COGNITIVE DEVELOPMENT AND THE UNDERSTANDING OF INFORMED CONSENT

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To the Graduate Council:

I am submitting a thesis written by Lindsey Elizabeth Pearse entitled "Cognitive Development and The Understanding of Informed Consent." I have examined the final copy of this thesis and recommend that it be accepted in partial fulfillment of the requirements for the degree of Master of Science with a major in Psychology.

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Abstract

The informed consent process is an important criterion for all research studies. However, researchers rarely ask or even consider how many participants truly understand the informed consent information and their research rights. Currently, researchers base a participant's ability to understand informed consent information and research rights on age. In the present study it was hypothesized that cognitive development is a predictor of ethical knowledge. Accordingly, it was argued that a participant's ability to understand informed consent and research rights should not be based on a participant's age but instead on the participant's cognitive development. Students at the University of Tennessee at Chattanooga completed the Inventory of Piaget's Developmental Tasks and the Research Participants Bill of Rights measurement. Results demonstrated a positive correlation between cognitive development and ethical knowledge. Upon running a multiple regression, it was found that cognitive development is a predictor of ethical knowledge.

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Cognitive Development and the Understanding of Informed Consent

Individuals who voluntarily participate in any type of research must be involved in the informed consent process. An informed consent is a waiver that consists of eight points of information, which, when fully understood, allows a participant to make an informed decision about committing to the research (Bruzzese & Fisher, 2003). These eight points include the following: purpose of the study; an explanation of the benefits and risks associated with the outcome of the research; an explanation of how confidentiality will be maintained; who to contact after completion of the research; whether the participant will be compensated; if the consent is for treatment then the participant must be given a list of alternate procedures; and an explanation that the participant is volunteering and can withdraw from the study at any time.

Agreeing to volunteer to be a participant in research is one of the most essential aspects of the informed consent process. Participants must understand that they are never forced to start or complete a study. Bruzzese and Fisher (2003) state that the best means of protecting the rights and welfare of participants in research is to have a voluntary informed consent. They also state that we assume participants understand their rights as research participants if they have been presented with an informed consent, because all ethical concerns are covered in informed consents. Researchers assume that all participants have the cognitive development to understand all the information that is presented in the informed consent.

To acknowledge an understanding of the nature of informed consent, participants are asked to read and agree to the informed consent. If the study is conducted on individuals who are age 18 or older, then only the participant's signature is required. If,

however, the study is being conducted on minors, then the signature of a parent or guardian is also required to allow the individual to participate in the research or medical treatment and procedures (Bruzzese & Fisher. 2003)

Purpose of Study

The purpose of this study was to show with empirical evidence that the level of one's ethical knowledge can be predicted by his or her level of cognitive development. In cognitive development research/ literature, research suggests that a participant is capable of making an informed decision once he or she has completed the concrete operational stage (Muuss, 1996). At this stage in his or her cognitive development, a participant is able to use logical reasoning and understand the simplest level of informed consent information. While Piaget did not give the stages of cognitive development a set age at which they begin, the concrete operational stage is said to begin around the age of seven (Dugan, 2006). This information suggests that children who are well below the legal age of consent (age 18 years but differs by state) are capable of understanding the information to make a decision on informed consent and are able to understand the information presented to them on a participant's research rights.

Literature Review

In recent years, concern has been expressed for those participants who are under 18 years old and their voice in the participation of research studies or medical treatments. Participation is only allowed when the parents or guardians of a minor agree to the informed consent. It is often assumed that the legal guardians of a minor act in the best interests of the minor, especially in the case of medical treatments and procedures. It has also been viewed in the past that minors are incapable of making decisions. The

assumption that the parents are acting in the best interests of the child does not take into account what the child wants (Kuther, 2003).

Kuther (2003) states that the informed consent is a form of communication between the subject and the researcher. To better facilitate communication with minors, the process of assent was developed. Assent is the opportunity for a minor to confirm his or her participation in research, medical treatments or procedures. Because of the mature level required to understand the basis of the information about research studies and medical treatments and procedures, the information is explained to the minor on a developmentally appropriate level for accurate understanding. Allowing the child to give assent recognizes the minor as an autonomous individual capable of making an informed decision. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research suggests that children, ages seven or older, should be required to give assent to all participation in any type of research (Kon, 2006). The Commission also states that if a child objects to giving assent for participation, then his or her decision should be upheld. A child's objection to participate will not be honored, however, in circumstances where research indicates that participation is going to directly benefit the health of the child.

There are many researchers who believe the age of seven is an inappropriate age for assent. These researchers believe that age seven is far too young for a child to comprehend the complicated information in the informed consent process based on a seven year old child's cognitive immaturity and inability to understand the importance of the research study or medical procedure. It has been suggested by some researchers that the age of assent should be raised to as high as 14 years of age (Kon, 2006).

