

## Northwestern University

### Stigma perceived by children with chronic conditions

**Jin-Shei Lai**

>> OK. WORKING ON HOW TO TAKE A NEURO LOGIC LOOK. SO FOR OUR CENTER -- LET ME SEE THAT ONE. OK. SO, OUR CENTER FOCUSES ON THE CHILDREN WITH ECZEMA. THE TITLE WAS ABOUT ADDITION OF PROMISE PEDIATRIC INSTRUMENTS IN-- OK. SO, WE HAVE CO P.I. CENTER AND SO ME AND THE DOCTOR AND DR. PALLER IS THE PROJECT ONE LEADER AND THE THE LEADER FOR THE PROJECT IS RAJ KUMAR MANY OF FOR PROJECT ONE WE HAVE CHILDREN'S HOSPITAL AND THE NORTHWEST AT PRIMARY FOR THE PROJECT ONE AND THE PROJECT TWO IS THE MORE COMPLICATED INVOLVED IN THREE DIFFERENT PROJECTS. SO THE OVER ALL ENDS OF NORTHWESTERN INCLUDE THE VALIDATION OF THE PROMISE MEASURES IN EXISTING WHERE THE CHILDREN WITH ECZEMA AND DERMATITIS AND THIS CAN ACROSS PROJECTS ONE AND TWO. WE ALSO HAVE AIM TO EXAMINE THE SENSITIVITY OF PROMISE THE CHILDREN WITH A.D. AND ECZEMA AND THE PROJECT ONE, WE AND THE NEW MAJORS IN THE CHILDREN WITH AD AND OTHER AGE-OLDERS AND AND THE SPEE PEDIATRIC. WE HAVE BASED ON THE PROJECT ONE IN WHICH WE EVALUATE THE COMPARATIVE ABILITY OF THE MODIFIED PEDIATRIC. WE NOW RENAMED THAT THE PROMISE PEDIATRIC STIGMA AND CHILDREN% WITH VARIOUS CHRONIC CONDITION. SO, IN THE CURRENT STATUS, WE FINISHED OUR RECRUITMENTS. WE ARE STILL AT OUR DATE FOR THE RECRUITMENT IN SEPTEMBER 30TH. SO IN PROJECT ONE, WE RECRUITED A TOTAL OF 963 CHILDREN WITH A TOPIC DERMATITIS AND EACH CONDITION AND SOME OTHER CONDITIONS YOU WILL SEE IN THE NEXT PRESENTATION. AND SO, THIS CHILDREN INCLUDING THE 712 IN THE CAL OPERATION PHASE. WE HAD A TOTAL OF 652 CHILDREN AND THEIR PARENTS. WE WILL PRESENT IT LATER AND THE LONGITUDINAL IS STILL ON GOING AND SO IN THE NEXT FEW MONTHS, WE ARE GOING TO FOCUS ON FINISHING UP THE LONGITUDE ANALYSIS AND THE MANUSCRIPT WRITING. WE FINISHED THE PROJECT SO THAT'S THE UNIT WE SELECT AND WE BEG AND FORCED TO DECIDE WHICH WE ARE GOING TO USE AND WE DECIDED THE LAST WEEK.SO IN THE NEXT -- SO IN THE NEXT ONE, I AM GOING TO PRESENT THE RESULTS FROM THE STIGMA PROJECT.

>> I LIKE THE TECHNOLOGY BUT SOMETIMES IT'S HARD IN PREPARATION.

>> THANK YOU.

>> OK.

>> SO UNDER STIGMA IS DEFINED AS A GROUP OF NEGATIVE AND OFTEN FORCED IDEA THAT SOCIETY OR A GROUP OF INDIVIDUALS ATTACHED TO AN OBJECTS, INDIVIDUAL, CONDITION OR IDEA. SO THE PERCEIVE STIGMA CAN HAPPEN AT ANY AGES IN THE INDIVIDUAL AND THERE'S A COMMON EXPERIENCE IN CHILDREN WITH CHRONIC CONDITION SO FOR THIS KIND OF NEGATIVE IMPACT TO THEIR HEALTH OF LIFE, THE KIDS MAY CARRY NEGATIVE FEELINGS THROUGHOUT THE LIFESPAN. THEREFORE, THE EARLY IDENTIFICATION IS TO INITIATE THE TIMELY INNOVATION TO MINIMIZE NEGATIVE IMPACT TO THE KIDS AND THEIR WHOLE LIFE. SO, CURRENTLY, THEY ARE VERY FEW SCALES AVAILABLE TO CHILDREN'S AND FOR THOSE AVAILABLE, MOST OF THEM WILL ALSO NOT GENERIC ENOUGH CROSS CONDITIONS YET SENSITIVE TO DISAPPEARANCES. SO, WE DEVELOPED THE NEURO CORE PEDIATRIC STIGMA ITEM BANK.WHICH IS NOW MAINTAINED AND DISTRIBUTED THROUGH THE

