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An Enhanced Model for Parental Decision Making for Pediatric Care

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AN ENHANCED MODEL FOR PARENTAL DECISION MAKING FOR PEDIATRIC CARE

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By

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ABSTRACT

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By

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Dissertation supervised by Henk ten Have, PhD, MD

Pediatric medicine, the branch of medicine dedicated to taking care of children, is a relatively new medical specialty, developing in the mid-19th century. Pediatrics emerged as society began to believe that children were different from adults and in need of specialized care. Soon after the development of specialty medicine for children it became evident that many challenging ethical issues were present with children that did not exist, or at least not to the same extent with adults. In some cases, issues are similar, however they become much more complex or challenging when applied to children. The field of pediatrics is constantly changing and developing, with tremendous advancements within the fields of genetics, neuroscience, and clinical research. Developments in these fields have led to the emergence of many new

diagnostic and therapeutic interventions for children, but with these new technologies come enhanced ethical issues and challenging decisions. Currently within pediatric medicine, decision-making processes are primarily guided by the models of adult surrogate decision making, in particular substituted judgment and best interests models. The substituted judgment model focuses on executing the wishes of the patient, while best interests asks the surrogate to select the course of action that will most benefit the patient overall. These models are ethically contested within adult medicine, the field in which they originated, and are even more problematic when applied to children, specifically mature minors with varying developmental levels. In pediatrics, the best interests standard is the typical model advocated for because children, as children, cannot legally make their own decisions, however that does not mean they should be automatically excluded from decision making processes or assumed to lack decision making capacity. These issues become larger when dealing with mature minors due to issues of agency, consent and assent, stewardship, and the vulnerable status of the child. Children are not only viewed as vulnerable by society, but many times parents as well. Many parents feel it is their obligation and duty to not only take care of their children but also advocate for and protect them. Additionally, because they are so emotionally invested and connected to the child, it is difficult to comprehend situations where the child is at risk or they are told something they never imagined or thought about, such as that their child is very sick and in need of advanced medical care. There are heightened emotions present due to the parent-child relationship. Despite parents wanting to protect their children, in most medical instances they are unable to do so, leaving parents vulnerable and full of emotion. Making decisions for another is very challenging in all instances throughout medicine, complicated even more so when the person for whom decisions are being made is a relative and a person that one strives to protect and take care of on a day to

day basis. Additionally in pediatrics many decisions have higher stakes and longer impacts, due to the age, status, and development of the child. Parents are in very challenging positions when making decisions for their children in light of the tremendous amounts of uncertainty that accompany new and emerging technologies, including obstacles that make determining the child's best interests and inevitably make a decision challenging. The addition of complicated medical information from presented by the new technologies within the fields of genetics, neuroscience, and clinical research, combined with the and heightened emotions only complicates this process, necessitating an enhanced decision making model.

As in areas of adult medicine, decisions are challenging and difficult to work through, complicated more by the lacking of explicit goals of pediatric medicine and an overarching framework to use to structure all decision making processes, which exists in adult medicine. The current decision-making models do not accommodate the fact that within pediatrics there is a long term relationship and partnership that must be created and nurtured by all those involved; decisions are therefore not isolated decisions but components of a continuum. Additionally, they do not ensure that parents receive support and guidance, identify the level of involvement of an older child, or facilitate and assist with decisions when parents and physicians disagree. Along with some of the objective elements of medicine, pediatric decision making has many subjective components, and emerging technologies create even more. On the basis of these considerations, it is argued that there is a need for an enhanced decision making model developed out of the field of pediatrics, centered around the goals of pediatric medicine. Current models need to be reconsidered in order to outline a model that enables parents to make the optimal decision for their child in light of the possibilities of emerging technologies.

This dissertation will look at the question "Why should an enhanced model for parental decision making be advocated for within pediatric care, and how can such a model be developed and applied?" In Chapter 2 the history and development of the field of pediatrics will be looked at, followed by an analysis of the current decision making models of adult medicine in Chapter 3, demonstrating that they do not apply well to mature minors and are not sufficient for pediatric medicine. In Chapter 4 the changing field of pediatric medicine will be explained, the new technologies will be introduced, and the ethical issues that the current models of decision making do not accommodate will be presented. In Chapter 5, an enhanced model of shared decision making related to the goals of pediatric medicine will be developed followed by an analysis of the roles of parties involved and how they should work together to achieve the best results for the child who is the patient. In chapter 6 the enhanced decision making model will be applied to areas of genetic screening, neuroscience, and clinical research to show how it will better facilitate decisions within these areas and address the concerns that the new technologies and developments create throughout present-day pediatrics. Pediatric medicine is in great need of an enhanced parental decision-making model that addresses the goals of pediatric medicine to ensure that the best decisions are made in the face of new technologies and the continuous advancement of care for children.

DEDICATION

To Mom, Dad, and Nick –

Without each of you and your unwavering support,

this would never have been possible!

I love you.

Table of Contents

Chapter 1 – Introduction

Pediatric medicine, the branch of medicine dedicated to taking care of children, is a relatively new medical specialty, developing in the mid-19th century. Pediatrics emerged as society began to believe that children were different from adults and in need of specialized care. Today, children receive a great deal of attention from the government, their families, and society in general, including the medical world, however this was not always the case. In the Middle Ages children were thought of as miniature adults and it was thought that society and the medical world could care for them and treat them in similar ways. The concepts of "childhood" or a "child" were not present at that time and these "miniature adults" had an ambiguous place in society. At this time children were viewed as important purely for their economic value and benefits, specifically being the property of their parents. Over time children were acknowledged as being unique and different from adults in many ways, including being in need for education and protection, however these ideas were not immediately applied to medicine and the medical care of children. For a long time adult medical practices were applied to children directly without consideration given to how they might need to be modified or adjusted to accommodate the unique elements of children. Children and adults were in the same wards or floors of hospitals, treated by the same staff in very similar fashions, including the enforcement of the rule of no visitors, including parents, after a certain time. Over time, the uniqueness and differences of children from adults were more fully developed and elaborated, leading to the specialty of pediatric medicine with its own guiding principles and an emphasis on children *as children*, not simply miniature adults. Societies slowly changed from being completely ignorant about and uninterested in children and childhood, in many instances wanting to segregate them from the

rest of the population and society, to seeing children as a central component of the family with an actual role in society and in need of protection.

The evolution of healthcare for children has been greatly impacted by society's lack of differentiation of the needs of children from those of adults, however once these differences were realized and understood, the lives of children were greatly improved. Children were no longer excluded from the medical world and received specialized attention and care developed specifically for them. Children went from being viewed as property of their parents and of economic value to individuals with rights and privileges, of significance to society. The field of pediatric medicine emerged as the conceptions and ideas about children changed but also because it came to be understood that they need their own specialized care. Preventative measures for children soon became a focus of advancement and development, emphasizing their central component to society and the strong desire to protect children. It was not only acknowledged that children are different from adults but that they are of importance and value and overall, vulnerable necessitating additional protections and measures to ensure their successful growth into contributing adults in society. These changes were the beginning of the development into the current state of society, with children as a central component with many focused efforts on protecting them from harm and best facilitating the development and growth.

The creation and development of the field of pediatric medicine did not come without challenges though. Soon after the development of specialty medicine for children it became evident that many challenging ethical issues were present with children that did not exist, or at least not to the same extent with adults. In some cases, issues are similar, however they become much more complex or challenging when applied to children. Children are not only viewed as vulnerable by society, but parents as well. Many parents feel it is their obligation and duty to not

only take care of their children but also advocate for and protect them. Additionally, because they are so emotionally invested and connected to the child, it is difficult to comprehend situations where the child is at risk or they are told something they never imagined or thought about, such as that their child is very sick and in need of advanced medical care. There are heightened emotions present due to the parent-child relationship. Despite parents wanting to protect their children, in most medical instances they are unable to do so, leaving parents vulnerable and full of emotion. Making decisions for another is very challenging in all instances throughout medicine, complicated even more so when the person for whom decisions are being made is a relative and a person that one strives to protect and take care of on a day to day basis. Additionally in pediatrics many decisions have higher stakes and longer impacts, due to the age, status, and development of the child. Parents are in very challenging positions when making decisions for their children every day, ranging from where they should send them to school, what they should feed them, as well as the core values they should teach them. The addition of complicated medical information and heightened emotions only complicates this process, necessitating a model of some kind to facilitate decision making processes.

Throughout medicine there are many challenging decisions to be made ranging from the development of overall goals of care down to the selection of a specific treatment, therapy, or medication.[1] Overall, it is well accepted that adult patients make their own medical decisions, but this was not always the case and at one time, patients relied on their physician to diagnose and select a proper course of action. Eventually, western societies gained an appreciation for personal autonomy, and believed individuals with decision making capacity should be able to make decisions for themselves in light of their personal beliefs and values through a process of informed consent. Decision making in adult medicine is based on the concept of personal

autonomy, enabling adult patients to make choices and select therapies that align with their own personal values and beliefs. On the other hand, when a patient is found to lack the capacity to make his or her own decisions that does not eliminate the need for a decision, so someone is appointed to make decisions for the patient. This appointment can occur in several ways, either by a legal document created by the patient before the loss of capacity or by legal standards of the area or jurisdiction. In these cases the individual who makes medical decisions for the patient is known as his or her surrogate. Surrogate decision makers are held to higher standards and required to act in a manner that is consistent with how the patient would have acted if capable. In most cases, surrogates may not choose to withhold or withdraw treatment when it is in the objective best interests of the patient, unless the patient has made an advance directive before losing decision making capacity. Surrogates are argued by many to be able to exercise the "autonomy" of the patient lacking capacity.[2] Despite this, it is not clear that a surrogate, or anyone, can exercise the autonomy of another individual. Ethical obligations of respect for autonomy do not extend to persons who cannot act in a sufficiently autonomous manner, so it is not necessarily and unlikely possible that the surrogate is executing the autonomous wishes of a non-autonomous patient.[3] Making decisions for another is not an easy task, as it is seemingly impossible to know what the patient would do in every instance, but surrogates are asked to do just that. In response to this, ethical standards, specifically the substituted judgment and best interests models, have been developed to guide the decision making process of surrogate decision makers so the best possible decision is made for the patient in given circumstances.

As in areas of adult medicine, decisions are challenging and difficult to work through, complicated more by the lacking of explicit goals of pediatric medicine and an overarching framework to use to structure all decision making processes, which exists in adult medicine. The

goals and guiding principles of adult medicine do not directly apply or fully capture the goals and dynamic attributes of pediatric medicine and care. The goals of pediatrics should include beneficence and non-maleficence, however autonomy cannot be directly applied or used as a guiding principal for the reasons just elaborated. Even though autonomy cannot directly be applied, that does not mean it is not important, if not crucial, to decision making in pediatrics. Some argue that parents can exercise the autonomy of the non-autonomous patient, as a surrogate would in adult medicine, however it is first, not clear that that is where the authority of a surrogate is based, and additionally, unlikely that parents could exercise the not yet developed autonomy of their child.[4] The principle is that of "respect for autonomy" rather than the exercise of autonomy, so it is possible that parents are selected as the most appropriate individuals to make decisions that would respect the child's future autonomy. These fundamental characteristics should be thought of as goals and should be incorporated into the specialty of pediatric ethics, a field that developed just as most pieces of pediatrics, out of the adult model as it was recognized that issues of pediatric medicine could not be handled in the same way as adult issues. In response to these unique challenges and considerations, a special area of ethics was developed. Pediatric ethics emerged out of the realization that issues within a pediatric ward or hospital are not only different but must be handled in a way that is not similar to adult medicine. The field of pediatric ethics emerged to handle the ethical issues of pediatric medicine created by scientific breakthroughs, research, and an increasing interest in and the awareness of children and their individual needs.[5] The ethical issues that children and their families face are different from those in adult cases and cannot be handled in the same manner, inevitably leading to the specialty and emergence of pediatric ethics and the use of pediatric ethics committees (PECs).

Throughout pediatric medicine a shared model of decision making is recommended, however due to the heightened ethical issues and dilemmas that arise within pediatrics, it becomes even more crucial that parents and physicians not only work together, but that they do so in a way that upholds both of their obligations and responsibility to the child that is the patient. Pediatric decision making involves both protection of the vulnerable child and the weighing of all of the factors in the child's life appropriately.[6] In order to do made the best decision for the child patient, all essential roles and stakeholders, specifically parents and physicians must be involved. Decisions that are made for children are not simple and carry a lot of weight. Many individuals have large responsibilities, specifically the parents or guardians and physicians, however the child and society as a whole also have impacts, although the boundaries of these impacts are not definite. Children do not have autonomy or the legal right to make their own decisions, but they are at a stage in life where they are approaching the necessary capacities that they would need for making medical decisions.[7] Because they do not have autonomy or decision making capacity children cannot make their own medical decisions however they should be involved at an adequate and appropriate level based on several factors including age and development, but most importantly the specific child him or her self. By including the child, as the patient, in decision making they are validated as individuals, they can have confidence and trust in the staff, and additionally will cooperate and comply better with their therapies, which all lead to better medical results.[8] Pediatricians, like all physicians, are supposed to place their patient at the center of their medical care and do what is both right and good for the patient. However, when dealing with children, it is not only the child and his or her interests involved. The parents and family are closely tied to that of the child, and this adds a different dimension to pediatric care.[9] In cases with minors it is unclear who the doctor should involve and whether his

formal obligations and responsibilities lie the child, parents, family, or a combination. There are many stakeholders in pediatric medicine and the opinions and conceptions of all parties must be listened to and properly balanced.[10] Although the parents legally have the final say and authority to make the child's medical decisions, ethically this is not sufficient for the best decision to be made and there is a need that all who have a role be acknowledged in the decision making process for the sick child.

In the past, physicians made most of the treatment decisions, however over time adults slowly started to argue for personal autonomy and the right to make their own decisions, inevitably based on the argument that they have a right to decide what would be done to their own body. This shift however is not one that is clear and directly applicable to pediatrics since the patient is and never has been decisionally capable or autonomous, and normally is in the process of acquiring and developing such capacity. Many parents believe that they have the right to make decisions for their children as they do for themselves, however children do not have autonomy or decision making capacity. When parents act for their children it is not clear if they are executing the autonomy of their child or potentially some kind of autonomy for the family unit.[11] Parents are not the only individuals with a stake or role in the decision making process for children. Pediatricians have a responsibility to not only give the child good medical care, and ensure that the parents have enough information to give informed consent, but also be an advocate for the child if necessary. However he or she must balance this responsibility with the additional duty to not be paternalistic and influence the decisions of parents. With the new emphasis on patient autonomy, physicians have concerns of acting paternalistic and influencing parental decisions more than they should. There seems to be a fine balance physicians must hold of telling parents enough to make the decision and not tell them so much as to sway their

decisions. Physicians and parents must be partners in pediatric medicine to ensure the best decisions are made and the highest level of care is provided for the child, however their individual roles are not well defined, and the two parties sometimes appear to be conflicting or at odds with one another. Beyond parents and the physician, the exact role of the child, who is the patient, in this decision making process is unclear. Parents, physicians, and children do not always agree or think of things in the same way, however they are all asked to work together to make treatment decisions. Additionally, it is not clear when the state, which also has interests in protecting the life of the child, can and should step in. Despite the recognition that children are unique and different, the models of adult decision making are still applied, as best they can be, to pediatrics. Specifically, parental decision-making is guided by the models of adult surrogate decision making, substituted judgment and best interests models. The substituted judgment model focuses on executing the wishes of the patient, while best interests asks the surrogate to select the course of action that will most benefit the patient overall. The substituted judgment model requires that the surrogate substitute the patient's goals and opinions for his or her own, inevitably making a decision that would emulate that of the patient. This requires a great deal of intimate knowledge of the patient and what he or she would want in a myriad of situations. The best interests model on the other hand requires the surrogate to make the best decision for the patient, with the highest potential benefit and lowest net harms. These assessments are challenging because determining benefit and burden, as well as what is "best" is challenging and has very subjective components. Additionally, it does not necessarily take into account what the patient would want or select. These models are ethically contested and challenging to incorporate within adult medicine, the field in which they originated, and are even more problematic when applied to children, specifically mature minors with varying developmental

levels. In pediatrics, the best interests standard is the typical model advocated for because children, as children, have never had autonomy or the ability to make decisions, therefore it is challenging if not impossible to emulate their decisions. Children cannot legally make their own decisions, however that does not mean they should be automatically excluded from decision making processes or assumed to lack decision making capacity. These issues become larger when dealing with mature minors due to issues of agency, consent or assent, and stewardship.

There is a great need for a new decision making model for children not only because the models of adult medicine do not apply or are insufficient but also because, first and foremost, pediatric decision making is more complex than adult decision making due to the vulnerable position of the child who is additionally incapable of making medical decisions due to the fact that many individuals are involved in the process with relevant opinions and responsibilities, but also due to enhanced emotional dimensions, and the enhanced potential and possibilities associated with working with such a young patient with ideally a long life ahead. Pediatric decision making involves both protection of the vulnerable child and the weighing of all of the factors in the child's life appropriately.[12] Children are considered to be a vulnerable population therefore parents, as their guardians, have the task of looking out for their interests and doing what is best for them in all areas of their lives including medicine. Parents are charged by society with responsibility for the welfare and upbringing of children, and responsibility for children requires having the rights for decision-making for them.[13] Parents know their children in ways that others cannot. Personal gut feelings and observations over time are valuable in ways that go beyond medical "test" in many ways.[14] Overall, parents and their children have a special relationship and bond that is distinct from the relationship that the child will have with others.[15] This bond is one of the main reasons that parents are argued to be the best decision makers for

their children, specifically that they know them better than anyone else. In most cases, that is arguably true, however parents cannot do anything that they want and they additionally have obligations to their children that they must uphold. While making medical decisions for their children many parents have noted feeling isolated, ostracized, misunderstood, overwhelmed. Parents making medical decisions for their children are already in an extremely difficult and undesirable position, and by adding all of the ethical dimensions of pediatric medicine including the new array of technologies available and the additional levels of uncertainty, it becomes more challenging and burdensome.

The delicate balance of the involvement of relevant parties in the decision making process becomes even more challenging in light of the many advances within pediatrics and modern medicine including the use of new technologies and additional therapies. Pediatrics has always been a field full of innovation and advancement, however within the past decade tremendous progress has been made in several crucial areas, saving and improving the lives of many children, but additionally presenting enhanced ethical challenges. The fields of genetics, neurology, and research all are expanding at an exponential rate, with promises of enhanced therapies, earlier or more accurate diagnoses, better care, and inevitably improved quality of life.[16] Within the field of genetics common practices such as newborn screening, which have ethical issues in and of themselves, now have the potential to be coupled with the increasingly more affordable practice of whole genome sequencing (WGS), which could be additionally utilized at later points throughout the child's life. Genetic screenings bring new prediction tools to the table, many times for conditions without therapies, clear medical significance, or a complete understanding of future implications for the life of the child in society. Children began to be screened at birth after the development of a simple test to identify PKU, and the panel has

steadily increased to include anywhere from 20-54 conditions, some of which have no therapies, despite recommendations from many groups to only test for disorders with available and accessible treatments. Other groups argue additional benefits other than therapy, such as planning for the future or identifying subjects for research, making it unclear if it is in the child's interests to be screened or not. With the addition of WGS the therapeutic gap will be increased drastically, identifying children with disorders lacking therapies, those that do not develop until adulthood, or those with misunderstood clinical significance, including the fact that even when a mutation is found it is uncertain whether the child will develop the disorder, it is just a possibility. The space between what tests can identify or diagnose and those that have valuable and available treatment options to mitigate or even eliminate the disorder has grown exponentially in recent years, and only will continue to do so as science progresses.[17] Deciding what should and should not be screened for becomes a much bigger issue with the decreasing costs of whole genomic sequencing (WGS), and the possible detection of a multitude of diseases, and can be utilized at birth or later in life. Genetic testing is becoming an important diagnostic tool in medicine, making discussions of determining benefit and burden crucial, as well as the creation of regulations and a decision making model to guide their utilization.

Another field that has seen tremendous growth is that of neurology. Neuroscience is the study of the brain and nervous system, encompassing many aspects, from molecular and cellular biology, to psychology and behavior.[18] Neuroethics is a recently developed field that focuses on the ethical and legal issues and societal implications associated with neuroscience and the rapidly developing technologies of the field.[19] The creation of its own subset of ethics emphasizes the critical decisions and challenging issues that arise in the field, made only more complex when applied to children. Neuroscience has led to many innovations in clinical medicine that have not

only therapeutic but also non-therapeutic dimensions, all with ethical implications.[20] Some of the controversial developments of neuroscience are functional neuroimaging, brain mapping, psychopharmacology, and enhancement opportunities with the potential to impact behavior, personality, and consciousness. Current researchers are beginning to identify brain processes that are related to experiences and concepts such as free will, agency, moral judgment, self and personality.[21] New techniques for monitoring and manipulating brain functions are developing rapidly but it is not clear how these tools and interventions should be used together.[22] It is currently not known how all of the different systems of the brain interact, or what a particular brain abnormality can predict about an individual, and it is further unknown how intervening in these systems can affect the beliefs, desires, intentions and emotions that constitute the human mind.[23] Other issues of neuroethics arise when dealing with individuals with disorders of the brain including developmental and neurological disorders and new ways to assess, diagnose, and potentially treat them.[24] New technologies have increased the burden on the physician to obtain informed consent in theses scenarios and additionally challenges them to refuse treatment when inappropriately demanded or when there is unclear benefit to the patient..[25] Due to these uncertainties careful consideration must be given and precautions must be taken, but this does not mean that the field should stop expanding or developing new technologies. When dealing with the brain, there are many issues that arise immediately, even before the introduction of technologies and therapies. Many people have personal ideologies and conceptions of the brain, including those of the self, free will, personal choice, and even personality and consciousness, and when something challenges that or even presents new information, it raises concern and the need for extra considerations.[26] Technological advancements of neuroscience, just as those of other fields of medicine, bring with them both new possibilities and new problems to address.

The field of neuroethics looks specifically at resolving these issues so the positive outcomes of the technology can be utilized.[27] Neuroethics has emerged to address the theoretical and practical issues of neuroscience that have moral and social consequences in the laboratory, health care, and society.[28] Neurotechnologies such as brain scans, fMRIs, transcranial magnetic stimulation, or the placement of brain chips all carry with them questions of personhood and identity of the child, and issues of how to handle incidental findings.[29] Currently genetic screening is being used to identify many neurodevelopmental disorders, however in addition the findings of neurotechnologies such as brain scans and functional MRIs are associated with psychological and social disorders, labeling children with conditions such as autism, ADHD, schizophrenia, and bi-polar disorder.

The final area, pediatric research, is additionally expanding at a tremendous rate. Pediatrics is drastically changing because of clinical research trials in many areas, including the areas of genetics and neuroscience. Research with children has always raised ethical issues, and much has been published on how research with children must be conducted. A great deal of regulations and oversight exist to improve understanding and guide research, however current studies still show great misunderstandings of parents about the basic elements of research and the specifics of the trial. Ethical issues only increase as more and more research trials are being developed to include children who are healthy or without a terminal illness. Typically research of the past has focused on children with irreversible or terminal conditions, and research trials were in some ways a last resort for parents. However when the research extends to include seemingly healthy children, it is unclear if parents should or even can enroll their child. Studies have shown that parents have a hard time comprehending many aspects of research trials. Greenly and colleagues found that parents did not understand the concept of randomization or random

selection, specifically that their children may not receive a specific drug or intervention, being part of the control group.[30] Parents also did not fully comprehend the different phases of the trial, overall putting into question their actual consent for the child to participate in the study.[31] This emphasizes the other issue of clinical research in that many assume there is a medical benefit purely because it was offered to them by a provider who, in most cases, has the goal and intention of treating illnesses. A key component of informed consent in medical research is the understanding that the research trial is not the same as treatment, however this was not what most studies found in practice with parents consenting for their children.[32] Research with children is possibly the most troubling area of development for the current decision making models as it encompasses the issues of both genetics and neuroscience, highlights the vulnerable status of children, makes it possible that they will be exploited, and makes issues of therapeutic and non-therapeutic interventions immediately more troubling. There are many legal and ethical issues associated with vulnerable populations such as children, especially those with genetic, neurological, or developmental abnormalities making conducting pediatric research challenging.[33]

The areas of genetics, neuroscience, and clinical research are associated with uncertainty (medically, ethically, and socially), placing parents in difficult positions, and necessitating a new model to facilitate interactions between all involved to assess and determine the best interests of the child while acknowledging the ethical dilemmas and issues that arise every day. Parents are in a unique emotional position when making decisions for their children, however the addition of new technologies make these issues even larger, with potentially greater implications and levels of uncertainty.[34] As science and technology progress, increasing numbers of options are added to the range of therapies or treatments that can be provided for children. It is up to physicians to

give parents adequate information to make decisions, and then the parents will be able to decide, however there are not many guidelines for either of those tasks. With the addition of new uncertainties and possibilities, and sometimes unrealized impacts, these decisions begin to carry even more weight than the already challenging and complex decisions throughout pediatric medicine. New therapies bring more challenging decisions, leaving parents in difficult positions and physicians unsure of how to help or guide decision making processes. There is not a sufficient decision making model to help parents to make decisions. In most cases, the models of adult medicine are applied to children, specifically the best interest standard, and parents are asked to make decisions that are in the best interests of their child. However these models do not provide much structure or guidance or even inform the parents of who should be involved in the process and at what levels they should be involved, making these models insufficient for pediatric medicine. Decision making is a significant concern in healthcare, especially when the patient is unable to make his or her own decisions, and this becomes even more challenging when making decisions for children. Best interests determinations are very difficult to make in any area of medicine, even more so in pediatrics where the decision maker is not the patient him or herself, and additionally the patient never had decision making capacity or a life to judge things upon to make decisions. In these instances it is unclear what parents should consider or take into account when making these determinations.

These issues of pediatric decision making not only need more attention, but they require a model developed specifically within the field of pediatrics, rather than introduced and applied from adult medicine. A new model must identify the roles of all relevant parties to the decision making process and specifically outline how they should work together to achieve optimal care results for the child in light of the enhanced ethical dimensions of new technologies. There are

many studies that examine how parents made decisions and worked with the physician, however none of them specifically look at emerging technologies, whereas many deal with end of life, or life threatening conditions. The ethical issues become enlarged when the child is not in a life or death position, and parents are making decisions that carry with them a lifetime full of potential burdens and possibilities. As technology grows at an exponential rate, a new model is required that facilitates and guides parents, physicians, and children together through uncertainty and challenges that were not present twenty, ten, or even just a few years ago. The issues of modern pediatrics are not going away, quite the contrary, they appear to be developing at a rate much faster than ever before, making it necessary to have a model to adequately handle and facilitate the ethical decisions in regard to new technologies.

Overall, parents are placed in an incredibly difficult position when asked to make treatment decisions for their children, especially when there is not an adequate model that provides sufficient support or guidance to facilitate decisions. With an unclear basis for decisional authority, and an insufficient way to manage the ideal "shared" roles of all involved in pediatric care and to determine the child's "best" interests, parents are left many times feeling unsupported or lost when presented with uncertainty and a multitude of options, or even overshadowed and insignificant by a potentially overbearing physician. This is not even to acknowledge the undefined role of the opinions and feelings of the child, and how it is taken into account throughout the process. There are not clear roles for all involved in decision making in pediatrics, especially with regard to decisions surrounding the utilization of new technologies. It is not clear if parents have a right to know everything about children, when they need to ask for more information or another opinion, or what to consider and weigh in the decision making process. It is additionally unclear how much physicians should tell parents and how to involve

the child in the decision making process. To address these questions, a new model and conception of shared decision making will be necessary to support the complexities and uncertainties of technology, accommodate the many stakeholders, and ensure overall understanding. Decision making is challenging in all areas of medicine, but it becomes even more complex with new and emerging technologies in the field of pediatrics.

It is argued that neither model of adult medicine addresses the conflicting roles and dimensions of pediatric medicine, especially with the enhanced complications and issues of emerging technologies with tremendous possibility but also uncertainty and unclear benefits and burdens. With these new and emerging technologies there are additional considerations, uncertainties, and obstacles that make determining the child's best interests challenging. The current decision-making models do not, for example, accommodate the fact that within pediatrics there is a long term relationship and partnership that must be created and nurtured by all those involved; decisions are therefore not isolated decisions but components of a continuum.[35] Additionally, these models do not ensure that parents receive support and guidance, identify the level of involvement of an older child, or facilitate and assist with decisions when parents and physicians disagree. Along with some of the objective elements of medicine, pediatric decision making has many subjective components, and emerging technologies create even more. On the basis of these considerations, it is argued that there is a need for an enhanced decision making model developed out of the field of pediatrics, centered around the goals of pediatric medicine. Current models need to be reconsidered in order to outline an enhanced model that enables parents to make the optimal decision for their child in light of the possibilities of emerging technologies.

This dissertation will look specifically at the question "Why should a new model for parental decision making be advocated in pediatric care, and how can such a model be developed and applied?" In chapter 2, it will be explained how pediatrics emerged out of the field of adult medicine, looking at the changes in the conception of a child leading to the inevitable creation of pediatric medicine as its own field of medicine. Following that development it will be looked at how the field expanded with an emphasis on protecting children, with the development of preventative measures. Once the field had emerged, it led to the need and creation of the sub discipline of pediatric ethics and the articulation of the goals of pediatrics as distinct from those of adult medicine. All of these components show how pediatrics developed and emerged, leading to the field as it is today. Then, in chapter 3, the current decision making models of adult medicine will be analyzed and critically examined, demonstrating that they are not sufficient for pediatric medicine because they do not adequately support all roles involved in decision making processes or accommodate the child patient, especially adolescents into the process. Pediatric medicine requires its own decision making model, addressing the unique elements of pediatrics. In the fourth chapter, the changing field of pediatrics will be elaborated, focusing on the changes and developments of the field, with great promise to enhance the lives of many children, but also with many more ethical issues that the current decision making models of pediatrics cannot handle, making a new model necessary. These ethical issues will be expanded here including those surrounding informed consent and assent, the therapeutic gap, uncertainty, privacy, future implications, and enhancements. Emerging technologies within pediatrics have added more complexities and challenging decisions to the field, placing parents in even more difficult situations that current models of decision making do not address. In Chapter 5, an enhanced model for parental decision making, related to the goals of pediatric medicine will be developed.

This will be followed by an analysis of the roles of parties involved. The enhanced model looks at the roles of parties involved and how they should cooperate to achieve the best results for the child who is the patient when making decisions and best interests determinations with regard to the use of technologies. In Chapter 6 the new model is applied to areas of neuroscience, genetics, and clinical research to show how it will better facilitate decisions within these areas and better address the concerns that the new technologies and developments create throughout present-day pediatrics. This chapter will review the importance of the model to accommodate the ethical issues in those fields and overall facilitate decision making processes. Pediatric medicine, as a field of continuous growth and advancement, is in great need of an enhanced decision-making model to ensure that the best decisions are made in the face of new and emerging technologies and the continuous advancements in care for children.

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Chapter 2 - Background and History

2.1. Introduction

Children make up a large part of society throughout the world, although their specific role and significance has only been realized over the past few centuries, giving them a more central and defined place in society. Pediatric medicine, the branch of medicine that specifically takes care of children, emerged over time in response to this realization and the slowly developed conception that children are different from adults. Children in modern society receive a great deal of attention from the government, their families, and society in general, including the medical world, however this was not always the case. Children were not ignored or unacknowledged in previous societies; they were simply not seen as children or different than adults. Societies went from being completely ignorant about concepts and ideas of children and childhood to seeing them as a central feature of the family and in many cases, even society.[1] This development led to the realization that children have unique needs and require specialized care, thereby leading to the emergence and development of the specialty of pediatric medicine. Once specialized care developed for children, it quickly became evident that there were many issues, problems, and scenarios that are uniquely present within pediatrics, requiring new regulations, medical standards, and eventually, ethical standards. These new regulations and standards, created from adult medicine rather than the field of pediatrics, do not directly address the specific elements of pediatric medicine, including the relationship between or responsibilities of parents, physicians, and the child him or herself. The unique situations present in pediatric medicine, however, combined with the tremendous focus on and utilization of emerging technologies and interventions, necessitate special attention and new ways to determine courses of action and to make decisions.

Children are not simply miniature adults, and are no longer treated as such in society, however the models of adult decision making are still utilized by parents to make decisions for their children in many instances. In order to argue against this, it will first be pointed out that pediatric medicine developed directly from the field of adult medicine, creating problems for the field and inevitably parents, physicians, children, and even society. This chapter will first look at this development and the inevitable creation of a place in society for children by looking at the changes throughout history and the emergence of concepts of "child" and "children." The place of children in society, though arguably still somewhat ambiguous and ill defined, directly led to the emergence of pediatric medicine as it was recognized that adults and children needed and deserved distinct medical care. These ideas encouraged the development of measures to protect children, such as child labor laws, education mandates, and a shift in focus within pediatric medicine to preventative measures. These preventative measures will be looked at in the next section to elaborate the initial focus and direction of medicine, emphasizing the importance of children and the inevitable focus throughout pediatrics of doing everything possible for children. Before looking at the preventative measures it will be discussed how the field expanded, specifically with the utilization of research with children. The final section will briefly introduce the ethical issues unique to pediatric medicine, the overall goals of pediatrics, and the inevitable creation of pediatric ethics. These goals will be used to reframe the way decisions should be made for children to explicitly address the unique needs of children as well as the sometimes conflicting relationships and responsibilities of all involved. This argument will be fully developed in a later chapter, but will be briefly presented here to emphasize differences from the goals of adult medicine. Pediatric medicine has slowly distanced itself from adult medicine making tremendous progress and advancements in the specialized care of children, however this

needs to expand to the decision making process. Making decisions should not be done in the same way as in adult medicine.