Concern for the competence in a minor's decision making capability is the reason there are laws to keep children under the age of 18 from signing informed consents. Competence defined by Levine, Anderson, Ferretti & Steinberg (1993) is stated as the level that an "individual is able to understand sufficiently to make an autonomous decision" (p. 89). This simply states that an individual is able to make an informed decision without the coercion of another person.

Based on previous studies, there is a lack of agreement between researchers on how to measure whether an individual is capable of making an informed decision. Grisso & Vierling (1978) believe that a minor's capabilities should be evaluated in three areas: knowing, intelligence and voluntariness. By using these three areas to measure competency, age is not a factor as to whether one is capable of understanding an informed consent.

Knowing consent is the first area of evaluation and in determining whether an informed decision has been made. To determine this, a minor will be asked to reiterate the information that has been provided and to put it in his or her own words. According to Grisso and Vierling (1978) the second area is intelligent consent; and there are five points in which a minor should be capable: 1) capability to attend to task; 2) capability to delay response in order to process information; 3) possess cognitively complex processing ability; 4) capability to weigh treatment benefits and risks; 5) capability to reason both inductively and deductively. The last area of evaluation is voluntary consent, which means a minor is able to provide consent without interference from outside sources. Voluntary consent is more difficult for minors who often look to others for approval in their actions. Minors often believe that physicians and parents or guardians always act in

their best interest, which sometimes makes it difficult for a minor to separate his or her feelings from those authoritative figures around him or her (Grisso and Vierling, 1978).

In order to further prove the importance of consent being based on cognitive development, there has been research completed to look at a child's cognitive understanding as a predictor of assent capability. Lane, (2007) considered using cognitive screening as a method of determining whether a minor is capable of assent as opposed to simply using a child's age as the determining factor. The researchers in this study chose the School- Years Test for the Evaluation of Mental Status (SYSTEMS) as a screening tool to assess a child's cognitive development. The study showed that a child's score on the SYSTEMS and the number of elements recalled by the participants in an adapted scenario were mediated by the relationship between the child's age and the number of understood elements.

The SYSTEMS provided a complete cognitive screening tool for researchers to look at a child's understanding of assent. Subsequent to Lane's (2007) testing, researchers began asking whether the SYSTEMS provided the same cognitive assessment for adults. Can this screening tool be applied to adults and provide the same type information on their level of understanding? To evaluate this possibility, a small pilot study was conducted and college age students were given the SYSTEMS screening tool as well as the adaptive scenario in which they were asked to recall items. Upon looking at the results of this pilot study, it was shown that the difficulty level of the SYSTEMS test is not suitable for college age participants. All students in the pilot study received a score of 90 to 97% on the SYSTEMS test.

The SYSTEMS cognitive screening tool is not the right screening tool for adult participants who are assumed to be at a more advanced level of cognitive development. While the purpose of this study is to determine if cognitive development is a predictor of ethical knowledge, it is important to determine a measurement for cognitive development that can have the same diagnostic relationship with adults as the SYSTEMS has with a child. To find a tool that can assess the cognitive development of adults and their ability to assent to participate in research, in the same manner SYSTEMS does with children.

When looking for a cognitive screening tool that can assess the cognitive development of adults, it is important to look at the structure of cognitive functioning. Jean Piaget provided much research on his theory of moral development and the progress of cognitive development from a child to an adult (Dugan, 2006). Piaget believed that all children begin in a "heteronomous" stage of moral reasoning, at which time a child can only account for his or her own views and reasoning and is unable to consider the views and reasoning of others. This is the beginning in the cognitive structure for children (Devries & Zan, 1994).

As children develop and interact with other children, they eventually pry away from heteronomous thought and progress into an "autonomous" stage of moral reasoning. In the autonomous stage, a child becomes able to consider his or her own views in conjunction with the views of others and he or she learns to cooperate so the rules are fair to all in the group. This moral development shows a shift in cognitive thinking in children, where the child becomes able to incorporate the perspective of others into his or her own.

As they progress through moral development, Piaget believes that children move through different stages of cognitive development as well. There are four stages of cognitive development, including sensorimotor, preoperational, concrete and formal operations. While Piaget did develop an age guideline, he also noted that these four stages are continuous and children will go through each stage at various times (Dugan, 2003).

A child's cognitive development, according to Piaget, begins with the stage sensorimotor, which occurs from birth to age 24 months. During the sensorimotor stage, a child will often experience development in hand-eye coordination as well as move from reflex activity to activity invoked by thought. In the sensorimotor stage, a child is ruled only by egocentrism (Dugan, 2003).

The second stage is the preoperational stage is broken into two different sub stages: egocentric (2-4 years), and intuitive (5-7 years). Egocentric, in moral development, means a child cannot see any views or rules but his or her own. Children in the egocentric stage begin to understand more complex issues but are still dependent on their senses and can only focus on one dimension at a time (Crain, 2005). Intuitive is when the moral development starts to shift and a child is able to use perception when developing thought (Devries & Zan, 1994). In the preoperational stage, a major developmental task is for a child to develop a rational solution to a problem.