HEALTH ADMINISTRATOR. IN THAT, I STAND A PROMISE AND FOR THE STIGMA, WE DEFINE THEM AS UNDER THE MENTAL HEALTH FRAMEWORK. SO FOR THE PEDIATRICS STIGMA CONSIST OF 18 ITEMS. FIVE-POINT SCALE IS USED SO IN THIS ONE, YOU CAN SEE SOME EXAMPLE ITEMS HERE. BECAUSE OF MY ILLNESS, OTHERS MY AGE AVOID ME AND I FEEL LEFT OUT OF THINGS. OTHERS MY AGE MAKE FUN OF ME. AND SO, THE STIGMA CAN BE ADMINISTERED BY USING THE FORM. BECAUSE THE STIGMA WAS DEVELOPED TARGETING CHILDREN WITH NEUROLOGICAL CONDITIONS, HOWEVER, THE STIGMA IS A COMMON EXPERIENCE BY CHILDREN SO THEREFORE, IN THIS STUDY, WE HAVE OUR AIM ON THIS STUDY WAS TO EVALUATE THE MAJOR EQUIVALENCE OF THE STIGMA AND CHILDREN WITH CHRONIC CONDITIONS AND ALSO TO ESTABLISH A COMMON METRIC TO MAJOR STIGMA AND THIS CONDITION. SO, WE BEGIN WITH ENHANCING THE STIGMA BY AIDING SOME SCHEME CONDITIONS TO THE ITEM AND SO THIS ITEM WERE ADDED BEST UPON THE EXPERIENCE OF THE CONCERN RISK BY CHILDREN, THEIR FAMILY AND ALSO THE EXPERIENCE AND ALSO BASED ON THE REVIEW. SO THIS IS SIX ITEMS AND THEY FEEL THEY CAN GET. SO MOST OF THEM ARE INVOLVED IN CHANGES IN ADVISABLE VISIBLE APPEARANCES AND THAT IT'S CONTAGIOUS BY OTHER KIDS. BECAUSE THE ORIGINAL ITEMS USED THE TERM OF THEY USE THE TIMEFRAME SO IN HERE WE REPRESS IN ORDER TO INCREASE GENETIC ABILITY AND STIGMA SKILLS WE ALSO NEURO THE TIMEFRAME TO LITERALLY IN THE LESS ONE TO TWO MONTHS. SO, THE 979 CHILDREN ARE RECRUITED FROM THE FOUR DIFFERENT PROJECTS WHO ARE ANALYZED INCLUDING THE PROJECT FOUNDER NEURO CORE TESTING, WE HAVE ONE TESTING AND WE HAVE TWO TESTING AND ALSO THE PROJECT ABOUT NEURO FIBER MITOSIS. IT'S A LONG NAME. ALSO THE CHILDREN FOUND THE PEPR PROJECT. THEY SHOW THE DIAGNOSIS AND WHERE THIS CASE WAS RECORDED AROUND WHICH PROJECT. AND SO THIS ONE SHOWS THE AGE AND THE GENDER ACROSS THIS FOR DIFFERENT PROJECTS WITH CONDITIONS OF CANCER AND ECZEMA AND PSORIASIS AND EPILEPSIES. SO IT SHOWS THE OTHER APPROACHES WE TOOK. SO BASICALLY IT'S A LITTLE BIT COMPLICATED BECAUSE WE ARE THE FIRST ONE, THE PROJECT, THE SAMPLE FROM THE MIRACLE PROJECT AND THE END TAP, IT WAS SECONDARY ANALYSIS AND THE CHILDREN FOUNDED THE STREETS PROJECT COMPLETED ORIGINAL 18 ITEMS AND FOR THE PEPR PROJECT, BECAUSE WE MODIFIED SOME OF OUR ITEMS AND ALSO THE SIX ADDITIONAL ITEMS. SO THESE KIDS COME 15 CORE ITEMS AND SIX ADDITIONAL ITEMS. THEN TWO ITEMS WE FEEL NOT APPROPRIATE FOR CHILDREN WITH THIS CONDITION WE FEEL THEY DID NOT INCLUDE IN THE ANALYSIS HERE. SO WE BEGIN WITH EVALUATING THE NATIONALITY OF THE MIRACLE ITEMS AND THE SIX NEWLY ADDED ITEMS AND THE RESULT IS THE NATIONALITY OF THIS NEW SET. WE THEN USE THE GREATER RESPONSE MODEL TO ESTIMATE THE ITEM OF THIS 18 ITEMS THAT WE CONSIDER THE COST OF ITEMS. WE THEN USE THIS ANALYSIS TO EVALUATE THE MEASUREMENT IN GROUPS INCLUDING THE GENDER, AGE, CONDITION, AND ALSO BETWEEN PROJECTS. THE REASON WE DO THE PROJECT WAS BECAUSE TO EVALUATE WHETHER THE MODIFIED ITEM WOULD FROM THE CONDITION AND THE NEURO TIMEFRAME WILL IMPACT THE MEASUREMENT PROPERTY OF THESE ITEMS. AND FINALLY, WE CALIBRATE THE CO ITEMS AND THE SIX ADDITIONAL ITEMS TO THE MEASUREMENT, SO FOR THE ANALYSIS WE USE THE PACKAGE IN OUR FOR THIS ANALYSIS AND THE GROUPS INCLUDING THE GENDER AND THE AGE AND THE CONDITION WE USE CHILDREN WITH ECZEMA AS THE REFERENCE GROUP. SO THEY SHOW THE DIFFERENT RESULT AND FOR THE PROJECT BETWEEN THE THEY SHOW A PEPPER VERSUS A LEVEL ONE AND TESTIN AND WE THEREFORE CONCLUDED THAT THIS KIND OF MODIFIED ITEM DID NOT REALLY IMPACT ON THE MAJOR PROPERTY OF THIS ITEM. AND THEN WE FOUND THREE ITEMS IDENTIFY DIFFERENT AND INCLUDING HOW THEY EFFECTED APPEARANCE AND FAILED TO EMBARRASSED ABOUT YOUR LOSS OF FRIENDS BY ABOUT THE UNITS. WE TRIED TO LOOK AT WHAT HAPPENED HOW THE CONDITION EFFECTS THE APPEARANCE OF

