

**JENNIFER  
ROMANO:**

Welcome to this great conference. It's a pleasure to be able to kick off the research part of this meeting.

I have no financial disclosures, but I do have a disclosure that Karen Uzark is a huge collaborator with me and helped me significantly with my slides and said that I can steal shamelessly from her. So thank you, Karen.

Just to give you a little perspective and background, I'm sure you are wondering why a surgeon is talking to you about developmental care and how the conference coordinator has gone completely mad.

So early on in my career, I received beautiful letters from families thanking me following their surgery. The child on the left is a single ventricle, middle is a neonatal arterial switch. And you'll recognize the little guy on the right as the guy who's on the front of your conference brochure, who's now six. That's at his third birthday.

But getting these letters about these patients and being so thankful and then they say, oh, well, they're doing really well, they're finally either sitting up or rolling over. And I look back at the calendar and realize they were eight or nine months old and wonder, what did we do to these kids? Some of them having relatively short hospital stays that they were so delayed so early on.

So we know that developmental care now is increasingly important. I think we've long known that developmental delays are significant for our patient population, but quite often we're not identifying them until they're older, even in school age. And I think understanding that children who require heart surgery within that first year of life are extremely vulnerable for developmental delays. And are 11 times more likely to have gross motor impairment than healthy infants.

A 2-month-old infant who spends less than 15 minutes a day in a prone position has a significantly higher percentage of gross motor milestone delays. If you think about it, at that age many of our patients are undergoing major surgeries in our ICU.

So again, those patients that are at highest risk for developmental delays we know are those patients with recurring surgery in their first year of life. Those are cyanotic heart lesions, prematurity, other associated abnormalities. Those who require mechanical assist devices such as ECMO and VAD, heart transplantation, ever requiring CPR, having prolonged hospital stays or other neurologic issues.

We know that infants are at significant risk for neural developmental delay. We have a lot of biological risk factors that we look at and there are certainly attempts to try to modify those, but there are significant environmental risk factors. Here's a typical baby in the ICU, bright lights, lots of blinking noises, laying flat on their back. We have the ability to change this environment for our patients.

So, again, when you look at the ICU and hostile environment, I think immobility is one of the biggest detriment to our patients and leads to significant impairments in their motor development. But immobility is just the tip of the iceberg. There's so many things that are in our ICU and hospitals are trying to save these babies. Sedation, noxious stimuli, lack of positive touch from their parents, delayed enteral feeding. They all impact late development.

In a survey looking at current practice patterns for cardiac ICU's in terms of developmental care. This is a concept that's well known in neonatal intensive care units, where really the focus is in growing and feeding those babies and getting them back on track. Unfortunately for our patients, we're also dealing with major medical issues and trying to save their lives along the way.

And looking at 35 dedicated cardiac ICU's, it was great to hear that 90% had targeted efforts for developmental care. But when you dive deeper, only 50% have a developmental care committee, and even less than 50% actually of formal developmental care rounds.

And really the key to success to developmental care for our patients is having a strong commitment from leadership, a multi-disciplinary commitment, a focus on educating staff, supporting our families, valuing our parents as key primary caregivers for their patients-- for their children, even in the hospital. And really having clear policies to increase practice consistency in terms of developmental care.

When looking at environmental adaptations, there are many things that we do routinely. If you look on the far left-hand you see things that we routinely do, darkness in the evening, trying to minimize indirect lighting. In the middle of a slide we make sure that every infant has a TV available in their room, but interestingly we don't do anything to really-- many centers report that they're not doing anything to control TV time and volume in the patients' rooms.

Again, looking at this in terms of different developmental care options that are available, yes being the dark blue, and the light blue is no. Looking at things like clustered care and supportive care for soothing infants. But when we look at using parents to help support babies, especially during difficult or painful procedures, many centers don't employ that method. And specifically, physicians writing medical orders about developmental care-- this is an area where we have a lot of potential for growth.

In terms of holding policies having a sense of what tubes the lines are safe for babies to be out of bed or in a prone position. I asterisked two areas where I think we can probably improve. And you look at a lot of centers are allying babies to be held with arterial lines or when intubated. If you have clear policies to make sure those lines are safe allowing those babies to be healthy can have a huge impact.

In terms of developmental care formalizing rounds that are just like medical rounds is incredibly important. Having clear developmental care rounds have been shown to reduce neural developmental delay, poor awakening, decreased length of hospital stay and mechanical ventilation, as well as reduced physiologic stress for both parents and the patients.