The third stage is concrete operational (7-11 years). In this stage a child can start to apply others' points of view into his or her own view. This is the stage in moral development when a child turns from heternomous moral reasoning to autonomous moral reasoning. Concrete development allows a child to face problems that are realistic and

that have realistic outcomes. Children in this stage are now seen as sociocentric and can now participant in conversations; a child is able to take in the information he or she is hearing as well as understands the conversation logically. In concrete development, children are more capable of making decisions as well as moral judgments because they are able to understand reasoning behind rules and regulations (Dugan, 2003).

Reaching the concrete operational stage marks a large shift in a child's thought process. A child not only develops cognitively but also logically; these two processes happen simultaneously. During this stage, a child is able to understand the principle of conservation and weight; and they begin to understand the conservation of volume. Conservation is defined by Webster's Dictionary as the preservation of physical quantity during transformations or reactions. In the concrete operational stage a child develops four elements of logical thinking: combinativity, reversibility, associativity, and nullifiability (Muuss, 1996).

The last stage of cognitive development is the formal operational stage. This stage may begin in early adolescence (11 years old), but continues to develop through adulthood. The main addition to the formal operational stages is that a person uses all the attributes of the other stages but can now incorporate abstract thinking into cognitive function (Dugan 2003).

The formal operational stage is broken into two substages: almost full formal operations and full formal operations. While both stages are included in the formal operational stage, Dugan (2003) notes that not all people will reach the full formal operational stage. Crain (2005) says that for one to obtain full formal operations that formal education will have to be obtained. To reach full formal operations, Piaget has

suggested that people will reach that goal in their own area of interest, the area that one chooses to study more than any other (Crain, 2005).

Piaget's theories of cognitive and moral development have been supported by many and some have elaborated on his ideas. In the article by Power, Higgins, and Kohlberg (1989), Kohlberg agreed with Piaget's theories but believed that it was a longer process and that moral maturity took more time. Kohlberg expanded Piaget's original four stages into six stages of moral development (Power, Higgins, and Kohlberg., 1989).

Another researcher who accepted, but adapted Piaget's theory of development was William G. Perry. Through a fifteen year study of college age students Perry produced a scheme of cognition and intellectual development. While Perry (1999) agreed with many of Piaget's ideas of cognitive development, there were several points that separated the two researchers. Perry believed a student's transition is much the same structure as Piaget, "by assimilating and accommodating new information into existing cognitive structure" (Perry, 1999, p.xii). But he believed the process was less stable than stages, and rejected the idea, instead using the notion of *position.* Perry's development scheme was also more in depth for the post-adolescent cognitive development.

Perry also believed in Piaget's idea, "that the sequence of cognitive structures that constitute the developmental process are both logically and hierarchically related, insofar as each builds upon and thus presupposes the previous structures" (Perry,1999, p.xii). But, Perry thought that there were many other factors that would affect one's approach to learning such as: gender, race, culture and socioeconomic class. This is where Perry placed his concept of positions instead of stages, that each person can see learning and cognitive development from a different position. And while with the Piagetian stages, one

can only occupy one stage at a time, Perry believed that one could occupy several different positions at once.

Perry developed four phases that hold 9 positions in cognitive and intellectual development. The first phase is Duality, which holds position 1 and 2. In this stage "the world, knowledge and morality are assumed to have a dualistic structure. Things are right or wrong, true or false, good or bad" (Perry, 1999, p.xxii). The purpose of a student in this role is to learn the information given to him or her and display what he or she has learned. Most students have moved past this position when they begin college. The second phase is Multiplicity, positions 3 and 4, which are seen as transitional positions because students are developing cognitively to distinguish that there is more than one answer. The next phase represents position 5 and 6, Relativism. Perry says, "The world, knowledge and morality are accepted as relativistic in the sense that truth is seen as relative to a frame of reference rather absolute" (Perry, 1999, p.xxxiii). In these positions, the dualistic framework has completely left the cognitive scheme.

The last phase is Commitment, positions 7, 8, and 9. In the previous position, one was beginning to develop his or her own personal point of view and learning commitment to certain areas of life. In the last position, a learner comes to understand that all knowledge is relative to the circumstances and he or she also determines that his or her commitments as well as his or her future are always changing (Perry, 1999).

In looking at the progression of Piaget's and others' moral and cognitive development, it supports the idea that informed consent can be understood and given by someone younger than the age of 18. Piaget argues through his stages, that a child in the concrete operational stage, 7-11 years, has the capability of making a decision. Children

in this stage can now see another's point of view and they are able to understand reason behind a rule or concept.