AN EXAMPLE AND SO IT'S A THIEF AND THAT MEANS THE LEVEL OF PERCEIVED STIGMA WAS THE HIGHEST GOAL WITH STIGMA AND THE LOWEST GOAL REPRESENTING THE STIGMA. AND SO, SO ON A GIVEN LEVEL, YOU CAN SEE THE CHILDREN WITH ECZEMA WITH THE WORST RATING COMPARED TO CHILDREN WITH EPILEPSIES AND ON THE OTHER HAND, CAN YOU SEE WITH THE SAME LOW SCORE, CHILDREN WITH A BLOOD TO HAVE PERCEIVED STIGMA AND SAME AS THE CHILDREN WITH ECZEMA TO CHILDREN WITH -- WE WILL DECIDE, SO TO WHAT EXTENT THIS IDEA WOULD IMPACT OBJECT THE STIGMA SO WE TRIED TO DECIDE AND COMPARE THIS GOAL AND WE INCLUDE THIS ITEMS YOU CAN SEE THEY'RE NOT JUST IMPACT ACROSS IN THE LOW END OF THE CONDITION UM THE CHILDREN PERCEIVED THE MINIMAL STIGMA. IT WAS MINIMAL WITH MOST OF THEM WHICH MEANS THAT ABOUT LIKE POINT ONE STANDARD DEVIATION. WE THEN CONCLUDED THAT THE OLDEST 18 ITEMS COULD BE USED AS A CORE ITEM SET. AND SO, WE FINALLY, USING CALIBRATE, THERE IS SIX ADDITIONAL SEEKING ITEMS TO THE 18 NEURO CORE ITEMS. AND SO THE CORRELATION ON THIS 24 ITEMS VERSUS THIS, I FORGET. THESE 24 ITEMS VERSUS 18 ITEMS WERE PRETTY HIGH ABOUT A .997. IT'S ALMOST PERFECT. SO WHAT DOES THIS REALLY MEAN IN ASSUME THIS IS A STIGMA SO WE ALIGN OR INCUR THE 18 CORE ITEMS AND TO THIS SIGMA AND WE ANCHORED THE SEVEN OR SIX DISTINCT ITEMS ON TO THIS CONTINUUM SO THEREFORE, HOLD THIS INSTRUMENTS IS ABLE TO CAPTURE UNIQUE CONDITION WITH THIS EXPERIENCE. SO, WE CAN'T USE A CENT APPROACHES TO EIGHT ITEMS SPECIFIC TO OTHER CONDITIONS SUCH AS A CANCER WHICH WILL MAKE IT POSSIBLE TO COMPARE STIGMA PERCEIVED BETWEEN PATIENTS WITH CANCER VERSUS SKIN CONDITION WITHOUT LOSING THE SENSITIVITY TO CATCH A STIGMA RESULTED FROM EACH CONDITION. BECAUSE THIS NOW THE INSTRUMENT IS NOT REALLY ABOUT A NEURO, WE MAKE IT MORE GENERAL TERM SO THAT'S WHY WE CAME UP WITH THE PROMISE OF PEDIATRIC STIGMA AND WE CAN SIT IN THE FUTURE AND WE CAN SAY THE PROMISE IS PEDIATRIC STIGMA MODULE AND THE CANCER MODULE IS LIKE A STROKE MODULE. AT END OF THE DIFFERENT MODULES, THEY'RE ON THE CONTINUING SO WE'RE STILL BEING ABLE TO COME HERE WITH THE STIGMA ACROSS DIFFERENT CONDITIONS. AND SO, THIS IS JUST SOMETHING WE TRIED TO SEE HOW TO COMPARE THE STIGMA ACROSS THE CONDITION AND YOU CAN SEE THE CHILDREN WITH EPILEPSIES HAVE STIGMA AND CHILDREN WITH CANCER HAVE THE WORSE STIGMA FROM OUR STEM. WITH OUR CONCLUSION, IT'S DOABLE TO PREPARE COMPARED STIGMA ON CHILDREN WITH VARIOUS CONDITIONS BY USING APPROACH. WE CAN USE A CORE ITEM AND CONDITIONS ITEMS AND BECAUSE ALL OF THEM ARE ON THE SAME CONTINUUM, THEREFORE WE ARE ABLE TO COMPARE THE OTHER STIGMA LEVEL. SO, ONE OF THE MAJOR DEMONSTRATIONS OF THE STUDY WAS SOME OF THE PATIENT POPULATION WERE FROM A SECONDARY ANALYSIS. AND SO WE DO NOT HAVE ANY CONTROL ABOUT VARIABLE. WE ARE GOING TO ANALYZE SO IT'S AN ANALYSIS THAT WE WERE ABLE TO DO AND ALSO BECAUSE THEY HAD A GROUP AND IMPACT SOME OF THE VARIABLES OF THE RESULT TO THE OTHER CONDITION. SO, THIS SO ANY QUESTIONS.

>> WE'RE A LITTLE BEHIND BUT MAYBE ONE QUESTION IF YOU HAVE ONE.

>> IT SHOWS YOU THE POWER OF ITEM BANKING AND HOW YOU CAN ADD IN ADDITIONAL ITEMS, CO CALIBRATE THEM TO THE SAME SCALE. IT'S A NICE DEMONSTRATION.

>> THANK YOU, INTO YOUR NEXT SPEAKER.

>> THE NEXT ONE IS DR. PALER AND SHE'S GOING TO PRESENT THE PROJECTS THE CHILDREN WITH.

## **PIQ-C (PROMIS Itch Questionnaire - Child) in pediatric atopic dermatitis**

**Amy Paller**

>> I'M JUST ADD HOW THIS IS STIGMA SCORE IS BEING USED. WE JUST STARTED A STUDY FOR 36 CENTERS FOR THE PEDIATRIC RESEARCH ALLIANCE AND WE'VE ALREADY ENROLLED 600 PATIENTS IN THE LAST MONTH OR TWO. WE HAVE ANOTHER FOUR OR FIVE MONTHS TO GO AND WE'LL USE THE STIGMA SCORE AND OTHER PROMISE INSTRUMENTS.

>> 3500 TOTAL.

>> THE QUESTION IS ACROSS WHAT THE INVESTIGATOR WOULD CONSIDER A VISIBLE OR STIGMATIZING SKIN DISORDER WHAT IT IS RELATIVE TO THE ESTIMATE BY THE PHYSICIAN APPEARING VERSUS CHILD AND WE'RE ASKING ABOUT ANXIETY AND DEPRESSION, PEER RELATIONSHIPS AND COMPARING THAT TO STIGMA AS WELL AS USING A TOOL CALLED SKIN TEXT TEEN WHICH IS DOWN TO EIGHT YEARS OF AGE, WHICH IS LOOKING AT QUALITY OF LIFE AS A TOTAL MEASURE. ALL OF THOSE WILL BE COMPARED.

>> THANK YOU.

>> GOOD.

>> SO A LITTLE BIT ABOUT THE -- THIS S WEIRD. THIS IS BACKWARDS. I'M GOING TO TELL WHAT YOU WE DEVELOPED THROUGH THIS GRANT AND I'M GOING TO FLY THROUGH THE INTRODUCTIONS BUT I KNOW SOME OF YOU HAVEN'T BEEN HERE BEFORE. IT'S ONE OF THE MOST COMMON SKIN DISEASE SYMPTOMS AND IT VERY MUCH IMPACTS PATIENT QUALITY OF LIFE AND THEY LACK ONE OR MORE OF THE FEATURES OF PSYCHO METRIC SOUNDNESS OR EASY CLINICAL PRACTICE IMPLEMENTATION OR THE ABILITY TO CAPTURE PATIENT EXPERIENCE OR CORRELATING WITH OTHER QUALITY OF LIFE MEASURES. IN FACT, MOST OF WHAT IS USED IS A SINGLE QUESTION. THERE IS SINGLE ITEMS EMBEDDED WITHIN A P.R.O. INSTRUMENT AND WITHIN A SEVERITY MEASURE AND THEN THERE ARE VERY FEW THAT HAVE MORE THAN THAT THERE WAS ONE GENERATED CALLED THE CAT A SCALE AND 3-D ITCH DEVELOPED TO EIGHT YEARS OF AGE BUT I RARELY SEE IT USED FOR ANYTHING IN CHILDREN. HERE IT IS. SO, AT ANY RATE, YOU CAN SEE THAT THERE ARE MANY, MANY MEASURES THAT ARE AVAILABLE BUT WHAT WAS MISSING WAS ITCH, AND THE NEW ONE IS SLEEP WHICH IS IMPORTANT AND AND RED SKINS SCALING AND LOTS OF IMPACTS ON SLEEP AND ON MEASURES AND OUR OBJECTIVE WAS GIVEN IT THAT THEY COULD SERVE FOR OTHER QUALITY OF LIFE MEASURES AND IT WOULD CORRELATE BETTER WITH MEASURES OF ITCH THAN A SINGLE ITEM ITCH MEASURE. I'M SORRY, WITH THESE OTHER MEASURES, RATHER. SO OUR CONTENT SELECTION IN DEVELOPING AN ITEM POOL WE USE THE FOLLOWING APPROACH. FIRST WE DID CONCEPT -- BASED ON LITERATURE REVIEW AND THEN ON SEMI STRUCTURE INTERVIEWS WITH CHILDREN AND PARENTS OF CHILDREN WITH ITCH AND WE WENT DOWN TO EIGHT YEARS OF AGE FOR THE CHILDREN AND FIVE YEARS OF AGE FOR THE PARENT PROXY DEVELOPMENT AND WE HAD TWO INDEPENDENT REVIEWERS LOOK THROUGH AND DEVELOP THE HUMANIC ANALYSIS. SECONDLY, WE DID AN ITEM OPTIMIZATION CONSOLIDATION WHICH A TEAM OF PEDIATRIC ALLERGISTS AND EXPERTS ON MEASURE DEVELOPMENT GOT TOGETHER TO PERFORM THIS AND WE WENT ON TO COGNITIVE NOT VIEW INTERVIEWS WITH READABLE REVIEW AND YOU CAN SEE SOME OF THE QUESTIONS ASKED OF BOTH PARENTS AND CHILDREN IN PERFORMING THE COGNITIVE INTERVIEWS. AFTER ALL WAS SAID AND DONE, WE HAD 53 QUESTIONS DOWN TO 52 OF WHICH SIX WERE ALTERED AND THREE WERE ELIMINATED AND SOME OF THESE ARE SHOWN HERE BECAUSE OF ITCH, MY PHYSICAL ACTIVITIES WERE LIMITED AND IT WAS CHANGED TO I COULD NOT DO SOME ACTIVITIES OR IF