2.2. Development of Pediatric Medicine

Pediatric medicine developed in response to the recognition that children were different than adults, and should be treated as such. Prior to this realization, children were viewed as miniature adults, and not seen as valuable members of society or families. However, over time, these views changed and it was recognized that children were in fact unique and different than adults. This change in perception is clear by looking at the historical trends of art, literature, clothing, as well as the education practices of children. This first section will look at these developments, and explain how the views of children changed, concepts of childhood and adolescence emerged, and inevitably, the specialty of pediatric medicine was born. The next section will look at the emergence of the field of pediatric medicine and discuss how it developed out of adult medicine. In the final section, some of the unique elements of pediatric medicine, as well as the emergence of pediatric ethics, will be introduced and it will be argued that the goals of adult medicine do not directly apply, and specific goals and principles are needed within pediatric medicine. The changing views of children led to the creation of a specialty of medicine for children with adult medicine as a base. This was not wrong and has inevitably saved the lives of millions of children, and slowly led to the development of therapies and practices specifically for children, however that was not initially how it was. Most concepts of adult medicine were initially applied to pediatrics and then modified to accommodate the child. Therefore, it will be argued in this chapter that the same is true for the goals and guiding

principles, leaving room for enhancements and goals that specifically address the unique elements of pediatric medicine.

2.2.1. Changes in Views of Children

Throughout history the concept of childhood has not always been present and it was not until the past few centuries that it was acknowledged that children are different than adults.[2] Over time, the views surrounding children changed and there was an increased desire to study and realize these differences.[3] It was not until the previous two centuries that emphasis was placed on the period of childhood and defining concepts of child and adolescent. During the Middle Ages a period of "childhood" did not exist and it was thought that infancy was followed immediately by adulthood. Words for "child," "childhood," or "youth" did not exist, and children were considered to be miniature adults, dressing in a similar fashion and expected to work for money at a young age.[4] It was hard to classify or define these concepts since childhood is different for each child and it is a changing and temporary state.[5] Even though children were present in almost every period of history in some way, which is evident by looking at art and literature, they were not labeled as children or thought of as different.[6] During the Middle Ages, some laws were created which prohibited infanticide and the selling of children into slavery, however they were not strictly enforced.[7] At that time, children were more akin to property than actual persons, valued primarily for their economic benefits and the potential of what they could grow in to, specifically a "normal" adult.[8] During the Middle Ages, children were not mentioned in literature and were almost completely absent from art.[9] Children appear at the end of the Middle Ages during the 13th century, but evidence of emerging and changing ideas surrounding children became much more noticeable by the end of the 16th and throughout the 17th century.[10]

The increasing prevalence of children in art and literature, combined with the changing and emerging patterns of dress and education for children show the transition of ideas surrounding children, inevitably leading to them being recognized as different than adults.[11] During the 16th and 17th centuries ideas of children needing additional attention and protections arose, however only among the upper class.[12] The lower class, still needing children as sources of income, still viewed children as little adults. This change is apparent by looking at art and distinct changes in the dress of upper class children.[13] Children of lower classes continued wearing the clothes as adults and depicted as such in art, however children of upper classes began to wear robes and false sleeves, drawing attention to them as being different from adults. The uniqueness of children was first prevalent among the upper classes, however in the late 19th and early 20th century, the idea began to spread to the lower classes, and slowly, the concept of childhood emerged.

Once a concept of childhood emerged, the situation of young persons in society began to change and concepts of their innocence and vulnerability led to a desire to protect and shelter them from the adult world. Scarre noted that men should be treated as men, and children should be treated as children.[14] In 1836, the first versions of child labor laws passed in the US, requiring that all children under the age of 15 working outside of the home attend at least three months of school.[15] Slowly, societies and families began the separation of children from the rest of the adult world, starting with identifying them as children, and then by sending them away to school, to their own "world." During previous centuries, children were educated in the home, however as it was acknowledged that they needed protections and assistance in their development to adulthood, parents began sending their children to day schools or in some cases, boarding schools far away.[16] Beginning at the end of the 18th century and continuing throughout

the 19th century, boarding schools were a common choice by parents, as an increased desire to separate children from society developed in order to facilitate their proper development and transition into adulthood.[17] A wide array of social institutions for children including schools, reformatories, orphanages, foundling homes, and asylums, and hospitals arose and in a way, replaced general society for children.[18] This idea of a substituted society slowly disappeared as boarding schools became less popular and there was a shift to day schools for children by the end of the 19th century and children started to find a place in society, specifically within the family. Towards the end of the 19th century, children were not only viewed as vulnerable and in need of protections and proper preparations for adulthood, but as an integral part of the family.[19] This transition in place in the family is evident by looking at the changes in the portrayal of the child in family portraits and art. Prior to the 19th century, children were either absent from family portraits or portrayed as an infant in their mother's arms, regardless of their age.[20] However during the 19th century, a much more accurate family portrait developed and in many cases, planned around the child. At this time, the idea of children being an important part of the family emerged, an idea that continues in many modern societies. Societies came to believe that children were not only unique and different from adults, but also a central piece of the family, vulnerable, innocent, and in need of protections. Societal changes greatly impacted the advancement of views of children creating enhanced social protections.[21] Social movements and legislation brought attention to the special needs of children, leading to the implementation of stricter child labor laws to protect children and prevent them from entering the workforce too young and better facilitate the transition to adulthood.[22] These laws attempted to implement the fundamental rights and obligations societies have towards children, highlighted by the 1989 UN Convention on the Rights of the Child and the Children Act of 1989, which gave children more

of a voice and additional protections within society.[23] In addition, in England and Wales the Children Act of 2004 and the Children Act of 1989 have seen increasing amendments and changes giving children more of a voice and creating additional protections for them within society. In response to all of the changes, the European Academy of Pediatrics (EAP) was created to promote the health of children as well as to alleviate suffering from diseases in infancy, childhood and adolescence up to the completion of growth and development, both within and outside the confines of Europe.[24] Other protections were put in place outlining an age of responsibility, ensuring that children take some kind of responsibility for their actions, but also acknowledging that children are vulnerable, still learning and growing, and in need of protections from minor wrongdoings, giving them the chance to change.[25] Many argue that children have a right to an open future, a right that must not be violated to ensure their development and ability to make choices to shape his or her own life. The idea of an open future closely relates to ideas that children have a right to self-determination, specifically that they can develop into autonomous adults.[26] Despite these claims, it is not argued that they should be given autonomy in their decisions or that they can guide all aspects of their lives, but rather that their futures are important and that they should be empowered to work to a successful future and not make decisions now that would negatively impact their future self-determination or autonomy. Throughout the world there has been an increasing amount of attention given to children and legislation passed to ensure that children are protected and advocated for and have a place within society unique from adults.

Central to their reasoning for the new legislation and protections is an acknowledgment of the child as a human being, as an individual greatly influenced by his or her environment and deserving of respect.[27] In deserving respect, children should not be treated as a means, but rather,

as developing persons and individuals who have actualized some of the characteristics associated with adulthood.[28] Throughout the world, attention has been given to children to ensure that they are protected, advocated for, and have a defined place within society unique from adults. Although it was acknowledged that children were different from adults and society created protections and opportunities for them, it was not entirely clear what a child was, or what exactly was meant by "child" or the period of "childhood." Throughout the world different definitions of childhood exist, for instance, in some places individuals can participate in government and vote as young as 16, while in others not until 21 or 25. Despite these differences in practices, there is some general agreement that the transition from child to adult occurs at 18 years of age.[29] The age of consent for medical treatment or therapies however, like voting, is different in different countries, and even in different places within some countries, such as in the United States where such decisions are made by state not federal regulations.[30] Within the UK, there is not a single law that defines the age of a child, however the United Nations Convention on the Rights of the Child, ratified by the UK but not the USA, states that a child is "every human being below the age of eighteen years unless, under the law applicable to the child, majority is attained earlier."[31] [32] In the UK, specific age limits are set out in relevant laws such as voting or issues of consent, but there is not one age where childhood stops across the board. There are also differences between the UK nations, for instances, England, Wales, Northern Ireland and Scotland each have their own guidance setting out the duties and responsibilities of organizations to keep children safe, but they generally agree that a child is anyone who has not yet reached their 18th birthday. Despite the agreement over 18, in all countries there are exceptions, different ages for voting, military service, consenting to medical treatment, research, and even sex. Even if at age 18 a child transitions to adulthood, it is not a clear if this change occurs the

day he or she turns 18, approaches it, or hits a certain threshold, placing children approaching the age of adulthood in an even more vulnerable and ambiguous place. There is not agreement about how to define the stages or development process of the child, specifically the transitions from infant, to child, to adolescent in relation to being under the control of their parents.[33] Children between the ages of 12-18 are still considered minors, and subject to their parents decisions, however they are in a transition period, often referred to as adolescence, with very unclear implications on the parent-child relationship and the role of each in the process.[34]

Legally in most places parents are thought to be guardians of their children, empowered to make choices and decisions for them until they reach adulthood.[35] Further, due to the ambiguity of the exact transition to adulthood, society, in need of a legal decision maker, typically defers to parents. Societal deference to parents as decision makers for their children rests on the respect for the integrity of the family, and the assumption that parents act in their child's best interests, however many decisions made by parents fall into gray areas, and it is not clear what will or will not benefit the child.[36] The idea that parents have total control over their children as they had in previous centuries is no longer as prevalent however the explicit role of parents is not well defined.[37] Society typically gives parents a great deal of autonomy to make decisions for their children, although there are regulations that prevent parents from causing harm to their children and allowing the government to step in in these instances.[38] This then leads to the other large issue of when the parent's actions have crossed a threshold that warrants a societal intervention. There is much disagreement surrounding this threshold and a delicate balance of state and parental rights, both arguably working to protect and advocate for the "best" overall health and wellness of children and promote their wellbeing and transition into autonomous adults.[39] It can be argued that the goal of the state interventions should be to respect

reasonable decisions made by parents for their children, leaving significant legal space for reasonable differences of opinion, beliefs and values.[40] Brock and Buchanan argue for state intervention when parents abuse or neglect their children making them unacceptable parents, further arguing that the focus of parental choices and decisions should be on the current and future interests of the child only. Parents may not be the best decision makers for their children due to potentially large conflicts of interest that can exist, therefore parents should legally only be able to make decisions that will benefit the current and future interests of the child, without taking other factors into account.[41] Ross however, disagrees with this, arguing that parents should have more authority to make choices for their children and families, raising them in the way that they see most fit with minimal interventions from outside sources.[42] Ross argues for parental autonomy based on the intimate relationship between parents and their children, and the natural desire to do what is best for the child. She believes that parents must provide for the basic needs of the child and uphold a threshold of "primary goods" for their children, but beyond that, parents should be allowed to do what they want.[43] Further, Ross makes a distinction between the autonomy of the parents and that of the family, arguing that parents should be able to take into account and pursue goals of the family, based on family autonomy, provided they do not require the sacrifice of any member's basic needs.[44] It is hard to separate the goals of the child immediately from the goals of the parents, and additionally, there are things other than the immediate and future interests of the child that impact the lives of the parents.[45] There is much debate surrounding what both the state and parents can and cannot do, when parents should be left alone, and when the state should step in.[46]

Much discrepancy exists about what rights children should have from both a humanistic and legal perspective, and further, if any of those rights should be guaranteed by society.[47]

Vardin and Brody believe that society has a duty to work as the child's advocate in some instances. Children should be respected and treated as whole and complete individuals, in and of themselves. Children deserve the same respect as adults, however it is unclear how this translates into rights. Some believe that they should be treated fairly and given the same respect and potential rights as adults, including the right to information, self-determination, alternate home environments, education, freedom from physical punishment, sexual freedom, economic power, and the right to justice.[48] To not allow them these freedoms and show them the same level of respect as adults could arguably further their dependence, incompetence, and vulnerability.[49] Even more extreme arguments have been made that children should be freed from their parents' legal authority and limitations, and in turn, parents be freed from the burden of complete responsibility for their children's behavior.[50] Although this is extreme and not argued for here, it emphasizes that disagreement exists about the exact roles of parents and society in the lives of children. Children are not property, however they are not fully autonomous individuals allowed to make life decisions, so their place in both society and the family is slightly ambiguous and unclear.[51] There further may be situations when the child, specifically during the period of adolescence, should have the ability to make decisions, and parental authority should be limited.[52] It is further argued that because all children develop at different paces, capacity or the ability to be involved in decision making processes should not be dependent upon chronological age, but rather capacities.[53] These ideas will be developed further in later chapters, looking at what capacities should be evaluated and the developmental stages children go through. However it will be emphasized that although children were given a place in society, that place has not been explicitly spelled out, nor the roles of society or parents.

2.2.2. Emergence of Pediatric Medicine

Pediatric medicine emerged as a specialty of medicine as the views of children developed and society realized that children need specialized medical care. The previous section explained how children were initially thought of as miniature adults and only as valuable for what they could become, not what they are. Over time, this view slowly disappeared and children received increasing attention throughout society, leading to the inevitable creation of the specialty of pediatric medicine, a specialty that is less than 200 years old.[54] Prior to the creation of the specialty field of pediatrics, children and adults were cared for in the same way, and specialized medical training for physicians or caretakers did not exist. However, as children became a focal point of attention within society, the medical world realized that the differences between adults and children were significant and eventually developed specialized care for children distinct from the care of adults. Children were not only different, but they were an underserved population in need of social institutions including orphanages, infant asylums, dispensaries, and hospitals, launching the initial phases of the field of pediatric medicine.[55]

The history of medicine and children began with references to specific childhood illnesses and conditions in texts dating back to the ancient Egyptian, Greek, and Roman physicians, however, these references were more observational in nature rather than addressing the unique natures of children or ways to take care of them.[56] Discussion of children and their illnesses became larger in the 1400s after the invention of the printing press when books were published discussing medicine and children for both physicians and the general public.[57] These publications however, did not address the ways in which children were different than adults or unique, or the ways in which physicians or medical professionals should care for them, but rather the specifics of their illnesses and the overall course of diseases.[58] The development of the field

of pediatrics was international however it did not begin in North America until the 17th century.[59] At that time, medicine in general was a mixture of religion, folklore, and scientific principal, and there was little if any understanding that children were a special group with distinct medical needs, let alone how to care for them in a meaningful way.

Over time, as children developed a place in society and were studied as a unique population, they slowly began to receive more medical attention, but not right away. In 1840, 30% of the population was under the age of 10, but only 50% of them survived to adulthood due to infectious diseases and epidemics. In addition, infant mortality rates were sometimes as high as 99%.[60] Although it was recognized that children were a special population, they did not receive a great deal of medical attention as less than 0.1% of hospitalized patients were children, and when they were, it was within adult wards in the same manner as adult patients. This lack of distinguishment of children from adults and a general concern over the lack of medical services for children, led several physicians in Dublin to start the first English-speaking hospital, the National Children's Hospital, in 1821 devoted exclusively to the care and treatment of sick children.[61] One of the founders of the National Children's Hospital in Dublin moved to London thirty years later and helped launch the Great Ormond Street Hospital in 1852. Then in 1855 the first children's hospital opened in the United States in Philadelphia, PA. Soon, pediatric hospitals began showing up in all of the big cities and the field of pediatric medicine became a specialty with its own training programs launching around the world. Then slowly pediatric medical schools and nursing programs began to develop. The first school of pediatric nursing began at the Children's Hospital of Philadelphia in 1895 and by 1900 more than half of the US medical schools had dedicated chairmen of pediatrics.[62] Additionally, pediatric medical societies such as the American Pediatric Society (APS) developed in the United States and Europe, and

children received more attention in academic medical writings, including journals and textbooks.[63] Soon after, the American Medical Association acknowledged pediatrics by adding a section on diseases of children in 1880, further giving credibility to the specialty.[64] The APS pursued many strategies to improve the care of children and standards of pediatric medicine and attempted to link the APS to the Association of American Physicians, connecting pediatrics to the upper strata of American medicine, deserving elite status within medicine.[65] With its initial start in Dublin, pediatric hospitals began opening around the world in response to a growing interest in children, solidifying the emergence of pediatrics as a distinct and arguable elite specialty of medicine.[66]

The launch of specialized hospitals and education were among the first big steps in the development of pediatric care and medicine. It was the beginning of a period of history in which children were not thought of as property of their parents and incomplete organisms. They further had a bit more status and warranted their own specialized medical care. The creation of pediatrics established children as beings in and of themselves with unique needs, no longer ignored, however it did not solve all problems. Despite the creation of children's hospitals and specialized pediatric wards separating children from adults, there were still many issues related to not fully comprehending and understanding the ways in which children were different than adults. During the initial phases of pediatric medicine, physicians cared for children in the same manner as adults, applying many of the same regulations, practices, and delivery methods from adult healthcare directly to the care of children.[67] One of the biggest problems was the enforcement of adult visitation hours, limiting the time parents could spend with their children and in many instances keeping children from parents all together.[68] Before the development of antibiotics, visitation was limited in adult wards to prevent the spread of diseases, however even

after antibiotics were developed, parental visits were kept at a minimum because, as in adult medicine, visitors were thought to upset the patient and disrupt the routines of the ward. Then in the early to middle 1900s researchers became aware of the emotional effects of isolation of children from their families on medical outcomes and new policies and practices emerged.[69] In 1986 the American Academy of Pediatrics said that the design of pediatric environments may need to be changed to accommodate the emerging philosophies of care-by-parent and family-centered care.[70] Over time, parents became a "necessary nuisance," and an important component in the smooth hospitalization and best care of a child. In the 1960s Pediatric Intensive Care Units (PICUs) began to flourish, initially with restrictive visitations as well, but that too changed eventually as it was realized how much family centered care impacted children and their results.[71] By including the family in every phase of a child's care involved benefit, including the patient, family members, hospital staff, and the overall community. In light of these realizations and new research studies, family centered care became a major piece of pediatric medicine.[72]

The family is not the only crucial component of pediatric care that emerged over time. Pediatricians, specifically physicians focusing solely on the treatment of children, soon emerged and became central to the care of children. During the initial phases of pediatrics, physicians received little financial gain from working with children and most of the initial children's hospitals were run by charities and dependent on philanthropy. However many physicians went into the field out of a desire to help children.[73] Pediatrics developed to bring medical care to the underserved population of children, and there were many practitioners who wanted to do this, regardless of the financial incentives. Money was not the only major difference between physicians and pediatricians; pediatricians have a very unique role that physicians of adult medicine do not always share, not only caring for sick children but also maintaining support for

and communication with parents and potentially an entire family.[74] Pediatricians not only had to know how to medically care for the child, but also understand the social and developmental stages of childhood. Additionally, they have to present all medically reasonable alternatives to parents, including what is not only possible but reliable.[75] Pediatricians became a source of advice and guidance on not only the medical care of the child, but also the observation of healthy children, and the overall management and rearing of the child, taking on the role of a child and family advisor in the 1930-1940s.[76] By 2000, 216 pediatric training programs with more than 15 subspecialties emerged and there were more than 7500 residents and 60,000 fellows in the American Academy of Pediatrics.[77] Although the role of the pediatrician is necessary in modern society, with parents scheduling appointments with pediatricians before they even have the baby, there are still many issues faced by pediatricians including their undefined role in the relationship with parents and the child, elaborated in a later chapter.

Despite some of the initial challenges, the field of pediatrics has led to tremendous improvements in the health of children.[78] For example, when pediatric medicine first emerged, newborns were not part of the spectrum of "children" cared for and both children's and regular hospitals were refusing the admittance of children under the age of 2 because they did not know what to do with them or how to help them.[79] Then with the invention of the incubator, newborns became part of the realm of pediatrics, and the infant mortality rate significantly improved, although there was still a great need for more research and specialized care for newborns.[80] This shows one of the many ways in which the development of a field that uniquely recognized the differences of children has improved the status of children. Additionally, with new technologies and the study of the ways in which children were different than adults, medical subspecialties within pediatrics developed, including pediatric surgery, cardiology, neurology, urology, and

orthopedics. Without the creation of pediatrics and the realization that children needed specialized care, there would never have been the chance for the development of subspecialties within pediatrics. Specialties within pediatric medicine have led to the improved care and lives of thousands of children, of all ages.

The evolution of healthcare and medicine for children significantly impacted by society's lack of differentiation of the needs of children from adults, has accomplished a great deal in the past two centuries.[81] Soon after children were identified as individuals with a unique place in both the family and society, they were no longer excluded from the medical world and the lives of children were greatly improved. Children went from being property of their parents and of economic value only to individuals with rights and privileges who were valued in themselves.[82] Despite the changes and improvements, continued development is essential for the health and welfare of children throughout the world, making scientific research crucial. There are however, many ethical issues that come with scientific advances, specifically the creation of new therapies with ethical dimensions and potential problems. This is true in all medicine, but especially within pediatrics due to the heightened risks, an increased desire for innovative technologies, the extreme vulnerability of children, and their lack of decision making capacity.[83] Although the creation of the field of pediatric medicine has positively influenced children and their families, along with the enhanced care of children additional considerations have emerged, some of which will be looked at in the remainder of this chapter. Medical advances do not come easily and in order for advances to actually impact children and be safe for them, physicians must do research and continue to develop new therapies and interventions.

2.2.3. Central Components of Pediatrics

Research has served as a central component to the advancements made for children.[84] Specifically without clinical research, children would not be able to benefit from the many therapies and treatments, nor would pediatricians understand how the body of a child works and is different than that of an adult. On the other hand though, research is one of the most contentious aspects of adult medicine, bringing up issues of exploitation and vulnerable populations. Children belong to a vulnerable population, so this section will look at how the field expanded as children were allowed to participate in research and additionally it will focus on prevention for children that quickly emerged as a concern when advancements for children were made. As the care of children developed into its own field and new technologies emerged also came an immense need for research and the development of therapies and drugs specifically for children. Children are both vulnerable subjects who need protection from research risks and "therapeutic orphans" who have been denied access to the benefits of research.[85] The long term tradition of protecting children, extending to include medical research was recently shifted when the US created mandates promoting the inclusion of children in clinical research.[86] The development of lifesaving cures for terminal childhood diseases depends on advances in pediatric research, but good intentions do not eliminate risks, -- risks that are even greater for child subjects.[87] Despite the fact that children are vulnerable subjects and the population is smaller, the need for more pediatric studies is compelling.[88] Scientific advances and therapies cannot be denied to children as a class based on these concerns. Translating knowledge gained from scientific advances in biology, genetics, and neuroscience into treatments for children is possible only through research.[89] But pediatric research is not like adult research and it must be treated that way. The overall needs of children differ from those of adults, but both are entitled

to a healthcare system that supports a healthy and productive life, making further research with children necessary.[90] Children cannot be excluded from research, as they have been before, because they themselves need treatments, therapies, and inevitably drugs. But because they are children more things must be considered. If new advances are not tested or studied with or on children, then they will be blindly used on them without knowing exactly how these will work in a child. [91] Children are developing and changing at a much more complex rates than adults, and things that would not be issues for adults may be for children, and vice versa - adults and children cannot be lumped together and treated the same.

Children are not just "little adults" as they were once thought and they cannot be treated as such. In addition because of their exceptional vulnerability, the structure of research methods is even more important because children must not be exploited or abused. During the Nazi regime children were used as guinea pigs for research and because of this horrible experience, the Nuremberg code addresses children and appears to suggest an absolute prohibition against pediatric research: "the voluntary consent of the human subject is absolutely essential. This means that the person involved should have the legal capacity to give consent."[92] In the 1970s the United States developed regulations that allow advances and the participation of children in research while protecting them from unnecessary and uncompensated risks and discomfort.[93] Current US regulations are there to provide additional protections to children participating in pediatric research. However despite regulations, bad outcomes are inevitable in all situations when dealing with an unknown.[94] A harmed child does not immediately mean that the study was unethical, this add too high of a standard to research. There is always risk and it cannot be eliminated from research, the mistakes must however be learned from to prevent future occurrences.

Children have been exploited for research in the past, but this cannot be held as a reason not to continue, it merely argues that more things must be taken into consideration and extra precautions taken. Without clinical research on pediatric illnesses and medical interventions, children might receive dangerous or ineffective treatments.[95] In light of the need for research, society is obligated to protect them from excessive risk to foster their development that could potentially be threatened by involvement in research studies. This is the ethical dilemma that most societies are facing. The United Nations and the US have both commented on pediatric research and offer some ways to potentially enhance the process so it is ethical. The UN Convention on the Rights of the Child adopted in 1989 stipulated several things that pediatric research can to do improve results and limit the exploitation of children.[96] The Convention stated that children's views should be given attention and should be taken into consideration in medicine, including new treatments and therapies. However, the Convention did acknowledge that research with children raises additional ethical questions. Children and parents must be given details about the purpose and nature of the research, the methods and timing, in addition to the possible harms, benefits, and outcomes.[97] Beyond the basics, doctors must also work with patients and their families to explain the concepts, such as consent, and give as much information as possible.[98] Children should be given a leaflet to explain the research in their native language as well as given the opportunity to talk directly to the researcher. The child should be encouraged to ask questions because they themselves must be informed.

Research impacts both the young participants as well as those feeling the long term impacts from changes in attitudes or policies about similar children and young people and services for them so it is crucial that all of this be taken into consideration.[99] The effects of research may or may not be intended and there may be impacts throughout society. One

example that Anderson discusses is misinterpretation of the findings and results by the media to portray what the media wants, not what actually was found when the entire study is taken into consideration. Many researchers who work with children are wary and concerned of presenting their findings because of how the media can misrepresent the information in ways that could harm young people. In many cases these researchers feel that their work is not valued and seen to be of little influence or importance. Despite these feelings, in the last 15-20 years, there has been tremendous growth in research with children, the reporting of children's own views and experiences, formal pediatric research ethics committees and ethics training for pediatric research.[100] There is a need for change and continued development. It is argued that the current research model does not adequately protect children from harmful and useless research nor promote their participation and interests overall, but that does not mean research should be stopped as it is a necessary component to the growth of the field. The ethical aspects of research with children will be elaborated in the following chapter as a key component to the expansion of pediatric medicine. There is a need for balance between protecting young people and preventing and reducing harms while respecting and involving them and listening and learning from them, to not silence and ignore them.[101] There are basic issues with pediatrics in general, specifically that children must be seen as different than adults and they must receive their own attention, and research provides additional issues. Children require specific safety measures due to their limited capacity to give informed consent. Well-designed and well-regulated research with children is needed to improve children's health, specifically with a focus on prevention methods for children. Prevention has been identified as a central way to improve the lives of children and adults, seeking to prevent illnesses before they happen. With more research, and the increased

desire to protect children and improve their overall health, the focus shifted to preventative measures.

Over time, preventative measures became the focus of developments with children. As the field of pediatrics medicine has expanded, significant developments have been made, impacting the lives of thousands of children and their families. Science and technology have been able to enhance pediatrics on such a great level due to the heightened attention given to the care of children. It has been acknowledged that children are unique and require additional attention, precautions, and levels of expertise. Some of the major impacts of science and technology for children concern the development of prevention methods and tests for certain illnesses and conditions. In this section three major pediatric preventative measures will be examined briefly: vaccines, genetic and newborn screening, and the increasingly popular practice of pediatric brain scans. Many preventative measures have been developed for children including the creation of hearing and vision screenings in the 1940s and height and weight charts in the 1930s all to see if they were developing abnormally, but the preventative measures looked at in this section are those that specifically lead to ethical issues

Vaccines are arguably the biggest technological breakthrough and most effective preventative measure, however over the past 10-15 years they have been challenged and the benefits have become less obvious.[102] In the early 1900s, advances in immunizations resulted in improvements in the smallpox vaccine and the deployment of a diphtheria immunization.[103] Following this, researchers intensified their efforts to control common communicable diseases of children, many of which even killed them, and found immunizations for more diseases.[104] Because of this, vaccines are considered one the greatest public health achievements of the past 100 years, and the benefits of vaccination seem obvious once their successes are discussed.[105]

Vaccines led to the eradication of an entire organism (variola virus) and the global control of many others (such as measles and polio), and the significant reduction of common diseases in some countries. But vaccines do not come without risk, and as vaccine-preventable diseases become rare, the benefits individual children receive from vaccines becomes less apparent. On the risk side, vaccines are not inert and they are actually intended to endanger the immune system of the recipient to induce immunologic protection, so all vaccines have side effects, and are rarely 100% effective.[106] Some individuals who receive a live viral vaccine may develop mild symptoms associated with the transient replication of the virus, for example 6% of the children who receive the varicella vaccine will develop vesicles near the site of the vaccine administration.[107] For the benefits, although the diseases that are typically immunized for are severe, due to the success of vaccinations and how rare the illness are, it is unclear why parents should put their child at risk. Benefits are very specific to each child and unpredictable with regard to different interventions. It is not possible to predict a given child's future exposure to a specific organism or other high risk behavior that would lead to a greater risk of developing a disease.. One argument is that of an "umbrella effect" specifically that by protecting most patients possible, those who are not immunized are covered and not as susceptible to the disease, specifically those who cannot be vaccinated due to medical conditions or age.[108] On a global level, international public health officials have questioned whether the benefits of vaccines may outweigh the risks in some developing countries. However, clinical trials in such locations are lacking, so the results of administering the vaccine are unknown or unpredictable.[109] Despite the lack of research done on an international level, many infections, including those with rotavirus, remain a serious threat to children at the global level, so it is crucial that enough research is done so vaccines can be used on an international level in a safe and effective way. In light of

challenges and skepticism of vaccines over the past few decades, vaccines remain one of the most important ways in the 21st century to improve child health and the future of vaccines will rely on the preservation of public trust in the mechanisms used to assess vaccine safety and the science and development of vaccines that are effective for the most vulnerable children.[110] Vaccines however bring up ethical issues including those of consent and parental authority, but also new issues including justice and how far preventative measures should go to help others when there may not be a direct benefit to the child, similar to research.

The next preventative method that emerged is genetic testing and newborn screening. This too will be elaborated in the following chapter, but is emphasized here since it was one of the first major prevention methods with children. Screening is a public health initiative that surveys an entire population for evidence of an illness before symptoms are exhibited symptoms.[111] The purpose is to identify those who are suffering from or are likely to develop a disease and who are likely to benefit from early detection and intervention.[112] In the 1960s a simple genetic test involving the absorption of a few drops of blood was developed for PKU, a disorder that causes severe mental retardation if left untreated but can be easily regulated by diet.[113] Following this development, screenings began in the US and most states passed laws requiring the prick of the heel of all newborns so that their blood could be analyzed.[114] Currently about 200 cases of PKU are diagnosed in the United States each year and education is provided to the family on how to regulate this and prevent the side effects of the illness.[115] Soon other illnesses were found to be identifiable through blood and over the years the practice has steadily expanded. Depending on the state, newborns are screened for 29 up to 54 conditions.[116] Almost all babies born in the US undergo screening soon after birth to identify genetic defects that could cause serious illnesses if left untreated in order to detect the diseases as soon as possible so that

treatment could potentially be given even before symptoms arise. In most states newborn screening is mandated by law and of the 4 million screened each year 5,000 are found to have heritable disorders.[117] Tremendous ethical issues arise when determining what should be screened for and should be part of the standard panels for all newborns, which will be looked at in the following chapter.

The other area of development with predictive power is that of functional MRIs, also known as brain scans. Brain scans offer a way to analyze how different parts of the brain work together functionally and can then be applied to patients who lack certain abilities or have deficits. By comparing data with standardized models of how the brain functions or how a specific disease develops a variety of new clinical insights becomes available and it can be seen how the child's brain is out of sync with the normal developmental curve.[118] This approach is expected to enable treatment before any onset of symptoms and help physicians track the results of clinical trials of new therapies, but for the time being, the focus is on understanding the brain and being able to relate behavior to brain activity. Pediatric brain scans are not an extremely large practice at this time, but there is a great possibility that this will be one of the new interventions more commonly used to care for children, along with genetic screenings, to understand, diagnose, and inevitably treat.[119] It is currently not known how all of the different systems of the brain interact, or what an identified brain abnormality can predict about the patient, but there is great potential for predictive and eventually preventative power with these scans.[120] It is difficult to assess and diagnose individuals with disorders of the brain and even more challenging to use new therapies to treat them, but brain scans have made great progress. The many advancements of neuroscience, just as those of other fields of medicine, bring with

them both new possibilities and issues to address, but great hope for the future and current abilities to predict and eventually prevent disorders in children.[121]

Pediatric medicine has a strong growth in the area of prevention methods, only to expand with the continued developments and new technologies looked at in the next chapter, which will expand upon the methods just introduced. Research led pediatric medicine to where it is today, but it has not been an easy journey and it is one filled with regulation and continuous changes. Additionally prevention methods to protect children were developed including vaccines and newborn screening, showing their importance. There is a strong desire to prevent illnesses and identify those that may not be preventable but where an intervention could be performed or identification can enable some kind of action. With the newborn screening come additional ethical issues, specifically with the expansion of the field which will be looked at in the next chapter, however it was introduced here to show the initial developments and focus of the field of pediatrics. The emphasis on prevention and the desire to help children and improve their lives directly relates to the overall goals of pediatric medicine, which will be elaborated in the following section. Children were once orphans from the medical world, left out and lacking their own specialized care, however over time this changed and they have taken their seat as a central component of society, receiving a great deal of medical attention and focus throughout the world.