Having increased parental involvement is huge. Having a developmental care rounds helps to promote that cultural change of really making developmental care a formal part of the medical care of these patients and supporting those care practices.

When you look at developmental care rounds and What they can incorporate, the core content is quite often discussing positioning, holding, and increasing skin-to-skin contact for babies, clustering care to reduce disruptions into their regular sleep and wake cycles, using non-pharmacologic ways to soothe patients, modifying the environment, as well different things to improve feeding as many of our patients have significant feeding issues.

But this is not without barriers. From a nursing perspective, it is often perceived that this will require more time from nursing, which is already quite often strapped. Having adequate resources to support the nurses and support families. Really changing the culture and making developmental care a priority in addition to the medical care.

Obviously we have to take into consideration an infant's acuity and other underlying medical condition as to where developmental care falls in the overall priority scale. And also parental anxiety. Most parents want to be involved with caring for their babies, but they're also very afraid to care for those children. So incorporating them early on in the hospitalization is key.

So this is where the research that I've been interested comes in. And the issue was, we needed a more proximate measure. So we created something called CHASMS. There are really no current tools to assess patients in the immediate hospital setting. We have a lot of tools to test patients' motor development in terms of the test of infant motor performance for babies less than four months of age. And the Alberta Infant Motor Scales, which is for babies over four months of age. These all need to be administered by a trained and certified individual, and take 45 minutes or more to administer. These are usually administered in the outpatient setting.

So there was no validated metric to objectively evaluate early motor impairments for patients while they're in the hospital. And without this measure, it also makes it impossible for us to do research and see if the things that we're trying are actually making a difference.

So we developed and field-tested the CHASMS, which is the Congenital Heart Assessment of Motor and Sensory Status. It's kind of like a Glasgow Coma Scale for motor development in babies. This is based on expert consensus and focus parent interviews. It involved our center with multidisciplinary teams, also with Toronto Sick Kids and Children's Health Care of Atlanta, involving physicians, nurses, and therapists.

The instrument has elements that are sequenced for developmental progression and looks at gross motor, fine motor, and sensory development. It's been field-tested in 100 infants. It's been administered by a trained nurse that can be easily trained in the methodology and usually takes about 15 minutes. So this is something that we performed at the bedside-by-bedside ICU nurse or floor nurse.

There's a high degree of interrater reliability of 95% to 100%. But most importantly, there's a high degree of correlation with both TIMPS and AIMS. showing that it's possible for us to really assess patients within a week of surgery, two weeks of surgery as to where they're going.

So this is a study we did looking at patient infants undergoing cardiac surgery. And we found of 39 infants who had pre and post-operative assessments, 64% had gross motor declines post-operatively. This included single ventricles, STAS, AVSD's, Hemi-Fontan's. 64% motor delays just in their first post-operative assessment.

Most importantly, there was no correlation between gross motor scores and what's called the STAT surgical complexity or the complexity of the operation. Really the primary driver for these motor delays was the complexity of their post-operative care. So what we are doing in the ICU.

And for those babies who are over four months of age, over 50% could not sit as expected for age. So supporting the letters I was receiving in the mail.

When we look at the predictors of CHASMS, we found that just being on the ventilator for more than two days or being in the ICU for more than five days significantly increases your risk for motor delay. You can imagine we've got a lot of patients that fall into that category.

This is an invited commentary by Christian Pizarro, stating that the CHASMS "is an important step towards early recognition and modification of environment and practices, which can be so noxious for the early development of these infants. As such, this tool could be helpful to shed some light on issues such as correlations between modifiable developmental care activities and CHASMS scores, and predictions for how infants with perioperative motor impairment will fare long-term with or without intervention."

So, really, this helps us realize the importance of early identification of patients who are exhibiting motor delay, looking at how we're caring for these babies and being able to potentially modify their care and hopefully to mitigate some of these delays.

So this led us to determining our first interventional trial. So you don't hear a lot of surgeons talk about tummy time, but it's really important. So it's crucial for the development of head control and upper body strength. It provides babies an opportunity for anti-gravity motor activities, it facilitates their interactions with their environment, motor control against gravity is a prerequisite for the attainment of most early motor milestones, rolling over, sitting up.

It's recommended that babies get 81 minutes per day-- any mom out there. I don't know how babies actually get 81 minutes a day-- necessary to achieve motor milestones without delay. That's really hard to achieve in a patient in the hospital.