YOU LOOK TOWARDS THE BOTTOM, WE DROPPED SOME OF THESE BECAUSE OF SOME COMPREHENSION ISSUES LIKE BECAUSE OF SCRATCHING, ANY SKIN FLAKED OFF OR I COULDN'T WEAR WOOL. SOME CHILDREN DIDN'T KNOW WHAT WOOL WAS. THERE WERE ADDITIONAL ROUNDS OF COGNITIVE INTERVIEW WITH FIVE CHILDREN AND PARENTS. WE CONFIRMED THESE MODIFIED ITEMS WORKED WELL. WE THEN WENT ON TO THIS EVALUATE THE PSYCHO METRIC PROPERTIES BE A DIMENSIONALITY EVALUATION FACTOR ANALYSIS AND YOU CAN SEE HERE WE HAD A POPULATION OF 603 CHILDREN WITH ITCH THAT WE USED TO CALIBRATE. THESE WERE COLLECTED BOTH BY ENGAGING OUR PATIENT SUPPORT GROUPS, INTERNATIONAL GROUPS THAT OFFER TO SEND OUT SURVEYS OF US AND COMPLIMENTING THAT WITH AN INTERNET PANEL COMPANY. YOU CAN SEE THE MAJORITY OF PATIENTS I IN THIS SET WITH WERE ECZEMA AND A BLISTERING DISORDER THAT IS ITCHY WITH PSORIASIS AND A GROUP OF GENETIC SCALING DISORDERS ASSOCIATED WITH INFLAMMATION AND IN MANY CASES ITCH. WE IDENTIFIED FOUR IMPORTANT FACTORS WITH ITCH. INTERFERENCE OR IMPACT FUNCTION INACTIVITY, CLOTHING, MOOD, SLEEP, BEHAVIOR AND SCRATCH AND THEN WE DEVELOPED A SINGLE SCALE. UNIT DIMENSIONALITY WAS EVALUATED WITH BOTH EXPLORATORY AND CONFIRMATORY FACTOR ANALYSIS AND 46 QUESTIONS MET THE UNIT DIMENSIONALITY CRITERIA AND WERE RETAINED AND THEN USING A GRADED MODEL, A RESPONSE MODEL. WE EVALUATED PARAMETER AND HAD TO DROP ONE OTHER QUESTION BECAUSE OF POOR FITS. THE FINAL NUMBER OF ITEMS IN THE PICK SAY WAS 45. WE MOVED ON TO VALIDATION BETWEEN FIVE AND 17 AND MOST OF THESE CHILDREN HAD MODERATE TO SEVERE DISEASE BUT WE, DESPITE THAT BEING THE ORIGINAL PLAN OPENED IT UP TO MILD DISEASE AND WE CAN INCUP PASS ALL THE RANGE OF BITCH AND ALL TOGETHER, 181 OF THESE WERE CHILDREN 8-17 WHO DID THE SELF-REPORT VISION AND OF COURSE PARENTS OF ALL OF THESE COMPLETED THE QUESTIONNAIRES. YOU CAN SEE WE HAD A VARIETY OF OTHER SEVERITY ASSESSMENTS SHOWN ON THE RIGHT AND A PATIENT REPORTED OUTCOME ASSESSMENTS AS SHOWN ON THE LEFT AND SOME OF THESE SEVERITY ASSESSMENTS HAD WITHIN THEM SOME PATIENT REPORTED OUTCOMES. YOU CAN SEE SCORE ADD HAS A QUESTION ON ITCH AND SLEEP. THE OTHERS ARE STRICTLY SCORES THAT EITHER LOOK AT EXTENT OR REDNESS, SCALING, OBJECTIVE TYPES OF MEASURES AND IT WILL COME UP IN A MINUTE. THE DEMOGRAPHIC AGE AVERAGE 10 YEARS AND THEY WERE EVENLY DISTRIBUTED IN THE AGE OF 8-12. FEMALE VERSUS MALE AND A WIDE DISTRIBUTION WIDEDISTRIBUTION OF ETHNIC GROUPS. THE MOST COMMONLY USED SCORE FOR SEVERITY OF ECZEMA WAS IN THE UPPER RANGE OF MODERATE IN SEVERITY AND THE SCORE WAS JUST AT 9 CUSP OF SEVERE DISEASE. EFFECTED BODY SURFACE OFFICES SO THESE KIDS HAD AN AVERAGE OF ALMOST 30% OF THEIR BODY EFFECTED BY THE DISEASE AND AVERAGE TO CHASER ITCH AND A QUALITY AND LIFE ASSESSMENT THAT WAS QUITE SIGNIFICANT. WHEN WE LOOK OVER ALL THOUGH, THE MAJORITY OF THESE CHILDREN ENDED UP BEING IN THE MODERATE TO SEVERE RANGE, WHICH WAS WHAT WE OPENED. WE LOOKED AT THE T-SCORES OF THESE VARIOUS INSTRUMENTS FOR THE OVER ALL GROUP OF CHILDREN WITH A-TOPIC DERMATITIS AND THIS RANGES WITH THOSE FROM MILD TO SEVERE DISEASE. AND YOU CAN SEE THAT DESPITE THAT RANGE, THERE WERE INCREASES T-SCORES RELATED TO PSYCHOLOGICAL STRESS AND SLEEP IMPAIRMENT AND SLEEP DISTURBANCE. WHEN WE LOOK A LOT PEER SON COALITION, THERE WAS A CORRELATION THAT WAS SIGNIFICANT WITH ALL OF OUR VARIOUS INVESTIGATORS ASSESSED SEVERITY MEASURES AND I WOULD SAY THAT IT WASN'T THE HIGHEST CORRELATION BUT IT DOESN'T SURPRISE ME. I WANT TO POINT OUT, AGAIN, THESE ARE THE SCORES THAT HAVE TO DO WITH WHAT ONE SEIZE AND DOESN'T TAKE INTO ACCOUNT PATIENT REPORTED OUTCOMES. THE SCORE ADD HAS TWO QUESTIONS THAT RELATE TO THAT SO THERE'S A LITTLE BIT MORE IN TERMS OF THE PATIENT AND NOT SURPRISING THE CORRELATION WAS INCREASED