2.2.4. The Goals of Pediatric Medicine and the Emergence of Pediatric Ethics

Pediatric medicine began in the image of adult medicine treating children in the same way that adults were treated. Over time though, this view of children as the same as adults slowly transformed, and advancements were made that specifically addressed the different needs of children.[122] Pediatric medicine, as a unique specialty of medicine, requires its own set of goals

and principles, however in many ways, the goals of adult medicine have been applied to pediatrics and explicit goals of pediatric medicine do not exist distinct from those of adult medicine. This is problematic because the goals and guiding principles of adult medicine do not directly apply or fully capture the goals and dynamic attributes of pediatric medicine and care. Medicine needs to be guided by values and universal goals that directly apply to the populations being served, making it crucial to develop goals specific to the needs and attributes of children.[123]

Before discussing the goals of pediatrics, the goals of adult medicine will be introduced and argued to be insufficient to accommodate the unique elements of pediatric medicine. Adult medicine has many overarching goals, including the prevention of disease, promotion of overall health, the relief of pain and suffering, care or cure of disease, the avoidance of premature death, and the inevitable pursuit of a peaceful death.[124] Not all maladies or illnesses can be cured, so many times just the care and treatment should be the goal.[125] Additionally, it gets to a point when patients can no longer be helped, and the goals shift to avoid a premature death and when no longer possible, help the patient achieve a peaceful and painless death.[126] These general principles guide medicine on a basic level, however, it can be argued that the ethical principles of autonomy, beneficence, non-maleficence, and justice encompass them all, at least within the realm of adult medicine, and offer actual goals and more structure. The principles of autonomy, beneficence, non-maleficence, and justice are prevalent throughout medicine and are even identified by some in the Hippocratic Oath attached to duties of physicians.[127] Additionally, these principles are used to justify informed consent enabling adults to make their own medical decisions in light of their values and beliefs, one of the central components of adult medicine and decision making. Respecting the autonomy of the patient means supporting and facilitating the

patient's exercise of self-determination in decision making, overall allowing him or her to weigh the benefits and burdens in light of personal values and beliefs and make a decision that aligns with them.[128] Beneficence, specifically the physician's duty to promote the patient's best interests and protect the patient from harm when possible, can sometimes make the initial principle of respect for autonomy challenging, especially when they are contradicting, however physicians should still advocate for the best option.[129] Beneficent acts are demanded by the roles involved in fiduciary relationships between healthcare professionals and their patients. The exact scope of this beneficence is not clearly defined as physicians are morally obligated on some occasions to assist others and promote positive benefits while preventing harms, but not in others.[130] The next principle is non-maleficence, specifically to not cause any harm to patients. This principle is additionally challenging in that sometimes there is no good option, or one without any harms, however to "do no harm" means to have a balance of benefit or good over the harms caused.[131] Beneficence assumes an obligation to weigh and balance benefits against harms, benefits against alternative benefits, and harms against alternative harms. The final principle and goal of adult medicine is justice, referring to the fair, just, and appropriate treatment of individuals based on what is owed to them.[132]

The goals and principles of adult medicine outlined do not seamlessly apply to pediatric medicine and do not encompass all of the objectives of pediatric care. Goals of medicine must serve the good of the patient, as defined by the patient's values constrained by benefit and harm, as found in and defined by the doctor patient relationship, emphasizing the need for unique goals within the field of pediatrics.[133] Providing medical care for children is not the same as treating adults, therefore the goals of pediatrics should be framed differently than those in adult medicine.[134] The goals of pediatrics are complex and include protecting the child and furthering

his or her best interests, protecting the child from unjustified harms in regard to medical interventions, and showing respect for family autonomy.[135] Within adult medicine, the patient's preferences guide the decision making process, enabling the autonomous patient to choose what is most beneficial to him or her, but in pediatrics, parents are tasked with weighing benefits and burdens and making choices for their child who is the patient. Selecting the best therapy and weighing all of the benefits and burdens is especially challenging within pediatric medicine and many times, parental preferences may or may not reflect the good of the child, nor take into account the patient's values which may or may not have had the opportunity to mature.[136] This calls into question the utilization of autonomy as a guiding principle within the field of pediatrics, since by definition, children lack complete autonomy. Personal autonomy, defined as an individual acting freely in accordance with a self-chosen plan, cannot be seamlessly applied to children, and by definition as children, they do not have full autonomy, although since they are in the process of developing, are somewhere along the spectrum with varying levels.[137] Additionally, justice is not an arguable goal of pediatrics that impacts decision making or the roles of parents or physicians because in most cases, justice for children is addressed by society. For instance, society limits the rights of parents to refuse lifesaving interventions for their children, such as blood transfusions or actions that put the child's life in extreme danger.[138] Additionally, legislation like the Baby Doe Regulations, which determines that the withholding of medically indicated treatment cannot be done unless (1) the infant is chronically and irreversibly comatose; (2) the treatment would merely prolong dying and not be effecting to correct the infant's life threatening conditions; or (3) the treatment would be virtually futile in terms of the survival of the infant or the treatment itself would be inhumane under such circumstances, guarantees that care is given to infants regardless of parental decisions.[139]

Legislation also exists that ensures children receive medical care even when their parents cannot provide it. These societal impacts lead to a limited application of the principle of justice to pediatrics as a main goal. It is not to say that it should not be a goal at all, however it is not one that will be further elaborated here or used to frame parental decision making.

Some of the mentioned goals and principles of adult medicine do however apply to children and the practice of pediatric medicine. The goals of pediatrics should include beneficence and non-maleficence, however autonomy cannot be directly applied or used as a guiding principles for the reasons elaborated. Even though autonomy cannot directly be applied, that does not mean it is not important, if not crucial, to decision making in pediatrics. Some argue that parents can exercise the autonomy of the non-autonomous patient, as a surrogate would in adult medicine, however it is first, not clear that that is where the authority of a surrogate is based, and additionally, unlikely that parents could exercise the not yet developed autonomy of their child.[140] The principle is the "respect for autonomy" rather than the exercise of autonomy, so it is possible that parents are selected as the most appropriate individuals to make decisions that would respect the child's future autonomy. This would not ask them to apply the child's not yet developed values and beliefs, but rather, act in his or her best interests. This is why, for pediatric medicine, a reformulation of the concept of autonomy will be argued for and applied as a fundamental goal that respects the autonomy of the family, the future autonomy of the child, and the overall promotion of the current and future interests of the child.[141] Within pediatric medicine, there are additional levels of the duties and responsibilities of physicians, strongly connected to the goals of the field that complicate decisions and processes.[142] The professional goals are different for pediatricians as they must work with the parents, in most cases more than their actual patient, while upholding, balancing, and sometimes arguing for the

child's best interests.[143] In pediatrics, pediatricians and parents both are crucial to the selection of treatments for the child, as co-fiduciaries.[144] Pediatricians have an obligation to protect and promote the health-related interests of their child-patient and parents also have a fiduciary obligation to promote and protect the non-health-related interests of their child, who is the patient.[145] The doctor-patient relationship is a focal point of medicine in general, however this becomes more challenging within pediatrics when the parents are added to decision making processes, and both are simultaneously working to do what is both right and best for the child.[146]

The goals of pediatrics are different than adult medicine because in this field, the children-patients rely completely on adults, specifically parents and doctors, to define what is right and good for them, enhancing the roles of all involved.[147] A partnership exists between healthcare professionals, children and families which implies the need for shared objectives.[148] It is not clear that parents are in the best position to make decisions for their children in all instances. Parents have to deal with a great amount of emotions including feelings of sadness, anxiety, anger, and guilt combined with feelings of love, responsibility, and devotion.[149] Many times parents are confused or have conflicting interests, calling into question the family centered model as the basis utilized for decision making currently in pediatrics. Additionally, depending on the complexity of the disorder or condition presented to them by the physician, they may be confused or shocked due to the rarity or complexity of their child's illness and unknown components. It is not an internationally agreed upon idea that parents are the best decision makers, however it is the typical North American perception.[150] The goals of pediatrics, which will be fully elaborated in Chapter 4, are complex and should include protecting the child and furthering his or her best interests, protecting the child from unjustified harms in regard to medical interventions, and showing respect for family autonomy.[151] These fundamental goals

are incorporated within the specialty of pediatric ethics, a field that developed just as most pieces of pediatrics, out of the adult model as it was recognized issues of pediatric medicine could not be handled in the same way as adult issues.

2.3. Pediatric Ethics

Pediatric ethics deals with normative questions specifically related to pediatrics and addresses how ethical issues of pediatrics medicine are different and unique from adult medicine and should be handled in specific ways.[152] Pediatric ethics developed shortly after the emergence of the field of pediatrics itself and the realization that children cannot be treated in the same way as adults and that there are many issues unique to pediatrics.[153] The ethical dilemmas that children and their families face are different from those in adult cases in many ways and cannot be handled in the same manner. Pediatric ethics is distinct from general medical ethics for several reasons. It must account for a three way relationship involving the physician, patient, family (normally parents) rather than the dyadic relationship that is more common in adult medicine. When dealing with children, the parents are the consenting party, making the pediatrician more explicitly responsible to the parents and family than in other areas of medicine.[154] Within adult medicine and medical ethics, there is a focus on autonomy, in most cases giving the patient the ability to do what he or she wants. However within pediatric ethics, complete deference to patient autonomy is not an option since children are not presumed to be autonomous and capable of making decisions. In these cases, families must make decisions for and about their child that has never been autonomous or able to make such decisions for him or herself.[155] Instead of patient autonomy the issue becomes parental decision making, which is not as absolute as patient autonomy and in many cases can be overruled by the patient's best

interests, which are not typically easy to determine.[156] Determining the best interests of a patient involves weighing the anticipated benefits and burdens to select a course of treatment, however it is often a point of disagreement among family members and medical professionals, who consider different aspects and can weigh them differently since it is a very subjective analysis.[157] It is not easy to determine the best interests in adult medicine and it becomes even more difficult to do so for a child who has never had the capacity to make decisions for him or herself.

Another dimension of pediatric ethics is that as the field of pediatrics develops and grows, the ethical issues become more complex and challenging. As technology progresses, pediatrics has become a field full of experimentation and the use of the latest and most up and coming technologies, placing parents and physicians in an even more challenging role.[158] These technologies have benefited many children and infants throughout the world, for example, decreasing the infant-mortality rate, providing the ability to keep much younger premature neonates alive, and to cure or contain many childhood illnesses that at one time killed almost all patients with the disease. However, along with these technological breakthroughs and enhancements comes more medical concerns. Currently, many of the newest developments are connected to breakthroughs in neuroscience, raising ethical issues and questions of not only what to do, but how and when to utilize them. These new ethical issues of neuroscience will be more fully developed in the following chapters.

The field of pediatric ethics emerged to handle the ethical issues of pediatric medicine created by scientific breakthroughs, research, and an increasing interest in and the awareness of children and their individual needs.[159] The ethical issues that children and their families face are different from those in adult cases and cannot be handled in the same manner, inevitably leading to the specialty and emergence of pediatric ethics and the use of pediatric ethics committees

(PECs). As science progressed, pediatrics became a field full of experimentation and emerging technologies.[160] . Children, as distinct from adults, have their own specific problems and ethical issues, thus the specialty of pediatric ethics emerged. Even similar problems that exist in both regular medicine and pediatrics, such as the removal of care at the end of life, must be handled in different ways in pediatrics and adult medicine. In addition, there are more stakeholders, enhanced professional duties and obligations, and potentially more on the line due the potential for such a long life of a child. Pediatric ethics looks at these specific issues addressing both the pediatrician and parents as fiduciaries of the child within their specific realms working both together and at the same time for the child patient.[161] Pediatric ethics is a necessary field that addresses the unique ethical issues and challenges that arise within pediatric medicine and work to further the interests of the child.

2.4. Conclusion

The field of pediatrics emerged in the mid-19th century as the views of children as different from adults and in need of specialized care developed. Children in modern society receive a great deal of attention from the government, their families, and society in general, including the medical world, however this was not always the case. Societies changed from being completely ignorant about and uninterested in children and childhood to seeing children as a central feature of the family. The evolution of healthcare and medicine for children has been greatly impacted by society's lack of differentiation of the needs of children from adults. But once this was realized, the lives of children were greatly improved and they were no longer excluded from the medical world. Children went from being property of their parents and of economic value to individuals with rights and privileges. The field of pediatric medicine emerged as the

conceptions and ideas about children changed but also because it became understood that they need their own specialized care. The field of pediatric medicine has improved the condition of thousands if not millions of children worldwide, with new therapies and treatments continuously developing, leading to the creation of more ethical issues and even more difficult situations for parents and physicians. These unique ethical scenarios and more complex areas lead to the need for the reformulation of the goals of medicine to be applied directly to pediatric medicine. The goals of adult medicine do not apply, nor do they address all of the challenging issues presented in pediatrics. Pediatric medicine has many unique issues and problems such as heightened emotions, decisions with potentially higher stakes and longer impacts, and making decisions for someone else, specifically one's own child.[162] In response to these unique challenges, considerations, and goals, a special area of ethics was developed. Pediatric ethics emerged out of the realization that issues within a pediatric medicine are not only different but must be handled in a way that is not similar to adult medicine. Pediatric medicine emerged as children were given a place in society, however there is still a great need for developments in the field, not only of science, but also of ethics. The medicine, ethics, or decision making processes of adult medicine cannot be used as a model for those within pediatrics, and it is crucial that pediatric medicine have its own standards and models in order to balance the roles of the family, child, and society while providing the best possible care for the child.

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Chapter 3 - Medical Decision Making

3.1. Introduction

Throughout the medical world, patients, providers, and family members are continuously making decisions about therapies and medical interventions.[1] They select treatment plans, decide whether or not to have an invasive procedure, and can choose if and when to discontinue treatment. These decisions have ranging levels of complexity, time available to decide, and potential impacts.[2] Many decisions must be made in an instant and can impact the patient in many ways, while others are much more straightforward and do not place a tremendous burden on the decision maker. There are few easy decisions in medicine, but with the expansion and growth of science and technology, they become much more complex. New technologies and scientific breakthroughs create more available options, but with them come new decisions and benefits and burdens to determine. Challenging medical decisions due to technological advancements are not unique to the field of pediatric medicine, however the way in which they are dealt with is. Within adult medicine, the patient is typically given the authority to make decisions for him or herself, however this is not the case in pediatrics, where the patients are children. In pediatrics, parents are typically looked to as the decision maker for their children, placing them in a tough position. Not only do parents have tremendous emotional burdens, but they are asked to make choices that could have impacts lasting the duration of their child's life. New therapies and developments not only bring with them more options, but also possibilities and overall hope for parents who want to protect their children and do what is best for them. Technology has created great opportunities and enhanced the lives of children around the world, however until they are fully understood and proven, they place parents in difficult situations making decisions on incomplete or insufficient information. Parents need a model to make

medical decisions about interventions for their children that offers them support and guidance to make decisions consistent with the child's interests. In most cases, the models of adult medicine, specifically the best interests standard, are applied to pediatric cases and parents are asked to make decisions in the best interests of their child. These models however, do not provide enough structure or guidance or properly facilitate the involvement of all stakeholders, making them insufficient for pediatric medicine. Decision making is a major aspect of healthcare with many more ethical issues that arise when the patient is unable to make his or her own decisions, with even more ethical dimensions when the patient is a child.

In order to understand the ethical dimensions of decision making within pediatric ethics, decision making of adult medicine will be examined, followed by an application of the principles and concepts of adult medicine to pediatrics. In the first section of this chapter, the basics of medical decision making will be addressed, including the basis for and importance of allowing individuals to make their own medical decisions rather than the medical team. After looking at the development of this practice, and the shift away from paternalism, decision making capacity will be defined, followed by an analysis of the models utilized by surrogates when decision making capacity is lost. Within the analysis of the models, many of the problems that arise with them in practice will be discussed. These problems with application have led to a more comprehensive, subjective model. In the second section of this chapter the concepts and models of adult decision making will be applied to children, specifically looking at issues of consent and capacity, balancing the many stakeholders, and then the application of the substituted judgment and best interests model to cases with children. It will be argued that the models for surrogate decision making are problematic for adults and inevitably insufficient for parents to use when making decisions for their children. A new formulation is needed.

3.2. Adult Decision Making

In modern medicine it is well accepted that adult patients make their own medical decisions based on concepts of personal autonomy. There is a strong desire to allow patients make their own medical decisions and select therapies that they believe are best and fit into their lives. Despite this current practice of modern medicine, allowing all to make their own medical decisions, this was not always the case. At one time, patients relied on their physician to diagnose and select a proper course of action for them. Eventually, western societies gained an appreciation for personal autonomy, and believed individuals with decision making capacity should be able to make decisions for themselves in light of their personal beliefs and values through a process of informed consent. This placed the patient in control of his or her medical care, but also set guidelines for decisions that the patient could or could not make. With regard to decisions for him or herself, the patient is typically allowed to make almost any decision and weigh benefits and burdens in a way that is meaningful to them, but this is not the case if someone else must step in.[3] When patients lack the ability to make decisions, specifically do not have decision making capacity for a specific decision, a surrogate must come in to make the decision. Surrogates do not have the same freedoms and flexibility of the patient, and these decision making processes are more structured since surrogates are not the patient.

This section will look at the development of informed consent out of respect for personal autonomy, and the concept of decision making capacity as the foundation for informed consent. Decision making capacity, as the threshold to allow individuals to make their own decisions is a central component of adult decision making and will additionally play a crucial role in pediatric decision making and the enhanced model. The second half of this chapter will examine the models that guide surrogates to make decisions for adult patients who lack decision making

capacity, substituted judgment and the best interests models. There are many problems with the application of both of these models, leading to a much more comprehensive and shared decision making model in practice, which will be addressed in the final section.

3.2.1. Autonomy, Informed Consent, and Decision Making Capacity

Adult patients are given a tremendous amount of authority over their medical decisions and in most cases in modern medicine they are able to select, adjust, or even refuse certain therapies and treatment plans. Physicians advocate for what they believe to be the best option, however in the end, the adult patient more times than not will make the final decision. This authority is based on concepts of autonomy, which developed over time as a central component of medical decision making. This section will look at the key elements of decision making within adult medicine, initially addressing the change from the paternalistic model of physicians making choices for patients, to a focus on respect for personal autonomy, as the justification for allowing adults to make their own medical decisions. After elaborating the development of personal autonomy and the justification for individuals to make their own decisions, the concepts of informed consent and decision making capacity will be evaluated as major and necessary components of adult decision making. Decision making capacity is necessary for adults to make their own decisions, which is evaluated in relation to the decision made. Informed consent on the other hand is the mechanism in which decisions are made, set up to ensure the comprehension of the options and treatment courses by the patient before making a decision. Decision making in adult medicine is very complex and in order to look to pediatric medicine, adult decision making must be fully understood.

3.2.1.1. Personal Autonomy from Paternalism

Decision making in adult medicine is based on the concept of personal autonomy, enabling adult patients to make choices and select therapies that align with their own personal values and beliefs.[4] In the beginning of medicine, and throughout the early 1900s and almost until the 1980s physicians were thought of as the leaders of care for their patients due to their medical knowledge and experience, and made decisions for the patients.[5] This model for decision making is referred to as a paternalistic model. Dworkin defines paternalism as "the interference with a person's liberty of action, justified by reasons referring exclusively to the welfare, good, happiness, needs, interests, or values of the person being coerced."[6] In a paternalistic model, the patient receives the treatment or intervention that the physician has determined to be in the patient's best interests based on the medical facts and specific case.[7] The physician presents the information to the patient, encouraging him or her to consent to what they view as best, however at extremes the physician will make the decision, especially when the patient does not agree. In some cases, the physician does not even consult with the patient and just makes the decision and proceeds with treatment.[8]

There are many problems with this model, specifically that it limits the freedom and autonomy of the patient, but it additionally makes some assumptions that may have been accurate in the beginning of medicine, but can no longer be held to be true today. One of those assumptions made when justifying the paternalistic models is that the goals and objectives of the specific case are shared between the physician and patient, which is not always the case.[9] Physicians should place the patient's goals and views ahead of their own to help them structure the decision, however there is not a mechanism to ensure that happens with the physician as the sole decision maker. In most cases, the physicians select courses of treatment with little to no involvement from the patient, and typically without much thought about what is in line with the

patient's values, beliefs, or personal goals. Additionally, others believe that the physician is justified in overriding the patient only if they are convinced that it is the best course of action and the patient would agree later due to the outcome or results of the intervention.[10] Overall, the paternalistic model was widely recognized as the physician controlling and acting as the patient's guardian, which was not ideal, so it should only be leveraged in instances of emergency when there is no other option.[11] These arguments were made because it was thought that the physician knew more about the medical care than the patient, but medical knowledge is not enough to make a decision specific to a patient.[12] The overall goal must be to respect the patient's autonomy and allowing their views and opinions impact decision making processes, inevitably leading to a change in overall goals of medical decision making.[13]

During the latter half of the 20th century, there was a drastic shift in societal views and the patient-physician relationship placing an emphasis on the rights of individuals and his or her role in decision making processes.[14] Patient control was advocated, not only empower patients to make decisions in light of their own beliefs and views, but also to reduce the physician control and dominance.[15] Individuals should be informed of all options and relevant information and also be involved in their care and choose what does or does not happen to his or her body.[16] A new appreciation was gained for personal autonomy and the ability of individuals to weigh options in light of their own beliefs and values. With this change and focus on the rights on patients came new requirements of medical professionals to involve and inform their patients. In many parts of the world, paternalism is still common, although there has been a shift towards a more shared model with patients playing a larger role in care.[17] Over time, paternalistic approaches faded leading to the personal autonomy based model of today, however currently this model has slowly shifted back towards a more shared, centered model. It does not have to be at

one end of the spectrum or the other, specifically controlled by either the patient or physician, leading to a more common and advocated for shared model, which will be discussed in a later section.

3.2.1.2. Development of Informed Consent out of Autonomy

Personal autonomy is an extremely important concept in medicine, specifically with regard to decision making.[18] It is the basis and main argument for patients making his or her own decisions, and led to the shift away from paternalism. On a basic level, autonomy refers to self-rule or self-governance based on one's own goals and values.[19] In a medical setting, respect of personal autonomy acknowledges that individuals have the right to take actions based on their personal values and beliefs.[20] Individuals with decision making capacity are allowed to make their own decisions about medical treatment and care, and do so through a process of informed consent.[21] Informed consent is crucial to the medical field and medical decision making processes for many reasons.[22] According to Beauchamp and Childress, informed consent is an individual's "autonomous authorization of a medical intervention."[23] Without informed consent, it is not clear if patients comprehends the options presented or what they inevitably selected as a therapy, calling into question their decisions. Despite its importance, it should be acknowledged that informed consent is a process, rather than a specific action or authorization by the patient, and must be treated as such.[24] Informed consent is a process by which the patient works with the doctor, medical team, and in many cases family, to make the best decisions in light of personal values and ideals or at a minimum articulates a full understanding and demonstrates that they have decision making capacity, before making a given decision.[25] On a basic level, informed consent is a practical and effective recognition of human dignity that respects autonomy and

personal freedom, permitting the individual patient to play a primary role in health care choices, enabling the establishment of mutual respect among the physician and patient. The moral purpose of informed consent is to protect individuals from abuse, however it is also important that patients are not subjected to coercion, deception, or other kinds of manipulation.[26] Informed consent enables the patient to be a valuable and central component to the decision making process, working with the physician in a partnership.

There are two key elements of informed consent, (1) the disclosure of information from the physician and the comprehension of such information by the patient, and (2) the willing consent of the patient.[27] Disclosure is an important aspect because physicians are patients' only real way to gain an understanding of the medical elements in order to apply personal values to the situation and make a choice.[28] Choices and behaviors are guided by past experiences, knowledge, and are almost automatic in many instances, differing among individuals.[29] No two people will rank options in the same way, or come to a conclusion based on the same values or reasoning.[30] These differences emphasize the importance of informed consent processes and the need for their facilitation in all medical decision making processes. The informed consent process exists to attempt to acknowledge these differences, but because individuals all think differently, it is not always evident what information should be shared with the patients about the diagnosis, condition, and potential therapies.[31] The reason for emphasizing informed consent is that patients can make an autonomous choice, but if they do not have all of the information relevant to their personal situation it may not be possible to make such a decision.[32] In order for an individual to make an autonomous choice, consistent with personal values, patients must have access to the information that they find relevant and would be important in their decision making process. Physicians however, are human, and cannot be required to know absolutely everything

about medicine, and additionally cannot know exactly what the patient would find relevant and important to the decision making process. Legally, doctors must disclose enough information to enable the patient to decide whether treatment is in his or her best interests.[33] Typically, medical professionals should provide the facts or information that patients usually consider, in most situations, important while deciding whether to refuse or consent to a proposed intervention, as well as any information the physician believes to be relevant to the decision making process.[34] This must be presented to the patient in a way that he or she, typically lacking medical knowledge, understands and comprehends. It is important that physicians support and collaborate with the patients, enabling a smooth informed consent process that recognizes the patient's particular wishes and desires.[35] Medical treatments should focus on pursuing a better overall health and quality of life for the patient rather than only treating a medical pathology. Health and the desire for life are not always congruent and differ among patients; the definition of "healing" for one individual may mean the acceptance of his or her illness, even if that is the acceptance of death, while for another it means doing everything possible until the end.[36]

The growing importance of informed consent and the recognition of respect for personal autonomy exemplifies the shift from a physician centered, potentially paternalistic, approach to a patient centered model with the patient as the focus of decision making and medical care.[37] Respect for autonomy must be balanced with other principles including beneficence, non-maleficence, and justice, however as long as individuals retain the ability to make decisions his or her choice is to be respected.[38] Physicians cannot substitute personal values or conceptions of quality of life with that of the patient and must work with the patient to make decisions that align with their beliefs.[39] The process of informed consent is crucial to medicine as it recognizes the autonomy of the patient and also enables the patient to make a decision that is meaningful to him

or her. Each person values and ranks pieces of their lives and health differently, and must be able to evaluate options with their physician to ensure that they select the course of action that is best suited for them medically, emotionally, and personally. Decision making is not easy and must be a collaborative and informed process between physicians and patients, focusing on the patient and his or her own conceptions of quality of life and health, thereby respecting the autonomy of the patient.

3.2.1.3. Decision Making Capacity

Decision making capacity is a necessary component of informed consent. In order for individuals to make medical decisions and give informed consent, they must have the appropriate level of decision making capacity, specifically, they must be able to understand all of the relevant information and make a decision voluntarily.[40] Decision making capacity is different than and important to distinguish from competence.[41] Competence is misleading to use in the medical setting because it has legal implications; lacking decision making capacity to make health care decisions does not mean that an individual does not have legal competence, and vice versa. Capacity or decision making capacity is used throughout the rest of this dissertation to accurately identify and discuss what patients need to make medical decisions. Capacity for making healthcare decisions has three primary aspects: understanding, evaluation, and reasoning.[42] For a patient to be decisionally capable, they must be able to understand the relevant information about the disease or diagnosis, treatment options, and the recommendations and reasons of the doctor.[43] The patient must be able to evaluate this presented information against a framework of values to judge the elements of a particular health care decision. In addition, patients must be able to deliberate and reason about the impacts of all available courses

of action, including the option to not treat or elect to not participate in the proposed therapy, and grasp cause and effect relationships and ideas of probability and percentages. Concepts of probability are difficult to comprehend by patients and challenging to present by physicians since there is no way to give a percentage with complete certainty, however they are very common, necessitating that patients understand the implications and concept overall. In many instances a psychologist evaluates this capacity, however it can also be done by physicians. If it is contentious, it is not advocated that this evaluation be done by the service provider alone, to ensure an outside, documented perspective is taken into account, however many times this evaluation is done in this way. In an ideal world, two providers would be involved in capacity assessments, however this is more common when a lack of capacity is noted, rather than to confirm that it is present. It is important to note that decision making capacity it not necessarily a global issue, but rather task specific making it important that the specific decision is kept in mind by the provider assessing and evaluating capacity. Decision making capacity is on a spectrum, rather than an absolute that applies to all cases for a given patient. Specifically, more capacity is needed for higher risk decisions with many options to deliberate and consider, and less for those that are seemingly straight forward and of a lower identified risk.[44] The provider must take into consideration the decision itself when inevitably determining if the patient can make a decision for him or herself, so it must be fully flushed out and understood. Rationality is an additional important dimension of decision making capacity and overall medical decision making, however decisions made by individuals determined to have decision making capacity do not have to be rational, therefore it cannot be used as a definitive gauge of decision making capacity, but it can be taken into consideration when evaluating overall capacity.[45] Specifically, if patients are irrational and incapable of framing decisions or discussions about the given

treatments and options, that can impact their ability to make medical decisions, however if the patient is found to be rational and able to understand, overall having decision making capacity, the patient will be allowed to make whatever decision he or she wants, even if irrational. Capacity judgments serve as gatekeepers to health care by identifying patients whose choices must be upheld and when another decision maker is needed, making them crucial to medical care.[46] Decisionally capable patients can make any decision that they want, based on the principle of respect for autonomy, but this is not true for patients who lack this capacity.[47]

When a patient is found to lack the capacity to make a medical decision, someone is appointed to make decisions for the patient, either by a legal document created by the patient before the loss of capacity or by legal standards of the area. In these cases, the individual who makes decisions for the patient is known as his or her surrogate. Surrogate decision makers are held to higher standards and are asked to act in a manner that is consistent with how the patient would have acted if capable. In most cases, surrogates may not choose to withhold or withdraw treatment when it is in the objective best interests of the patient, unless the patient made an advance directive before losing decision making capacity explicitly outlining what he or she wanted. Surrogates are argued by many to be able to exercise the "autonomy" of the patient lacking capacity however it is not clear that a surrogate, or anyone other than the individual, can exercise the autonomy of another.[48] Ethical obligations of respect for autonomy do not extend to persons who cannot act in a sufficiently autonomous manner, so it is not necessarily and unlikely possible that the surrogate is executing the autonomous wishes of a non-autonomous patient.[49] Making decisions for another is not an easy task, as it is seemingly impossible to know what the patient would do in every instance, but surrogates are asked to do just that. In response to this, ethical standards have been developed to guide the decision making process of surrogate

decision makers so that they make good choices for the patient.[50] In the following section the guidelines and models for surrogate decision making will be explored.

3.2.2. Surrogate Decision Making

When patients lose decision making capacity, a surrogate must make medical decisions for the patient.[51] Individuals can identify a person to be their surrogate before losing decision making capacity with an advance directive (AD). Advanced directives can appoint someone to make decisions and can even go as far as to tell the decision maker what he or she would want, and in some instances only enable the surrogate to make specific decisions. Advance directives are a way for patients to express and outline their wishes for care and treatment when they are still able to do so, to be upheld even if they lose capacity. Despite the powers of an advance directive, and a significant increase in the past decade, most people in the United States do not have a directive.[52] Although more people have advance directives than ever before, a study by Rao et al, it was found that only 26.3% of the 7946 respondents had an advance directive, with lack of awareness as the most frequent reason for not having one.[53] Silveira et al 2014, found that this trend was not associated with hospitalization and hospital death, suggesting that AD completion is unlikely to stem from hospitalization before death, which was hypothesized to be one of the major areas for their creation.[54] When looking only at an elderly population who needed a surrogate, Silveira et al 2010 found that 67.7% of respondents had an advance directive, however less than 30% of those studied required a surrogate, so the sample was small.[55] These numbers emphasize that many people, even those who are of an age or medical status that most greatly need the advance directive, lack explicit directions or identified decision makers, therefore necessitating the identification of a surrogate. Without an advance directive, a surrogate

must be determined through an ancillary process, typically guided by legal regulations. Currently in the United States, each state has legislation that establishes a hierarchy for identifying a decision maker for a patient without the capacity to do so for him or herself. This legislation however does not take into account the social relationships with the patient, specifically whether or not the potential surrogate is close to or has a relationship, other than biological, to the patient. This creates confusion and can lead to the selection of therapies that the patient may or may not have wanted as surrogates navigate and make decisions for others.[56]

Advance directives allow patients to prevent unwanted treatments, and enable them to plan for their medical care should they ever lose capacity. Advance directive have a tremendous amount of power, however are not nearly as prevalent as they should be nor do they have the level of detail that they are needed for on a regular basis. Even when patients have an advance directive, substantial decisions will still need to be made that were not explicitly outlined or discussed with the surrogate, leading the surrogate to need guidance and assistance.[57] The number of decisions that must be made with minimal or a complete lack of guidance from the individual patient make the standards by which these decisions are made crucial. It is widely accepted that surrogates are held to higher standards and regulation than individual, autonomous patients would be, but it is not completely clear how decisions are made and what should guide these overall processes. In most instances surrogates are guided by the two most widely recognized standards, substituted judgment and best interests, both of which are patient-centered, to make decisions for the patient.[58] Substituted judgment focuses on executing the wishes of the patient, while best interests asks the surrogate to select the course of action that will most benefit the patient overall. These two models, substitute judgment and best interests, will be further elaborated and discussed in the next two sections, followed by a discussion of the problems with

these models, and finally the reality of surrogate decision making and what typically happens in practice, a more shared decision making process.

3.2.2.1. Substituted Judgment

The substituted judgment model, as the ideal model for surrogates, asks decision makers to make the decision or choice that would be the same as the patient if he or she were able to make decisions.[59] This model focuses on respecting and upholding the autonomy of the patient.[60] Surrogates should make decisions that take into consideration the patient's life, goals, values, beliefs, and the things that he or she considered most important in life. Specifically, the surrogate is asked to be a "substitute" for the patient and make decisions in the same manner as the patient if he or she retained capacity.[61] This model acknowledges the rights of the patient to have his or her autonomous decisions executed, but because he or she is decisionally incapable and unable to exercise these rights, someone else should for them.[62] This model is usually utilized when the decision maker knows about the patient's values, beliefs, and overall wishes.[63] Due to this, in a practical setting however, this model is almost impossible to execute. It is seemingly unrealistic to believe that an individual has told his or her surrogate what he or she would want in every situation or for the surrogate to know the patient well enough. Without such knowledge, it is not substituted judgment. Without such knowledge, the surrogate applies the life of the patient to the current medical situation, making inferences and guesses in an attempt to determine what the patient would have wanted. Many times surrogates are unfamiliar with the patient's wishes and will even express this to hospital staff. In these cases, the substituted judgment model is no longer relevant and the best interests model is utilized. Additionally, many times decision makers are impacted by the decision that is being made,

specifically, they may be the future caregiver or have another stake in the decision that is being made. It is almost impossible to completely substitute the opinions and thoughts of one person for those of another without some overlap.[64] Ideally the decision making process is guided by how the patient lived his or her life and the beliefs and values of the patient, however this is challenging for surrogates without the close knowledge of the patient's wishes.

