The people we are all trying to serve, our patients, get stuck easily, so if you can take steps or friction out of the experience, it makes the right thing to do the easy thing to do sometimes." - Mr. Boyle
  - **"I'd add that there's a growing awareness that diabetes is very important and it attracts people who don't have a health background that are now realizing they want something that is more meaningful than online advertising and are going into healthcare.** That will also be a contributing factor to growing awareness and accelerating some of the developments that will have more meaningful impact." - Mr. Goldsmith
  - **"There's no excuse for bad design, but there is plenty of it** ... there is a link between disposability and cost and usability, but people needing these shouldn't be suffering from bad design. I think this group needs to put their foot down and demand better design." - Mr. Boyle

### 3. WHAT OUTCOMES MATTER? HOW SHOULD DATA ON OUTCOMES BE COLLECTED?

**Both days saw ample debate and commentary on:** (i) What outcomes matter; and (ii) How should information about outcomes be obtained?

- **Is engagement an important outcome?** As noted above, Onduo CEO Dr. Josh Riff's memorable one liner argued against the use of engagement as a meaningful outcome in healthcare - "engagement is for Angry Birds; outcomes are for healthcare companies." In the succeeding panel on defining metrics of success, WellDoc Chief Strategy Officer Dr. Anand Iyer took a different stance, arguing that engagement outcomes are important. Lark CEO Ms. Julia Hu later proclaimed that immersive experiences are effective adherence-promoters. (Lark has a text message-like interface driven by AI, but it feels like a real person is talking to you and giving you advice.) Glooko CEO Mr.

Rick Altinger countered that it is ultimately about health outcomes, which lowers cost. Dr. Iyer later took a more quality-of-life stance, saying that success should be measured not only in outcomes, behaviors, but whether "we can unequivocally say what happened, why, and prevent it." We believe that "engagement" can be a means to end, but not the end itself; the goal with any of these tools is to help people with diabetes have better glucose outcomes, emotional well-being, and lower rates of long-term complications.

- **A more bipartisan debate centered around the value of RCTs (randomized, controlled trials) vs. real-world data collection in evaluating digital health products.** Our own Adam Brown framed the issue in Q&A: "I want to push back a bit on faith in RCTs in this area. They take enormous time to get off the ground, complete, and publish, and by then, you may be working with outdated technology. How do we reconcile this? We also know that RCTs are not very real world and are usually performed in a self-selected segment with the best clinicians. What's the balance? When should we do an RCT vs. gathering real-world pilot data?" Livongo CMO Dr. Jen Schneider shared that Livongo is primarily using real-world evidence, building a process where it can iterate to drive adoption of its product cellular-enabled meter and coaching service. She added that "as a US healthcare economy, we won't get where we need to go fast enough if we rely only on those [RCTs]." Omada Director of Medical Affairs Dr. Cynthia Castro Sweet said that Omada is doing both because it has to - the company prefers to collect data on-the-go, but she acknowledged that trials are needed to change policy, as decision makers are still attached to pristine, rigorous trials. Lilly's Dr. James Malone agreed that both are needed because payers want to see that a tool works when it is used as directed. Meanwhile, Norwest Venture Partners's Mr. Casper De Clercq said that his firm views RCTs as "essential" to obtain funding and reimbursement - maybe, but how many RCTs have created evidence that hasn't been repeated in the real world? (Early GLP-1 RCTs come to mind.)
  - **UCSF's Dr. Saleh Adi offered an idea for expedited RCTs: Use blinded CGM in two- to three- week trials, offering a faster path than A1c outcomes.** He noted that digital health is different from drug studies because there are no side effects or safety concerns (for the most part), and stakeholders just want to see patients use it effectively, continuously, and to the ends of better outcomes. Such valuable commentary!

#### **4. HOW SHOULD WE SEGMENT PATIENTS BEYOND T1D VS. T2D?**

**Sansum's Dr. David Kerr posed one of the most provocative and discussion-stimulating questions of the meeting: How should the world of diabetes be segmented beyond type 1 and type 2 diabetes?** Responses varied, and the audience was highly engaged. Ascensia CEO Mr. Michael Kloss proposed that it shouldn't be about segmenting groups, and that he'd rather see individualization, down to an n=1. Wow! Orbital Diagnostics' Mr. Giles Hamilton does see many positives around segmentation, but not in the typical fashion; he suggested segmenting around life events (diabetes onset, adolescence) and the patient's "journey in life" (But can this be made actionable? We do like the "cohort" argument.). Tidepool CEO Mr. Howard Look noted it may be incredibly difficult to predict how to segment *a priori*, but it would become more apparent if diabetes data were available to all people all the time. When that happens, perhaps different behavior types and sub-classifications would materialize. DiabetesMine's Ms. Amy Tenderich suggested that the "ultimate segmentation" is between those who rely on insulin and those who don't. Last, both Mr. Kloss and Lilly's Dr. James Malone pointed to the fast-growing population of people with prediabetes as a key group. All of these views are of course valid, and segmentation it ultimately a *tool* for tailoring product features and marketing to those most likely to benefit.