IN THAT GROUP. WHEN WE LOOK BETWEEN THE PICK C AND THE COMMONLY USED ONE ITEM ITCH N.R.S., THERE WAS A MODERATE CORRELATION THERE AS WELL. I JUST WANT TO SHOW YOU, HOWEVER, WHEN WE LOOKED, BASED ON THE DIFFERENT SEVERITY LEVELS REGARDLESS OF WHAT ANALYSIS WE USED, THE PICK C IS DIFFERENT. THE INVESTIGATOR GLOBAL ASSESSMENT OF SCORES SHOWING YOU MILD VERSUS MODERATE VERSUS SEVERE YOU CAN SEE THE ECZEMA SEVERITY INDEX SCORES AS THEY'RE FROM CLEAR TO VERY SEVERE. NICELY DISTRIBUTED AND FINALLY THE POEM SCORE, WHICH IS THE PATIENT ORIENTED ECZEMA MEASURE AND THIS BRINGS IN SOME OF THE WAY THAT THE PATIENT ASSESSES THEIR OWN DISEASE AND THAT DOES ININCLUDED SOME OUTCOME MEASURES. YOU CAN SEE THERE'S VERY GOOD DISCRIMINATION. WHEN WE LOOK AT THE PEARSON CORRELATION TO ADDRESS THAT QUESTION OF WHETHER THE PIQ-C IS ABLE TO SERVE AS A SURROGATE. WE SEE CORRELATIONS ACROSS THE BOARD. THOSE WITH HIGHER SCORES MEANING WORSE SYMPTOMS, WE SEE POSITIVE CORRELATIONS WHILE BEING SIGNIFICANT WITH PAIN, DEPRESSIVE SYMPTOMS, FATIGUE, ANXIETY, PSYCHOLOGICAL STRESS, SLEEP DISTURBANCE AND SLEEP IMPAIRMENT AS WELL AS WITH THOSE THE HIGHER SCORES REFLECTS BETTER FUNCTION. WE SEE THE NEGATIVE CORRELATIONS HERE. AND EVEN WITH MOBILITY, WHICH ACTUALLY SURPRISED ME A LITTLE BIT. SO, WHERE ARE WE IN THE PROCESS OF VALIDATING PIQ-C? FIRST, WE'VE COMPLETED THE CONTENT VALIDATION AND THE CROSS SECTION OF VALIDITY EVIDENCE. I WILL SAY THAT THE STUDY THAT WE DID ACTUALLY TOOK UP TO FIVE DIFFERENT TIME POINTS FROM EACH OF THESE SUBJECTS. BECAUSE WE WANTED TO CAPTURE NOT JUST WHEN WE HAPPEN TO SEE THEM AT THAT SINGLE BASELINE MEASURE THAT I SHOWED YOU HERE, BUT ALSO WHEN THEY FLARE, WHEN THEY GET BETTER, SO WE HAVE A RANGE. NOT EVERYBODY WAS ABLE TO CAPTURE THE FULL FIVE ON BUT WE HAVE MANY MORE ASSESSMENTS OVERTIME SO THAT WE'LL SHORTLY BE LOOKING AT THOSE AND BE ABLE TO LOOK AT RESPONSIVENESS TO CHANGE. AND THEN, MOVING FORWARD, LOOKING AT REAL WORLD EVIDENCE. PEOPLE HAVE ALREADY STARTED TO ASK US TO BE ABLE TO USE THESE FOR CLINICAL TRIALS AND WE HAVE MOVED ON ALREADY IN OUR OWN PATIENTS TO TEST IN ITCHY CONDITIONS BEYOND A TOPIC DERMATITIS SO WE EXPECT TO HAVE THAT DATE IN THE FUTURE. SO FINALLY, WHY USE PIQ-C. THIS ITEM POLL ASSESSES IMPORTANT ASPECTS OF ITCH INCLUDING ITCH QUALITY, INTENSITY, DURATION AND TRIGGERS. IT CAPTURES THE IMPACT OF ITCH ON THE CHILD'S EMOTIONAL, COGNITIVE AND INTERFERENCE WITH PEER AND FAMILY RELATION SLEEP AND IT'S WELL CORRELATED WITH OTHER QUALITY OF LIFE INSTRUMENTS AND WE THINK IT CAN BE USED AS A FAIRLY SHORT SURROGATE FOR ALL THESE OTHER TOOLS AND IT'S SIGNIFICANTLY DIFFER IT'S A BETWEEN SEVERITY GROUPS, REGARDLESS OF WHETHER THEY'RE STRICTLY OBJECTIVE OR WHETHER THEY'VE START TO PULL IN SOME PATIENT REPORTED OUTCOMES. AND THIS CONTRIBUTES TO ITS CLINICAL VALIDITY. I'M HAPPY TO TAKE ANY QUESTIONS. [APPLAUSE]

>> I WANT TO SAY, WHEN YOU FIRST STARTED IN THESE MEETINGS, YOU KEPT MINIMIZING -- I DON'T KNOW ANYTHING ABOUT PATIENT REPORTED OUTCOMES I'M JUST A DERMATOLOGIST. YOU KNOW IT'S NOT THAT WAY ANYMORE.

>> I'VE GOT A WAYS TO GO, CHRIS, BUT I'M LEARNING. QUESTIONS?