In the concrete operational stage, children can make moral judgments differently from when they are younger, because they have a more logical point of view. At this stage children also begin to question authority because they see rules as structure but know that they are not always absolute (Dugan, 2003).

In seeing that Piaget's theories of moral and cognitive development were widely accepted and elaborately described the shift in a child's growth of in moral development, Piaget created tasks to determine which stage of cognitive development his students had completed. These tasks are usually given to an individual during interviews with participants. Because it is not always possible to test students in individual interviews; an inventory of Piaget's tasks was developed. The Inventory of Piaget's Developmental Tasks (IPDT), " was designed to translate some of Piaget's concrete and formal operational tasks into an objective, quick, standardized paper and pencil format requiring minimal reading ability" (Patterson, & Milakofsky, 1980, p. 342).

This inventory covers five different problem areas: conservation, images, relations, classification and laws. Each area has subtests within, for a total of 18 subtests; each subtest has four items. The inventory is important because it fulfills five of the six criteria that are needed to construct an assessment tool, say Patterson & Milakofsky (1980). These five criteria are 1) covers concrete and formal tasks; 2) requires minimal language and reading skills; 3) can be administered to a wide range of ages; 4) can be quickly and easily administered to virtually any size group; and 5) can be quickly and

objectively scored (Patterson & Milakofsky, 1980). The sixth criterion is: has been standardized and adequately studied for reliability and validity.

Because of the great need for such a useful screening tool of cognitive development that fulfills almost all criteria for adequate assessment tools, Patterson and Milakofsky (1980) thought it was most important to study the validity and reliability of the IPDT. If reliability and validity were found within the inventory, then it could be more widely used as an assessment of one's cognitive functioning.

Patterson and Milakofsky (1980) have provided the evidence that supports that the IPDT fulfills the last criterion, which was that the measurement must be standardized and adequately studied for reliability and validity. There are also suggestions of how to make the test more difficult for students of high school and college ages, which allow the inventory to remain reliable and valid, but decreases testing time by half.

Bruzzese and Fisher (2003) developed the Research Participants Bill of Right's to determine the competency of participants, at different ages, to understand his or her rights in research. They believe that by giving the participants a brief lesson in the Bill of Rights of participants, they could increase rights related consent capacity at any age. This study was performed on 4 different groups: fourth graders, seventh graders, tenth graders and college students. In this study, participants were given an informed consent and then asked to perform the task of answering Consent Form Comprehension questions. After participants answered the questions, they were then read the Research Participants Bill of Rights aloud and were also allowed to follow along with their own copy of the Bill of Rights. After reviewing the Bill of Rights, participants were then asked to complete four more tasks, Rights Definition, Rights True-False, Rights Violation Labeling and Rights

Violation Awareness. The results suggested that while fourth and seventh graders showed a good understanding of the information, their performance was poor relative to those students who were in the tenth grade or college students. This led Bruzzese and Fisher (2003) to suggest that children under the age of 10 years old are not capable of understanding their research rights. Their measurement proved to be a useful measurement in determining the level of ethical knowledge in participants.

With the IPDT proving to be a reliable and valid measurement, it will be important in the measurement of cognitive development in the present study. To determine a participant's level of cognitive development, the IDPT will be completed. One's level of ethical knowledge will be determined by completing Bruzzese and Fisher's Research Participants Bill of Right's. The outcome variable of the present study was cognitive development and the predictor variable was ethical knowledge. The purpose of the present study was to provide empirical evidence that cognitive development can be used as a predictor to one's ethical knowledge.

Also the current study will be compared to previous studies that have tested the IDPT and the Research Participant's Bill of Rights. A comparison will be conducted between the current group of college age participants and the group of college age participants in the previous studies.

Method

Participants

Originally, there were 104 participants but due to incompletion of the two measurements, some participants were eliminated. The participants (n = 73) for the

present study are all currently enrolled at the University of Tennessee at Chattanooga. In this study, there were 37.7% (n =26) males and 62.3% (n = 43) females, several students (n = 4) chose not to divulge their gender. Of the 73 students who chose to participant in the study, 46.6% (n = 27) were seniors, 25.9% (n = 15) were juniors, 13.8% (n =8) were sophomores and 10.3% (n = 6) were freshman. Only two graduate students participated in this study, 3.4%. Students were informed of this study during regularly scheduled classes and were given the opportunity to volunteer to participant, if they chose not to participate, there would be no penalty. The participants were given no compensation for their participation, except for extra credit opportunities that were dispersed at the liberties of the professors of the classes. By participating in this study, the students did not encounter any risks by completing The Inventory of Piaget's Developmental Tasks or The Research Participants' Bill of Rights.