3.2.2.2. Best Interests

When a patient's preferences are not known the substituted judgment model is not applicable, so surrogates are asked to use the best interests model to guide decision making processes.[65] According to this model, the surrogate must weigh the potential benefits and burdens of each available option and select the best course of action. The best interests model focuses on the current and future interests of the decisionally incapable individual and is guided by the overall "good" and "benefit" to the patient, but this is not always straightforward.[66] Best interests assessments are continuous processes rather than a one time decision to be made, as they are impacted by many components throughout the treatment cycle.[67] There are many pieces that must be taken into consideration when making these determinations including, but not limited to, potential outcomes and impacts.[68] It is not easy to determine all of the benefits or burdens of a course of action and no two individuals weigh them in the same way.[69] The benefit-burden analysis is intended to protect the well-being of the decisionally incapable individual, however because it is a subjective analysis, it can be very challenging or even confusing to the surrogate.[70] The concept of "best" is somewhat misleading in itself because it does not mean that the surrogate must provide the best treatment possible for the patient, for instance finding the best surgeon or hospital, but the surrogate should decide on the basis of what he thinks is good

for the particular patient, specifically what he or she thinks will truly benefit the patient. In the next section some of the problems with the best interests and substituted judgment model will be looked at and it will be explained why in practice, a combined, shared model is used to make decisions.

3.2.2.3. Problems with the Decision Making Models

There are many problems with both the substituted judgment and the best interests models as the guiding models for surrogate decision making in practice. In most instances substituted judgment is an unachievable ideal for surrogates because even when advance directives exist or the patient had discussions with their surrogate, they could never plan for every potential circumstance that may occur or map out every possible decision that may need to be made. If decisions are executed in accordance with this model alone, it should not be the surrogate formally making the decision, he or she is merely executing a decision that he or she knows the patient would want or would have made, however this is likely unrealistic.[71] This model in itself appears to undermine the autonomy of the patient, asking another to make the patient's autonomous decisions, despite them not even entirely knowing what a person would do in a specific instance.[72] The surrogate could know what the patient would want from several places including being told directly or through a written advance directive, or indirectly, the patient could have made his or her wishes implicitly known through comments, or it is possible that the surrogate knows enough about the patient's thinking and value system to figure out what he or she would have wanted. None of these appear to be extremely solid bases for decision making and the pure execution of the autonomous wishes of a patient, although it is argued by some to be possible in specific instances, such as when done by the patient's spouse or partner.[73]

This model gives families, who may not be reliable sources of information about the patient, a great deal of power.[74] In the absence of an advance directive, the legal surrogate could be someone who the patient has lost contact with, never finalized a divorce from, or does not agree with on a fundamental level. In these instances, the surrogate may not be in the best place to make a "substituted judgment," or misrepresent what the patient would want if decisionally capable.[75] The substituted judgment standard is overused in statement and reference; however it is almost impractical in practice. The surrogate would have to have a very deep relationship with the patient and know the specific views and values that led them to make judgments when they were able to do so.[76] They additionally would have to be able to differentiate and separate the opinions and beliefs of the patient from their own, and leave their own emotions and personal biases out of the equation.[77] Many times surrogates are also care takers or financial supporters, who have additional considerations and motivations, complicating the process of pure substituted judgment. For a true execution of substituted judgment there must be evidence that the patient would have chosen the specific therapy or treatment option.[78] This is difficult though due to the high levels of uncertainty present in many of the decisions surrogates are routinely asked to make, many times with complex details or gaps in information.[79] There are additionally many times social expectations to make a certain decision, and factors that can impact decisions outside of the medical facts such as support system or finances. In addition, surrogate must have evidence and reasons, both of which are subjective, to believe that the patient would have chosen a specific action, which becomes unreliable, especially in instances when the surrogate was appointed by the law and not the patient him or herself.[80] All of these components make surrogate decision making very challenging and the substituted judgment model almost impossible to utilize as written.

The best interests model, though it has benefits, is challenging in practice as well. When determining an individual's best interests many things come into play, including what the patient personally thought of as "best," how he or she has defined quality of life, and what he or she valued overall. For some, being in a nursing home where they can no longer be in control of all elements of their day to day life and do tasks for themselves is an unacceptable quality of life, but for others that might be perfectly acceptable as long as their pet can sit on their lap or they can visit with their family. Weighing benefits and burdens is personal and subjective, and actually involves some of the ideas and concepts of substituted judgment that are challenging for surrogates to determine, weigh, and consider. Both models have their flaws, giving too much power to or placing too much of a burden on the surrogate or overall families, who may or may not be reliable sources of information about the patient.[81] Even in cases where they have the knowledge, these decisions are challenging and burdensome for surrogates to make, necessitating some guidance and structure to the process. Both models are impossible to execute ideally or exactly as described in practice, and regardless of the decision-making model utilized, decisions will typically be made in a shared effort, elaborated in the following section.

3.2.2.4. Shared Decision Making in Practice

Regardless of which model is followed, in practice, decision making is likely to be a shared process. Physicians and medical team members generally play a large role in shaping decisions due to their expertise, but also because families wish to diffuse the responsibility for making difficult or painful decisions under conditions of uncertainty.[82] Shared decision-making, by definition, is a process of medical professionals and patients working together to select therapies, treatments, tests, and make other medical decisions based on clinical evidence and the

patient's preferences.[83] Shared decision making (SDM) involves an exchange of information between the medical team and the patient or surrogate where they each express preferences and negotiate treatment plans.[84] There are four main characteristics of shared decision making, all of which are important when thinking of it as a guiding principle for medical decision making. Charles et al believes that shared decision making involves on a basic level, (1) the physician and patient making treatment decisions, (2) both the physician and patient sharing information with each other during the decision making process, (3) they both take steps to participate in the decision making processes and express individual preferences and opinions, and (4) a decision is made and both the physician and patient agree on the selected course of action.[85] This method, even though executed inconsistently and differently throughout medicine, enables the physician to provide his or her medical expertise, but for the patient to be involved and elaborate their personal desires and beliefs.[86]

Many times, clinicians do not know how involved patients or their families want to be in decision making processes and are uncertain how to work them into the process. All individuals have varying capacities and desire different levels of involvement in their care and amounts of details and information, but it is very important for providers to determine this so the patient is able to be involved in a way that is meaningful to them. SDM processes enables patients and or their surrogates and families to be involved in decision making even when they many times lack the confidence to question health care providers, having a limited understanding of the medical field. Patients and providers do not typically have an equal relationship initially due to the education and emotional differences and barriers, making a shared process where this relationship can be built and expanded upon.[87] Shared decision-making involves negotiation and compromise, recognizing that clinicians have a lot to offer, including knowledge of the

diagnosis, likely prognosis, treatment and possibly outcomes, while the patient is able to determine the impacts of the condition and therapies on his or her everyday life, and incorporate his or her own values, preferences, and beliefs. SDM recognizes the patient's right to make decisions and respects them as autonomous individuals, while still involving the physician and medical team, to enable the patient to have the most accurate information and ideally information on the benefits and harms of interventions or actions, including any uncertainties and risks. The most common areas where shared decision making is utilized in adult medicine are when major health decisions must be made that have more than one feasible alternative, the utilization of screening or preventative therapies, and for the management of long term conditions, however many other medical decisions involve the core components of shared decision making.

Shared decision making is highly desirable if properly structured to ensure accountability and lessen impacts of conflicts of interest or personal biases. Additionally, the shared decision making process has been shown to lead to much higher levels of satisfaction in patients and families.[88] Medical decision making is not an easy task and becomes even more challenging when the sick individual is not able to make his or her decisions, however by utilizing a shared decision making model based on complete medical facts, some understanding of the individual and his or her values and beliefs, and a general idea of what is best for the patient both personally and medically, decisions can be facilitated. This shared process, as just explained, is not directly possible with children because the child patient has never had decision making capacity but are in the process of developing it, making their role in the process unclear and ill defined. This problem of pediatric medicine will be looked at in the following section. The ideas and concepts of adult medicine that are currently applied to pediatrics will be analyzed and argued to be insufficient for decision making in pediatric medicine.

3.3. Pediatric Decision Making

Decision making is challenging throughout medicine as patients struggle on a regular basis to weigh benefits and burdens of treatment options and inevitably select a course of action. It is rarely straightforward as more options are available each day, giving patients more complicated and challenging decisions to make. Decisions are not easy or straightforward in adult medicine, especially when a surrogate is involved, meaning that someone other than the patient must weigh the benefit and burden for the patient, which is seemingly impossible to do accurately. This section will argue that it only becomes more complex when the decisions being made are for children and the stakes are higher. In the first section, ideas of autonomy and consent will be applied to children, reviewing the basic status of children as minors and the connected issues. It is unclear how the concepts of autonomy and consent apply to children since by definition, they are not applicable. There are however ways that these concepts can and should be used throughout the medical world and understood in a way to enhance shared decision making. An additionally challenging element of pediatric decision making is the fact that there are many, legitimate stakeholders involved in the care of children. Specifically the child him or herself, parents or guardians, the physician and medical staff, and society as a whole have interests, obligations, and responsibilities to the child patient. All have vested interests and obligations in these decisions, which must be balanced and upheld by the decision making process, making the associated relationships crucial to the field. In the final section, the decision making models of adult medicine will be applied to pediatric medicine and decision making processes, and it will inevitably be argued that there is a need for an enhanced model for pediatric decision making that recognizes the status of the minor, incorporates the

many dimensions and stakeholders, and offers enough structure and guidance for the parents or legal guardian.

3.3.1. Autonomy, Consent, and Assent

Children, unlike adults, are not considered to be fully autonomous individuals in society. They are additionally in the process of developing the capacities needed to be decision makers and have full autonomy. This section will look at the status of children in society and how the concept of autonomy can be applied to them. It does not directly apply in the way that it does to adult patients, however there are still relevant components that must be addressed in order to fully show respect to the child as a person, and as an individual in the process of developing capacity. After addressing the place of children in society, concepts of consent, assent, and respect for persons will be applied to them as they will be used as a basis for their involvement in the decision making process. Children must be included in decision making processes and in order to do that, they must have a way to participate that respects them as persons. The final section looks more fully at the application of decision making capacity to children. In order to do this, the developmental stages of children will be elaborated, focusing on mature minors who are approaching adulthood and have varied levels of development and inevitably decision making capacity that must be evaluated so that the child patient can be included in the decision making process in a meaningful way.

3.3.1.1. Status and "Autonomy" of Children

To fully understand the dimensions of issues surrounding the capacity of minors, the legal status of children will first be briefly discussed. Legally, children do not have the ability to make their own medical decisions. The law presumes those under the age of 18, defined as a

child, to be minors in the United States and many other countries.[89] This age of 18 is not necessarily attached to a specific level of development or mental status, which will be looked at in a coming section, however this is the age at which a child becomes an adult in many societies. For children, specifically those under the age of 18, parents and or guardians make their decisions.[90] The justification for this varies, but primarily minors are argued to lack the ability to make judgments and experience necessary for responsible decision making and generally are denied legal power, requiring the consent of one or both parents or a legal guardian to authorize medical care. There are some instances where minors are allowed to make their own decisions, and there are exceptions to the age requirement, however this is not the norm. In many places, there are minor treatment statutes that allow children of a certain age to give consent for certain medical treatment without consent from their parents, and without notifying them. In instances such as sexually transmitted diseases, drug use, prenatal care, contraception, and abortion, children may be allowed to make their own decisions without the notification or involvement of parents or guardians, however that is not consistent in all places. Outside of the defined exceptions, there is also a "mature minor" status where the minor has been found to be mature enough to make his or her own medical decisions through an evaluation process, however the criteria and age limits for this varies between locations and are ill defined.[91] Outside of those exceptions and specific instances, children are not allowed to make their own decisions and many times do not even have a voice in the decision making process.[92]

In adult medicine, patients are seen as autonomous, and out of respect for their autonomy, are involved in the decision making process and afforded the ability to participate in the process of informed consent.[93] When patients make their own decisions, they are allowed to make any decision or choice, executing their autonomy. This becomes more challenging when surrogates

make decisions for the patient and additionally troubling when the patient has never had decision making capacity, which is the case with children. Patients who have never had decision making capacity and lack autonomy do not have the ability to give formal consent or participate in a standard way in the informed consent process. In general, minors lack the attributes associated with full autonomy and decision-making capacities and are therefore, not formally included in all decision making processes.[94] Parents or guardians are typically given the legal authority to make decisions for their child, however, it is unclear where this authority comes from. Many argue that because they are the guardian of the child and person responsible for their care, they should additionally make medical decisions.[95] It is also argued that the parent or guardian is in some way executing the future autonomy of the non-autonomous child, as some argue the surrogate is for adult patient who have lost decision making capacity. It is argued that surrogates execute the autonomy of the patient when making decisions based on the previous wishes and decisions of the autonomous patient, but minors have never had autonomous decision making capacities, so this application is not clear. If parents are simply the final decision makers because they are the legal guardians of their children, decision making capacity of the child becomes a much more crucial issue as the child should be able to act on his or her own behalf, or at least participate in the process, when he or she is capable of doing so.

Due to their legal status, children are not always included in decision making processes nor are their opinions consistently taken into consideration despite the tremendous benefits from their involvement.[96] Some physicians involve minors in the decision making process even when they do not have capacity, but this is not legally required nor standard practice in all placed. If the child disagrees with his or her parents it is not clear what would happen or how this disagreement would be handled since the parents are the legal decision makers.[97] At one point

children were thought to be the property of their parents and it was never questioned what parents did or what the child thought.[98] However over time, children have gained a status in society as well as the medical world and it is now argued by many, including the American Academy of Pediatrics Committee of Bioethics, that they should be involved in the decision making process to the highest degree they are capable.[99] Involving children in medical decisions leads to better medical results and also prepares them for later in life when they will be in control of their decisions, allowing them to take some responsibility for their life, especially when they are of an age that is approaching adulthood.[100] In many countries there is a strong recommendation, if not requirement that the assent of the child is taken into account when the child enters a research study, however this is not standardly applied to all areas of pediatric medicine, specifically cases of mature minors and new technologies where it becomes most relevant and beneficial.[101] Assent, which will be looked at in the next section, acknowledges the child as a participant in the decision making process and shows respect for them as a person, acknowledging their future autonomy.

In order for children to be given a voice in the medical world there needs to be a process or system to determine decision making capacity that then translates into a role in the process of making medical decisions. Most of the major issues surround adolescents, as they are approaching the age of consent and in the process of gaining decision making capacity. Adolescents and older children occupy a position on the decision making continuum that is both legally and ethically ambiguous.[102] They are not legal decision makers, nor do they have full decision making capacities in all cases, but they also have some capacity in most cases, making their involvement challenging. Legally they do not have a right to be involved in their healthcare decision making but there are many benefits to having them involved, including better results

from care.[103] Additionally, since they are close to adulthood this enables them to feel empowered and in control of their healthcare and overall lives. Despite their legal status they have a legitimate interest in the matter at hand, specifically their own medical care and decisions, and ideally they will be able to participate in a meaningful way that carries legal weight.[104] It is argued that children have a moral and ethical claim to being involved in their care if they have the ability to do so, even if it is only on a minimal level.

3.3.1.2. Consent, Assent, and Respect for Persons

It is regularly accepted that children, as a population, do not have decision making capacity and are not fully autonomous individuals, therefore unable to give legal consent in almost all instances. This does not however mean that they should be excluded from decisions surrounding their heath and medical care. It is crucial that children are involved in the decision making process to any extent possible, and that they are listened to throughout the process.[105] Much of this is dependent on the developmental stage and overall abilities of the specific child.[106] As all children grow, they develop, learn, and progress at different paces, all of which must be taken into account and will be looked at further in the following section. Even though concepts prevalent throughout adult medical decision making, such as autonomy and informed consent, are not legally applicable to children, much can be gained from applying them to pediatric populations. A person who consents bases the decision upon his or her personal beliefs, values, and goals. Concepts of respect for autonomy and informed consent are both aimed at showing respect for persons, which is applicable to children and the field of pediatric medicine. Respect for persons demands that patients lacking decision making capacity be given the opportunity to participate in the decision making process to the extent that they can. This

concept and application of the theory leads to the more common conception of consent in pediatrics, assent. Assent is the expression of the child's will to participate in the given therapy or treatment and is driven by the principle of respect for persons, making it possible for children to express their opinions and desires. Assent of the child is a desired outcome in pediatric medicine, but as discussed it is not legally required.

When pediatric decision making is grounded in autonomy, it holds children to a higher standard for involvement in decision processes than what is developmentally appropriate, making their involvement unlikely. On the other hand, the concept of respect for persons incorporates a full range of potential decision making roles for children and supports a linked approach to assent and permission while acknowledging the future status of the child as his or her own decision maker.[107] Children will one day be fully responsible for their own care and life choices, making it important that they are involved in medical decisions as they approach adulthood, especially when they are in the ambiguous stage of adolescence. This participation and empowerment is consistent with the intent of the United Nations Convention on the Rights of the Child (1989) to give children a voice in the medical world.[108] Providing children with a shared role in the process treats them with dignity and respect, and upholds their moral worth as children. Additionally, it encourages their development and leads to enhanced abilities for self-governance in the future. Overall, mature minors are the most problematic and challenging group of children to involve in the decision making process since they are much closer than other children to being legally adults and their level of competence and development is continuously changing and varies greatly among children. Mature minors are approaching the threshold of becoming the stewards of their own care, so the balance of these future interests and roles must be taken into account with the current state and interests of the child. Children must be stewards

of their own care and involved to the highest degree possible. On the other hand, too much control and power should not be given to children, even adolescents, because they are not fully autonomous or experienced to make decisions in all cases. It is crucial that the child be evaluated in a diligent and meaningful way so that they are able to participate in a meaningful way however not so that they are carrying heavy burdens or making complex decisions that they may not understand the long-term effects of. As children develop, specifically mature adolescents, they should gradually be granted decision making authority, and seen as partners in the medical decision making process in a way that they can until they are able to achieve full decision making abilities.

3.3.1.3. Developmental Stages and Decision Making Capacity

Children have a right to involvement in their medical care, making it necessary that there is a reliable and effective way to evaluate them, determine capacity levels, and facilitate a bigger role in their own care. Children have never fully had decision making capacity, rather are in the process of developing it, placing them in an uncertain place on the spectrum of decision making capacity.[109] Decision making capacity is not global and decisions require different levels of competency based on the level of risk, options, and uncertainty associated with the specific decision. For instance, the same amount of capacity is not needed to decide to take medicine for pneumonia compared to that of selecting a cancer therapy after years with the disease. Many adults without full capacity are able to make certain medical decisions after capacity has been assessed, making it crucial that such capacity is reviewed with developing minors and they are empowered be involved when possible.[110] Within the classification of "minor" there are "infants," "children," and "adolescents." The American Society of Pediatric outlines four stages

of development: infancy (prenatal-1), early childhood (1-4), middle childhood (5-10), and adolescence (11-21). The transition from infant to adolescent can be explained by going from a state of complete dependence, infancy, to that of being an autonomous individual.[112] According to Belsky et al, the developmental stages begin with infant then transition to early and middle childhood, adolescent, and finally adult.[113] According to Scarre, childhood starts at about 3, when children can move about on their own and communicate, prior to that they are infants. Infants are fully dependent whereas children are less dependent and considered active agents that can begin to lead their own lives with choices. In these conceptions of infant and child, language skills and mobility are key components because they make the separation from the mother possible, therefore the infant moves out of "infancy" and into childhood. After childhood, or within later childhood, children reach a point of adolescence. Adolescents are described as individuals between the age of 10 and 21 years of age by Fleischman and Collogan.[114] Their constant state of physiological and psychological development sets them apart from younger children and adults, but development is something that is not the same for all children, everyone grows and changes at different rates. This view promotes the idea that childhood is about development, making it different for each individual, so not necessarily tied to a specific age, which also explains discrepancies throughout cultures and societies.[115] In different places children are raised differently, taught different things, and expected to do certain things at specific ages or times in their lives, all leading to their pace of development. It appears that the key to defining a child lies within developmental and mental changes.[116] As children grow up and gets older they begin to look and feel differently and they begin to define their self image and attempt to understand the self. This is also accompanied by cognitive changes, making them able to imagine what "could be", thus possibilities. They comprehend more, also the hypothetical

and abstract become possible to envision.[117] There are other conceptions and ideas of when childhood begins, but there does not appear to be much agreement, even within similar societies. This general disagreement, or agreement that it is dependent on the child, makes it evident that children are different than adults in numerous ways, including that they are constantly growing, changing, and developing, calling for additional levels of care, specifically for the development of pediatric medicine.

Adolescents are especially troubling because there are many mature adolescents with more capacity to make decisions than some adults, however society has an inclination to let the adult decide more while sheltering or protecting the child and allowing parents to guide.[118] The growth from infant to child is facilitated by the parents however the transition to adolescence has much more independence. The entire transition from infant to adolescent can be explained by going from a state of complete dependence (infancy) to that of being an autonomous individual.[119] The main problem with this however is that it does not explain if a child is considered autonomous once they reach adolescence or if it is not until adulthood, or the even more troubling response of "it depends on the child." Some conceptions of childhood argue that individuals are considered children after the stage of infancy, and this is supported by historians, language, and common speech as well as, specifically the use of words such as "infant" and "child" and them not being used interchangeably.[120] This only emphasizes the ambiguous and complicated dimension of adolescents. Adolescents are somewhere on the spectrum of capacity, however it is very unclear where since all individuals are different and develop at different rates.[121] Good decision making comes with time, practice, and experience, all of which children lack, inevitably limiting their overall ability to make decisions, but adolescents may have some levels of decision making capacities. Adolescents are neither children nor adults and appear to

have a "foot in each world" because their intellectual and emotional development is greater than that of young children, yet most are not fully mature and have not been exposed to the same types of things that adults have. Children between the ages of 9 and 17 have varying degrees of decision making capacity.[122] When it comes to decision making, older children present many problems related to their emerging cognitive abilities, self-awareness, and moral authority.[123] Many times older children can grasp core pieces of the information and can have the ability to give consent with regard to a specific decision, yet lack the maturity or ability of an adult to make decisions.[124] In these cases, children should be involved in the process, but they should be provided support and guidance, enabling them to overcome their maturity levels but still participating. The evaluation of decision making capacity with minors is a different process than with adults; adults are presumed to have capacity until it is proven that they do not, whereas children are presumed to lack capacity until they are able to demonstrate that they have such ability.[125] In both cases, evaluation of overall capacities is necessary, however due diligence must be done to ensure that the child is not overlooked or incorrectly assumed to not be of the correct capacity because if differs that that of an adult.

Capacities in some way necessary for decision-making include communication, comprehension of information, reasoning and deliberation, and the ability to have and apply a set of values or conception of the good, all of which are difficult to assess in mature minors.[126] Comprehension is a questionable requirement because many times patients, adults and children alike, are unable to comprehend and understand much of the medical terms, concepts, or information in general due to circumstances and a lack of medical knowledge.[127] The analysis of adolescent decision making capacity is complex and nuanced and evaluation must look beyond basic cognitive abilities. These evaluations must consider personal values, patterns of decision

making, and behavior including risk taking behavior, biological and emotional maturity, life experiences such as health care and treatment, their ability to appreciate the cause, effect, and consequences, and abilities to think about the future.[128] These attributes and characteristics have direct implications for the capacity to make decisions, especially those with high stakes and potential negative consequences.

The difficult issue then becomes when or at what level decision making abilities have reached a point that the minor can be considered capable.[129] There are basic estimates about what ages children acquire different skills and capacities, however all children reach different stages of development at different times, especially the capacities needed for decision making such as reasoning and deliberation, which are not purely biological capacities but greatly influenced by experiences and environment.[130] Children by the age of 14-15 usually have developed some of the capacities necessary for healthcare decision making to a level roughly comparable to that attained by most adults.[131] Starting as early as 12, many children demonstrate the capacity to reason, including the ability to understand the cause and effects of illness, that is both as good as and as flawed as it can be in adulthood, however their autonomy is limited by their inability to make authentic statements about values and commitment.[132] Some studies argue for an absolute minimum of 12, but it is not definite for everyone.[133] Age in general is troubling because even at 18, there is not a switch that goes off that turns an adolescent into an adult, merely a legal cut off that is accurate in most cases. Every situation is different, and must be evaluated in and of itself, although it is good to have a basic understanding of the developmental stages and how children develop capacities while doing so. Many believe that children who have had chronic illnesses for many years achieve an understanding and an ability to make decisions about their treatment long before other children.[134] It should not be troubling

to evaluate and find adolescents to have some level of capacity because decision making capacity of children does not imply their ability to make decisions alone without the influence of the health care team, medical professionals, or primarily their parents who remain the legal authority.[135] Ideally all children will be evaluated, but it does not appear that this is what happens in practice. The presumption that children under the age of 18 are unable to make their decisions needs to disappear and criteria and evaluation methods need to be created to determine the capacity of minors.[136] In order for pediatric medicine to be as effective as possible and enable patients to achieve meaningful outcomes and do what is right for the patient, children need to play a bigger role in their medicine, therefore it is extremely crucial that a method for evaluating the capacity of children be created that can effectively determine an appropriate level of involvement. The role of the child should vary depending on the circumstances and overall situation, including the complexity of potential risks and benefits, and the availability of alternatives, however they should not be immediately excluded without evaluation. The presumption that all under the age of 18 are unable to make their decisions needs to be replaced with ideas that all should be evaluated based on the decision that needs to be made and allowed to participate at the level of their developmental capacities.[137] There also should be legal standards giving children an acknowledged not a final say, however some level of involvement in a meaningful and legal way is important.[138] Parents, as legal decision makers for their children rather than executors of their child's autonomous wishes, must work hard with all involved in the care of the child and with the child if possible to select the most appropriate option. The next section will look specifically at the stakeholders involved in the decision making process and the many relationships that must be upheld and balanced for optimal care decisions to be made for children.

3.3.2. Decision Making in Pediatrics

Decision making is a complex issue throughout medicine, and is even more challenging when the care involves mature minors who have an undefined amount of capacity and ability to make decisions. These minors are not autonomous like most adults, however they have some level of capacity and in many cases, enough to make a given medical decision. It is crucial to both the care and future outcomes for the child that he or she be involved to the extent possible.[139] Involvement leads to better overall medical results as well as the child taking responsibility for his or her life, empowering the child to grow into a successful and autonomous adult. This section will develop the additional complexities of decisions for children, including the roles and relationships of the parents, medical team, the child patient, and society. All involved have varying interests in the outcomes of the child and future development, therefore all have some interest and stake in the decisions that are made and the overall process. There are additionally more levels of complexity within pediatric care that must be incorporated into a decision making model. In the final section, the decision making models of adult medicine will be applied to pediatrics and argued to be insufficient for framing decisions made for minors.

3.3.2.1. Dimensions of the Pediatric Decision Maker

Pediatric decision making is a complicate process with involvement from many different individuals and roles. Children do not have autonomy or the legal right to make their own decisions, but are at a stage in life where they are approaching the necessary capacities and they must be properly evaluated so they can be involved in the decision making process.[140] Decisions for children are not typically straightforward or easy to quickly make, carrying great importance

and the potential for lifelong impacts. Many individuals have large responsibilities in the process, primarily the parents or guardian and physicians, however the child and society as a whole also have impacts, although the boundaries of these roles are not well established.[141] The child, as the patient, should be looked at first during the decision making process to determine an adequate and appropriate level of involvement. Adolescents, in an ambiguous place on the spectrum of decision making capacity, are especially challenging to evaluate as they grow and transition from child to adult.[142] Parents are a central component to the transition from infant to early and middle childhood, however during transitions to adolescence and adulthood, minors have much more independence but are still closely connected to and supported by their legal guardians or parents in most instances.[143] According to the US legal system, an individual is an adult at age 18, however according to the American Society of Pediatrics adolescence extends to the age of 21, emphasizing the non-existence of a standard definition and the ambiguity of age.[144] As a child gets older he or she begins to look and feel differently, developing a self-image and conception of the self. These changes are also accompanied by cognitive developments, enabling them to look to the future, picturing what could be or is possible. As they develop, children comprehend more, including the hypothetical and abstract, making them valuable to the decision making process. By including children in decision making they are validated as individuals, they can feel in themselves, and trust the staff, and additionally will cooperate better with the treatment or therapy selected, all leading to better medical results.[145]

The child's self-determination, and when possible opinions, should be considered but the interests of the parents who are making important decisions for their minor are also involved and many times interconnected with the interests of their children.[146] For the most part, parents are thought to be the best decision makers for their children, argued to be best suited to judge the

child's interests.[147] Children and their parents are closely related and many values and personal preferences flow from parents to child as they are the individuals caring for all aspects of the child's life.[148] There is additionally a presumption that parents will do a better job of making decisions for their child than anyone else could because in most cases they deeply care about their children and know them better than others, placing them in a unique overall position to serve the child's interests and advocate for him or her.[149] In addition, parents must deal with the consequences of treatment choices for the child on a daily basis and many times there are severe financial or long-term effects to consider.[150] Many parents often willingly become parents prepared to sacrifice their own interests for the sake of their child in ways they would not, nor could they be expected to, do for others.[151] The job of parents as parents is to stand between their children and danger and protect them from injury and illness, and often with that comes feeling of obligation and duty. Parents are likely to feel the obligation to advocate strongly for anything that holds even the slimmest prospect of success and they can perceive refusal to provide therapy as not fulfilling their nurturing, parental duties.[152] It was ruled by the US Supreme Court that parents have a right to make decisions for their children, specifically, "the law's concept of the family rests on a presumption that parents possess what a child lacks in maturity, experience, and capacity for judgment required for making life's difficult and challenging decisions... more important, it is historically noted that the natural bonds of affection lead parents to act in the best interests of their children.[153]" Parents have an incredible role in all aspects of their child's life and are argued by many to be in the best position to make decisions for them, however this becomes much more challenging in cases where they may not understand what doctors are telling them, or instances where personal choices of lifestyles impact the decisions. It is unclear if parents can force their religious choices or morals on their children

who are unable to make decisions and choices for themselves. Parents have a legal right and authority to make decisions for their children, but it is not always black and white as they cannot make any decision that they want. These grey areas are where additional roles come into play, instances where others may have stakes or responsibilities to advocate for the child or participate in the decision making process.

In addition to parents and the child him or herself, physicians have obligations to the child as his or her doctor. The goals of medicine and the doctor patient relationship are a focal point of good care and medicine and doctors must do what is both right and good for their patient.[154] Physicians not only have to make an accurate diagnosis and treat the child, they also must communicate with the patient and family. In cases with minors though, it is unclear who the doctor should involve and where his or her formal obligations and responsibilities lie – the child, parents, family, or a combination. The idea of patient centered care focusing on the autonomy of the patient is not easy to directly apply to pediatric medicine and pediatricians appear to have many, sometimes even conflicting obligations.[155] In order to best serve patients, doctors and nurses need to address issues with the patient or their family in a timely manner to give them adequate time to make decisions. There are immense amounts of feelings, emotions, and outside impacts on family members, and extra time and care needs to be taken to deal with them all differently. This is why within pediatrics, parents and physicians are many times thought of as co-fiduciaries, both having strong obligations to the child patient.[156] There is a great disparity in most instances between what the pediatrician understands about the medical case and what the parents are able to understand. As laypersons, parents do not have the expertise to promote the medical interests of their child and must defer to the evidence-based clinical judgments of pediatricians. Pediatricians have many conflicting roles including listening

to the child, upholding the family unit, and supporting the parents, while first and foremost serving the child's best interests.[157] Pediatricians have an obligation to present all medically reasonable alternatives, specifically all options both possible and physically available with reliable evidence of clinical benefit and from there, parents are free to select any one of such medically reasonable alternatives. Parents are not however ethically free to reject all medically reasonable alternatives, because doing so is no consistent with protecting and promoting the child's health-related interests. Pediatricians have an obligation to protect and promote the health-related interests of the child while parents have a fiduciary obligation to promote and protect the non-health-related interests of the child. Pediatricians should be willing to make strong recommendations and potentially greatly influence parental decision making.[158] Balancing the roles of physicians and parents is challenging, especially when incorporating the opinions of the mature minor, and becomes slightly more challenging when decisions are constrained by society.[159]

Society as a whole has a stake in the overall health and wellness of children. At one point, children were thought of from a legal standpoint as the property of their parents, however over time this has changed. There has been a transition from the state not wanting to infringe on family life and allow parents to raise children as they see fit, to now advocating for the child's interests and even overriding the parents in some instances. In cases when parents or legal guardians fail to exercise appropriate parental responsibilities for their children, in many cases the state assumes legal custody of the child or appoints a guardian to make the decisions for them.[160] States have the legal authority to step in when they believe that the minor patient would benefit or that the best interests of the child would be served with someone else as decision maker.[161] In addition, legislation has established things parents can and cannot decide for their

children. There are limitations of parental rights to refuse treatment for their children and to insist on treatment, such as instances when specific interventions are determined by the care team to be inappropriate or ineffective, or when the burdens and risks clearly outweigh the benefits.[162] In these instances, physicians have an obligation to protect their young and vulnerable patients from measures that are not clinically indicated and the state can step in.[163] The role of society is not one that is involved on a daily basis for decision making however legal systems have stepped in to ensure the protection of the well-being of children and the legal dimensions of what is and is not allowed must be considered during the decision making process. There are many stakeholders in pediatric medicine and the opinions and conceptions of all parties must be balanced. Although parents or guardians currently in the way legislation exists have the legal final say and authority to make the child's medical decisions in most instances, ethically, this is not sufficient for the best decision to be made and there is a need for an enhanced model that incorporates and acknowledges all parties.