>> JUST A LITTLE UPDATE ON THE DISCUSSIONS YOU'VE HAD WITH THE F.D.A. BECAUSE THERE WAS A BIG INTEREST IN ITCH. IT'S CLOSE SO THE BIOLOGY OF SKIN DISORDERS, WHERE DOES THAT STAND?

>> WE WANT TO TALK ABOUT OUR F.D.A. FOLKS HERE.

>> INITIALLY, IT'S ONE LATER OF INTENSE USING THE ITCH AS ONE INSTRUMENT. AND THEN WE HAVE FEEDBACK FROM F.D.A. THAT THEY WOULD LIKE TO SEPARATE THE ITCH INTO TWO MAJORS, ONE IS THE EXPERIENCE AND THE OTHER IS INTERFERENCE. SO WE ARE IN THE PROCESS OF REVISING AND RESUBMITTING THE REGULAR INTENT INSTEAD OF ONE.

>> SO, THEY'RE ALL THE SAME -- IT'S FROM THE SAME MEASURE?

>> IT'S FROM THE SAME MEASURE, YES.

>> THE EXPERIENCE.

>> FROM THE SAME BANK, YES. SO WE'VE DIVIDED UP THE ITEMS INTO WHAT WE FEEL IS MORE – IN FACT, WE REFERENCE LEVERAGED OUR GROUP TO DIVIDE IT INTO THE INTERFERENCE.

>> THE MEASUREMENTS PERSPECTIVE IT WILL BE ONE BANK AS A PIQ-C AND THERE WILL BE TWO SEPARATE OUT CODED SORT FORM FROM ONE CALIBRATED.

>> BUT SCORED ON THE SAME SCALE. IT'S CONFUSING. I DON'T WANT TO GET INTO THIS CONVERSATION. WE HAD THE SAME WITH THE PAINT INTERFERENCE BECAUSE THEY'RE NOT SEPARATE MEASURES. AND IN KIDS THEY GO TOGETHER. SO THAT'S WHERE WE STAND WITH THAT.

>> THAT'S WHERE WE STAND. WE HAVEN'T HEARD BACK FURTHER. SOON!

>> SOON.

>> OTHER QUESTIONS OR COMMENTS?

>> GREAT.

>> RAJ.

>> WELL, RAJ, OUR ASTHMA SPECIALIST FROM CHICAGO IS WALKING UP TO THE PODIUM, I WANT TO REMIND EACH OF THE CENTERS WE'RE GOING TO GO AROUND FOR A DISCUSSION TO PREPARE YOURSELF FOR THAT. THE ORDER IS LISTED IN THE AGENDA. WE'LL JUST DO YOUR COMMENTS FROM YOUR SEATS AND THEN WE'RE GOING TO GET RESPONSE FROM OUR FEDERAL COLLEAGUES AND OPEN IT UP FOR GENERAL DISCUSSION.

## **Asthma impact and AAD-PEPR**

### **Raj Kumar**

>> SO, THANK YOU AGAIN FOR INVITING US TO SPEAK. I'M GOING TO PRESENT THE RESULTS, INITIAL RESULTS OF PROJECT 2 FROM THE AEDPEPR AND NEW CONSORTIUM. MY DISCLOSURE, I HAVE NO MONEY. LIKE THE MONOPOLY GUY. THESE ARE INITIAL AIMS FROM THE PROJECT AND OUR HYPOTHESIS. FROM THE ASTHMA PROJECT, WE'RE IN THE DATA ANALYSIS PHASE. THE FIRST TWO GOALS WITH RELIABILITY, VALIDITY AND CORRELATION ARE UNDERWAY AND WE'RE WORKING ON SOME OF THE ISSUES AROUND RESPONSIVE TEE AND THE RELATIONSHIP WITH STRESS. SO, I'M GOING TO PRESENT MOSTLY THINGS RELATED TO THOSE FIRST TWO AIMS. AND WE'RE FOCUSING ON THE PEDIATRIC ASTHMA IMPACT SCALE. JUST BY WAY OF BACKGROUND AND I PROBABLY BRING COALS TO NEW CASTLE HERE BUT THIS WAS DEVELOPED FROM 169 ASTHMA QUESTIONS FROM A NUMBER OF