#### **5. UNRESOLVED ISSUES: DIGITAL HEALTH FOR VULNERABLE POPULATIONS**

**We were delighted to hear conversation in a panel turn to the prospect of technology in the care of vulnerable and underserved populations.** UCSF's Dr. Courtney Lyles was a fantastic voice in this discussion area, raising issues on tailoring technology to these populations. Her main (very valuable) argument was that we as a community think about generalizability far too late in the development of healthcare tools. The current model is to develop the content and product first, test it in people who are

already well-resourced and engaged in their healthcare, and then look for differences in use cases only after the technology has been distributed and spread. She made the plug, "if we're thinking about changes in the purchasing model for the entire population of people with diabetes, then we need to think about generalizability way earlier in the process." What would this look like? Work early and often with people of varying language and literacy backgrounds, readiness to change, past experience, and other health problems to figure out how to best generalize OR individualize the product. She also pushed back on the common sentiment that, since smartphones are so ubiquitous, mobile health interventions should be easy to implement en masse. Aside from the point that members of underserved populations may be overwhelmed trying to figure out where their next meal comes from, let alone thinking about their diabetes, she also reasoned that low-income populations may not be using phones in the same way that we are; "there's a bigger divide in experiences and knowledge than we might think. They might have a phone and call and email, but using an app and manual data entry, small font, scrolling, complex passwords, these are tasks that I see barriers with over and over again that I think we're not paying as much attention to." We want to hear much more on this topic at digital health conferences - how do we design products for those with the *least* resources and most in need of help?

## **6. FDA'S DR. COURTNEY LIAS ON INTEROPERABILITY AND COMPONENT AUTOMATED INSULIN DELIVERY SYSTEMS**

**In a panel on pathways to regulatory approval, FDA's highly-respected Dr. Courtney Lias reiterated the Agency's platform-agnostic viewpoint when it comes to bringing software to market and wished for an ecosystem of compatible, interchangeable pieces (i.e. pumps, CGM sensors) from different companies that could be assembled into systems.** She put a rest to the misconception that FDA has an exceptionalism about mobile platforms, expressing that it sees the phone as a handheld computer and it makes sense to put diabetes products of all classifications on them. The Agency just asks that the developer have a plan for handling extraneous factors such as silent mode override for alarms, features like incoming calls that could interrupt functions, and device updates. On interoperability, Dr. Lias again shared her long-term vision of component automated insulin delivery systems that allow CGM sensors and pumps from different companies to be combined - users could simply plug-and-play and the whole "system" would not need a regulatory review. Instead, each component would be reviewed. This is a compelling vision for user choice and companies' efficiency, and we wonder how long it will take to make this a reality. Dr. Lias pointed out that such a system would even benefit manufacturers that create their own full system (i.e., Medtronic), because it would allow them to adeptly and swiftly innovate within products. Nice! Dr. Lias has shared similar sentiment many times over the past year - recently at [AADE](#), the [NIH AP workshop](#), and [ADA](#) - and we're thrilled to hear her driving the consistent message for a more vibrant and safe ecosystem of compatible components and systems.

- **In Q&A, JDRF's Dr. Vincent Crabtree pushed Dr. Lias on the slow progress toward component systems to allow multiple devices to interact in an automated insulin delivery systems, pointing out that FDA's AP guidance came out in 2012 and there hasn't been much movement since.** Dr. Lias replied that the lack of significant progress is because the focus hasn't been on this for the past five years, but on getting the first hybrid closed loop product on the market. **"In the process, it has become clear why this needs to be fixed. It's not sustainable. We hope to have some discussion with the community. Step one is to get everyone on board - what are the fears. If we don't have buy-in from someone in the community, then it won't happen because FDA can't just make it happen. We can provide guidance or regulatory incentives, but the first thing to get on the same page, and we will focus on that for the next year or two."**