3.3.2.2. Decision Making Models Applied

Pediatric decision making is not an easy process with many individuals and stakeholders involved, including the minor patient with a varying degree of capacity. In order to properly balance all of these dimensions and elements, a model is needed to facilitate and guide the process. Currently in pediatrics the best interests standard is utilized for children but before moving to discussions of that model it will be briefly addressed why the substituted judgment model does not apply to children since it is the ideal model utilized by surrogates within adult medicine. Substituted judgment is not typically relevant to children because they have never had the capacity for decisions, which is the basis of this model.[164] This standard for the model is

impossible to apply to children as it is formulated because the autonomy of an individual who never had autonomy cannot be upheld or executed on his or her behalf, nor have beliefs or values that have not been developed be applied to scenarios.[165] Despite this, children have varying levels of capacity and experience, and can sometimes be involved to a certain degree with their care, so these experiences can potentially be taken into account when making decisions, even if they do not have full decision making capacity. Parental decisions may or may not reflect the values of the child, as they are not required to be since the child has not had the opportunity to mature and is not an autonomous individual.[166] The substituted judgment model can be a comforting tool for parents to feel better about decisions or think of things in a different way that may incorporate what they child believes by thinking their son or daughter may have wanted a particular intervention or removal of therapy. Additionally, this model can help guide parents of older children who are unable to participate or share their thoughts and opinions. Although not directly applicable, because this is the ideal model of surrogate decision making in adult medicine and children are found to have varying degrees of competence, it should be taken into consideration when reformulating a decision making model for children although obviously not used as the stand alone model for pediatric decision making.

Substituted judgment cannot be used as a comprehensive and applicable model for pediatric decision making, making the best interests model the next candidate. The best interests standard is the typical model parents are asked to utilize in pediatrics, requiring that parents select the treatment for their child that is in their child's best interests after considering all options and relevant information.[167] During the deliberation process, parents are asked to weigh all potential benefits and burdens and select the option with the greatest net benefit for the child which additionally causes the least burden. The standard is argued to give parents the guidance

they need when making choices for their children because they have personal discretion to judge what is in their child's best interests but additionally have a duty to provide them with acceptable care.[168] Under this standard, parents should use all available information to assess the child's immediate and long term interests and should then select the option that maximizes the child's overall or long-term benefits and minimizes burdens.[169] The problem with this is that there are objective and subjective elements to these crucial assessments, and since parents are the legal decision makers the burden is placed on them without arguably enough support or ensuring understanding.[170]

The best interests model is increasingly used by judges, physicians, lawmakers, and teachers to make judgments for those lacking the capacity to do it themselves.[171] This standard has been discussed frequently in medical, legal, and bioethics literature, and given different meanings by different authors, such as "requiring decision makers to do what is ideal"[172] . These formulations however are problematic because they make the best interest standard require something that is potentially impossible, and parents cannot have a duty to do the impossible therefore these explanations of the standard do not capture the "practical" meaning. In practice, the best interests standard is more of a guidance tool rather than an ideal, and even as a guidance tool it is lacking.[173] As a guide, the principle does not require what is ideal, but what is reasonable.[174] The best interests principle, even as a guidance principle, it is only supposed to be a regulative ideal, not a strict requirement. Parents' obligations toward their other children as well as their own legitimate self-interests can conflict with doing what maximizes the child's well-being, and sometimes may take precedence. It cannot be expected that parents ignore their own important interests to benefit their child, but they are supposed to be making the decision in the best interests of their child according to the definition of the best interests standard.[175] The

model should not be thought of as requiring literal optimization of the child's interests in all cases, but also suitable intervention principles will allow parents considerable leeway- tolerating departures from what would be best for the child.[176] The standard interpretation of this model is that it requires the choice of what is reasonable given all of the information and options available. It is however, unclear who evaluates and determines whether the choice is reasonable since the parents, physician, child, and even society have roles and a stake in the process and decision that is made.

In addition, the best interests model places too much responsibility and burden on the parents, who are already in an undesirable and extremely difficult position. Parents may not always make good judgments about what is or is not in their child's best interests for two reasons: (1) some find it difficult to accept the birth of a defective child so that they decline reasonable treatment, and (2) some find it too difficult to accept the death of a child so that they insist on unreasonable treatments.[177] The best interests standard is argued to be vague and subjective because determining what is ideal or best is very difficult and in these cases individuals, specifically the parents or guardians, fall back on personal biases and experiences for formulate their conceptions of best and ideal.[178] Parental distress upon discovery of infant's problems is understandable and this distress increases as the future impact on their lives and potential entire family begins to set in. Assessments of the best interests of the child are formally guarded by the parents, however the clinician is best placed to judge them on the basis of medical criteria.[179] These conflicts make it necessary that the physician and parents work together to outline options, benefits, and burdens to enable the best decision to be made.

Overall, there is a great deal of controversy over how to make good treatment decisions for children.[180] The best interests model does not acknowledge the many dimensions of pediatric

decision making, only explains that the parents must weigh the benefits and burdens and select the option that is best for their child, which is beneficial, however not sufficient for pediatric decision making. In addition, this model does facilitate the participation of the child patient to the level that they are capable unless the physician and parents enable such interaction. Despite claims that they are the best decision makers for children, parents are not in the ideal place to make medical decisions for their children due to outside impacts, emotions, and a lack of medical knowledge, among others. Additionally, neither the substituted judgment nor the best interests model gives enough guidance or support to parents, even combined. Both models have a lot to be gleaned from them that could arguably be incorporated into a new, enhanced model, however it is crucial that the enhanced model be developed for pediatric decision making to enable parents or guardians to make the optimal decisions for their child.

3.4. Conclusion

Pediatric decision making is more different than adult decision making, however it is important to understand the concepts of both decision-making processes and models since pediatrics emerged from adult medicine. The model that is most widely argued for and used in practice with pediatric decision making is the best interests model, however due to many limitations and issues, it is insufficient to guide and facilitate the proper coordination of all parties involved and help the parents on a level that they need. Physicians have an obligation to look out for and protect the interests of their patient, the child, and according to the best interests model are asked to give parents enough information to determine what is in the medical best interests of the child. They are additionally not supposed to coerce or be paternalistic in their guidance and discussions with parents, which is a fine balance for them to uphold. From this

information, parents are given the daunting task of selecting the best treatment option for their sick child taking all other dimensions into consideration. Society has an interest in protecting the lives of children and works to ensure that parents are making decisions that are in the child's interests and do not put the child at risk while also not overstepping their boundaries. Society has an important role because it have the ability to impact all decisions, however societal influences should not go too far and cannot restrict the autonomy and liberties of the patient, parents, or even physicians. The final, and most challenging yet crucial role in the decision making process is the child patient, him or herself. The child must be evaluated as a possible decision maker, even if that is simply to say they are unable to participate in a meaningful way, but things become grayer when the child is an adolescent of undetermined capacity. Children of all ages need to feel that they have been listened to and taken seriously and additionally medical professionals have a duty to respect the child's voice.[181] Even when children are not found to be decisionally capable, they should still be listened to and involved in the process, despite the fact that they will not have the final say or legal stake in the decision.[182] The voice of the child must be held in balance with the views of the other legitimate stakeholders in the decision making process. The goal of the process should be to identify the decision that is in the best interests of the child, which can only be achieved through a new formulation of a decision making model governed by practical ethical principles applied to pediatric medicine in a way that enables the participation of the child.

There is a great need for an enhanced decision making model for children not only because the models of adult medicine do not apply nor are sufficient but also because, first and foremost, pediatric decision making is more complex than adult decision making due to the additional dimensions, individuals involved, and the vulnerable position of the patient as

incapable of being a decision maker. The overall goal within pediatric medicine is for the patient, family, and caregivers to work together in a process of education and support enabling collaborative decision making.[183] In order for this to occur and the best results to be achieved within pediatric medicine an enhanced decision making model is needed that acknowledges the capacity of the child, includes all relevant parties including the child to a level that they were found to be able to participate, and offers more guidance and support for parents while attempting to determine a course of action for their sick child.

Notes to Chapter 3

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Chapter 4 - Changing Field of Pediatrics and the Need for an Enhanced Model

4.1. Introduction

The field of pediatric medicine is continuously changing and developing with new technologies and innovations. These developments are made in hopes of curing illnesses and providing more effective therapies for devastating pediatric disorders and illnesses. With these new interventions comes much promise for the future, but also many complex ethical dilemmas, numerous issues, and challenging decisions that must be made. This chapter will specifically look at expansion within the areas of genetic screening, neurotechnologies, and clinical research in genetics and neuroscience. New technologies have developed in each of these areas and have led to tremendously enhanced ethical issues and decisions to be made unaccommodated by the current models of decision making utilized within pediatric medicine. Each of these areas has been the focus of a great deal of experimental research leading to the utilization, and potential expanded use, of many new therapies and technologies. In the field of genetics, newborn screening panels have steadily expanded, depending on the location and many times including the identification of disorders without accessible or affective therapies. Advancements in the area of whole genomic sequencing, including the ability to reduce cost and identify more disorders, leads to its utilization as a diagnostic tool and the potential use of it coupled with newborn screening in the future. Within the field of neuroscience the development of diagnostic tools to view brain processes and areas of engagement have led to the diagnosis of many neuroaffective disorders and other conditions of the brain. Clinical research trials have been central to the development of new interventions throughout medicine, particularly within pediatrics and the areas of genetics and neuroscience. This chapter will look at the expansion of each of these fields, emphasizing the ethical issues that they create, including the challenging

decisions to be made, placing parents, medical providers, and the child patient in difficult positions.

After reviewing the advancements that have been made in the areas of genetics, neurotechnologies, and clinical research, the second half of the chapter will explore the ethical challenges associated with them. There are many ethical issues that these new interventions bring with them when applied to the field of pediatrics including issues of informed consent and assent, the creation and broadening of the therapeutic gap, great levels of uncertainty, privacy of information that is found about the patient, future implications for the child and his or her family, and the great potential for enhancements or modifications with these interventions. Due to the evolving nature of these interventions and continued growth and expansion leading to the ability to know and treat more disorders and illnesses each day, these ethical issues are very challenging to address and continuously changing. Overall, it will be argued that the issues associated with the new advancements in the areas of genetic screening, neurotechnology, and research with children make central components of decision making processes, including determinations of benefit and burden and the ability to give meaningful consent, extremely challenging, if not impossible in some circumstances. Additionally, cases of mature minors make this even more troubling, necessitating that a new variation of the shared decision making model is created to facilitate decision making and enable parents to make the best decisions for their children.

4.2. Emergence of New Technologies

The challenge of parental decision making in pediatrics becomes increasingly complex as new technologies and interventions enter into the spectrum of care. Pediatrics has always been a field of innovation and advancement due to heightened attention given to the care of and for

children however, within the past decade, tremendous progress has been made throughout the field. This progress, specifically within several crucial areas, has saved and improved the lives of countless children, but additionally presents enhanced ethical issues to work through and difficult decisions that must be made.[1] The fields of genetics, neuroscience, and clinical research are expanding at an exponential rate, with promises of enhanced therapies, earlier or more accurate diagnoses, better care, and inevitably an improved quality of life for sick children. Advancements in each of these areas make decisions challenging in all of pediatrics, but even more so with adolescents as their role is not clearly defined in the decision making process, nor is a there an easy way to calculate potential benefit and burden of both current and future interests of the child in both therapeutic and non-therapeutic interventions. This section will develop the innovations and developments of the fields of genetic screening, neurotechnologies, and clinical research that have led to more complex ethical issues and decisions throughout the field, placing children, parents or caretakers, physicians and even society in difficult positions and charged with making very challenging decisions.

4.2.1 Genetic Screening

The area of genetics has grown tremendously in the past few decades as a great deal of attention and focus has been placed on this field.[2] There was a great deal of enthusiasm and excitement generated after the Human Genome Project and many gained strong beliefs that the role of genetics was to identify health risks, dispositions, and inevitably develop care and treatment options for many illnesses, such as cancer, diabetes, or heart disease.[3] This project brought attention from the media, politicians, and the general public, leading to a great deal of attention and financial support leading to a great deal of growth and expansion of the field, that is

only increasing over time.[4] The pace at which new genetic interventions are developed and implemented throughout the field of medicine is quickly expanding and not likely to decrease in the near future.[5] With this great expansion come many therapies that are valuable but also those that are not and may lead to inaccurate diagnosis or misleading results. Genetic screening has seen tremendous growth in the past decade and is only going to continue to grow in coming years. Genetic screening tests are performed throughout the world, and on every baby born in the United States and many other countries.[6] Screening is a public health initiative that can be used to survey an entire population for illnesses to identify those with a predisposition before they exhibit symptoms.[7] It can additionally be used on a smaller scale for a subpopulation or even individual. The intended purpose is to identify those who are suffering from or are likely to develop a specific disease or condition and are likely to benefit from each detection and intervention.[8] Genetic screening for newborns began primarily with newborn screening in the 1960s after a simple genetic test involving a few drops of blood was developed for PKU, a disorder that causes severe mental retardation if left untreated but can be easily regulated by diet.[9] Shortly after this development, most states in the US passed laws mandating that the test be performed on all newborns.[10] It was decided that the burdens of the bloodspot were outweighed by the positive impacts that could come from the identification of the child carrying the genetic disposition for PKU. Currently about 200 cases of PKU are diagnosed each year through newborn screening and education is provided to the family on how to regulate the disease and prevent side effects.[11] The utilization of genetic testing for PKU is a successful intervention as there is something that can be immediately done for the child to lessen and ideally prevent symptoms of the disease. Over time though, and with the development of tandem mass spectrometry (MS/MS), newborn screening has expanded to over thirty disorders, all of

which are not as predictable or treatable.[12] In the past, tandem mass spectrometry was time-consuming and expensive, making it impractical for newborn screening with unpredictable results. But after the automation and advancements of MS/MS, it became possible to use the increasingly sensitive genetic microarray in newborn screening on a larger scale, specifically with the entire population of newborns.[13] MS/MS can be utilized to screen infants for many disorders without needing more blood collected than for the initial PKU newborn screening test, leading to the rapid expansion of newborn screening.[14] Due to the effectiveness and no additional blood needed than the existing test, MS/MS was added to newborn screening panels and led to screening processes that were quick, accurate, and relatively inexpensive. MS/MS makes it possible to test for many more disorders though, leading the issue to then become what disorders are tested for as part of the panel. Depending on the state, newborns are screened for anywhere from 29-54 conditions.[15] In most states in the US, laws mandate newborn screening and of the 4 million newborns screened each year, 5,000 are found to have heritable disorders.[16] Almost all babies born in the United States undergo screening immediately after birth to identify genetic defects and dispositions that could cause serious illnesses if left untreated and all but 6 states charge for these tests.[17] These disorders are included in order to identify the diseases as soon as possible so that treatment could potentially be given even before symptoms present or parents could be aware, ready, and able to give a therapy as soon as symptoms onset.[18] There are however, many disorders that are screened for that are not as treatable or easily diagnosed as others, making the expansion of the panel complicated.

Beyond screening at birth, genetic testing is available for older children and quickly becoming an important diagnostic tool in medicine.[19] It has become common for adolescents to participate in some kind of screening and there have even been high schools who have screened

for disorders such as Tay Sachs disease.[20] A number of different approaches to broadening newborn screening beyond tandem mass spectrometry, such as proteomics, microarrays with bead technology and nanotechnology approaches, pulse oximetry, and DNA-based technology, are in various stages of development, making it likely that the number of disorders screened for will only increase as will the use cases for them throughout society.[21] Additionally, advances in whole genome sequencing (WGS), including decreasing cost, heightened accuracy, and more predispositions for diseases that can be accurately identified, it is possible that this process will be added to or done in conjunction with screenings performed at birth.[22] It is additionally possibly that WGS could be performed at the request of parent or included in other screening initiatives, as it is already beginning to be utilized in older children for diagnostic purposes. WGS has the potential to expand upon the positive outcomes of other genetic screening, however with these benefits come enhanced ethical concerns.[23] As WGS steadily expands, so does the list of disorders that can be tested for, many of which have limited to no therapies available, do not develop until adulthood, or have uncertain clinical significance.[24] One of the biggest challenges is that sequencing is not full proof nor does it lead to certainty; the identification of a disease causing genotype does not guarantee a child will develop the disorder, predict when it will happen, or give details about the extent of the disorder.[25] In the near future WGS will become both financially accessible and scientifically feasible throughout medicine with the potential for it to expand to society in different ways, such as large scale screenings, leading to many ethics issues. It will be difficult to determine what should be done with the results from the genetic sequencing including who should have access, how much they should have access to, and where the information will be stored to ensure privacy.[26] Whole genomic sequencing, as well as the other expanding technologies and interventions of genetics, have tremendous

implications for improved quality of life and the early detection of many disorders, however the associated ethical issues and problems examined in the second half of this chapter must be dealt with in order for sequencing to positively impact society.[27]

When newborn screening initially began, and until very recently, there was a consensus that screening should be guided by inclusion of disorders that can be effectively diagnosed and treated relatively close to the time of the screening.[28] In light of this, both the American Society of Human Genetics and The American Academy of Pediatrics believe that testing for disorders without therapies should be limited.[29] There are unclear and limited benefits to testing for disorders that are not treatable and additionally those with inaccessible therapies or unclear diagnosis results. Despite these recommendations, there are arguable benefits other than therapy, such as planning for the future or identifying subjects for research, making it unclear if it is in the child's interests to be screened or not.[30] Many parents argue they have a right to know, and that the knowledge from the test provides them with benefits.[31] Deciding what should and should not be screened for becomes a much bigger issue with the decreasing costs of whole genomic sequencing, the growing number of diseases that can be identified, and the increased use of screening not only at birth but also later in life.[32] Genetic testing is becoming an important diagnostic and therapeutic tool in medicine, making discussions of determining benefit and burden crucial.[33] In the future there is likely to be a large array of DNA-based tests to diagnose genetic disorders and identify predispositions to genetically influenced disorders.[34] Whole genomic sequencing will greatly expand the therapeutic gap, identifying children with disorders lacking therapies, those that do not develop until adulthood, or those with very misunderstood clinical significance. As these panels expand and technology progresses, health services, public policy and oversight will play a crucial role in establishing boundaries and informing decision

makers about genomic interventions.[35] When a mutation is identified it is unknown whether the child will develop the disorder, it is just a possibility which is both confusing and misleading to patients and families, necessitating guidance and oversight from many groups. The expansion of the field of genetic screening has created many new and enhanced ethical issues that parents and decision makers for children must deal with and work through in order to make good decisions for the child patient. As science expands quickly in this field, there is a great need for a way for parents, physicians, and children to work together to determine what they should or should not screen for in their children.

4.2.2 Neurotechnologies

Neuroscience is the study of the brain and nervous system, encompassing many aspects, from molecular and cellular biology, to psychology and behavior.[36] Neuroscience has led to many innovations in clinical medicine that have not only therapeutic but also non-therapeutic applications, all with ethical implications.[37] In the last decade tremendous technological advancements have been made in understanding basic brain and behavior relationships, leading to new possibilities and opportunities to diagnose or even predict, treat, and potentially enhance capacities.[38] Many believe that the twenty-first century will be viewed by later generations as the century of neuroscience, leading to tremendous breakthroughs for the medical world as well as society in general.[39] These interventions enable physicians and patients to better understand how the brain impacts the way they interact with the world and even begin to diagnose and treat disorders or conditions of the brain. Some of the biggest yet controversial developments of neuroscience are functional neuroimaging, brain mapping, psychopharmacology, and enhancement opportunities with the potential to impact behavior, personality, and

consciousness.[40] Many doctors believe that they can analyze the development of a child's brain and track possible psychological or developmental disorders after a simple five-minute scan.[41] This would enable physicians to diagnose the child, however there is also the possibility that it is misinterpreted or overanalyzed since not all brains are identical. Researchers are beginning to identify brain processes that are related to experiences and concepts such as free will, agency, moral judgment, self and personality.[42] They are able to review activation or activity of the brain and different areas of the brain and determine emotions, how people feel, and even which areas of the brain are necessary for certain functions. This is especially helpful in the monitoring and treating of patients with psychiatric and developmental disorders. Additionally these tools can be utilized to create targeted medical approaches based on the specific patient and his or her disorder.

Another area of development is that of functional MRIs.[43] A functional MRI also offers ways to analyze how different parts of the brain work together functionally and can then be applied to patients who lack certain abilities or have deficits.[44] By comparing data with standardized models of how the brain functions or how a specific disease develops a variety of new clinical insights becomes available and it can be seen how the child's brain is out of sync with the normal developmental curve.[45] This approach could enable treatment before any onset of symptoms and help physicians track the results of clinical trials of new therapies, but for the time being, the focus is on understanding the brain and being able to relate behavior to brain activity. Pediatric brain scans are not an extremely large practice at this time, but there is a great possibility that this will be one of the new interventions more commonly used to care for children, along with genetic screenings, to understand, diagnose, and inevitably treat.[46] New techniques for monitoring and manipulating brain functions are developing rapidly but it is not

clear how they should be used together in the care of children.[47] It is currently not known how all of the different systems of the brain interact, or what a particular brain abnormality can predict about an individual, and it is further unknown how intervening in these systems can affect the beliefs, desires, intentions and emotions that constitute the human mind.[48] It is difficult to assess and diagnose individuals with disorders of the brain and even more challenging to use new therapies to treat them. New technologies have increased the burden on the physician to assess, diagnose, treat, and in many instances obtain informed consent. Additionally, due to uncertainties, careful consideration must be given, precautions must be taken, and in some instances, doctors may need to provide treatment when inappropriately demanded or if it is of uncertain benefit.[49] When dealing with the brain, there are many issues that arise immediately, even before the introduction of technologies and therapies due to societal views or actual vulnerabilities. Many people have personal ideologies and conceptions in regard to the brain, including those of the self, free will, personal choice, and even personality and consciousness, and when something challenges that or even presents new information, it raises concern and the need for extra considerations.[50] Technological advancements of neuroscience, just as those of other fields of medicine, bring with them both new possibilities and issues to address.[51]

The application of neurotechnologies to children creates even more ethical issues and dilemmas as they are an extremely vulnerable population. It is one thing to allow adults to take risks, participate in new treatments or therapies, and even to choose controversial therapies based on respect for his or her autonomy, but a completely different thing for parents or guardians to make those decisions for children.[52] Brain scans and other new technologies can be utilized for children with both therapeutic and non-therapeutic benefits, but it is not clear if parents can make such choices for their child, and if they can it is not evident how it should be made.[53] There is

the possibility that parents could even request enhancements for their children but with that come even more ethical dilemmas and issues ranging from justice to the rights of the child. There is a great need for the identification of the key ethical issues and the formulation of regulations, policies, and guidelines for all those involved with the advancement of neuroscience to enable the benefits of the technology to be utilized. Neuroscience has great potential to treat disorders of the brain, many of which impact children tremendously. Many neurodevelopmental disorders that affect early brain development are misunderstood.[54] Neurodevelopmental disorders have genetic as well as environmental influences and can place a large burden on families, patients themselves, and society on the whole. A lack of effective therapies is a major problems but neuroscience has begun developing new techniques and methods for assessment and diagnosis, treatment, and potentially even fixing some of them, however it is still in the early stages.[55] There is a lack of evidence about what neurological interventions *can* do, and even less about what it *should* be doing. With all of the developments of the brain and neuroscience it becomes crucial to look at these issues and more importantly define a system for how decisions should be made and outline the role of all involved in pediatrics. Children with neurological disorders are in a very difficult and vulnerable position and one of the biggest issues that come with the advancements of neuroscience is how decisions of care should be made for the child.[56] The child, who is the patient, cannot make the decision for him or herself, placing a large burden on both the parents and physician complicated by the uncertainties and new technologies of neuroscience. Disorders of the brain in children can be extremely burdensome to not only the child but his or her parents and entire family, adding additional dimensions and ethical issues.[57] There are many issues that arise with neurological and developmental disorders that impact decision making, which will be looked at in more depth in the second half of this chapter.

4.2.3 Clinical Research

Clinical research has been the cornerstone to advancements within medicine enabling the creation of new therapies, the application or modification of those therapies for new populations, and the use of pharmacological interventions created for one condition to be accurately developed and applied to others.[58] Research studies are crucial to the expansion of the field of medicine and development of new technologies and interventions, but is also full of ethical issues and troubling dimensions, especially when applied to children and pediatric populations.[59] Research with children is potentially the most troubling area of development for the current decision making models as it encompasses the issues of both genetics and neuroscience, highlights the vulnerable status of children, makes it possible that they will be exploited, and makes issues of therapeutic and non-therapeutic interventions immediately more troubling.[60] There are many legal and ethical issues associated with vulnerable populations such as children, especially those with genetic, neurological, or developmental abnormalities making conducting research challenging.[61] By definition, clinical research trials involve the "trial" of a new therapy, typically with only a selection of the enrolled subjects receiving the therapy.[62] Additionally, due to the many unknowns, it is not even clear if it is beneficial to be receiving the therapy, or to be part of the control. Even in studies without a control group receiving a placebo where all participants engage in the new therapy, the levels of uncertainty of the therapy are great and the roles of all involved are not clear, nor is there a way for decisions to be facilitated for the child to participate in the research study.[63] New technologies create the possibility for parents to enroll their children in research trials both with and without therapeutic benefits utilizing the new technologies of genetics and neurology, but it is not clear if they can make such a choice for their child, and if they can, it is not understood how they should decide.[64] There are many issues with

pediatric research, but the largest issues that will be elaborated is the fact that children are vulnerable and need to both be protected and advocated for so they are appropriately included in research but not exploited or taken advantage of.[65]

The current research model does not consistently protect children from harmful and useless research nor promote their participation and interests overall; research with children must protect their vulnerable status while ensuring that they are not exploited.[66] Children are both part of a vulnerable population that needs certain levels of protection from research risks and "therapeutic orphans" who were at one time denied access to the benefits of research.[67] In the past children have been exploited as research subjects, however over time, as they gained a role in society, this changed and they became the central part of society and the family that they are today, viewed as vulnerable and in need of protections.[68] Until recently, this desire to protect children led to their exclusion from most, if not all medical research in order to not exploit their vulnerable status and harm them. This created many problems for pediatric care, specifically the lack of personalized therapies and treatments developed for and tested on children, leading to regulations in the United States promoting the inclusion of children in clinical research.[69] The development of lifesaving cures and treatments for childhood diseases and illnesses depends on the advancement of pediatric research, necessitating their inclusion in these processes.[70] Translating knowledge gained from scientific advances in biology, genetics, and neuroscience into treatments for children is possible only through research and research trials to prove efficacy and overall value as well as learn more to enhance the therapy or intervention.[71] Just as with all areas of pediatric medicine, pediatric research must be handled in a different way than adult research; the overall needs of children differ from those of adults, but both are entitled to a healthcare system that supports a healthy and productive life, making further research with

children necessary.[72] Children are developing and changing at a much more complex rate than adults, and elements that would not be issues for adults may be for children, and vice versa; adults and children cannot be medically lumped together and treated in the same manner necessitating pediatric research.[73]

Research methods must take the exceptional vulnerability of children into consideration in order to avoid exploitation and abuse. During the Nazi regime children were used as guinea pigs for research and because of this horrible experience, the Nuremberg code addresses children and appears to suggest an absolute prohibition against pediatric research emphasizing that the voluntary consent of the subject is essential and that those who cannot legally give consent should be excluded.[74] In the 1970s, the United States developed regulations that allowed advances and the participation of children in research while protecting them from unnecessary and uncompensated risks and discomfort.[75] Current regulations are in place to provide additional protections to children in pediatric research, however this does not mean that there will not be negative outcomes as these are inevitable in all situations when dealing with an unknown.[76] Risks cannot be eliminated from research due to the inherent nature of medical research, however clinical researchers must be learn from mistakes to prevent future occurrences of abuse or harm and maximize benefits. With research, benefits cannot always be the "best interests" of the child because sometimes the child does not stand much of a chance of receiving a benefit, but other future children do.[77] Additionally, there are other factors that come into play in the decision making process including altruism, compensation to parents or child, the maintenance of hope, or even confusion coming from the therapeutic misconception that anything offered will be of benefit.[78] Informed consent, as a crucial component to pediatric research, is the combination of parental permission and assent of the child, but also must fall within the

allowable limits of society and should additionally involve the physician in a large role helping to navigate through these many dimensions.[79] It must be clear what the parents or guardians are consenting to, the must demonstrate actual understanding, and the child him or herself must be involved if possible. All of these issues will be expanded in the following sections, and answered with the enhancements offered to the shard decision making model in chapter 5.

There is a need for balance between protecting children and preventing or reducing harms and respecting and involving them and listening and learning from them, to not silence and ignore them.[80] Overall there are many ethical issues with pediatric research including consent, current and future autonomy of the child, comprehension of the child or family, vulnerability, and possible exploitation.[81] Children require additional safety measures due to their limited capacity to give informed consent and vulnerable status, but well-designed and well-regulated research with children is needed to improve children's health, and pediatric ethics can work with doctors and researchers to help ensure that this happens.[82] Children are in a unique position in that they must be protected while also advocated for so they are appropriately and meaningfully included in not just research, but also decision making processed to select to enter into a study so the child is not exploited or taken advantage of. The advancements in neuroscience and genetics have great potential but also a tremendous amount of unknown information and uncertainties surrounding impacts and outcomes, leading to the need to continue research with children but also to develop a way to address the many enhanced ethical issues that arise, including consent and assent to the trial, unclear benefits, burdens, and outcomes, privacy of information, and future implications for the child and his or her family.[83] These issues, and others, will be looked at in depth in the following sections.

4.3. Enhanced Ethical Issues & Challenging Decisions

Decision making is one of the most complicated issues throughout all areas of pediatric medicine, and it becomes even more complex in light of the advancements in genetics, neuroscience, and clinical research. Due to these advancements there are complex decisions for parents to make, a complicated role for the child, a challenging demand of the physician to present complicated and unclear information, and the increasingly important role of society as these technologies bridge into areas that they must address and make decisions to either allow, prevent, or regulate and restrict. This chapter will elaborate the specific ethical issues that accompany these new technological breakthroughs and advancements, focusing on those that are troubling for the current decision making models and make enhancements necessary. The issues that will be developed are informed consent and assent, the growing therapeutic gap, increasing levels of uncertainty, privacy of information and future implications for the child and his or her family, and the potential for enhancements or modifications. All of these issues make decision making challenging and pose an increasing numbers of problems for the current decision making models in pediatrics, creating issues for parents and leaving them without a sufficient way to work through them and make the best decision for the child. Throughout the areas of genetics, neuroscience, and clinical research many advancements have been made, however there is a need for a modified version of the shared decision making model that accommodates and addresses the enhanced ethical issues that come with those developments and those that will continue to develop with time.

4.3.1 Informed Consent and Assent

Informed consent is a complicated aspect of medicine with adults and children.[84] There are two basic components to informed consent, the disclosure of information by the physician to the patient and the decision that the patient makes.[85] Patients must have enough information to make educated and informed decisions that are meaningful to them. The concept of informed consent is grounded in respect for persons and enabling individuals to be in control of and make choices about what happens to them.[86] Informed consent is crucial to decision making processes in the medical world as treatments cannot be selected without it, unless it is an emergency situation. There are three main criteria to informed consent being valid specifically that the person giving consent is competent to make the specific decision, that the patient understands the information and is able to relate the details to their own life, goals, and values, and additionally they must participate freely and without coercion from others.[87] These components are very important to decision making processes and inevitably informed consent. Patients must not only be able to comprehend the options and potential courses of action, but work with the physician to understand them in relation to their own lives and goals to make a decision that is meaningful to them. With children, this becomes difficult because the child is not the legal decision maker and his or her parents are making decisions that should be guided by the child's current and future interests as well as medical facts.[88] Informed consent is challenging with children in general and even more complicated by the new technologies.

The role of the child is typically incorporated into decision making processes through an idea of assent, since they are not autonomous and able to give formal informed consent for themselves. Within pediatrics, parents or guardians are the legal decision makers for their children.[89] Children, however, are encouraged to participate in decision making processes

through assent. There are many issues with assent, including that there is not an entirely clear definition of assent, nor way to incorporate the child's assent into decision making processes, but there are some standard components.[90] Assent, at a minimum should include (1) helping the child achieve a developmentally appropriate understanding of his or her condition, (2) explaining to the child what he or she can expect from the different options, (3) an assessment of the child's understanding of the situation overall, including emotional responses and reactions to stress or pressure, (4) the child's opinion and willingness to accept proposed options or therapy.[91] It is crucial that the child is incorporated in a meaningful way and that they understand what is going on before being able to actually give assent. Assent is most common within research trials, in order to ensure that they child is aware of the details of the study and incorporated into the decision making process, however it is not entirely clear what assent actually means.[92] Many times, the responses of parents and children will be different, and it is not clear how these cases are or should be handled.[93] In practice, parents can override a child's assent, calling into question the weight that the assent of the child carries. If the child is easily overruled, assent does not serve a purpose, but if the child's assent prevents them from entering into a research trial, thereby overruling their parent's consent, which calls into question if parents are actually giving consent.[94] Inevitably the parents carry the responsibility to make the final decision, leading to them being the focus and many times, overlooking the child in the decision making process and failing to ensure that children understand the research protocol and overall process.[95] Children can and should be involved in deliberation processes, but the final decision is to their parents. In light of this, it is complicated to require both the consent of the parents and assent of the child.[96] If they agree, it acknowledges the child and incorporates them into the process, however if they do not, and are overruled, it undermines their role, potentially causing more harm than good.