SETS INCLUDING PEDESTRIANS ASTHMA DIARY WITH INITIALLY 34 ITEMS CHOSEN REDUCED TO 17 BY I.R.T. AND THEN IT WAS PREVIOUSLY VALIDATED IN ONE CENTER AT USF WITH ABOUT 160 KIDS. MOSTLY AFRICAN AMERICAN AND SHOWING THE GOOD ASTHMA CONTROL WAS ASSOCIATED WITH A HIGHER QUALITY OF LIFE. THERE'S ALSO BEEN SOME WORK ON RESPONSIVENESS TO CHANGE. AGAIN, WITH TWO CENTERS LOOKING AT ABOUT 230 KIDS. THEY DIDN'T EXAMINE PROXY VERSUS SELF-REPORT THERE AND SO, GIVEN THAT AS BACKGROUND, WHAT WE SEE AS OPPORTUNITIES HERE, WHERE ONE TO VALIDATE IN A LARGER NUMBER OF SUBJECTS AND TO LOOK AT SUBJECTS NOT ONLY PRIMARILY AFRICAN AMERICAN BUT ALSO LA SEEN OWE INDIVIDUALS AND WHO ARE OVER REPRESENTED IN ASTHMA POPULATIONS AND ALSO TO LOOK ACROSS A VARIETY OF SETTINGS SO WE WILL LOOK AT ITS FUNCTIONING ACROSS VARIOUS SETTINGS HOME, SCHOOL, AS WELL AS MEDICAL AND EMERGENCY ROOM. WE ALSO THOUGHT IT WOULD BE IMPORTANT TO LOOK AT THE INTERNAL CONSISTENCY OF THESE MEASURES WITHIN DIFFERENT SUPPOSE JOKE ANANDVALIDATE AGAINST OTHER BENCHMARKS INCLUDING MORE COMMONLY USED SEVERITY BENCHMARKS OR CONTROL BENCHMARKS LIKE A.C.T. AS WELL AS THINGS LIKE LUNG FUNCTION. SO, TO DO THIS, WE LEVERAGED THREE TRIALS. ONE WAS THE CHICAGO PLAN AND THE OTHER ASSIST AND YOU HAVE A RANGE OF SEVERITY ACROSS THESE TRIALS. IN TERMS OF THE INITIAL ASSESSMENT, WHICH IS MOSTLY WHAT I'M GOING TO SHOW YOU TODAY, WAS CONDUCTED IN THE CHICAGO PLAN AND THE EMERGENCY ROOM, ASSISTED STUDY VISITS SO SORT OF A MEDICAL SETTING AND WITHIN SCHOOLS. AND WHAT YOU CAN SEE IS THAT THEY HAVE SIMILAR DURATIONS TO FOLLOW-UP AND THE AGE RANGES ARE FROM 5-11 AND ASSIST GOES FROM SIX TO ALMOST ADULTHOOD. IN TERMS OF KEY MEASURES, IN TERMS OF THE TIMING, WE HAVE THE BASELINE MEASURE IN ALL OF THE STUDIES WITH THE EXCEPTION OF LEGACY IN THE CHICAGO PLAN. WE ALSO HAVE ONE MONTH MEASUREMENT IN CHICAGO PLAN AND SIX MONTH MEASUREMENTS IN MOST OF THE STUDIES FOR LEGACY MEASURES IN ALL THOSE STUDIES FOR THE PROMISE MEASURES. SEW IF YOU LOOK AT AGE DISTRIBUTION, I'M SEEING IF THAT'S OK THERE. I CAN'T SEE WHAT I'M DOING THERE. WHAT YOU CAN SEE IS THE MAJORITY OF KIDS, AS WE GO ARE IN THE YOUNGER AGE RANGE AND MOST OF THE STUDIES EXCEPT FOR ASSIST WHERE THEY'RE A LITTLE BIT OLDER AND IT'S FROZEN. I'LL STOP USING THAT. IT'S OK, I'M JUST NOT GOING TO FOOL WITH THE FORCE HERE. AND ALSO, THERE'S ROUGHLY EQUAL NUMBERS OF MALE AND FEMALE IN TWO OF THE STUDIES IN THE CHICAGO PLAN, WHICH IS EMERGENCY ROOM STUDY. WE HAVE OVER REPRESENTATION OF MALES. WE HAVE AN ASSIST ALL AFRICAN AMERICANS AND IN 23% AFRICAN AMERICANS, 44% WHITE, IN CHICAGO PLAN, MOSTLY AFRICAN AMERICANS, 31% WHITE AND WITH WE LOOK AT ETHNICITY, WE HAVE GOOD REPRESENTATION OF THE HISPANIC AND LATINO INDIVIDUALS IN A THIRD OF THEM ARE HISPANIC IN THE CHICAGO PLAN AND ABOUT 60% ARE HISPANIC IN THE SAMPLE WE HAD. SO, THAT'S -- WE'RE COVERING VARIOUS AGE RANGES AS WELL AS RACE AND ETHNICITY HERE. WHAT WE'RE GOING TO LOOK AT NEXT IS THE VALIDATION WE'RE GOING TO LOOK AT IT BY SUB GROUP. THIS IS THE RAW ALPHA AND THE INTERNAL CONSISTENCY IS GOOD ACROSS THE STUDIES AND IT'S VERY SIMILAR AND YOU ARE SEEING FOR THE PROXY, AND THE PAIS ABOUT .91 TO .94 SO EXCELLENT INTERNAL VALIDITY. BY GENDER, WE ALSO DON'T SEE VERY MUCH DIFFERENCE AND IN FACT THIS IS BETTER INTERNAL VALIDITY THAN OUR LEGACY MEASURES. SIMILARLY, IF WE LOOK OUT BY ETHNICITY, WE SEE VERY GOOD INTERNAL CONSISTENCY AND LITTLE DIFFERENCE WHETHER YOU ARE HISPANIC, LATINO OR NON HISPANIC HISPANIC. WE DIDN'T HAVE ENOUGH NUMBERS TO LOOK AT THIS BECAUSE WE ONLY HAD 770 OBJECTS. WE THOUGHT IT WAS A VERY INTERESTING AND SOMETHING IMPORTANT TO NOTE FOR FUTURE STUDIES. BY RACE, WE AGAIN SEE VERY SIMILAR INTERNAL CONSISTENCY AND LITTLE DIFFERENCE BY RACE AND WHILE WE DIDN'T HAVE ENOUGH SAMPLE TO SPLIT OUT WHITE, NON