Materials

The materials that were used in this study were the Inventory of Piaget's Developmental Tasks (IPDT); this is a 72 question pencil and paper test of cognitive development. The IPDT is divided into 18 sets of tasks, with 4 items in each set. The IPDT covers 5 areas: conservation, images, relations, classification, and laws. Each set starts with an example that is correctly answered in the test booklet. To test the validity and reliability of the IPDT, the test was delivered in four different forms: 1) *Group Test,* groups of students were given test booklets of the IPDT and answer sheets and were allowed as much time as possible to complete the inventory, 2) *Group Test, Part 1,* groups of students were given test booklets and answer sheets, but were asked only to answer item 2 and 3. Items 1 and 4 were covered in the booklets and in the answer sheets.

3) *Group test, part 2,* the group of students were given test booklets and answer sheets but this time were asked to only answer items 1 and 4 in each subtest. Items 2 and 3 were covered in the booklets and answer sheets. 4) *Individual Test,* in this administration of the inventory, materials were brought out that reproduced the questions in the test booklet and individuals were asked by trained Testers items 2 and 3. This method was used to see if the format of paper and pencil adequately explained the ideas in the inventory.

In the Patterson and Milakofsky (1980) study there were approximately 542 participants, who ranged in age from 8 to 19. All participants were placed into 12 groups, with three different sets of 4 age ranges. The different formats of the test were administered in a counterbalance design to control contamination by being exposed to the test more than once. Reliability was tested in several ways, through test-retest using the coefficient of stability, internal consistency using split-half reliability and also the total IPDT group test and retest score were compared using an analysis of variance. Using these three measurements of reliability, it was shown the IPDT is stable and has considerable internal consistency. To assess the concurrent validity of the test, an ANOVA was performed to see if there were significant differences in the individual test and group test scores. In looking at each age group, there were no significant differences found. Construct validity was assessed by mean scored for each age group on the IPDT. Upon comparing IPDT group to other standardized measurements, there were strong correlations with achievement tests and IQ scores. Patterson and Milakofsky (1980) found that there was a significant correlation between the IPDT and IQ measurements, r (20) = .68, p<.001, also there was a significant correlation between IPDT and SAT measurement, r (53) = .63, p< .001. Developmental progression was shown through the

IPDT in five areas that follow the theories of Piaget as well as other researchers. Results show the IPDT has both concurrent and construct validity (Patterson & Milakofsky, 1980). Copies of the IPDT can be acquired through the Catholic University in Washington, DC, Department of Psychology, Center for Research in Thinking and Language.

Participants were also asked to complete The Research Participants' Bill of Rights. This measurement allows the researcher to test the participants understanding and knowledge of their rights in research. This measurement consists of 5 tasks: 1) Consent Form Comprehension; 2) Right Definition; 3) True- False; 4) Rights Violation Labeling; 5) Rights Violation Awareness. In order to use these measurements so that all levels of cognitive development could understand, the words and definitions were put into the simplest level possible. Also, to ensure understanding, the measurements directions and questions were read out loud to the participants.

Construct validity was obtained for the consent comprehension tasks, right violation labeling and right violation awareness by allowing three experts to test the tasks. The consent comprehension tasks had a 100% agreement between the three expert raters. The rights violation labeling and rights violation awareness task had 100% agreement between two of the expert raters and 97% agreement between all three expert raters, differing only on one question. To acquire a copy of The Research Participants' Bill of Rights tasks, contact should be made with Jean-Marie Bruzzese at New York University, Child Study Center, Parenting Institute.

Procedure

Participants were asked to complete each test while in their classroom, permission to be in the classroom was granted by the professors prior to the class time. Before beginning the study, all students were asked to sign an informed consent and reminded that the study was voluntary and there were no penalties if they chose to withdraw. Each student first took The Research Participant's Bill of Rights and Psychology: A Science of Human Behavior tasks. This test consists of 5 different tasks: Consent Form Comprehension, Rights Definition, True-false, Rights Violation Labeling and Rights Violation awareness. Each of the tasks was read aloud to the students by the researcher and they were also given a written copy of the information, so they could follow along as the researcher read aloud. After completing the research rights task, the participants were then asked to take the Inventory of Piaget's Development Tasks (IPDT); this test consists of 72 paper and pencil questions. Completing both measures took approximately one hour, but the participants were not given a time limit to finish the tests.

Results

The data points used to assess these data were constructed from the response to the instruments used to assess cognitive development and ethics knowledge. The IPDT can be scored to provide an overall cognitive development score (IPDT Total), as well as subtest scores on 18 dimensions of ability defined by Piaget: Quantity, Levels, Sequence, Weight, Matrix, Symbols, Perspective, Movement, Volume, Seriation, Rotation, Angles, Shadows, Classes, Distance, Inclusion, Inference, Probability. The work of Bruzzese and Fisher (2003) resulted in a set of five scored from individual subscales measuring; Consent Form Comprehension, Rights Definition, True-False, Rights Violation Labeling,

Rights Awareness Labeling. For this study's purpose, a total ethics score was created (Ethics Score) by summing the subscales. In this section, the psychometric properties of the scales were reviewed, and then the degree to which the sample matched the published data from earlier studies using these instruments was considered, and finally addressed the question of the relationship between cognitive development and ethical knowledge.