Similar to informed consent, the emphasis in assent processes with the child patient should be on sharing values, information, and opinions openly to ideally make a joint decision.[97] Institutional Review Boards, the body guiding and regulating research processes, individually have policies for including and adding the assent of the child, but there are very different definitions of assent are prevalent among different.[98] In a study by Kimberly et al, it was found that there was tremendous variation in process and tools used to document assent of the child among IRBs.[99] Many IRBs were found to have up to three forms: one for consent or permission from the parents, another for the assent of the child in accord with their development level, and a consent form for emancipated minors or young adults. The Belmont report and the American Academy of Pediatrics (AAP) Committee on Bioethics have both outlined that researchers should ensure that all research subjects, adult and child, comprehend the information about their research participation, however federal regulations have not made this a requirement.[100] Although sometimes assent forms are used within research, they cannot replace the central component of assent, which is the relationship and process. Just as informed consent is not only about the decision made, assent is not only about the end result that is the child's assent or dissent to the proposed therapy. In order for consent processes to appropriately incorporate the child, it is argued that a formulation of parental permission and patient or child assent. The American Academy of Pediatrics argues that in most cases, physicians have an ethical and legal obligation to obtain consent, which is primarily made of parental permission, before a medical intervention is selected for a child.[101] They further argue that the physician should solicit the child patient's assent when appropriate and direct consent from the child if he or she is of decision making capacity, even though this is not always assessed, in addition to when otherwise directed by law.[102] Federal regulations require that, whenever possible, children affirmatively

agree to participate in research, specifically that they give "assent," before enrolling in research , however due to the fact that this regulation is only required "whenever possible," it does not happen in all instances.[103] The assent component is a challenging recommendation though because it is unclear how to handle cases where there is disagreement between the child and either physician or parents.[104] It is a good idea for assent to be added to processes when the child has been found to have enough decision making capacity to be involved in a specific instance, but conflicting opinions must be dealt with in order to not cause harm to the child or overall consent process.[105] The concept of assent is possibly harmful, placing children, parents, and the physicians in challenging positions to incorporate dissent. It is important to note that no one should solicit a child's opinion or views without intending to weigh them seriously into the process and overall decision and in instances where they do not have an option, they should be informed of this so they are not lied to or deceived.[106] As children develop decision making capacities they should gradually become the primary decision makers and guide their healthcare.[107] A child patient's refusal to assent should carry weight, especially when the proposed intervention is not essential to his or her welfare or could potentially be deferred without substantial risk to the child.[108] It is important that the child be incorporated in a meaningful way into decision making processes, and the idea of assent, in theory, does this, however due to its conflicting definition and different applications throughout the practice, not to mention the fact that it is almost never used outside of research, leads to the need for the role of the child to be revisited.

Issues of consent and assent are prevalent throughout the field of pediatrics, but they become more difficult with emerging technologies leading to complex information to comprehend, barriers to communication and understanding, and unclear roles for all involved in

the process, primarily the child him or herself, overall complicating decision making.[109] The legal status of the child in society and their developmental status make consent challenging throughout pediatric medicine, as parents are looked to as the legal decision makers in most cases.[110] However, new therapies in the areas of genetics and neuroscience, and the growing number of pediatric research trials, make these issues more pressing and convoluted.[111] Issues of who should be involved in the decision making process and how they should make decisions become much more challenging to determine and balance with the additions of complex information, unclear benefits, and the assent or refusal of the adolescent child.[112] As children approach adulthood they have different levels of capacity and decision making abilities but must be included in consent processes to the appropriate degree. It is relatively straightforward that parents are the decision makers for young children under the age of 5, especially when it is evident which option is in the child's best interests, however this role becomes more difficult to justify and solely rely on when the child is an adolescent. Adolescents are in a challenging position with varying levels of decision making capacity as they approach adulthood and gain control over their lives. Additionally, many of the new therapies have varying degrees of uncertainty and benefits to the child. With older children, assent becomes important to care and decision making processes. Similar to decision making capacity, the ability of the child to give assent should be evaluated on a scale after evaluating the child's capacities and abilities including both maturity and understanding in comparison to the decision to be made.[113] The assent of children with more maturity, life experiences, and overall levels of comprehension of the specific situation and medical options should be given more weight in the decision making process.

Consent and assent become even more complicated with pediatric research trials in genetics or neuroscience. The role of the parent is troubling for older children in all areas of pediatric medicine, but even more so as which much research there may or may not be therapeutic benefits for the child.[114] For research, it is not clear if the consent of the parents carry the same weight as in other areas of pediatric medicine, as the assent of the child is highly sought after in research.[115] Although children do not have autonomy or the legal right to make their own decisions, they are developing the necessary capacities for making medical decisions, placing adolescents in a unique and undefined place.[116] Their explicit role in consent is not clear and despite the many benefits of including them, specifically validating them as individuals and recognizing their agency, there is not a standard way to do so.[117] The child cannot give formal consent, however if the focus shifts from autonomy and consent to that of respect for persons and the best interests of the child, formal consent for research should be achieved through a combination of parental permission and assent of the child.[118] It is typically strongly recommended that the assent of the child be collected before entering them into a research study, but this is not absolute. In therapeutic clinical trials, the permission of the parents carries the greatest importance, however in those that are non-therapeutic with minimal benefit to the child, the assent should be considered more heavily and arguably even in cases of young children. Barfield and Church argue that in older adolescents, assent should carry the same weight as informed consent, even though parental permission is still required, acknowledging the self determination of the child and right to direct their lives.[119] New therapies in the areas of genetics and neurology are exceptionally troubling for this as these decisions carry much more complexities, uncertainties, and possibilities for impacts lasting the duration of the child's life. All of these issues, which will be developed throughout the rest of this chapter, make it crucial

that there is a way to evaluate and incorporate the child patient when possible and his or her assent in addition to the formal consent and permission of the parents.

As the well accepted decision maker for children, parents have many challenges and barriers to meaningful consent for new therapies and interventions beyond the involvement of the child him or herself in the process.[120] Parents are emotionally involved and connected to the situation, many times clouding their judgment or ability to fully assess a situation. [121] Within the fields of genetics and neuroscience, many therapies are hard to comprehend and determine when to use, both for parents and children, as there are many unknown elements to all involved, many times including providers.[122] These uncertainties will be further developed in a later section, but without full comprehension of the therapy, the possible outcomes, and future implications informed consent and assent are very challenging, if not impossible. Outside of unknown elements, new interventions in the fields of genetics and neuroscience are difficult to comprehend due to the complexity of the information. It is up to the physician to explain all options and likely outcomes in a way that is comprehendible by the parents, but this is not always what happens. Studies show that parents are reluctant to ask for help or an additional explanation, and many times make decisions based when they do not understand everything, or in many cases, let providers guide care decisions.[123] Most parents are typically not of a medical background, many times placing a large educational and language barrier between the medical team and parents. Low health literacy, culture, ethnicity, socio-economic status, and overall education levels greatly impact decision making processes for parents and their overall role in the process with physicians and their children.[124] Low health literacy was found by Yin et al, 2012 to lead to difficulties in comprehension and processing of basic health information, needed for appropriate decision making, with parents having difficulties in many areas including

reading, listening and engaging, and analyzing information, leading to dependence on providers and the medical team.[125] In a study by Simon et al it was found that when English speaking physicians presented details to non or limited English speaking parents they left out important details and information such as the concept of randomization or even the right to withdraw from the study.[126] This information is extremely relevant and needed by parents to make the best decisions for their children, and there must be a way to not only ensure the information is conveyed and delivered to parents, but also that they comprehend the details in a way that is meaningful and enough for them to give proper consent.[127]

Research poses another complexity for parental consent and comprehension due to the therapeutic misconception.[128] The therapeutic misconception refers to the problem created when providers offer therapy to patients, that may or may not have benefit to them, and the patient perceives such a benefit based solely on the fact that the provider offered them the intervention. In research, in addition to the complex treatment options and unique terms to research, such as randomization of placebo, many times parents assume that there is therapeutic benefit to be gained from the study.[129] New medical interventions are dependent upon clinical research trials, making them necessary for the advancement of medicine, making stringent informed consent processes needed.[130] Comprehension barriers of parents many times lead to great misunderstandings when enrolling children in research trials and there is disconnect between what parents understand or expect and reality.[131] A study by P. Applebaum et al. found that 24% of subjects believed the study had no risks or major disadvantages, despite singing in depth consent documents explicitly outlining the risks and potential disadvantages.[132] Parents must fully comprehend what they are signing their children up for as the benefits cannot always be based on the best interests of the child because many times because sometimes the child does not

have great potential for benefit.[133] Informed consent for pediatric research must be a combination of parental permission and assent of the child, where the assent or possible refusal is worked into the process.[134] Issues of consent and assent are challenging throughout pediatrics and tremendously complicated by new technologies, requiring a facilitated decision making model that accommodates all aspects of consent.

4.3.2 Therapeutic Gap

The therapeutic gap is another major issue associated with the new technologies emerging within the fields of genetics and neuroscience. The therapeutic gap refers to a gap created when disorders are identified however there are not therapies, treatments, or available options for the disorder. [135] Advancements in the areas of genetics and neuroscience have greatly widened this gap, making it possible and in many cases common to identify disorders that are not fully understood and many times lack proven or accepted treatments. This gap is evidence of strong growth in the fields and progress being made, however it places physicians, researchers, and possibly parents in challenging positons. The therapeutic gap connects ideas of fate, destiny, and suffering with the predictive power of genetics, giving great hope for the future, but additionally creating gaps that place parents in challenging positions.[136] Within the field of genetics, whole genomic sequencing will make it possible to screen for many diseases and identify risk factors for multi-genetic diseases, carrier status for many autosomal recessive conditions, adult-onset conditions, or those with uncertain clinical significance.[137] This creates a large gap in what can be identified and what can effectively be treated. Another field that has seen tremendous growth from the expansive genetic screening is that of neuroscience and neurology. Currently, genetic screening is used to identify many neurodevelopmental disorders,

but when they screen for the neurological disorder, they are able to identify other aspects of the child's genome, many of which fall within the therapeutic gap and are not treatable.[138] Genetic tests are becoming more expansive, accurate, and affordable, leading to the potential that they are used on a much more regular and widespread level, possibly venturing into unclear areas. Just as with newborn screening, the possibility exists that disorders will be added to a genetic panel due to lobbyists, patient advocacy groups, or even the sole reason of being able to that are not necessarily ethically permissible with effective and readily available therapies,.[139] Outside of genetic tests for neurological disorders, other advancements in the field of neuroscience include functional neuroimaging, brain mapping, and psychopharmacology, all of which have tremendously increased the therapeutic gap.[140] These technological interventions shed light on many personal and affective disorders of the brain which are very different than typical diseases and disorders in that they carry with them many stigmas and are even viewed by some as personality traits.[141] The findings of neurotechnologies such as brain scans and functional MRIs can be associated with psychological and social disorders, labeling children with conditions such as autism, ADHD, schizophrenia, and bi-polar disorder, which can have great implications for the future and unclear therapeutic benefit for the child. These issues are magnified by the uncertainty and diversity surrounding these interventions, and the inability to establish consistent thresholds for "positive" screens.[142] A genetic predisposition does not equal a diagnosis, however in cases of personality or brain disorders, there is a fine line to walk due to society and future implications.[143] Many of these conditions carry with them social stigmas and could hinder the child's future by labeling them with them, however by identifying it at an early age the child would have a better chance at treatment and the ability to take care of the disease and lessen the impacts.

The World Health Organization argues that screening for diseases should be based on stringent criteria in order to do what is best for the child and in his or her best interests.[144] WHO argues that in order to include something in a panel or to ethically allow for a disorder to be screened for, there must be an accurate diagnostic process, specifically the findings are meaningful and understood, and additionally adequate and accessible treatment must exist for the disorder. The American Academy of Pediatrics agrees with WHO emphasizing that conditions should be screened for when there is an effective therapy that is available to all who are screened close to the time when they are screened.[145] For example, if a disorder cannot be treated until a patient is in his or her teens, there would be no reason to screen the child as a newborn. Additionally, if a treatment exists but it is not available to the general public and is too expensive, there should not be a screening program for this nor should a standard panel include this disorder. It is important that clinicians only run tests if results could change care and clinical management, not just to test and be able to diagnose the child. Despite these recommendations, many of the currently recommended illnesses that are regularly screened for as part of newborn panels are poorly understood, untreatable, or lack effective therapies. [146] If there is not an immediate benefit to the child, ethical issues arise and the use of the intervention is not straightforward or clear.

There are arguably other benefits to knowing than treatment including for the family to know and prepare themselves, or even for society at large for planning or budget purposes or to gain more knowledge of diseases and inevitably increase the ability to treat them.[147] It is argued that by knowing if an individual has a disease, even if untreatable, there are benefits including psychosocial and research benefits to other recipients, such as family members or society as a whole, and the ability of the family to plan for the future, even if it is uncertain and not

definite.[148] Tarini and Goldenberg discuss these other benefits in relation to newborn screening, and argue that if a therapy does not exist the specific test should not be added to the screening panel.[149] Outside of newborn screening in light of the expanding technologies, this idea becomes even more crucial because even if not mandated by society, as newborn screening is, it is not clear how providers should offer tests and handle requests by parents or how parents should decide what to learn about their child. Bennet asked several physicians to elaborate the negative impacts of expended screening and the ACMG's recommendations, and all elaborated some of the outcomes of recommended testing for rare disorders or those with unclear clinical significance including the therapeutic gap, false positives, and elements of uncertainty or future implications, both of which will be looked at in following sections.[150]

The therapeutic gap has always been an issue of medicine, as the first steps to the development of a therapy or treatment for a disorder is the identification and then studying of the disease, however these new technologies bring forth new identifiable diseases exponentially faster than in the past. New conditions or predispositions are identified on a regular basis, not always while looking for them, many come up while researching or elaborating on established research and disorders.[151] In addition to lacking therapies, many of the newly identifiable disorders are not definitive, and a diagnosis, or finding that the patient has a genetic disposition or abnormal brain scan, has very unclear meaning; the patient could develop the disorder, but he or she also could never show symptoms or manifest the disease. Without being able to accurately determine if a patient will develop a disorder, even if a therapy exists it is unclear if it should be tested for and additionally if it is, when you would utilize the intervention. The gap between what is known and what is not is a large issue prevalent throughout genetics, neuroscience, and clinical research trials, only to be made larger and more serious in the coming

years.[152] The therapeutic gap will ideally get smaller, however it does not appear to happen any time soon since even if therapies are found for the genetic or neurological disorders currently identifiable, there are growing numbers each day, making this a huge issue throughout the areas of genetics, neuroscience, and clinical research.

4.3.3 Uncertainty

Uncertainty is prevalent to a certain degree throughout medicine, however it is a much bigger issue with new technologies as they do not have established histories and foreseeable outcomes in all instances. With the new therapies available on a regular basis it is unclear what the actual benefits of intervention currently are, will be, or even could be due to many unknown elements.[153] The new interventions throughout the fields of genetics, neuroscience, and clinical research are surrounded with a great amount of uncertainty. Physicians do not know what they will find before performing each intervention, they do not definitively know what diagnosis or the identification of an abnormality means in all cases, and they do not know what the outcomes will be for individual children. Some of the therapies have much more established histories and physicians are able to have more concrete reasoning for the selection of a therapy and better help parents weight benefit and burden, however with some, specifically within research, there are many components that the researcher or clinician has no way of knowing. Advancements and new interventions, by definition, are filled with more uncertainty than other areas of treatment in medicine, and the areas of genetics, neuroscience, and clinical research are several of the areas where this is prevalent.

Advances in genetics have led to the ability to test for and identify predispositions for many more disorders than therapies exist, creating the therapeutic gap and great levels of

uncertainty.[154] It is unclear if it is in the child's best interests to identify conditions that cannot be treated based on the fact that a therapy does not exist, but also because much uncertainty and unknowns come with these identifications.[155] The identification of a mutation does not guarantee that the gene or disorder will manifest at any point or even if it will, the test results do not allude to when the disease will develop or begin, placing parents, providers, and children in challenging positions. It is difficult to determine the likelihood that a child will develop a certain illness and identify what a "positive" result is or means. Some tests do not have a definitive yes or not but rather a probability of developing the disease and in these cases, a certain probability is associated with a positive result. It is challenging to determine what to tell parents when a probability is identified since parents all weigh importance and significance differently and the results may or may carry significance to them.[156] A positive result does not even mean that the child has the gene or condition as false positives are common, and depending on the disorder being screened for, the definition of positive is not always meaningful, complicating the communication of these findings to parents. False positives lead to parental stresses, impact the parent-child relationship, and can lead to perceptions of the child's health impacting their whole lives.[157] Levels of uncertainty surrounding genetics lead to a great need for a formulation of decision making that enables physicians to feel empowered to communicate the necessary information to parents but also ensures that parents understand and involve the child when possible since these findings have implications for the future.

There is additionally great levels of uncertainty surrounding neurotechnological interventions. Researchers within neuroscience are beginning to identify brain processes that are related to behavior, experiences, and concepts such as free will, agency, moral judgment, self and personality and ways to read and interpret them.[158] However when venturing into these new

areas, there is not an established "normal" to compare to nor are every two individuals the same in response, making these reading challenging and filled with unknown elements. New techniques for monitoring and manipulating brain functions are developing rapidly but it is not clear how these interventions should be used together and when they can be presented to or used with patients.[159] It is currently not known how all of the many systems of the brain interact or what a particular brain abnormality may be able to identify or predict about an individual. [160] It is further unknown how intervening in the systems of the brain can affect the beliefs, desires, intentions and emotions that constitute the human mind and elements that many believe, make the patient who he or she is. There is a great need for more evidence on what neurological interventions can do and should be doing for patients.[161] When an abnormality is identified in a brain scan, for instance, its significance is not entirely understood at this point other than to label it "abnormal" as with the newborn screening test for Krabbe disease, where a diagnosis of "likely to develop" does not carry much weight.[162] In order to see the benefits and be able to use these interventions, there is a need for more research and understandings of the brain.

Assessment and the determination that the intervention is necessary is another uncertainty that comes with these technological advancements. A major issue of the new technologies that overlaps with the concept of children being vulnerable, is whether or not the interventions may be classified as "medically necessary." The potential risk and benefit of new technologies as well as the potential for exploitation is much greater in pediatric medicine, which is why many physicians only use them when they are found to be medically necessary.[163] For example, an MRI scan has risks associated with sedation, which is necessary with children to keep the child still long enough, which outweighs the potential benefits in many cases, however not in all cases. An MRI might be more easily selected with adult patients because of the lower risks, but with

children this heightened risk must be taken into consideration. It is difficult for physicians to ascertain whether or not an intervention is medically necessary though, and if it carries great possibilities with it, excluding the pediatric patient because it may exploit them is just as damaging to the child. The imaging of children with neurobehavioral and psychiatric disorders may help to identify subtypes of the disorders that were established by behavioral criteria, however they may not directly guide treatment for the specific child and may introduce undue risk associated with sedation use to vulnerable populations. Data collected from such studies may contribute much to our understanding of developmental processes yet it is debatable whether imaging of children where it is not ‘‘medically necessary” is justified, and again, something that parents or physicians can and should be doing or offering for children. These neuroimaging studies have provided valuable information about the biological nature of many different neurological disorders, but it was noted that they have not directly contributed to the medical *treatment* of the individuals participating. This leaves many questions of whether or not these interventions are medically necessary or justifiable. Pediatric neuroimaging offers an unprecedented opportunity to examine the complexities of development and holds immense potential for helping to treat both neurological and developmental problems. However with those benefits are many risks, uncertainties, and the potential for misuse of information.

Other issues of uncertainty include incidental findings and the always troubling issue of informed consent that is made very challenging when information is not clear. Incidental findings from both genetic and neurological interventions are a great concern that must be addressed.[164] For instance, if a brain scan is done to determine if a child has ADHD and it is found that they do not, but another area of their brain looks “abnormal” it is unclear how this will be handled or what type of diagnosis will be given to parents, or if the physician should order

further tests to determine if there actually is another problem. These issues are prevalent throughout the new technologies discussed necessitating guidance and structure in the decision making processes to select what should and should not be tested for or reviewed. Additionally, informed consent, which is troubling throughout medicine, becomes especially complicated without levels of certainty. Without complete understanding, meaningful consent is very difficult, if not impossible. With regard to these new technologies, more research and information is needed to determine what the therapies do and how the information that they collect can and should be used in a meaningful way. There are many impacts, some of which are unforeseeable and in the future, which is the issue that will be looked at next. It is unclear how knowing that a child has a significant chance of developing something that is untreatable and not preventable will impact the child, their family, or society in general. In addition, it is not evident how to determine when a child has a "significant" chance. It would be unfair to not allow children to benefit from the developments of neuroscience and genetics, however because of this status more protections and measures must be taken to make sure they are not being exploited and things are done that are truly in their best interests and overall benefit. These technological breakthroughs have tremendous possibility to enhance the lives of children and their families, however with those come many new issues and considerations, all which must become part of the decision making process. The concerns and dilemmas are real, complex, and numerous, however with the right precautions and steps, they appear to be manageable and the negative impacts should be able to be minimized.[165] These new issues and considerations make an enhanced shared decision making model extremely important and necessary for the best outcomes for children.

4.3.4 Privacy of Information and Future Implications

There are many issues that need to be resolved throughout the areas of genetics, neuroscience, and clinical research that have future implications before genomics and neurotechnologies can be appropriately translated into clinical practice and care including the privacy of the child, family, and results, and larger ethical issues surrounding future implications for the child.[166] In the last decade tremendous technological advancements have been made, leading to new possibilities and opportunities to diagnose or even predict, treat, and potentially enhance capacities.[167] These new technologies may make financial sense and lead to good medical outcomes in many instances, however there is the potential for the misuse, overuse, or even incorrect use of the information generated. Many of the disorders tested for are relatively common and have a substantial impact on both the individuals who have them and those who interact with them, and improved treatment could have significant benefits for all involved.[168] The use of new technologies with pediatric patients is accompanied by all the ethical dilemmas associated with their utilization with adults, magnified exponentially, like other therapies of adult medicine applied to pediatrics.[169] There are many future implications for the information discovered with the technological interventions that impacts both the child and family making it necessary that privacy and security are top priorities in order to protect the information of patients.[170] With newborn screening, because the tests are conducted by the state, positive test results are shared between the state health department, hospitals, parents, and patient's provider.[171] It is not well known where all of the genomic information that is collected is stored or what can be done with it in the future, if anything, and if the patient's permission would be needed if the specimen has been unidentified. Great concern arose in the 1990s about what was being done with the bloodspots that were taken at birth, including concerns of storage, access,

and research or tests performed on them.[172] These issues become even larger with whole genomic sequencing and the ability to test for more diseases and disorders, and DNA tests which seemingly eliminate the privacy of the sample. There is unclear ownership over the sample, specifically if it is not labeled, can the state do what they want with it, or should it be labeled and then parents and or the child request its utilization or destruction.[173] Clinical research could benefit from the unidentified research and testing on the blood samples to be able to have a clearer medical picture for the future and enable societal planning, but even unlabeled due to DNA tests, it is not really possible to "de-identify" a genetic sample. Clear processes were not established in the beginning of newborn screening practices, and they are regulated by each state, however there must be a more consistent approach or recommendation in light of the expanding technologies broadening the spectrum of things that can be screened for and what could be done with the sample.

In addition to the storage and utilization of genetic information, other issues of privacy are troubling throughout the areas of genetics and neuroscience.[174] Conditions that previously were understood through fate, destiny, or even environment and lifestyle choices may now be explained using genetics or medicine, which is troubling and even alarming to come individuals.[175] Children may be labeled, treated differently, denied benefits such as enrollment into competitive schools, a job, or medical insurance for presumed pre-existing illness, and even subjected to low self-esteem or additional stress based on things that have been identified before there are genuine symptoms or proof of the illness.[176] There is a very real possibility that the information will become a means of "describing" the child, which makes the issue of privacy of the information tremendously crucial and problematic.[177] If the benefits of testing for disorders without therapies inevitably do outweigh the harms, leading to standardized testing for disorders

that are untreatable at the time of the test, this issue becomes very important. Children could be identified to have a predisposition for a disorder that is untreatable, enabled to take lifestyle precautions to lessen the chances that it will develop, but then still be labeled as "pre-disposed" for that illness, or even thought by some to actually have the disorder, impacting the child throughout his or her life in ways that have not been fully understood. Another area that falls within future implications is the issue of how to handle incidental findings of both neurological tests or genetic screenings.[178] There is currently not a mechanism in place for consistent follow up or provider education of families, creating the problem of identifying an abnormality, and then not doing anything about it, leading to issues down the road for the family and child.[179] New technologies and both the opportunities and implications of these technologies is a tremendous issue that impacts the roles of parents and physicians and emphasizes the need for a shared role. Overall, it is crucial that information is evaluated in terms of both current and future outcomes.[180] There is a great need for caution as progress is made and arguments are taken on to expand panels and test for disorders of the brain without clear diagnosis attached because inevitably, more harm can be done to the child's future than benefit.

An additional problem that is magnified with the addition of new technologies impacting the future of the child is the over-interpretation or misrepresentation of results.[181] Once physicians have brain scans or the results of a genetic sequence, it is quite possible to read too much out of them, and over-interpret the findings.[182] Since all children develop differently and at different paces it is hard to define "normal" and develop standards, so it is unclear what an "abnormal" result that is not linked to a specific disease or disorder means for the child or family. Additionally, since it is unlikely that any two results will be identical, if the physician or parents think something is wrong with the child there may be bias associated with how the

results are read and then judgments are made from there. If there is not an accepted "normal" there is the potential that physicians will begin to look for something that is wrong. Another area that falls within future implications is the issue of how to handle incidental findings of neurological tests or genetic screenings.[183] Overall, it is crucial that information is evaluated in terms of both current and future outcomes.[184] Additionally, some findings may simply show that the child has an increased risk for an underlying disorder, not that they currently have the condition or even that they certainly will develop it, but once you have the information that they may, that has the possibility of being attached to the child.[185] A child may be labeled, treated differently, denied benefits such as enrollment into competitive schools or medical insurance for presumed pre-existing illness, and even subjected to low self-esteem or additional stress. There is a very real possibility that the information from the scan will become a means of describing the child, which can have lasting impacts on many aspects of a child's life and future.[186]

4.3.5 Enhancements

New technological advancements in the fields of genetics and neuroscience have greatly changed the face of pediatric medicine, making it possible to identify and potentially treat many disorders or conditions that were previously impossible. With these advancements come much promise and hope for the future in both of these fields, but also much territory that has rarely if ever been entered into before, including those of enhancement.[187] Decision making is extremely complex in light of the continuously developing options and studies that bring with them social policy implications, including cognition, violence, and the genetic influences on the structure and function of the brain.[188] With the ability to identify impacts on these concepts, both genetic or neurological, there is more potential to enhance and make modifications. However, just because

it is possible to modify or enhance capacities and abilities, it does not mean that these interventions should be taken or done, especially with children. It is currently not clear what adults can request for themselves, including enhancing mood, reducing appetite, or even helping with sleep.[189] Many of these "enhancements" are considered general parts of society and life for adults, however it is unclear how to apply them to children. Children with disorders in these areas may benefit from some of these interventions, however adults use them without a specific diagnosis or disorder, and it is not clear if parents can use them with children. Most would agree that in most cases, without a diagnosis or intervention from a provider, parents should not be able to use these pharmacological enhancements with their children.[190] However, the developments in the fields of genetics and neuroscience make these issues much more pressing, as they bridge into areas that are much more grey, such as memory and cognitive enhancements, making it crucial to look at how decisions are made for the utilization of enhancements with children. Developments in genetic screenings give hope that it will be possible to identify a spectrum of heritable disorders and conditions, both treatable and not, but this only adds to the complexities that parents must go through when making decisions for their children. The identification of more diseases not only leads to issues of uncertainty and an expanding therapeutic gap, but also the potential for enhancements and modifications requested by parents, society, or even by providers in the medical best interests of the child, making it crucial that there is a way for all stakeholders to make decisions that will benefit the child.

There is much hope for the future including the treatment and possible cure of these identified disorders as more is learned and understood about them through research and the utilization of the therapies with patients. Many things are possible today that were not even thought of a decade ago emphasizing the exponential rate of growth that has occurred recently.

Within the field of neuroscience, recent fMRI studies have shown the potential to read into processes of the brain connected to thought and behavior with diverse medical benefits.[191] Issues arise further with ideas of cognitive enhancement, psychopharmacological interventions and enhancements for memory or mood, and even the prediction of disease.[192] Additionally, new technologies bring hope for the ability to diagnose disorders such as ADHD and autism. With regard to genetics, it may be possible to modify a genetic mutation, both with therapeutic and non-therapeutic benefits, creating the possibility that parents may want to request changes or modifications for their children after seeing results. Though not definitive at this time, many believe that this is where these technologies are going, which additionally pose questions and issues of possible enhancements. There are many opportunities for enhancement and it is possible that the rights of the parents and child potentially conflict with each other and additionally ideas of society.[193] Parents could request enhancements for their children, beyond a level of "normal," but with that come many ethical dilemmas and issues ranging from justice and access to the current and future rights of the child.[194] This leads to problems in defining ideas of normal, which could be more abstract, defined by science or lead to more stringent public screening initiatives to definitively elaborate the concept of normality. Developmental stages of children make assessments of normality very challenging for children because each child of a specific age does not have the same capacities or results of these interventions. Even if it is possible to define a conception of normal, it is not clear if the parents should be able to enhance their child above normal, which would lead to those who have access to more resources and means having the more "enhanced" children, creating an even bigger social gap. Additionally, it will come into question whether or not society could require parents to enhance their children to a normal level, if a way were found to do so that was accurate and financially feasible.[195] It is

unclear where to stop testing, or what constraints to put on the utilization of the information found. Lines must be drawn surrounding enhancement, including when physicians and society can refuse parental requests and when they should potentially suggest them for therapeutic reasons.[196] There are many promising aspects of both genetics and neuroscience, however when they are applied to children the stakes become higher, and determining benefits and burdens become very challenging, especially in light of enhancement. These issues lead to the likely utilization of policy oversight to ensure that access to the therapy is available when needed, patients are not subjected to unjust screening or interventions, and privacy is respected with regard to the information.[197] Additionally policies should help formulate what parents can and cannot request for their children with regard to enhancements to ensure that the child is not put at risk. Once so much personal information is easily gained of children it is difficult to determine where it will go or what it will be used for, making the decisions to obtain this information extremely important.

4.4 Conclusion

Pediatric medicine is a complicated field filled with great innovation, many invested stakeholders, and overall, many difficult decisions. Throughout the past few decades, tremendous advancements have been made in the areas of genetics, neuroscience, and clinical research with children, leading to better care and therapy options for children now, and promise for even more in the future. Within the field of genetics, whole genomic sequencing and other genetic assays have made it possible to test for numerous conditions, both for the identification of or the pre-disposition of genetic disorders, many of which are not treatable. Despite this, there are many conditions that can both be identified and are able to be treated, or possibly improved

with choices that the child could make throughout his or her life, giving argument for some level of testing. Additionally there are some disorders, such as several neurological conditions, that can be identified and diagnosed through genetic screening. There is great potential with these developments, however many ethical issues as well that must be addressed. Within the area of neuroscience, new technologies looking at brain and behavior relationships and overall function leading to new possibilities and opportunities to diagnose or even predict, treat, and potentially enhance capacities. Some of the most controversial new technologies and developments of neuroscience include functional neuroimaging, brain mapping, and psychopharmacology, all with the potential to impact behavior, personality, and consciousness by looking at how the brain interacts with the rest of the body and environment. There is not enough evidence about the impacts or affects that both neurological interventions or genetics screenings can do and even less about what they should be doing or used for. The final area of expansion discussed was clinical research especially in connection to genetics and neuroscience. This research is combined with all of the ethical issues of the areas themselves, more complicated by the fact that it is research and the outcomes are even more unclear and issues of informed consent and comprehension become even more complicated and challenging. With all of the developments of genetics and neuroscience it becomes crucial to look at these issues and more importantly define a model for how decisions should be made and outline the role of all involved in pediatrics.

Throughout pediatrics, parents and physicians work together to make decisions each day, however the additional dimensions and issues brought with the technological advancements in the fields of genetics and neuroscience complicate these decisions. They additionally emphasize the need of the child to have a role in the process, since many of the ethical issues have impacts that will last for the duration of the child's life and could constrain or form the child's future.

The increasing number of research trials, while are necessary for the continued expansion of pediatric medicine, bring tremendous ethical issues and decisions that parents, as the guardians and decisions makers of their children, must make, alongside physicians and researchers who must balance the need for research trials with the interests of the child. All of this happens within the constraints of societal regulations that both advocate for and attempt to protect the interests of the child, who has an undefined role in the process. The undefined role of the child, primarily adolescents approaching adulthood and gaining decision making capacities, combined with these new technologies make the need for them to have a role in the decision making process crucial as these bring with them issues that can impact the child for the duration of his or her life. Issues of informed consent from the parents, the assent or potential refusal of the child, the identification and potential screening of diseases without therapies, privacy of and access to information found or genetic information collected, future implications for the child, and potential enhancements all add dimensions to care and place tremendous burdens on all involved in decision making processes. These additional burdens are currently not accommodated by the models of decision making utilized by parents and providers. In addition, the current models do not facilitate the involvement of the child in these decision making processes that will impact their whole lives, necessitating modifications of the shared decision making model that both facilitate a role for the child and additionally accommodate the enhanced ethical issues. Throughout pediatric medicine a shared model of decision making is recommended, however due to the heightened ethical issues and dilemmas that arise within the areas of genetics, neuroscience, and research with children, it becomes crucial that stakeholders not only work together, but that they do so in a way that upholds obligations to the child and includes him or her in a meaningful way. Overall, there is a need for a modified shared decision making model

that accommodates the enhanced ethical issues of the emerging technologies and all of the stakeholders appropriately in order to facilitate not only the decisions currently being made, but also decision that will be associated with new developments and technologies.

Notes to Chapter 4

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[192] Fuchs, “Ethical Issues in Neuroscience,” 602.

[193] Hinton, “Ethics of Neuroimaging in Pediatric Development,” 459-460.