So this is a little reality check and the benefit of modeling. So this is my son, who hated tummy time. I put him on his tummy, he'd scream and immediately I'd pick him up and go do something else. This is a picture sent to me by my nanny, who subsequently had raised six other babies, demonstrated to me how happy he could be with appropriate tools. Thankfully, I got the second try. This is my daughter, me successfully putting her in tummy time using many of the same supportive devices

so there was a study done at the University of Michigan looking at tummy time specifically in Down syndrome patients. Not all heart disease patients, but many of our patients do have Down syndrome. It was a small study, but prospectively randomizing babies to either early time-- early tummy time at less than 11 weeks of age or after 11 weeks of age.

And the upper bar-- the upper line demonstrates those patients who had tummy time at earlier than 11 weeks of age. And at every single time point, they've better motor scores than their comparative group. So that's what led us to think that implementing a tummy time protocol can make a big difference for our patients.

And, then when you do a PubMed search for tummy time and congenital heart disease you can see there are zero publication's. So it's always good to get on the bottom floor of research. So this is a great opportunity.

So this led us to the DAISY trial, which is the first interventional trial using the CHASMS instrument to monitor how patients are doing. It's for infants who are less than three months of age having cardiac surgery. They need to be intubated for at least 24 hours but less than seven days. Patients are randomized to a standardized care group, where they receive a generalized instruction manual and a couple of supportive tools, a Board book and a taggie blanket.

And then there are two other groups, the inpatient only and inpatient/outpatient groups, who receive the above same care as the standard care, but also having tummy time implemented as part of their hospital course. So they have an opportunity to watch the nurses put their children in tummy time and are able to model those behaviors and continue them at home. These patients are also followed up at three months for an assessment to look at their performance using both AIMS and CHASMS.

So, again, everybody gets the back-to-tummy-- *Back to Sleep, Tummy to Play* brochure from the American Academy of Pediatrics. Standard of care also gets a taggie blanket and a board book. My secretary loved ordering my research tools.

[AUDIENCE LAUGHS]

In terms of the inpatient/outpatient intervention group-- again, these babies are actually being put in prone position in the hospital, so their parents can witness this. They also receive an activity boppy. And what we found is really the best tool is a simple mirror to keep the babies engaged.

Preliminarily, we're finding those babies that are having tummy time in the hospital are performing much better as an outpatient because, again, the parents feel a little bit safer putting their babies who have significant heart disease and have just had sternotomy and in the prone position seeing nurses do it.

So what are the key drivers for progress? I think the biggest thing was myth busting. I think we're so used to just worrying about keeping these patients alive. Finally having somebody say it's OK for a baby after her surgery to be on their tummy. Most of them will not be comfortable with their chest tubes in place, but once their chest tubes are out it's encouraged that they get put on their tummy as soon as possible.

There shouldn't be regards-- concerns regarding internal stability, unless I'm not doing my job well enough. They can be held under their arms and that's important for helping them to position and assisted sitting positions. And I think the biggest thing has been a multi-disciplinary collaboration, as Karen alluded to. Getting physicians, surgeons, ICU doctors, involved.

Karen has been a key driver of this overall project and deserves a huge amount of credit. Myself and then Cindy Smith, who is here, is our amazing research nurse who has really taken this on passionately. And now, as Karen is selling this developmental care model to the overall Congenital Heart Center, there is a huge amount of enthusiasm. s have a fleet of nurses, nurse practitioners, therapists, physicians, and parents who are really excited to get involved.

So this is where we developed the clinical practice guidelines and our goal is to improve the neural developmental outcomes in infants with congenital heart disease. We're going to implement developmental interventions that will be provided by multi-disciplinary teams.

These are just a few examples using breast milk during oral care to increase oral stimulation, using bumbo seats to help patients in assisted sitting positions. And again, the favored near for tummy time.

And also periodically assessing our patients with CHASMS to determine how they are performing and to make sure we're adequately addressing delays. The hope is to apply this to all infants less than one year of age undergoing cardiac surgery within our center.

There are many things that you can look at when you're talking about developmental care. This is just a cluster of one of the-- many of the things that are often looked at other centers. Promotion of breastfeeding, kangaroo care, again, environmental changes, facilitate checking for patients to be comfortable, and clustering care.

When we think of the physical environment, it's important to decrease light and sound, most importantly TV volume in after-hours to help the babies have a little bit more of a normal schedule. And really encouraging positive visual and auditory interaction is having a lot of focus on eye contact, mobiles over their beds, having their parents talk to them, especially when they're intubated and there's not much else they can do, but reading books and singing to them.