HISPANIC WHITE HISPANIC, IN GENERAL, WE WOULD EXPECT SIMILAR PERFORMANCE BASED ON THE LANGUAGE DATA I SHOWED YOU EARLIER. NOW, WHEN LOOKING AT CONTROL, I'M JUST GOING TO PREFACE THIS, THE A.C.T., IF YOU HAVE GOOD CONTROL IS HIGHER. SO THE CUT POINT, EXCUSE ME, OF OVER 19, IS CONSIDERED CONTROLLED. AND BELOW THAT IS CONSIDERED LACK OF CONTROL. AND THAT'S DIFFERENT FROM THE IMPACT SCORE WHERE HIGHER IS WORSE. YOU ARE HAVING MORE IMPACT. JUST WHEN YOU SEE THE NEXT SLIDES, KEEP THAT IN MIND. AND SO WE'RE LOOKING AT THESE VARIOUS STUDIES, CONTROLLED AND UNCONTROLLED, AGAIN, BY THE CUT POINT OF A.C.T. AT 19. AND LOOKING AT THE KIDS SELF-REPORT, YOU SEE A DIFFERENCE IN THESE T-MEASURES THAT ARE SIGNIFICANT ABOVE WHAT HAS BEEN CONSIDERED TO BE THE M.I.D. UP TO NOW FOR EACH OF THESE STUDIES. IRRESPECTIVE OF WHERE THE KIDS ARE BEING SEEN. AND IT'S HIGHLY SIGNIFICANT IN THE COLUMN D IN EFFECT OF FACT SIZE WOULD BE MODERATE TO HIGH EFFECT. SAME KIND OF THING WHAT YOU SEE FOR THE PARENT PROXY. AGAIN, FAIRLY SIGNIFICANT. AND LARGE CHANGE IN SCORE. AND WHEN WE LOOK BY RACE, WHAT WE SEE IS THAT PEOPLE WITH THE GREATEST EFFECT ARE AFRICAN AMERICANS AND IN THE PROXY NON HISPANIC LATINOS HAVE MORE EFFECT THAN LATINO. SO THIS LINES UP PROPERLY. IN TERMS OF AGE, THIS IS INTERESTING. I THINK IT'S SOMETHING WE SEE AS CLINICIANS ACROSS ALL OUR PATIENTS IS THAT THE OLDER THEY GET AND WHEN THEY GET TO BE TEENS AND YOU SAY DOESN'T THIS BOTHER YOU, THEY SAY NO. THEY REALLY ARE TELLING YOU HOW THEY FEEL. BECAUSE YOU SEE LESS EFFECT FOR BOTH PROXY AND SELF-AS THEY GET OLDER. AND INTERESTINGLY FOR THE AREA OF DEPRIVATION INDEX, WHAT WE SAW IN OUR DATA, WAS THAT IF WE LOOK AT THE PROXY REPORT, AS YOU HAVE GREATER DEGREES OF DEPRIVATION, YOU SEE GREATER ASTHMA IMPACT. YOU DON'T SEE THAT IN SELF-REPORT WHICH MAY REFLECT HOW MUCH THEY ARE AWARE OF THESE DIFFERENCES. OR THESE ENVIRONMENTAL FACTORS. SO, IN CONCLUSION, IT WAS INTERNALLY CONSISTENT. THERE WERE NO DIFFERENCES BY RACE, ETHNICITY OR GENDER. THERE HAVE BEEN DIFFERENCES IN SCORES ACROSS EACH OF THE STUDIES -- THERE WERE NO DIFFERENCES ACTUALLY IN SCORES. THESE STUDIES WITH DIFFERENT CARE AND DELIVERY SETTINGS. THERE WERE GREATER IMPACT WITHIN AFRICAN AMERICANS SUBJECTS AND ACTUALLY INTERESTING THERE WAS LESSER IMPACT THAN HISPANICS. YOU SHOULD LESS IN HISPANICS. AND THE IMPACT SEEMS TO DECREASE WITH AGE. SO I THOUGHT -- THOSE ARE OUR INITIAL FINDINGS AND WE THOUGHT THERE MIGHT BE IMPORTANT FROM THE STANDPOINT OF INCLUDING THESE KINDS OF MEASURES WITHIN STUDIES BECAUSE WE HAVE TO TAKE SOME OF THESE THINGS INTO ACCOUNT. AND ALSO, THE IMPORTANCE WOULD BE THAT WE ARE SEEING -- THESE ITEMS FUNCTION VERY WELL ACROSS ETHNICITY, GENDER, AND OUR NEXT STEP WILL BE TO ANCHOR TO FA1 LIKE THEY'VE SEEN WITH RENAL DISEASE AND G.F.R. YOU WON'T SEE THE SAME LEVELS OF DIFFERENCE. WE MEASURE THESE AS CLINICIANS BUT IF ON FOR ONE PATIENT TO THE NEXT THEY FEEL LITTLE IMPACT COMPARED TO ANOTHER INDIVIDUAL AND THEN LOOK AT OTHER LEGACY QUALITY OF LIFE MEASURES WITHIN THE COHORTS. WE HAVE TO FURTHER LOOK AT THE PROFILE AND PSYCHOLOGICAL STRESSES AS WELL AS DIFFERENTIAL ITEM FINDINGS. I'D LIKE TO THANK EVERYBODY INVOLVED. BOTH THE ASTHMA TEAM WHO HAS BEEN WORKED ON THE DATA SO FAR AND AARON CAT WHO DID THE ANALYSIS AND LEWINSKY WHO HELPED AND THE STUDIES WHO WERE INVOLVED WITH THEIR P.I.s AND TEAMS INCLUDING WANDA AND KYLE AND THE CHICAGO PLAN WITH JERRY CHRISNAN AS WELL AS THE P.I.s OF OUR STUDY INCLUDING RICHARD WHO STARTED THIS. AND THEN NIH. THANK YOU. [APPLAUSE]

>> QUESTIONS OR COMMENTS?

>> RAJ, YOU DID A NICE JOB SUMMARIZING. IN THE SCHOOL STUDY AS WELL YOU ARE JUST DEALING WITH BASELINE DATA BECAUSE WE'RE FINISHING OUR RECRUITMENT IN THE FILE. THE BASELINE THE KIDS COME IN THE THE SUMMER AND THEY'RE USUALLY MORE WELL CONTROLLED. SO WE'LL HAVE A LITTLE BIT MORE OF THAT. YOU CAN PROBABLY GO AHEAD AND CONTINUE BUT WE'RE FINISHING THE TRIAL AND THIS IS THE LAST YEAR.

>> SO, WHEN WE HAVE THAT LONG DATA, IT WILL HELP WITH LOOKING AT SOME OF THE RESPONSIVENESS FOR CHANGE. FOR THAT FUTURE ANALYSIS, CHICAGO WHICH HAS THEIR INITIAL BASELINE IN THE EMERGENCY ROOM, WHERE THEY'LL QUOTE-UNQUOTE IMPROVE FOR THE FIRST TIME PERIOD OF TIME. WITH YOUR STUDY, U YOU HAVE PEOPLE AND THERE'S A PORTION OF THEM WHO ARE GOING TO EXACERBATE AROUND THE TIME THEY GET THEIR MEASUREMENTS SO HOPEFULLY WE'LL HAVE FURTHER RESPONSIVENESS TO CHANGE.

>> RAJ, THERE'S SO MUCH ATTENTION TO EARLY CHILDHOOD WEEINGANDB.M.I. STATUS. I WONDER WHETHER YOU ARE GOING TO LOOK A LOT DIFFERENCES, PARTICULARLY LONGITUDINAL TO GO BEYOND THIS KIND OF JUST ONE-SIZE-FITS-ALL FOR EVERYBODY WITH ASTHMA.

>> THAT'S A GREAT POINT. IF WE LOOK AT END OWE TYPING OF ASTHMA, ASTHMA IS PROBABLY AN UMBRELLA DIAGNOSIS. FIND A COMMON PATHWAY TO A SET OF CLINICAL SYMPTOMS WHICH ARRIVED AT VARIOUS DIFFERENT BIOLOGICAL PHENOMENON AND IF YOU CAN LOOK AT WHAT WE'VE DONE SOME NASAL BRUSHING STUDIES WHERE YOU SEE WHAT IS AT TH TOO HIGH PRO VILE VERSUS OTHERS AND IT CORRELATES WITH DIFFERENT KINDS OF DEMOGRAPHIC AND OR AGE GROUPS BEING MORE LIKELY REPRESENTED AND ONE TYPE VERSUS ANOTHER. IT WOULD BE INTERESTING TO SEE HOW P.R.O.s WORK WITH THESE DIFFERENT ENDO TYPES OF ASTHMA AND ON THE PEDIATRIC AND ADULT SCALE. THAT'S WHY VALIDATION OF THIS AND USING IT WITHIN MORE OF -- TRIALS WHERE IT WILL BE ENDO TYPING PEOPLE WILL HELP UNDERSTAND WHETHER THESE ENDO-TYPES HAVE ACTUALLY RELEVANCE TO ALSO HOW PEOPLE PERCEIVED THEIR DISEASE AND THEY MAY NOT CARE ABOUT.

>> OTHER COMMENTS OR QUESTIONS?