## **7. ADHERENCE TO DEVICES AND DIGITAL HEALTH APPS: WHAT ARE THE BARRIERS?**

**Stanford's Dr. Korey Hood, Lark CEO Ms. Julia Hu, Canary Health CMO Dr. Neal Kaufman, and OneDrop VP of Health & Behavioral Informatics Dr. Chandra Osborn discussed barriers and pull factors related to adherence to digital health devices and interventions.** On the barrier side, the most commonly mentioned factor was design - Dr. Osborn, in particular, commented a couple of times that, while academia can elucidate behavioral principles, the subsequent intervention "can't be

delivered on a paper airplane. It'd flop, not fly." The clinicians themselves also came up as a common barrier to adherence because they sometimes tell their patients not to use tools. On the other hand, the panel generally felt that financial incentives, individualization, good design, reduced burden (via automation and/or synthesis), and storytelling are strategies that draw users in to promote adherence. Immersive experiences and gamification were points of uncertainty on the panel - Ms. Hu spoke at length at one point about the Kim Kardashian app, and how it really sucks users in, making them feel like they are really speaking with and living the lifestyle of the socialite. Lark has tried to achieve a similar experience by building what Ms. Hu calls a "constrained universe." The counter-argument is that patients usually want to spend *less* time thinking about their diabetes, not more. Gamification is similar to immersion in that it requires more of the patient, and Dr. Kaufman is "not a big fan" of it at the population level. But he also said that he's not against this approach, just that Canary Health's partners have seen good outcomes in the absence of gamified interventions. Dr. Hood feels that gamification can be useful in some cases, like encouraging people to check their blood glucose. His philosophy is that if patients see better outcomes, then it doesn't matter how they get there. See below for our favorite quotable quotes from the panel:

- **"We don't do enough of asking what it's like to be the patient.** Some of our work is in profiling who is more likely to use which devices - not trying to profile people, but trying to figure out what makes an individual different from another. Having representatives from communities that you work with and partnering with them to figure out the best language to use, etc., is the first line of all of this good work." - Dr. Hood
- **"Five years ago when we started, conversations with the Lark nurse were more stilted, with long reporting structures, talking to or at the patient. People referred to the coach as 'it'.** As we developed the AI nurse more and infused her with personality and personal data, the feedback became 'she said something funny.' It started feeling like a relationship. **One of the biggest incentives is she makes them feel good about themselves - I think that's a core need.** A really important incentive is to tap into that basic need by seeing their efforts. **For example, you'd never tell a marathon runner 'good job, you ran a mile today.'** **But for someone who has never run a mile before, you want to see that effort...The incentive is to use great data to provide an internal sense of mastery and self-efficacy."** - Ms. Hu
- **"At OneDrop, we have an app coaching service, and we have users who are messaging their coach at all hours of the day.** Every day of the week, they are reaching out and engaged." - Dr. Osborn
- **"We're all relatively rational thinkers in this room, but most people making decisions about their health are making gut decisions and not thinking rationally.** We design more on rational-based decision making, and story-telling is on the emotional side. We need to do more research on how people make decisions - with their gut? Logic?" - Dr. Hood
- **"One of the things that makes people attracted to different apps is if it speaks to them in their narrative, there is some contextual factor that is charged.** Personalization and the cultural variable. A lot of what's out there is one size fits all. Many in the room have done work allowing people to design avatars and things in their own community, but then everyone on the team has to understand all of those contextual variables." - Dr. Hood
- **"The payer plays a huge role in promoting adherence; they pay the bills.** The issue is trust. When people hear that a payer wants them to use a product, they get nervous. Successful examples of how payers are creating adherence is when they work closely with the provider. The trust is really with the doctor, so incentives are truly aligned." - Ms. Hu
- **"Clinicians often serve as a pretty big barrier.** People who are polled will say 'my provider doesn't want me using xxx.' Clinicians and providers don't view themselves that way though. There is that mismatch." - Dr. Hood

- **"All of the research (almost) is done post show-up.** I would say that the biggest challenge is we don't have an understanding of what it takes to get someone to show up. We have an overrepresentation of motivated people." - Dr. Kaufman
- **"The DPP program has been administered with one-hour education in a social group.** But people are busy, so what if they had five-minute check-ins with the coach whenever needed? Leverage the teachable moments. It turns out that if you give them an unlimited amount of that, they spend more time talking to the coach. But the perceived value is that this method saves time. The perception of time is interesting." - Ms. Hu

## **8. ENTHUSIASM FOR INSULIN DOSE CAPTURE VIA SMART PENS**

**We heard significant enthusiasm for smart pens that can capture insulin doses passively - more mentions and excitement, in fact, than for closed-loop systems.** In just one example, mySugr's Kyle Rose said in Q&A, "If we're looking at insulin-treated people with diabetes, we're talking about what devices or systems will allow us to help them. Connected pens are a really exciting device. The majority of insulin users are using pens. Digital platforms can help give insight into this data. It's a really important and exciting time, and I commend Sean Saint (Companion Medical) and others working on this. I think it's going to be a real gamechanger." Several companies developing smart pens were in the audience, including Novo Nordisk/Glooko (expected to pilot later this year in Europe), Companion Medical (expected to launch this year in the US), and BD (late 2018 launch).

*-- by Brian Levine, Hae-Lin Cho, Adam Brown, and Kelly Close*