Infant positioning and handling is incredibly important. When patients are in the supine position, what we usually see is them flat on their back with their legs frog-legged out, which is actually the absolute worst position to put a baby. So trying to keep them a little bit more supported to help support their musculoskeletal system and getting them on their tummies as soon as we can.

This is an infant positioning assessment tool that's on the left-hand side of the screen, and you see the left column, whereas kind of the typical baby in the ICU after surgery where they're flat on their back, legs externally rotated, neck extended. Whereas on the far right hand is really the ideal positioning for babies. Having their shoulders tucked centrally, their necks flexed, knees and hips flexed.

This is a positioning audit tool that's actually used at Children's Hospital of Philadelphia to monitor how patients are being positioned. You can see here is a baby in the ICU just simply putting a roll under their legs to keep their legs flexed. Rolls next to their shoulders keep their eyes their shoulders more towards the midline.

Holding and feeding are incredibly important. And infant holding is something that I think we have-- [LAUGHS] a lot of progress. But this is, we're really promoting parents and even caregivers to hold babies at the bedside. It helps to put them in a prone position, but it's important for us to ensure safety, but increasing our comfort in moving these babies with lines and tubes in place.

Educating staff and family on the importance of this I think will help encourage more of this activity going on and really making this part of the care model. This is something that's kept in a log and documented and tracked, so we know when patients aren't reaching their goals.

Feeding and oral motor skills for any mom out there with a baby with congenital heart disease can be a major long-term issue. And I think being aggressive early on, cue based feeding rather than feeding patients on a schedule that comes up in MyChart saying it's time to feed the baby, giving a simple-- like this lovely toothy pacifier while the baby's getting a bolus, so they get the sense of the oral sensation while they're being fed. Parents holding their babies during feeding and breast milk with oral care.

This is a care partner pyramid, which I'm not going to go into great detail. But basically it just shows that as patients at the top have increasing medical and nursing care needs, there's still a role for parents to read to their babies and provide gentle touch.

And as the acuity of care decreases, you get to the base of the pyramid, having increasing roles of parents in changing diapers, being involved with the physical therapy, range of motion, all of those activities.

Pain management is a challenge for patients who want to make sure they're comfortable enough to be able to be moved, but we don't want to use a lot of sedative drugs that we don't need to because they also can impair mobility. There's lots of things we can do to encourage comfort for these patients, including skin-to-skin contact and tucking these babies and swaddling them.

The following thing is really incorporating daily care rounds and making this part of the medical model. Having regular bedside assessments, educating staff and parents on the importance of this within the patient's care, and having key participants and buy-in from physicians, nurses, and therapists alike standing together weekly to assess these patients, looking at their CHASMS metrics to see how these patients are doing, and documenting their progress.

And then, finally for those patients who are falling behind, make sure they get the appropriate referrals to physical therapy and occupational therapy while they're in the hospital. And then also we're incorporating a post-discharge neurodevelopmental follow up for our patients. This is incredibly important. Having parents see a video prior to going home to understand what developmental milestones we expect for their child.

Having guidelines and plans on how to achieve those goals, and really understand the impact of congenital heart disease on that development. Referring these patients to early on-- early on-- and having them be seen in our neurodevelopmental follow-up clinic.

But unfortunately, many patients are not able to actually make it to their neurodevelopmental evaluation. So this is a slide looking at-- of those patients referred, only 17% actually attended their appointment. This has to do with the insurance barriers, travel barriers.

So this just highlights even more that it's really important what we do in the inpatient setting to try to mitigate some of the risk for these patients.

So, and that I can say, we certainly can make a difference. This is one of our babies who was in the ICU for a while. I think these are Cindy Smith's hands encouraging this little guy in his tummy time. And he's doing a great job, pushing up at three months of age with his head held high.

So there is life beyond the ICU as we heard this morning. And there's a lot of life beyond the ICU. These kids have futures that are bright and full of potential. It is our job to make sure that in saving them we do not harm that potential.

And all three of these kids had neonatal operations. This is from our summer picnic. This little guy was in the ICU for a long time and is probably off to school. This little girl had a neonatal arrest and was on ECMO. I think it did impact her because she actually wants to grow up to be a pediatric heart surgeon. But nonetheless-- [AUDIENCE LAUGHS] they are all doing well and thriving. And I think we can continue to even improve their outcomes even further. And with that, I thank you for your attention.

[APPLAUSE]