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[195] Illes et al., "From Neuroimaging to Neuroethics," 205.

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Chapter 5 - Enhanced Decision Making Model

5.1. Introduction

The expanding technologies of genetics, neuroscience, and clinical research bring with them increasing amounts of ethical issues necessitating a new and enhanced way for decisions to be made within pediatric medicine. Currently in pediatrics, decision making is done through a shared process involving parents and physicians, primarily guided by the best interests standard. The best interest standard does not accommodate the many different ethical issues associated with the new technologies, including great levels of uncertainty, nor does the shared model, as it is, offer enough structure, support, or guidance to parents as the legal decision makers for their children. There are many dimensions to making decisions for another, specifically one's own child, and there is not a model that supports those many facets and barriers to decision making. As the legal decision makers for their children, parents are not the only individuals involved in their care or making decisions about treatment; physicians, society, and the child him or herself must play a role in the process, which the shared decision making model does not explicitly elaborate as it currently exists. Decisions should be made through a shared process over a course of time, not one specific instance or interaction. However, the lack of a consistent definition of shared decision making and a shared model that is specific to pediatrics makes a modification necessary. There is not a consistent definition of shared decision making as there are other decision making models, such as substituted judgment and the best interests models of surrogate decision making, other than that it is a shared process, which does not provide structure or guidance and elaborate the roles of those who are sharing in making the decisions. There are different applications of shared decision making utilized throughout pediatrics, which leads to

the need for an enhanced, more defined model that is developed specifically for pediatric medicine that accommodates the overarching and guiding principles of pediatrics. This enhanced model will elaborate who should be involved in the process and what their roles should be depending on the situation to ensure that the best decisions are made and the interests, both current and future, of the child are kept as the central goal.

In order to develop a model of shared decision making specific to pediatric medicine, the guiding principles of pediatrics will first be elaborated. The four overarching ethical principles of medicine will be applied to the field of pediatric medicine as well as the goals of pediatrics that this enhanced model will aim to achieve and accomodate. After the principles have been applied to children and the goals of pediatric medicine developed, the new shared model will be elaborated first looking at the current concepts and definitions of decision making in general, shared decision making, and how parents make decisions for their children. During this analysis the components and key pieces of information that parents find important or burdensome during the process will be elaborated and discussed to ensure that the new model adequately provides support to parents in the areas that are needed. Then the actual enhancements of shared decision making will be elaborated, specifically looking at the evaluation of the child so he or she can be incorporated into the process in a meaningful way, the classification of the treatment decision, the proposed roles of parents and physicians, and potential outside impacts on the process. The final component of the enhanced shared model is that of tools to enhance the decision making model that can be used in practice to facilitate the enhanced model and some possible areas for improvement, growth, and research in the future. There is great need for a new, enhanced shared decision making model to accommodate the growing and changing field of pediatric medicine

specifically designed for children and out of the field of pediatrics that accommodates the many unique and challenging issues presented by emerging technologies.

5.2. Ethical Principles of Medicine Applied to Pediatrics

Ethical principles guide care and duties throughout the field of medicine. It is important that the goals of medicine be in line with the values and principles of the specialty and population that it serves, making it crucial that pediatric medicine has a set of unique goals compared to adult medicine.[1] Adult and pediatric patients are not the same and cannot be treated in the same way, however there is overlap in general goals, duties of parties involved in medical care. The fields of adult and pediatric medicine share many baseline goals including the prevention of disease, promotion of overall health, the relief of pain and suffering, care or cure of disease, the avoidance of premature death, and the inevitable pursuit of a peaceful death.[2] Not all maladies or illnesses can be cured, so many times just the care and treatment should be the goal.[3] Within adult medicine, the guiding principles are used to uphold and guide medical care. The principles utilized throughout medicine to guide the duties of a physician and overall guide care are beneficence, non-maleficence, autonomy, and justice, and can and should be used within pediatrics to help achieve the same baseline goals of adult medicine. These principles do not apply to children in the same way that they do to adults nor yield the same goals, but it is important that they are evaluated in light of the differences of pediatric patients and they are applied in a way that is meaningful to them.[4] These guiding principles are direct and action guiding, and can be used to identify appropriate goals for pediatric medicine that can then be incorporated into an enhanced shared decision making model.[5] In order to accurately represent the goals of pediatrics, the ethical principles of medicine will be applied to and evaluated in light

of the differences and unique elements of pediatric medicine. This section will first review the principles of adult medicine, specifically concepts of beneficence, non-maleficence, autonomy, and justice and discuss how they can and should be applied to pediatric patients. Following that, the goals of pediatric medicine will be discussed with a final section focusing on the promotion of the future and current interests of the child, as a central ethical principle that will be leveraged as part of the enhanced shared decision making model. Decisions made for children should be guided by principles and goals specific to them in order to best facilitate decision making processes.

5.2.1 Beneficence and Non-Maleficence

Beneficence and non-maleficence are two of the central principles of medicine, guiding care and the actions of physicians and medical practitioners throughout the field of medicine. Beneficence refers to promoting the interests of the patient and protecting him or her from harm when possible.[6] When applied to medicine, this leads physicians to suggest therapies that are in the best interests of the patient and would overall cause the least harm when all benefits and burdens have been weighed. This guiding principle is prevalent throughout pediatric medicine and in line with the best interests model, asking physicians to advocate for the best option. There is not an obligation associated with this principle, specifically to uphold it requires the promotion of the good and overall interests of the patient, not necessarily doing what is in their best interests in all cases. Non-maleficence on the other hand means to not cause harm to patients, and unlike beneficence, this principle does impose an obligation.[7] Obligations not to harm are often interpreted as being stricter than those to help since they are more easily measured and the overall importance of avoiding harm. Despite the importance and obligation not to cause harm,

sometimes harm can be justified by potential benefits or good that can come in light of the burden or harm.[8] Overall it is about the overall net or benefit and burden, not the occurrence of a specific harm. For instance just because a certain therapy or intervention causes a harm does not mean it should be avoided at all costs, these harms just must be weighed against the benefits. The principle of non-maleficence does not require the initiation or continuance of medical treatment without considering the patient's pain, suffering, and discomfort. Beneficence requires action, whereas non-maleficence focuses more on refraining from actions, specifically those actions or interventions that cause harm.[9] Beneficence provides the primary goal of medicine rather than the obligation to do what is in the patient's best interests; "best" is not a requirement, but a goal, ideal, and overall commitment.[10] It represents a goal and responsibility of the physician, and central component of medicine being to do good and provide the best care. It does not require that the patient receive the best care in the world or access to any and all therapies that could lead to a good outcome, but that they receive the best medical care that their medical team and providers can provide, and that the team places the patient's interests above their own.[11] Beneficence and non-maleficence are overall guiding principles that physicians strive for and in and of themselves, explain a great deal about the medical field and its basic goals.

The principles of beneficence and non-maleficence can be applied to the field of pediatrics in a similar way as in adult medicine and can be used as central, guiding principles. One major difference however is that increased attention must be given to the opinion of the child and the concept of "best." Specifically, conceptions of what is good and best for the child must take into the child's own views and opinions, not only those of the parents, guardians, or physician. Competent adults are able to make their own assessments about what is good and beneficial, whereas children cannot always make those assessments. Even in instances where

they can participate in benefit and burden assessments and overall decision making processes, they are not the legal, final decision maker, so beneficence and non-maleficence cannot be applied to children as it can adults.[12] A possible interpretation of the application of beneficence and non-maleficence to children would be that decisions should be made in the child's interests, attempting to eliminate the subjective and ambiguous "best" from the determination. However, in many cases, the interests of the parents or whole family may be included in assessments, not only those of the child, which complicated this process and analysis.[13] Beneficence is commonly construed as incorporating the patient's autonomous wishes into care because "best" for a specific patient is typically closely linked to a his or her preferences and beliefs. The concept of best is important to determine for each patient and it is much more challenging to apply to children, as non-autonomous decision makers, than it is to adults with the legal ability to select and refuse therapies, making their own autonomous wishes and beliefs of best known. Beneficence can sometimes make the principle of respect for autonomy challenging, especially when the principles are contradictory and patients want to do something that is not in their best interests, however physicians should still advocate for the best option.[14] The promotion of beneficent and good acts while preventing harms is not absolute; in some instances physicians are not morally obligated to do so.[15] These principles are additionally challenging in that sometimes there is no good option, or one without any harms, however to "do no harm" means to have a balance of benefit or good over the harms caused.[16] Beneficence assumes an obligation to weigh and balance benefits against harms, benefits against alternative benefits, and harms against alternative harms, which must be included in the goals of pediatrics and additional held as central components to a decision making model. The goals of pediatrics should include ideas created from the principles of beneficence and non-maleficence. Promoting the good and overall benefits

for the child and preventing harm and risk, specifically protecting the current and future interests of the child, is very important to shared decision making, and will be a key component in the enhanced model.

5.2.2 Autonomy and Justice

Autonomy and justice are the two other guiding principles of medicine that impact and guide decision making and must be incorporated into the enhanced shared model. Principles of autonomy and justice must be applied to children in a unique way since they are not, by definition, autonomous individuals. The principle of autonomy is central to adult medicine and decision making, and is used to justify and as the basis for processes of informed consent, enabling adults to make their own medical decisions in light of their own values and beliefs. To respect a patient's autonomy is to acknowledge their right as a person to hold views, make choices, and take actions based on their personal beliefs and value system.[17] Respecting the autonomy of the patient means supporting and facilitating the patient's exercise of self-determination in decision making, overall allowing him or her to weigh benefits and burdens in light of personal values and beliefs and make a decision that aligns with them.[18] Specifically, to respect a patient's autonomy requires more than non-interference with them, it involves acknowledging them as decision makers and then enabling them to act autonomously.

In adult medicine, the patient's preferences guide decision making processes, enabling the autonomous patient to choose what is most beneficial to him or her, but in pediatrics, parents are tasked with weighing benefits and burdens and making choices for their child who is the patient. Selecting the best therapy and weighing all of the benefits and burdens is especially challenging within pediatric medicine and many times, parental preferences may or may not

reflect those of the child, nor do parents always take into account the patient's values or beliefs which may or may not have had the opportunity to mature.[19] This calls into question the utilization of autonomy as a guiding principle within the field of pediatrics, since by definition, children lack complete autonomy. Autonomy, defined as an individual acting freely in accordance with a self-chosen plan, cannot be seamlessly applied to children, because by definition children do not have full autonomy. They are however, in the process of developing autonomy, and fall somewhere along the spectrum with varying levels.[20] Some argue that parents can exercise the autonomy of the non-autonomous child, as a surrogate would in adult medicine, however it is first, not clear that that is where the authority of a surrogate is based, and additionally, unlikely that parents could exercise the not yet developed autonomy of their child.[21] Beauchamp and Childress argue that holding respect for autonomy above all other principles is not defensible within the field of medicine, and argue that autonomy and respect for autonomy should be a principle that is taken into consideration along with the other guiding principles.[22] This is important to consider and acknowledge as this is one of the only principles that does not directly apply to children. It can and will be looked at in relation to the child's development of decision making capacity and overall growth towards being an autonomous individual, however this principle should not be considered more important than the other guiding principles even though it is viewed that way many times within adult medicine. The principle of autonomy is based in "respect for autonomy" rather than the exercise of autonomy, so it is possible that parents are selected as the most appropriate individuals to make decisions that would respect the child's future autonomy. This would not ask them to apply the child's not yet developed values and beliefs, but rather, act in his or her best interests. This is why, for pediatric medicine, a reformulation of the concept of autonomy will be argued for and a fundamental goal will be

addressed in the following section that respects the autonomy of the family and the future autonomy of the child, while promoting the interests of the child.

Justice is another principle of medicine, although it has been argued to not be as meaningful or important as the others. With regard to justice, children deserve to be treated justly as members of society and to be granted access to healthcare and resources.[23] For this dissertation a communitarian concept of justice will be used to appropriately incorporate the impacts of society on the child and family. A communitarian conception of justice emphasizes that the community has responsibilities to individuals, and vice versa, with both communities and individuals sharing and working towards common conceptions of a good life and justice.[24] The principle of justice must be reformulated within pediatrics as frequently society addresses justice for children. For instance, society limits the rights of parents to refuse lifesaving interventions for their children, such as blood transfusions, or actions that put the child's life in extreme danger.[25] Society has an obligation and duty to protect children and overall promote their interests. There are however conflicting court rulings making judgments of what parents can and cannot decide for their children, which will be fully addressed in the section on justified impacts on pediatric decision making. Society attempts to balance allowing parents to make decisions for their children, as the legal decision maker and closest person to the child, but also ensure they are not placed in unnecessary harm.

Another component of justice that should be addressed is that of just access to resources within the field of medicine. The reason that justice is often excluded from discussions of guiding principles of medicine is that it can be held in conflict with the aspects of medicine that most are comfortable with and idealize, including love, mercy, compassion, and humanity.[26] In spite of this, and the arguments made that medicine is only about serving patients and promoting

"the good," there is no place in the world where a society is rich enough to provide all medical care needed or desired for all patients. Throughout the field of medicine, decisions must be made every day about who has access to what resources. Decisions to utilize resources range from a specific intervention, have a longer stay at a hospital, and even benefit from the physician's time. The face of medicine has greatly changed and people have access to less care overall with insurance companies and medical institutions making cuts and utilizing cost saving strategies.[27] These cuts and cost savings lead to the importance of justice within the medical world. From a standpoint of justice, what matters is who gets what, not that distribution and regulation exist.[28] To meet the standard of justice within medicine, the distribution of scarce resources should be both equitable and efficient with an overall goal of the most medical care for the cost. Additionally, specific to new technologies, there must be regulation and oversight to limit what is covered and what access individuals have to these new, typically expensive and not fully understood treatments.[29] Justice has a secure place within medicine at this point to ensure that the patient gets a fair share, but not more, of the medical resources and that the social system gets its money's worth.[30] Justice is not the part of medicine that most in the field like to talk about, and many times they speak of the way things used to be, when in reality, justice is a central principle in medicine that must be taken into account into a shared decision making model. Overall concepts of justice and respect for autonomy can be applied to children, especially adolescents, in a meaningful way that ensures them access to a decent minimum of healthcare and overall improved equality.[31]

5.2.3 Goals of Pediatric Medicine

Providing medical care for children is not the same as treating adults, therefore the goals of pediatrics should be framed differently than those in adult medicine.[32] The principles of medicine, beneficence, non-maleficence, autonomy, and justice, have been looked at in light of pediatric medicine and some of the different dimensions highlighted, specifically emphasizing the components that should be taken into account in both the formulation of the goals of pediatrics and the enhanced shared model. The goals of pediatrics are different than adult medicine because within pediatrics, the child patient relies almost completely on adults. Specifically, the child relied on his or her parents, medical professionals, and society to define what is right and good for them, emphasizing the importance of all involved.[33] A partnership exists between healthcare professionals, children, and families, emphasizing the need for shared objectives all with the child placed at the center.[34] It is not evident that parents are always in the ideal position to make decisions for their children as they can have conflicting interests and typically heightened emotions.[35] The goals of pediatrics are not only about the parents, as decision makers, the child patient, or the physician, but the relationship that they all must have together to advocate for and work to achieve the best interests of the child. In order to adequately incorporate beneficence and non-maleficence into pediatrics, all relevant stakeholders must work together to not only promote the overall interests of the child, but also to protect the child from harm.[36] They must both advocate for the child's best interests, and do what achieves the most good, while additionally focusing on not causing the child harm, either in his or her current state or in the future. These ideas bring up the principle of justice, as the communitarian interpretation of justice emphasizes the duties that the community has to the child, and vice versa once the child is old enough to do so, giving overall society impacts on the care of children. Children must have access to those therapies that promote their overall good and positive

outcomes. The goal of the impacts of justice must be, like those from the principles of beneficence and non-maleficence, to promote the interests of the child and protect them from harm, while also doing what is many times, best for society. Societal impacts shed light on another key goal of pediatrics, specifically that decisions must acknowledge not only the current interests of the child, but also the future interests. The current and future interests of the child will be elaborated more in the following section as a critical goal of pediatrics that the new model must encompass and acknowledge in order for good decisions to be made in light of the tremendous advancements of genetics and neuroscience.

Respect for autonomy, as the central principle of adult medicine also leads to goals within the field of pediatric medicine.[37] When respect for autonomy is applied to children, it not only requires that parents weigh benefits and burdens to determine the best interests of the child, but more importantly that the child's self-determination is acknowledged. For adolescent children, it is crucial that their self-determination, decision making abilities, and overall future autonomy be acknowledged in order for them to appropriately develop into autonomous, capable adults.[38] Adolescents, and all children, must be acknowledged as individuals and involved in decision making processes. Adolescents are challenging because they are closer to the development of autonomy, and should have more of a role and impact in decisions. Despite this, even when the child patient is an adolescent, that does not mean that the wishes of the parents, as legal decision makers in most cases, should be ignored. The final goal that is elaborated from the principle of respect for autonomy is that of the autonomy of the family. McCullough argues that families as a unit have autonomy, which must be respected and held in balance with the future autonomy of the child.[39] The balance of these two ideas and conceptions of autonomy respect and acknowledge the child as a person, facilitating their growth, and also give value to

the family unit. The goals of pediatrics include furthering the child's best interests, protecting him or her from unjustified harms in regard to medical interventions, and showing respect for family autonomy. These goals are central to the enhanced model of shared decision making that the later part of this chapter will describe and must be held as central components throughout pediatrics to ensure the best decisions are made for children, particularly in light of the new technologies provided and available to children.

5.2.4 Promoting the Future and Current Interests of the Child

One of the goals of pediatrics that deserves extra attention is the idea that the promotion and protection of the current and future interests of the child should be a central goal throughout pediatric medicine. New technologies pose unique issues to this goal due to the tremendous amount of uncertainty and inability to fully assess and understand future implications. More specifically, these new developments and therapies make it extremely challenging to really know what will happen with different interventions, that have unknown impacts on the child both at the time the decision is made, and those interventions that could possibly have effects that last the duration of the child's life. Respecting the current and future interests of the child emphasizes the importance of properly balancing the many influences on decision making processes, as many times different stakeholders have conflicting opinions or roles in the process. Within pediatric medicine, there are additional levels of the duty and responsibility of physicians, strongly connected to the goals of the field of medicine and pediatrics. The professional goals of pediatrics are different for pediatricians as they must work with the parents, in many cases more than their actual patient, while upholding, balancing, and sometimes arguing for the child's best interests.[40] In pediatrics, pediatricians and parents both are crucial to the

selection of treatments for the child, as co-fiduciaries.[41] Pediatricians have an obligation to protect and promote the health-related interests of the child and parents also have a fiduciary obligation to promote and protect the non-health-related interests of their child, who is the patient.[42] The doctor-patient relationship is a focal point of medicine in general, however this becomes more challenging within pediatrics when the parents are added to the model, and both parents and physician are simultaneously working to do what is both right and best for the child, which does not always go together.[43] The fact that there is some conflict in the roles makes is important that the goal of promoting the current and future interest of the child is a fundamental goal upheld by the enhanced model. Children are in a unique position in that they are continuously developing and have tremendous potential and hopefully long lives ahead of them, which cannot be ignored or forgotten. Decisions cannot be made for the child when he or she is a child that would undermine their future autonomy or interests, taking away decisions and choices that they should be able to make at a later date. This will be reviewed further with the application of the enhanced model as it is a central component to the process and a goal that must be held highly in the process. The enhanced model must respect the autonomy of the family, the future autonomy of the child, and the overall promotion of the current and future interests of the child, which are different than those of the parents or decision makers.[44] Each of the goals derived from the principles of medicine will have an important role in the model because each must be met in order for the model to be acceptable and actually facilitate decision making with new technologies.

5.3. Facilitated Shared Decision Making

Shared decision making is the most common result of decision making processes throughout medicine. In practice, decisions are typically reached through a shared process involving patients and physicians, both when the patient does and does not have the capacity necessary to make decisions. Individuals do not often make decisions on their own and there are often many involved in the process. Physicians work with patients, who frequently look to family or friends for guidance and assurance during the decision making process. Despite being accepted, advocated for, and commonly utilized, there is not a standard, accepted definition of shared decision making other than it being a shared process to make medical decisions. Shared decision making does not facilitate or guide the relevant stakeholders in the process or guide them to make the best decisions, it merely says that all relevant stakeholders should share in the process together to come to the best decision. This is somewhat easier to apply to adult patients who are able to determine who the relevant stakeholders should be in a specific instance and involve them in a way that is meaningful to them. It is however much more challenging with children as the model of shared decision making as it is currently elaborated does not apply in the same way nor does it accommodate the increasing complexity of the decisions that arise due to advancements in genetics, neuroscience, and pediatric research trials.[45] In this section, the enhanced shared decision making model will be developed that accommodates all necessary roles and the challenging decisions of these growing fields. This model, specifically a facilitated shared model, places an emphasis on the stewardship of the child and on a communitarian approach to parental decision making.

5.3.1. Current Decision Making

The current models of decision making utilized within pediatrics do not support parents in their role as decision maker nor does it guide the appropriate involvement of the physicians and child in the process, nor does it accommodate the challenging decisions of the rapidly growing fields of genetics, neuroscience, and pediatric research. Shared decision making is the model that is most advocated for throughout the field in order to address the fact that there are several relevant and important stakeholders, however there is not a consistent understanding, definition, or interpretation of this model for pediatric medicine that accommodates all necessary roles or the great levels of uncertainty, privacy, and future implications of the technological advancements Before developing the enhancements proposed to the shared model, the current understandings of shared decision making will be elaborated, including the different interpretations of and challenges to shared decision making in practice. It will then be reviewed how parents make decisions for their children, what they consider and find valuable during those decision making processes, and some of the limitations and challenges that they face. There are many barriers to decision making in pediatric medicine that must be addressed as enhancements and support tools will be elaborated at the end of this chapter. It is additionally important to ensure that the new model incorporates the details and information that parents find important. Pediatric decision making is challenging necessitating a modified shared decision making model that is meaningful to all involved in the process.

5.3.1.1 Shared Decision Making

Shared decision making (SDM) is the most common decision making model utilized to make medical decisions in practice.[46] SDM is advocated for instead of both the strict autonomy and paternalistic models by many European and Western countries as well as many medical

organizations including the American Medical Association, American College of Critical Care, the American Academy of Pediatrics, and the American College of Physicians.[47] Despite this advocacy and widespread appeal, there is not a common definition of shared decision making and much confusion over what it means.[48] Even research focusing on shared decision making lacks of a consistent definition, however much agreement exists that this is a problem for SDM in practice and some criticize it as nothing more than a name for the patient physician relationship.[49] The lack of a definition leads to a different process, inconsistent application of the model, and different levels of satisfaction among both patients and physicians.

The President's Commission argues that it is the physicians' role to help the patient understand the objective, medical situation and courses of action available, and the patient then conveys his or her wishes, adding the personal and subjective elements, both sharing in the process.[50] Some of the major and primarily agreed upon characteristics of shared decision making include the fact that both the physician and patient are involved in the process, they share information with each other bi-directionally, they both take steps to participate in decision making processes by expressing preferences, and a decision is then made where they both agree on the proper course of action and next steps.[51] In a shared decision-making model, information is shared in both directions rather than one sided, like paternalistic of patient driven models would be. At a minimum, physicians must provide the patient with all information needed to make a decision, specifically information about proposed treatment options or interventions, the benefits and risks of each and potential risks or impacts to the patient's psychological and social health. The patient additionally has requirements in this process and must provide the physician with his or her preferences, beliefs, and knowledge of his or her illness ensuring that the patient's preferences are taken into account and that he or she can make informed decisions.[52] Ideally the

shared model is based on the medical facts, a basic understanding of the patient and his or her values, beliefs, and autonomous wishes (if the patient is not making his or her own decisions), and a general idea of what is best for the patient both personally and medically.[53] Overall the shared process should be the mutual collaboration of patients and physicians that is different depending on the patients and decision to be made, however there is a need for some structure to guide this process and ensure that the patient is able to participate to the degree he or she wants to, and fully able to exercise autonomy and not subject to a paternalistic decision of the physician.[54] Shared decision making can be thought of as a balance between paternalism and pure autonomy, described by A. Kon as a pendulum swinging back and forth between the two extreme models.[55]

In addition to the balance of roles and sharing of information, the amount of information shared varies greatly between decision making models and specific scenarios. Typically the focus is on the minimum of information that must be shared, however there are additionally outside boundaries that should be mentioned, and bring into consideration issues of justice. [56] The amount of information that is shared is almost infinite, in that the provider could always tell the patient more or teach him or her more. However in practice, there are outside constraints and restrictions such as time and money, both of which are not infinite. Shared processes, including more discussion and deliberation to come to a consensus, are likely to take more time than models that are more paternalistic or even patient driven. It is up to the physician to work with the patient to navigate and enable him or her to be a decision maker with the appropriate level of involvement with the correct amount of information. This becomes challenging when the patient is a non-autonomous child, and parents are added to the relationship, there are additional

emotional barriers to comprehension, the patient is not always directly able to participate as he or she would in adult medicine, and time and money are just as limited.[57]

Typically many treatment options exist, and many times there is not one option that is superior or clearly in the patients' best interests, making shared decision making very beneficial.[58] Treatment decisions should result in the most desirable outcomes for the patient, which requires active engagement from both the physician and patient so both parties understand what is valuable and desired.[59] This process works well in adult medicine, where the patient can work with the physician to navigate care and participate as little or as much as they want to, however this is not possible with children in the same way. Children are not and have never been autonomous with fully developed values and beliefs of their own distinct from their family. The shared model, as described, does not immediately allow for the child to be incorporated into the process because by adding a child, a non-autonomous agent, the roles of all involved are no longer clear.[60] There are many challenges to shared decision making in practice, the biggest of which is that there is not a consistent definition or formulation of the model that establishes the appropriate boundaries and levels of involvement of all parties. Additional barriers to shared decision making exist for all involved in the process – patients, parents, and physicians. The child patient is not of the legal authority to make his or her own decisions, and parents have tremendous stress and emotions. Physicians many times worry about time and do not know how to engage seemingly disinterested patients and convey complex information.[61] All of these challenges lead to very different and inconsistent applications of the shared model throughout pediatrics.

Shared decision making is considered the ideal model for pediatric decision making and advocated for by most groups and organizations, however without a consistent and clear process

specific to children and the goals of pediatric medicine, it is impossible to be used in a meaningful way consistently yielding the best results for children.[62] The quality of care heavily relies upon the decisions that are made as the outcomes of the decision making process, making these processes a crucial and central component of pediatric medicine. Physicians must disclose to patients and parents enough detailed information about all options without bridging into territory where they are spending too much time with one patients. Patients and parents in pediatrics must additionally cooperate and participate in the process, being honest about their opinions and beliefs, enabling them to be addressed and incorporated into decisions. There is a need for a well-defined shared decision making process specific to pediatric medicine that incorporates the child, parents, and physicians in an appropriate manner and accommodates the challenging ethical dimensions of the emerging technologies and developments of pediatric medicine.

5.3.1.2 How Parents Make Decisions for Children

Each day parents make treatment decisions for their children, many times without the involvement of the child. This is not always a negative, as many times children are too young or incapable of being involved in the process, placing parents in challenging positons. Each person values and rates a given therapy in a unique way and has different outcomes that they view as acceptable or negative. This carries over into pediatric decision making in that all parents weigh impacts differently and think about unique elements when making challenging decisions. The way in which parents make decisions currently in pediatric medicine is important to a new model because the things that they value and are impacted by shed light on areas that can be improved in the enhanced model. Parents make decisions for their children in different ways as no two

people will weigh benefits or burdens in the same way nor will they understand information presented to them the same as another or even as the person presenting the information.[63] When making decisions, it is extremely unlikely that parents make the decisions alone, without the involvement of others, leading to a shared model in almost all instances.[64] The specific enhancements to the shared decision making model will be elaborated in the following section, but first it must be understood what impacts parents' decisions and the overall decision making process currently in pediatrics. Parents take many things into consideration when making treatment decisions for their children such as their own personal experiences or beliefs, the situation and availability of options, and ideally the desires of the child, if relevant.[65] Parents struggle to balance all of the influences and appropriately include their child in the decision making process.[66] Challenging decisions are faced each day in pediatrics and parents must balance many influences in the decision making process with the complex information, treatment side effects, and the probability of benefit and burden.[67] Parents work closely with physicians during this process in a bi-directional share of information, however, there are many outside impacts such as family, ranging from other children to extended family and including not only their opinions but also potential impacts that the decisions will have on them.[68] Parents can additionally be impacted by their religion, the internet, social media sources, and support groups with parents in similar situations.[69]

In medicine, most medical problems can be treated in numerous ways, each with potential benefits and burdens, and many times no objective best treatment, leading to complicated decisions.[70] These decisions can be very challenging for parents and despite their desire to be involved, they are not always included in a way that is meaningful to them or in a way that facilitates the best overall results for the child.[71] Cox et al., found that parents felt ill

prepared to participate in decision making processes and noted high levels of stress and anxiety throughout the process, only suggesting therapies or interventions 9% of the time.[72] Many times parents were involved in the decision making discussions with physicians but not necessarily meaningful deliberation processes.[73] Passive participation is very common in pediatrics and in many instances parents rely on physicians heavily for guidance and even the selection of therapy.[74] Parents routinely ask physicians what they would do if they were in the shoes of the parents, specifically what decisions they would make and why. They often rely heavily on them for guidance and assistance throughout the decision making process. Cox et al found that parents who were more involved in the processes were those with fewer outpatient visits in the past year compared to those who had more.[75] On the contrary, it was found that on the inpatient side, parental participation increased with prior hospitalizations.[76] The influence of prior hospital experiences may reflect parents' growing understanding of their child's illness, feeling comfortable with decision making processes, and with the overall medical setting. It may additionally emphasize that parents are involved in the basic care at a high level when it is not burdensome, specifically their child goes in for routine and regular visits, but once complexity increases, there is a point where knowledge barriers increase, and participation decreases. It then picks back up with the increase of hospitalizations, emphasizing that parents have now become familiar with and accustomed to this complicated information and environment. This difference shows that parents want to be involved in decision making processes for their child's care in a way that is meaningful to them and they are capable, but that there are barriers to work through. Physicians need to be able to work with parents in both settings from a diversity of backgrounds and prior experiences to elicit participation in the decision making process.

Beyond participation, there are many barriers in the decision making process for parents including the complex information, difficulties understanding all details, subjective elements of benefit and burden, uncertainty and unclear results or outcomes, language barriers, health literacy levels, education, stress, emotions.[77] Physicians and parents influence each other throughout the decision making process, and these external factors not only impact the decisions that are made, but also how they are made and the entire decision making process.[78] Decision making processes in pediatrics are based on the relationship between parents and physicians, and the child if possible.[79] It is crucial that this relationship is formed to enable all to work together appropriately and share information openly and honestly. Many times parents are not comfortable asking questions and worry they may be seen as incapable of making a decision or taking care of their child, but there is a great knowledge gap between physicians and parents in almost all instances.[80] Cox et al found that there was less deliberation between physicians and parents when the parents were college graduates and much more involvement when the parents were not of a college education.[81] Despite this, emotional barriers many times impede education and even if parents are of the correct education level, there are still challenges to making decisions for one's own child. Some additional barriers that parents face include financial impacts and restrictions, access to a telephone, proximity to the healthcare facility, and the availability of the physician.[82] These barriers will be more fully elaborated in later sections with suggestions to overcome them in the enhanced model. Parents value many things, but overall they want to participate in decisions, and do what is best for their child, there just needs to be a way for this to occur[83] There is a need for enhanced communication and education, different formats of informed consent documents, and physicians and parents to form a good relationship in order to work together in a productive, shared, and open way.[84]

5.3.2. Facilitated Decision Making and Proposed Roles

Concepts from adult medicine cannot be easily applied to pediatrics or the child-physician-parent relationship triad, requiring a unique decision making model that accommodates the roles and relationships and is able to address the enhanced ethical issues associated with new technologies.[85] There is a great need for an enhanced and defined shared decision making model that is specific to pediatric medicine that accommodates the complex decisions associated with emerging technologies within the fields of genetics and neuroscience that are available. Shared decision making, as the common model executed in practice in pediatrics and model that in theory encompasses all the roles, is used as the foundation for the enhanced model. It is crucial that the modified version of shared decision making addresses the goals of pediatric medicine and elaborates who should be involved in the decision making processes and how they should be involved. This section will develop the specifics elements of the facilitated shared decision making model specifically the evaluation of the child, who is the patient, the review and classification of treatment options and decisions to be made, the proposed roles of physicians and parents in addition to that of the child, and the justified impacts of outside stakeholders, such as society.

5.3.2.1 Evaluation of the Child

The first step in the enhanced, shared model is to evaluate the child and identify how he or she can participate in decision making processes. It is important that the child participate since they are the patient and must be empowered as individuals, making it a crucial step that they are evaluated first and their role in the process is established and clarified to all in the process. The

child must be evaluated first and foremost in the decision making process in order to include him in a meaningful way. Children do not have autonomy or the legal right to make their own decisions, but they are at a stage in life where they are developing the capacities needed for making medical decisions and including them has many benefits. These benefits include better medical results, empowering the child as an individual, enabling him or her to learn to make decisions, help them feel responsible for own care, show them that they are valued in the process, and overall enable them to begin to take control of his or her life while approaching adulthood.[86] Children will eventually, in most cases, be able to make their own decisions eventually, and incorporating children at a young age leads to not only better results when they are a child and with regard to a specific medical decision, but leads to more ideal outcomes later in life. The child's involvement in the process should be based on an assessment of their developmental capacities, not merely age which is done in many places. Buchanan and Brock discuss that there are general ages associated with specific capacities needed for decision making, but that they are merely estimates and there is a great deal of variation among children.[87] All children are different so it is important that each is evaluated by a clinician to determine how they can be involved.