Reliability and Comparability

A reliability analysis was conducted to test the internal consistency reliability of the measurements used in this study. To test the internal consistency of the IDPT, a reliability analysis was performed on the subscales comprising the total score used as a split half. The IDPT subsections were split into two halves so that each half was equivalent to the other half. The first half included the subtests: quantity, levels, sequence, weight, matrix, symbols, perspective, movement and volume. The second half included the subtests: seriation, rotation, angles, shadows, classes, distance, inclusion, inference, and probability. The Spearman-Brown split-half coefficient was .77, Cronbach's alpha was found to be.78.

A split-half coefficient and Cronbachs alpha were also computed for the individual questions in the IDPT. Again, each half was made equivalent, with 36 questions in each half. The value for the Cronbachs alpha was .85 and split-half coefficient was .84, indicating that IDPT has high internal reliability. The split-half coefficient found in the present study, .84, showed a higher internal consistency than reported by Patterson & Milakofsky (1980), who reported only a .71 split-half coefficient. These data suggest that the IPDT was internally consistent and had satisfactory reliability.

An additional set of analyses were conducted to determine the extent to which the UTC students compare to those who took part in the Patterson and Milakofsky (1980) study, UTC student scores tended to be slightly lower than those of the previous study. Upon looking at the mean scores of the 18 subsets of the IPDT, UTC students were lower on 16 subsets. For the subscale Weight, both the current and previous study had a mean of $\chi = 3.86$ and UTC students did receive a higher mean than those of Patterson and Milakofsky (1980) on the subset Shadows, $\chi = 3.11$ and $\chi = 2.95$, respectively. Patterson and Milakofsky rated their five most difficult subsets in the IPDT and when comparing the data of the UTC students, the top five most difficult subsets were the same but ranked in a different order. Please refer to Table 1.

Table 1

Mean Scores of Five Most Difficult Subtests in IPDT

	Present study		Patterson and Milakofsky*	
Subtest name	*M*	*SD*	*M*	*SD*
CLASSES	2.04	1.37	2.27	1.37
DISTANCE	2.26	.73	2.74	.76
ROTATION	2.18	1.39	2.96	1.07
SHADOWS	3.11	1.02	3.06	.84
VOLUME	2.47	1.28	3.25	1.03

*Patterson and Milakofsky, 1980

Bruzzese and Fisher (2003) did not conduct a reliability analysis on the Ethical Knowledge Measure. In the current study, the researcher chose to scale the measurement

and conduct a reliability analysis on the Ethical Knowledge Measure. There are five tasks within this measurement; a Cronbachs alpha was computed to test the internal consistency between the tasks. The value for the Cronbachs alpha, .65, indicated that there was internal consistency in the Ethical Knowledge Measure. Cronbachs alpha and split-half coefficients were also computed for the individual questions that make up the five tasks of the Ethical Knowledge Measure. The Cronbachs alpha for the individual question was .75, and the Spearman Brown split-half coefficient was .63. The Spearman-brown split-half coefficient and the Cronbachs alpha show that the Ethical Knowledge Measure was internally consistent and had satisfactory reliability.

An additional set of analyses were conducted to determine the extent to which the UTC students compared to the group of college age students in the Bruzzese and Fisher (2003) study. In two out of four of the tasks, UTC students reported lower means than those of the college students in Bruzzese and Fishers study. For the Rights Definition task the means were, $\chi = 7.19$ and $\chi = 7.58$, respectively. UTC students also reported a lower mean for the Rights Violation Awareness task compared to the students of Bruzzese and Fisher, $\chi = 13.8$ and $\chi = 14.20$.

Yet, in the remaining two tasks, UTC students reported a higher mean than those of the Bruzzese and Fisher study. For the True-False task, UTC students reported a mean of $\chi = 16.4$, while Bruzzese and Fisher college age students reported a mean of $\chi = 15.79$. In the Rights Labeling tasks, UTC also reported a higher mean than those of the Bruzzese and Fisher study, $\chi = 11.9$ and $\chi = 10.70$, respectively.

Predictiveness of Cognition

The relationship between cognitive development and ethics knowledge was first examined using a simple correlation analysis. A correlation was computed to determine the magnitude of the relationship between cognitive development, which is determined by the IPDT total score, and ethical knowledge, which is determined by the total score on the Ethical Knowledge Measure. The correlation between these two variables was significant, r (72) = .24, p = .043. Please refer to Table 2.

Table 2

Correlation Analysis between IPDT Total score and Ethical Knowledge Measurement (N = 73)

	IPDT TOTAL SCORE
Total Ethics Score	.043
Consent Form Comprehension	.608
Rights Definition	.151
True-False	.152
Rights Violation Labeling	.069
Rights Violation Awareness	.355

The positive relationship between cognitive development and ethical knowledge led the researcher to further consider the nature of this relationship. A multiple regression analysis was conducted to evaluate if the subscales of either variable were predictive of the total score on the other measure.

In the first regression analysis, the subscales of the cognitive development measure were used as the predictor variables and ethical knowledge was used as the outcome variable. The predicting variables were the 18 subsets of the IPDT and the

outcome variable was the total ethics score. The regression equation with all 18 subscales of cognitive development was a significant predictor of the ethical knowledge measure, $R = .63$, F (18, 53) = 1.88, $p<.039$. Based on these results, cognitive development was a predictor of ethical knowledge. Please refer to Table 3 for results.

Table 3

Regression Analysis for Variables Predicting Ethical Knowledge (N = 73)

Variable	B	SE B	β	t	Sig
(constant)	49.554	8.398		5.901	.000
Quantity	-.532	.702	-.100	-.758	.452
Levels	-.918	.664	-.191	-1.383	.172
Sequence	.892	1.252	.099	.713	.479
Weight	.990	1.440	.100	.687	.495
Matrix	-1.700	1.098	-.198	-1.548	.128
Symbols	.482	.859	.087	.562	.577
Perspective	.337	.654	.068	.516	.608
Movement	-1.614	.848	-.253	-1.904	.062
Volume	-.499	.510	-.137	-.979	.332
Seriation	1.140	1.627	.094	.700	.487
Rotation	-.488	.466	-.146	-1.047	.300
Angels	-.385	.580	-.092	-.664	.510
Shadows	.737	.655	.161	1.125	.266
Classes	.686	.447	.202	1.535	.131
Distance	1.428	.818	.224	1.747	.87
Inclusion	1.431	.676	.329	2.116	.039
Inference	-.369	.654	-.082	-.564	.575
Probability	.569	.592	.132	.960	.341

Note. Dependent Variable: Total Ethics Score

An additional analysis was conducted to determine the best set of subscales as predictors using a backward stepwise model. The four subsets of the IPDT that were found to be the best predictors of ethical knowledge are distance, seriation, movement and classes $R = .49$, $F\ (4, 67) = 5.27$, $p = .001$. These results can be seen in Table 4.

Table 4

Backward Stepwise Model to Determine Best Predictors for Ethical Knowledge (N = 73)

Variable	B	SE B	β	t	Sig.
(Constant)	43.586	5.571		7.824	.000
Movement	-1.286	.685	-.202	-1.878	.065
Seriation	2.876	1.329	.238	2.164	.034
Classes	.903	.365	.267	2.474	.016
Distance	1.333	.699	.209	1.907	.061

Note. Dependent Variable: Total Ethics Score

Next, a regression analysis was also performed with the subscale scores of ethical knowledge as the predicting variables and with cognitive development total score as the outcome variable. This regression equation proved not to be significant, $R^{=} .26$, $F\ (5, 66) = .99$, $p = .43$. Based on these results, ethical knowledge was not a predictor of cognitive development.

Discussion

The main hypothesis of this study was that cognitive development is a predictor in ethical knowledge, specifically in the understanding of informed consent. First a

reliability analysis was conducted to determine that both measures, the IPDT and the Ethical Knowledge Measure, were internally consistent and reliable.

After determining that both measures were reliable, a correlation was performed between cognitive development and ethical knowledge. Using the IPDT Score and the Ethics Score to conduct the correlation, it was shown that cognitive development and ethical knowledge have a statically significant positive relationship. Once a relationship was determined, a multiple regression was performed to determine if one of the variables was a predictor of the other.

A multiple regression was conducted with cognitive development as the predicting variable and ethical knowledge as the outcome variable. It was determined that cognitive development was a statistically significant predictor of ethical knowledge. A multiple regression was also run with ethical knowledge as the predictor and cognitive development as the outcome variable, where it was determined that ethical knowledge was not a significant predictor of cognitive development.

Through this analysis, the hypothesis that cognitive development is a predictor of ethical knowledge was supported. The data reports that there was a relationship between the two variables and that one's cognitive development is a predictor of one's ethical knowledge.

Limitations

The sample included in this study consisted of students from the University of Tennessee at Chattanooga, all of which were attending psychology courses. In order to generalize the results of this study to all students, further research would need to sample a

larger, more diverse population. Also increasing the sample size would increase the power of the results in the current study.

Time to take both measures was also seen as a limitation in the current study. Since all participants were tested during a regularly scheduled class period, time was limited to the duration of the class. Several students did not complete or were rushed through the IPDT and the Ethical Knowledge Measurement, because the class period was not long enough for them to complete all tasks. If the study were to be conducted again, the researcher would test participants outside of the class room, where there are no time restrictions due to their classes.

Also because the measurements took a long period of time to complete, the researcher believes that could have altered participants' answers on the both measures. Participants could have become fatigued or could have become bored with completing the measures. One way to avoid this situation in the future is to take each measure at two separate times. Allow a participant to complete the IPDT one day and return another day to complete the Ethical Knowledge Measurement.

Implication for Future Research

In the current study, age was determined not to be a factor in predicting ethical knowledge. But in further research, other variables should be taken into account in predicting ethical knowledge, such as gender, race or socioeconomic status.

Future research should also be conducted using the present study but with a different population, children. Using a younger population would allow the researcher to determine a better age guideline for when children have the cognitive development that allows them to have ethical knowledge.

Also, it would be valuable to see how much information a participant retains over a period of time. In the current study, participants were given the Research Participants' Bill of Rights and then immediately tested on the information. In future research, the participants could be given the lesson on the Bill of Rights and then tested on the information after a period of time. This process would allow researchers to know if participants were actually retaining the information over a period of time.

Testing the participants over a period of time would allow the researchers to eliminate the factor that participants are simply memorizing the information for a short period of time, and they would be able to test participants on how well they build the information into their cognitive structures.

In conclusion, the present study's hypothesis was to determine if cognitive development is a predictor of ethical knowledge. The findings of the present study have determined empirically that cognitive development was a predictor of ethical knowledge.

References

Bruzzese, J.M. & Fisher, C.B. (2003) Assessing and enhancing the research consent capacity of children and Youth. *Applied Developmental Science,* 7 (1), 13-26.

Crain, W. (2005). Theories of development concepts and applications (5th ed.). Upper Saddle River, NJ: Pearson Education, Inc.

De Vries, R. & Zan, B. (1994). Moral Children: Constructing a constructivist atmosphere in early education. New York: Teacher College Press.

Dugan, A. (2003). Assessing the validity and reliability of a Piagetian based paper-Pencil test. (*Masters Thesis, Wichita State University, 2006).*

Grisso, T., & Vierling, L. (1978). Minor's consent to treatment: a developmental perspective. *Professional Psychology,* 9,412-426.

Kon, A.A. (2006) Assent in Pediatric Research. *Pediatrics,* 117 (5), 1806-1810.

Kuther, T.L. (2003). Medical decision-making and minors: issues of consent and assent. *Adolescence*, 38 (150), 343-358.

Lane, C.M. (2007). Cognitive ability mediates age in children's understanding of the assent process. (*Masters thesis, University of Tennessee at Chattanooga, 2007).*

Levine, M., Anderson, E., Ferretti, L, & Steinberg, K. (1993). Legal and ethical issues affecting clinical child psychology. *Advances in Clinical Child Psychology,* 15, 81-117.

Muuss, R.E. (1996). *Theories of adolescence* (6th ed.) New York: McGraw- Hill.

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1977).

Patterson, H.O. & Milakofsky, L. (1980) A paper and pencil inventory for the assessment of Piaget's Tasks. *Applied Psychology Measurement,* 4(3), 341-353.

Perry, W.G. (1999). Forms of Ethical and Intellectual Development in the College Years. San Francisco: Jossey-Bass Publishers. Retrieved on November 20, 2008 from: http:/gsi.berkeley.edu/textonly/resources/learning/perry.html

Power, F.C., Higgins, A. & Kohlberg, L. (1989). Lawrence Kohlberg's Approach to Moral Education. New York: Columbia University Press. Retrieved on February 17, 2008 from: http://tigger.uic.edu/~lnucci/MoralEd/overview.html

Research Compliance

THE UNIVERSITY OF TENNESSEE
AT CHATTANOOGA

Institutional Review Board
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MEMORANDUM

IRB #: 06-071

TO: Avalon Gourlay
Cassie Lane
c/o Dr. Richard Metzger

FROM: Dr. Helen Eigenberg, Chair UTC IRB Committee

DATE: May 5, 2006

SUBJECT: The Role of Cognition in a Child's Ability to Assent to Research

The Institutional Review Board has reviewed and approved your application and assigned you the IRB number listed above. You must include the following approval statement on research materials seen by participants and used in research reports:

The Institutional Review Board of the University of Tennessee at Chattanooga (FWA00004149) has approved this research project (# 06-071).

Please remember that you must complete Form C when the project is completed or provide an annual report if the project takes over one year to complete. The IRB Committee will make every effort to remind you prior to your anniversary date; however, it is your responsibility to ensure that this additional step is satisfied.

Please remember to contact the IRB Committee immediately and submit a new project proposal for review if significant changes occur in your research design or in any instruments used in conducting the study. You should also contact the IRB Committee immediately if you encounter any adverse effects during your project that pose a risk to your subjects.

For any additional information, please consult our web page http://www.utc.edu/irb or email instrb@utc.edu

Best wishes for a successful research project.