Different levels of capacity are needed for different situations and decisions. Capacity is decision specific therefore physicians should evaluate a child's capacity to give consent in light of the decision to be made. It is essential that the person who will be evaluating the developmental capacities, typically the clinician but sometimes a psychologist or psychiatrist, understands the nature of the illness, proposed treatments and alternatives, and risks associated with all options including the refusal of treatment.[88] He or she should begin the process with a discussion of the illness or disorder being treated to ensure a complete understanding and

additionally that it is taken into account with the evaluation.[89] Developmental capacities that should be evaluated include the child's ability to understand information, make other decisions, and overall act voluntarily and without the complete control or influence of their parents.[90] Understanding typically refers to the child's ability to recall information that has been presented or explained to them, while making decisions refers to how this information is used to negotiate between available alternatives.[91] It is important that the child not only understand the options but also that they are able to use this information in a meaningful way in relation to the options. Effective decision making involves identifying alternatives, weighing benefits and burdens, making a decision, and then evaluating the effectiveness of the decision.[92] Additional qualities that should be taken into consideration during the evaluation include the ability to self-regulate and think about the future, their susceptibility to peers and family, and overall risk perception. Children should be able to understand not only the treatment, but the general concepts of benefit and risk. By judging how the child perceives risk and what he or she understands it to be, specifically in relation to his or her future, a lot can be judged about his or her decision making abilities. Additionally, it is important that the child be able to make decisions for him or herself, without the persuasion of peers or family members. This does not mean that the child must not interact with his or her parents, or ask their opinions; children gain much of their overall opinions and values from their parents, so it is not necessary that their goals be completely segregated, however the child must be able to make a decision without coercion.

The most challenging group of children to assess is adolescents as they are in an undefined place and can likely play a much larger role than other age groups in decision making processes. There is a great need to determine the developmentally appropriate involvement of adolescents as they approach adulthood and are in the process of gaining capacity rapidly.[93]

Young children may have limited decision-making abilities and not normally meaningfully participate, however adolescents have higher levels of decision making capacity and deserve greater levels of control and input into treatment decisions. Adolescents need to be the stewards of their care in any way that they can; allowing them to participate in treatment decisions acknowledges their self-determination and helps enhance their developing capacities to make decisions, facilitating their growth into autonomous adults.[94] Assessment of the child is not easy, which it why is does not happen in all cases currently. There are many challenges to overcome when physicians assess and evaluate the capacities of a child, especially when trying to do it at a young age when they are continuously changing. At a young age the capacities to respond, interact, or process information would not be present in a child that is developing at a normal pace, calling a need to give additional attention to those children who are not developing at that standard pace.[95] Many times children have difficulties understanding what is being asked of them by the clinician, making it almost impossible to give a meaningful answer, inevitably leaving the physician in a difficult place attempting to assess the child on poor representations of true capacities.[96] Assessment must take into account the full range of the child's development, not only specific traits, including the child's social and emotional capacities, cognitive abilities, language skills, social functioning, and environmental impacts including family, culture and beliefs.[97] Capacity assessments cannot be based solely on the individual belonging to a specific group, such as being a child or age. There should be a structured approach to assessments of capacity to yield more accurate and significant results.[98] Despite challenges, it is crucial that the capacity of the child be gauged as the first step. The child's role may vary depending on the circumstances, such as potential risks and benefits, and the availability of alternatives, however

they, as the patient, must be included.[99] Once the child's capacities are determined, their involvement in care should then be identified to the highest degree that their capacities allow.

5.3.2.2 Evaluation of Treatment Decision

The next step in the facilitated decision making model is the classification of the treatment decision to be made. In order to appropriately structure the decision making model and proper involvement of stakeholders in addition to the child, the specific decision must be understood and then labeled. Shared decision making is a powerful concept when applied appropriately and is especially valuable when there is more than one reasonable option.[100] Whitney et al classifies two basic types of decisions, (1) those with no reasonable medical alternatives, and (2) those with several reasonable options, emphasizing the need for shared decision making in the second type. The second category of decisions deserves extra attention with regard to new technologies as the number of options continuously increase. For this dissertation, the enhanced shared model will be utilized when more than one reasonable option exists primarily because decisions without alternatives are not as complicated or complex. The options do not necessarily need to be multiple therapies as the refusal of therapy is considered a valuable and reasonable option in many instances. A major component of decision making is the elaboration of all possible options along with their possible outcomes. When there are two or more reasonable choices, determined by evidence, the physician must encourage involvement of the patient with thoughtful and probing questions to help him or her work through uncertainty and reach a decision.[101] When there is not apparent agreement, or alternatives have unclear benefits and burdens, or unrealized potential due to the new technological breakthroughs, a facilitated decision making process is required. Depending on the specific case and situation, the

decision will fall somewhere on the continuum of shared decision making, described by A. Kon.[102] This continuum ranges from completely patient driven to paternalistic, physician driven, connecting the level of involvement with the complexity of the decision. Shared decision making is described as a continuum from autonomy to paternalism, with models on the spectrum including patient or agent driven, physician recommendation, equal partners, informed non-dissent, and physicians driven. Patient and physician driven represent pure autonomy and paternalistic models and are not shared processes, led by either the patient or physician respectively, therefore no longer included in this analysis as SDM is the desired outcome for the pediatric scenarios elaborated.[103] The other three options lead to the patient, or patient and parents when dealing with children, having more influence and control, an equal partnership where all work together, or the physician having more say and a larger role in the process. These correlate directly with three possible outcomes of the decision making process that Whitney discusses, where the patient may (1) accept the clinician's recommendation, leading to a clinician directed decision making model; (2) say no to the physician and the physician can reluctantly accept, leading to patient controlled decision making; or (3) the clinician may insist on his or her recommendation, leading to what Whitney refers to as the clinically controlled decision making model.[104] Weir et al. also discusses models that parents use with neonatologists when making decisions about life saving measures and discusses 1) an expertise and 2) a negotiated decision making model.[105] The expertise model is where the provider shares his or her "expert" opinion and then the parents are left to agree or disagree with this recommendation. In contrast, the negotiated model involves more collaboration where the parties work together to make decisions about treatment. The combination of these concepts will be utilized to classify and review decisions and then determine the appropriate level of involvement of all stakeholders.

It is important to note that all decisions cannot easily be classified as decisions since all patients are different, and each scenario has different elements or important factors to consider, however the decisions can be classified when the patient, situation and alternatives are taken into consideration.[106] Specifically, all decisions of whether or not to use a brain scan to determine if the child has ADHD cannot be made in the same way, using the same type of shared decision making, as the capacity of the child has not been taken into account, nor have the circumstances of the family or any outside impacts. However, by focusing on the child patient and treatment options, it is possible to classify the decision to them determine roles and how they should be involved in decision making processes. A good physician knows that they must explain things to the patient in ways meaningful to them.[107] By identifying the type of decision to be made, specifically if there is more than one reasonable option, and understanding that there are different, yet specific types of decision making processes that can occur, it is possible for the roles of the physicians and parents to be added to the decision making model in addition to the already determined developmentally appropriate role of the child.

5.3.2.3 Proposed Role of Parents and Physicians

The next component of the enhanced shared decision making model is the involvement of the parents and physicians. After the level of involvement of the child has been determined based on his or her appropriate capacities and the options and decision to be made has been evaluated and placed along the spectrum of shared decision making, processes can begin with the appropriate level of involvement from parents or guardians and physicians, in addition to the already determined role of the child. In order to ensure that good decisions are made for children and potential harms are avoided, parents and physicians must have a role in the decision making

process focused on the goals of pediatrics, including the furthering of the current and future interests of the child.[108] Balancing the goals of pediatric medicine with the duties and obligations of both parents and physicians is challenging as many times their roles, responsibilities, or opinions may conflict, making it necessary that they work together in a structured way with the child held at the center. Some physicians tend to use only certain decision making approaches with parents for decisions, however it is crucial that it is not only based on the decision or physician's common approach, but that it is also based on the family, child, and their preferences for involvement and overall values.[109] The goal of these interactions and decision making processes must be for the patient, family, and caregivers to work together in an ongoing process of education and support enabling collaborative decision making, and ideally mutual influence to work through the evaluated decision and proposed options.[110]

Relationships between decision makers are crucial to the decision making process. Parents and physicians, as co-fiduciaries in the process, must work together and have a level of mutual respect and trust. Additionally the relationship between parents and their children is central to the process as it can impact the way decisions are made, how empowered the child feels, the child's views, and inevitably the decision that is made. The parent-child relationship is an important aspect of pediatric decision making processes. Collaborative decision making between parents and children provides a foundation for the child's transition to become a decision maker for him or herself and gaining decision making independence, which is gained gradually. Parental influences greatly impact treatment decisions of younger children, but also young adults and adolescents as parents are often sources of support and advice, even as children gain independence.[111] Facilitating the parent child relationship is crucial, and enables parents and the child patient to work together in a meaningful way, identify decisions that are best for

them and their future, and additionally continue the development of the child's autonomy.[112] Parents should not override the decision or opinions of their children but enable them to be individuals and develop into autonomous individuals. This is why a central role for physicians should be to help parents determine when and how to include the child, bringing them into the process when it is appropriate.[113] This determination is initially made during the evaluation of the child at the beginning of the process, however throughout the process physicians should ensure that the child is included and advocating for his or her opinion when necessary.

Physicians have many important roles in the decision making process, requiring that they be open and honest with parents and child.[114] There are instances where full honesty may not be optimal for care or outcomes, however it should be the goal both furthering the trust and relationships present and additionally empowering the decision makers to make decisions on accurate information. Physicians must uphold the family unit and support the parents, while first and foremost serving the child's best interests.[115] Physicians not only have to make an accurate diagnosis and outline available treatment options, they also must communicate with the patient and their family, ensure understanding, and strive to empower parents and children to make decisions.[116] Most decisions should be made within a shared process where the physician provides all medically relevant and applicable options and work with the patient to negotiate the options and make a choice.[117] For value neutral decisions, physicians should be aware of patient preferences and beliefs and include them when possible and practical.[118] Additionally they should be aware of their own opinions and potential biases that could be impacting decisions. Despite this, in some cases, it may be appropriate for the physician to bear more of the decision making burdens, however they still must be guided by the values of the child patient and parents and keep them involved in the process.[119] Additionally, when parents ask physicians what he or

she would do, as they do in many cases, the physician must consider the patient's perspective and ensure that he or she is neither intentionally or unintentionally coercive in the answer.[120] Finally, physicians can, and should, refuse parental requests for therapies that pose substantial harm to the child with minimal benefit.[121] Parents, physicians, and children, when possible, must work through the potential burdens and benefits together and ideally select the therapy that is most beneficial with the least harm that promotes both the current and future interests of the child. Many times a clear option is not available, or benefits are minimal in all instances, making the expert opinion and role of the physicians crucial to the decision making process.[122]

Balancing the roles of parents and physicians with the role of the child is challenging in practice, making it necessary that the processes are focused on the specific decision that is to be made, on the unique elements and believes of the parents and child, and overall that the decision be fully evaluated. All decisions of a certain type cannot be handled the same way as different parents want and need different levels of involvement. Additionally, physicians cannot work with all parents in the same manner for all decisions that must be made as the child should be incorporated into the process based on the decision to be made and the child's specific capacity, which must be evaluated on the basis of the decision. For instance, all decisions about how and when to utilize whole genomic sequencing should not be physician led decision making processes, although it may be ideal model in some situations. It is crucial that the options be elaborated first, in order for the parents and physicians to work with the child and overall promote the child's current and future interests while maximizing benefits and avoiding potential harms. Decisions must not only respect the child as a person but also the fact that they will one day be an autonomous adult and are part of a family that has autonomy. Decisions also should take place within the continuum of shared decision making, and not at either end of the spectrum

being led completely by either the parents of physician. It is true that in some instances more of a role will be argued for with regard to one of the parties, however it is not a consistent recommendation nor should the decision even completely fall to one of them. Overall parents and physicians have central roles to the decision making process in pediatrics, and by first looking at the capacities of the child and identifying an appropriate developmental role, then fully exploring all options in a collaborative process, all can work together, exercise their duties, and achieve the goals of pediatric decision making.

5.3.2.4 Justified Impacts of Outside Stakeholders

Beyond the parents or guardians, physicians, and child him or herself, there are additional, outside organizations or groups that have impacts on the decision making process within pediatric medicine and therefore must be addressed as part of the model. These outside impacts are justified in many instances and further the goals of pediatric medicine, however in some instances, they do not provide benefit to the situation and potentially cause problems. Depending on the situation, there are many impacts on the decision making process, some of which directly parental decisions, such as extended family, the child's school, other parents, community members, pediatric societies, and even society as a whole.[123] These outside impacts must be held in balance with all of the relevant stakeholders in the process but can at times be challenging for parents to deal with and decipher as helpful or burdensome. Parents are free to incorporate the views of extended family or friends, and reach out to online support or community groups, however those external sources do not have explicit roles in decision making processes other than when parents seek to consult them. Pediatric societies or community groups have a right and many times duty to advocate for the interests of children overall, but their

actions do not directly impact specific decision making processes between parents, physicians, and children addressed here. They can however impact policies, such as leading to the expansion of screening panels. Advocacy groups are largely responsible for the great variance in panels among states due to groups working to add a specific disorder in one place. There are many impacts that these groups can have, many of which can be positive, however they must be evaluated by parents before incorporating their guidance into treatment decisions.

In addition to academic or medical societies and advocacy groups, society as a whole has a stake in the care of children. Children will eventually grow into adults, who contribute to the community and society at large, and may in some instances, impact or restrict individual decision making processes. There are many legal dimensions to society's role in medical care, and overall their intentions are not apparent due to somewhat contradictory regulations and rulings that exist throughout the country. Society should work to further the goals of pediatrics, specifically prevent children from undue and excessive harms, while enabling parents to work with physicians and make treatment decisions that are in the child's interests. However, not all measures that have been taken in the past or regulations that have been put in place accomplish that. Many times the state takes too much control of situations, while in other instances not giving enough support or guidance, leaving the child vulnerable to harm and potential negative impacts from parents. It is true that when parents, as the legal decision makers, are unable or unwilling to make good choices for their children, the state can step in and many times even appoint another decision maker for the child, but this should not be a common occurrence and many times is not what happens even in cases many would argue it should.[124] Courts are sometimes unduly intrusive into medical decisions, but many times they are justified to intervene, and even more so with children. Depending on the situation they many times do not

step in soon enough, if at all, placing the child at risk. There is a very delicate balance that must be upheld to protect the child and also enable parents to be parents. Parents know the child and are typically given a great amount of authority to raise their children in a way that is meaningful to them, and acknowledges their values, beliefs, and goals for their children.[125] There is a line however, of things that parents are not allowed to do, which is in place to protect the child from harm.

One specific instance of societal guidelines created for parental decision making are the Baby Doe Regulations.[126] These regulations elaborate that the withholding of medically indicated treatment cannot be done unless (1) the infant is chronically and irreversibly comatose; (2) the treatment would merely prolong dying and not be effecting to correct the infant's life threatening conditions; or (3) the treatment would be virtually futile in terms of the survival of the infant or the treatment itself would be inhumane under such circumstances. The Baby Doe Regulations were created in order to protect young children and ensure that care is given to infants regardless of parental decisions, however it is not clear if these regulations are actually in the child's interests.[127] These regulations do not give enough leeway for physicians and parents to weigh options and potentially even legally make the best decision that is in the child's interests. On the other side of the spectrum, Baines discusses that many US states allow for parents to refuse vaccinations for their children, despite the proven and acknowledged medical evidence that it is in their best interests, emphasizing that parents have a right to raise their children as they see fit.[128] The view on vaccinations seems to be contradictory to that of the Baby Doe regulations. Both emphasize that society has an impact on the medical treatment decisions made for children, however there is a need for a more consistent approach, especially with the developing technologies of genetics and neuroscience, both of which potentially have

societal impacts and many ethical issues in the near future. Overall there are outside stakes on parents as decision makers that cannot be avoided, so parents and physicians must be aware of them and ensure that they take them into account when necessary, but work to avoid those that may negatively impact the decision making process or inhibit the crucial triad of parents, child, and physician in working through treatment decisions and promoting the interests of the child.

5.3.3. Enhancement

The basic process for decision making in the new enhanced shared decision making model has been outlined, beginning with the evaluation of the capacities of the child to determine his or her appropriate involvement, the assessment of the decision to be made, the determination of the roles of the parents and physicians in the shared decision making continuum and the potential for outside impacts. This section will look at proposed enhancements that will enable decisions to be made in a manner that will properly involves all stakeholders and help facilitate the relationship between the child, physician, and parents or guardian. These enhancements are consistent with the goals of pediatric medicine, furthering the current and future interests of the child, specifically with regard to new interventions of genetics and neuroscience.[129] There are many challenges to shared decision making including limited parental health literacy, a lack of clinician training in the use and facilitation of shared decision making, and a lack of resources and decision aids for parents and children to use in the decision making processes [130] This section will look at the proposed enhancements including structured education for physicians, parents, and children, discussions of justice and access to resources, and the creation of tools to enhance communication between physicians and parents, and the overall understanding of parents. The

utilization of tools to facilitate the decision making process are crucial to its overall success as this will be the way that this model can be placed into practice in the field..

5.3.2.1 Education of Physicians, Parents, and the Child

Education is a very large part of an enhanced decision making model in order to ensure that physicians have the necessary skills to not only facilitate a shared decision making process but also enable parents and children to participate in the process and be validated as decision makers. The shared process is even more important in light of the new technologies that are not fully understood, come with greater levels of uncertainty, and need higher comprehension levels to make decisions and engage in the overall process. Physicians, or medical team members, as consistent and experienced members of the medical world, should bear the burden of facilitating the model and educating parents and children on their proper involvement because parents cannot be expected to know this. There are many skills, such as communication, interviewing, the ability to focus on key concepts, and the ability to incorporate teach back into discussions with parents, that many physicians have that enable them to have strong relationships with parents and children that facilitates shared decision making. [131] These skills that are very beneficial to decision making processes are not present in all physicians. These skills, currently not taught in depth to providers, should be taught to physicians to strategically place them in a position to succeed and inevitably work to engage parents to make the best decisions for children and promote the goals of pediatric medicine.[132] Physicians need strong communication skills that can elicit the patient's complete concerns and additionally strong listening skills to be partners with the parents and child and ensure they do not inappropriately take too much control in the situation.[133] Additionally, providers need to be able to determine, after full evaluation of

all treatment options, where the decision falls on the shared decision continuum and the level of communication the patient and family feel most comfortable with.[134] It is important that the provider be able to tailor the decision process to not only the decision but the parents and child, and additionally provide emotional support.[135] Physicians need to know what method to use in different circumstances and be able to elicit details and communicate with families and the child patient.[136]A recent study found that only 28% of physicians elicited the patient's complete agenda during decision making processes or overall courses of treatment.[137] Physicians need to present the patient with balanced reviews and how he or she can clarify and apply their own preferences to the decisions to be made in a meaningful way.[138] Specifically, medical practitioners cannot just present the options and medical details, they must ensure that the patient understands in a way that incorporates their opinions. For example if a possible outcome is that the child would need a wheelchair forever and the family is a group of runners, that would need to be considered and discussed. It obviously should not entirely guide decisions, but a discussion should occur about what is in the child's best interests in that situation, not all overall. Although the majority of parents in our study preferred being offered choices in their child's care, parents with low health literacy reported a preference for lower levels of participatory decision-making.[139] Patients and parents, must be enabled to seek information to ensure the interactions are appropriate and actually beneficial, making interviewing skills very beneficial.[140] It is possible to teach physicians how to engage in behaviors that lead to the sharing of information and research suggests that this is true for patients and parents as well.[141] In a study by Frosch and Kaplan, participants were educated during decision making processes and taught how to interview and participate in the decision making processes.[142] Prior to meetings with physicians it was emphasized that they could ask questions and they were reminded of issues that could be

discussed or elaborated with the physician. Additionally, they were taught basic negotiating skills to use during the interaction with the provider. These aids and overall basic education led to a much more engaging decision making process for all involved, more questions asked, and the collection of more overall information, emphasizing the need for parental education. Studies to date have additionally found that parents with low health literacy reported less participation in decision making processes and lower levels of empowerment.[143] One in five parents reported that their child's doctor did not help make them feel like a partner and more than half preferred to rely on the knowledge of the doctor.[144] Health literacy is a big issue that becomes tremendously more important with the complex information and high levels of uncertainty associated with new technologies.[145] In the new model, enhanced education of physicians to enable education of parents and the child to be decision makers is accomplished through a more structured decision making process that emphasizes the relationship between them as well as placing a burden on physicians to not only ensure understanding but to work with parents to make decisions.

5.3.2.2 Justice and Access to Resources

Justice and access to healthcare and resources is an issue that is prevalent throughout the Unites States. Regulations exist to provide healthcare to children when their parents cannot adequately provide medical attention for them, however there are still many barriers that come with the healthcare system in its current state.[146] Many insurance plans place limitations on choices parents can make, providers patients can see, or the number of visits that they receive. Parents face many limitations when taking care of their children including financial limitations, low education levels, or location of their home. Many times families do not live near a variety of

needed medical resources, making them extremely challenging to access. Financial restrictions can also greatly impact care since many times insurance companies will not pay for new, or experimental therapies, making research look more appealing to parents since the cost is lower in most cases. There are additional barriers outside of access to financial resources such as time and education levels. Physician's time must be thought of as a resource, as there is not an unlimited amount of it nor access to it for everyone. Additionally the education level of parents plays a large role in the process. The overall education level of parents as well as low health literacy are both major issues throughout pediatric medicine and have been the focus of much research in order to attempt to develop methods to overcome them and enable parents as decision makers.[147] Almost half of parents studied were found either be unable to reach someone after hours or not know that they could, despite this access being ensured for the study.[148] This study additionally found that parents of lower education were much more likely to be affected and not understand that they could call or reach someone after hours. Parents need to have access to the provider, or a medical team, outside of office visits and physicians need to have lower patient volumes or enough staff to do this.[149] There is a great need for the current healthcare system to accommodate the facilitated shared decision making model, specifically the interactions of parents, physicians, and the child. Some of the ways that the current model restricts shared decision making, and could be fixed to accommodate it in the future, would be to ensure patients have access to providers of the correct type and location, and have enough time with the provider..

5.3.2.3 Tools to Enhance Communication and Understanding

There are many tools that can be utilized in practice to enhance the shared decision making process by building and supporting the relationship between parents, patients, and providers. This relationship is a central component to making good decisions and the partnership that must exist between all relevant stakeholders.[150] A decision making tool can increase abilities of parents and children to participate in decision making, and improve overall levels of comprehension. The provider relationship with the parents and child in pediatrics is unique in that the patient is not the primary decision maker, nor a competent adult, but still must be incorporated into the decision making process in a meaningful way. There is a need for communication with providers outside of office visits, furthering the patient-parent-provider relationship that is crucial to pediatric medicine and the enhanced shared decision making model.[151] There are many tools that can be used to enhance the provider relationship with patients and their parents, the most beneficial of those being electronic communication and availability via the telephone, however with the growing number of technologies available, this list continues to grow.[152] Electronic medical records standardly offer a patient portal for parents to work with their physicians on their care, send message back and forth, and take a more prominent role in their care. These portals are not available to everyone, nor do all populations have access to the devices needed to access them, but they offer tremendous enhancements to care and enable patients to be more involved and feel a greater sense of control. The electronic medical record and patient portal becomes more complex with children since it is not clear what access parents should have for their children and what abilities they should have to speak on their behalf. The growth and tremendous development of patient portals however speaks to the growing desire of patients to be involved in their care and of parents to be involved for their children.

In addition to basic involvement and interaction between stakeholders, there is a need for tools to enhance the overall comprehension levels of parents and children, and elaborate their specific roles in the decision making process. Many times parents and children do not know how to participate in decision making processes , so it is important that the boundaries of this involvement is part of the education process they go through before making decisions with the physician. Parents and children must be provided with details about the treatments options including possible harms, benefits, and outcomes in their native language in a way that is meaningful to them.[153] Physicians must use clear communication and work to reduce the complexity of information while providing tools to enhance the discussion and improve overall comprehension, such as printed pamphlets or supplemental materials available through a patient portal.[154] Decision aids have been developed to help in decision making processes, however they are largely focused on adult conditions and processes.[155] Future work should engage pediatricians to develop decision aids for the pediatric health setting because currently very few exist for children and their families and this would add a great benefit to the field.[156] The use of decision aids is a recommended and proven approach as it works to enhance health literacy which is a difficult area for physicians to assess. Physicians typically assume parents understand more than they do, which is additionally complicated by the fact that parents do not always asks questions when they do not understand, worried that they will be embarrassed.[157] Electronic media and medical records should be leveraged in shared decision making, presenting information on treatment options and choices in a convenient way for parents and children.[158] Frosh and Kaplan emphasize that further research is needed to determine the best sequence for using aids in decision making processes as they have been very successful in the past and will continue to be a crucial component of decision making moving forward.[159] There are currently

holes in some of the research as there are not studies that look at the impacts of the Internet or took that into account, even though many parents use the Internet for decision making. There is a need for more research to determine how to best educate parents and children, however there is a definite need to do so through technology in a way that is accessible to parents, enabling them to have a relationship with the provider, be good decision makers and comprehend the medical information in a meaningful way to make good decisions for the child.[160]

5.4. Conclusion

The enhanced facilitated shared decision making model allows for parents, physician, and children to work together in a meaningful decision making process. The steps outlined provide structure and guidance to all who should be involved in the processes and enable them to work through the challenging decisions of the expanding technologies of genetics and neuroscience. They additionally provide structure and assistance that can be applied to the currently complicated and somewhat contentious areas of pediatric research. The utilization of new technologies, especially when they are in experimental stages, is very complicated to rationalize and determine to be appropriate. There are complicated issues and dimensions including uncertain outcomes, unclear benefits, heighten potential for harm or negative outcomes, and the status of the child, placing them in a vulnerable position. It is necessary that the child is included in the decision making process, and involved to help determine which interventions he or she wants to participate in for a given situation. The child, as the patient, should be the central focus of all decisions and involved in the discussions to determine interventions, which is why he or she is evaluated as the first step of the elaborated process. Physicians must assess the developmental capacities of the child, looking further than their age, and determine the

appropriate level of involvement that the child should have in the process. Not only must they determine and outline the appropriate involvement for the child, but the physician must also, in many cases, advocate for the role of the child and bring him or her into the process. After the role of the child has been solidified in the decision making process, the decision itself must be fully understood so that the appropriate level of shared decision making between all relevant roles can be identified. There are many stakeholders with large roles in the process and they must all work together in order to make the best decision for the child. When the decision is classified, the role of the physician and parents will be placed along the spectrum of shared decision making, ranging from paternalistic, physician driven to pure autonomy, which would be parental or guardian driven with regard to pediatrics. There are some instances where parents should be more in control, others where physicians should take more of the lead, and others where they truly are shared and equal decision makers. A model where the child leads has not been discussed yet, however this will come into play in the next chapter when specific cases with adolescents are looked at. After the decision has been evaluated, the physicians, parents, and child can all participate in decision making that acknowledges their duties and responsibilities and fully enables them as decision makers. The final component of the enhanced model that was elaborated is that of outside impacts, discussing how society, among other potential outside impacts, has a stake in the decisions made for children in many instances. The role of society is very important and must be engaged in many of the challenging decisions that arise within the fields of genetics and neuroscience. There is a great need for regulation and oversight, and potentially for re-evaluation of current laws and legislation that exist to properly protect children and enable parents to be caregivers and make choices for them that they believe to be in the child's best interests.

The final section of this chapter reviewed many of the changes that are needed to fully incorporate the enhanced model into practice. The enhancements discussed in the last few sections provide additional details for ways to improve decision making processes and fully enable children and parents to be decision makers, and ensure that physicians can properly coordinate the interactions and provide enough information. There is a great need for enhancements to increase communication and overcome the educational barriers between physicians and their patients, specifically parents and the child in pediatrics. Overall, this enhanced shared decision making model enables parents, children, and physicians to work together to make decisions in light of the tremendous uncertainty of the fields of genetics and neuroscience and the expanding number of research studies. The new suggestions and enhancements address the goals of pediatric medicine, incorporate all relevant stakeholders, as well as accommodate the new technologies, which will be the topic of the next chapter.

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Chapter 6 - Application of Enhanced Shared Decision Making to New Technologies

6.1. Introduction

Shared decision making occurs throughout the field of medicine each day as physicians work with patients to make medical decisions about treatment and courses of care. This process becomes challenging when the patient loses the ability to make a decision and someone else must step in to make decisions on his or her behalf. When the patient is a child, he or she by definition does not have the ability to legally make medical decisions, therefore parents, or legal guardians, must be involved and make decisions for the child patient. There is not a current model for parents to use to make decisions for their children that adequately incorporates all relevant stakeholders or supports the new and continuously emerging technologies present throughout pediatric medicine. New therapies throughout the field of pediatrics are developing at an exponential rate, especially within the fields of genetics and neuroscience, including clinical research trials in both of those areas. More options for diagnosis, treatment, and possibly even enhancement or prediction are available each day. These therapies bring with them tremendous possibility and hope for improved futures for children, but also great levels of uncertainty and questions about what should and should not be done for children, specifically what parents can choose and what physicians should propose. Over the course of the last 15-20 years, these three areas have tremendously expanded, offering new therapies and diagnostic tools, but also much uncertainty and complex ethical issues, leading to difficult decisions that must be made and the poorly structured models of adult surrogate decision making or the ill defined model of shared decision making to support them. The inability of current models to provide enough structure and support throughout decision making processes with regard to the utilization of new technologies led to the need for the enhanced shared model and overall a more

structured decision making process. Advancements and new therapies within the fields of genetics, neuroscience, and pediatric research trials lead to a great number of decisions that must be made, which this chapter will address in more detail, and apply the previously discussed model.

The enhanced shared decision making model elaborated in the previous chapter offers more support and guidance for all involved stakeholders while emphasizing the central role of the child, as the patient, where possible. This chapter will apply the enhanced model to the areas of tremendous growth and expansion, specifically genetics, neuroscience, and pediatric research. This chapter will briefly elaborate the expansions of the fields of genetics, neuroscience, and pediatric research focusing on the elements that make them challenging for current decision making models to facilitate. Although the ethical dimensions have been explained in an earlier chapter, the major issues that impact how decisions are made will be elaborated again to ensure they are directly addressed by the enhanced shared model in each of the case studies. Within each section, the new model will be applied to two cases to show how the model would work in practice and call attention to the variance between young children and older children, emphasizing that all decisions that parents must make for their children with the utilization of new technologies are challenging, however these decisions are exponentially more complicated with adolescents who have varying abilities to make decisions and some levels of decision making capacity. Decision making in pediatrics is very challenging, especially in light of the growth and enhanced ethical issues within the fields of genetics, neuroscience, and research, leading to the need for the enhanced shared decision making model that incorporates all relevant stake holders and offers more structure and support to the overall process, accommodating the many challenges and issues that arise.

6.2. Genetic Screening

The area of genetics has greatly expanded in the last few decades and will continue to grow at an exponential rate in coming years as technology progresses and becomes more accurate and accessible. This section will look at the developments within the field of genetics, beginning with the emergence and expansion of newborn screening, tremendously impacted by the development and expansion of genomic sequencing. There are many challenging ethical issues associated with genetic screening, including both newborn screening and whole genomic sequencing, all of which led to the need for the facilitated, enhanced shared decision making model for parents to work with physicians to make treatment decisions for their children, and incorporate the child when possible.[1] Once the ethical issues of the field are reviewed, the enhanced shared decision making model described will be applied to two cases of genetic screening to emphasize how the model addresses the issues and facilitates the decision making process. The first case involves parents requesting the genetic screening of their child with a strong family history of breast cancer. The second involves an older child exhibiting symptoms of a developmental disorder that the physicians would like to diagnose with whole genomic sequencing, however before beginning the sequencing they must determine what should be part of the panel. The parents request information of genetic disorders that the child does not have a family medical history for nor are immediate therapies available. The discussion and application of the model to these cases will emphasize the need for the enhanced shared decision making model to guide parents, children, and physicians to the best decision for the child.

6.2.1 Expansion of Genetics

Growing knowledge of the human genome has greatly expanded as the number of disorders physicians can screen for in children as both the accuracy and efficacy of sequencing has increased.[2] Genetic screening with children began with newborn screening in the 1960s with a genetic test for PKU, an easily identifiable and treatable disorder.[3] Over time, new technologies emerged, including tandem mass spectrometry (MS/MS), leading to screening newborns for over thirty heritable disorders. Currently, each state in the United States tests for different disorders on their standard panel with newborns, including some disorders that are not as easily remedied as PKU and many with unclear diagnosis or results.[4] Over time, due to lobbyists, activist groups, parents, and the availability of more accurate tests, the newborn panel has expanded to include genetic conditions that are not treatable and additionally, the identification of the trait is not meaningful.[5] Different organizations have argued for standards of the field and believe that children should only be tested for those disorders that are understood, can be accurately identified, and for which valuable treatments exist.[6] Infants, and children in general, should not be tested for disorders that cannot be treated because there is not clear benefit or overall good that can come from the identification of the condition.[7] As technology progresses, the lines between what can and cannot be treated however, will begin to blur as treatment may be available in some instances and not others.[8] Making it necessary there is a model to facilitate each individual decision and case, and not rely on blanket statements.

In addition to newborn screening, genetic testing is available for children as an important diagnostic tool that has become reliable and much more available throughout medicine.[9] In the last decade whole genomic sequencing (WGS) has become more feasible due to decreasing prices, heightened accuracy, and the identification of a continuously growing number of disorders.[10] WGS has made it possible to evaluate and many time identify disorders that were at

one time un-diagnosable and unknown.[11] Additionally, many argue that it is probable that WGS could be added to the newborn panel, sequencing the genome of children when they are born, or in some cases, even in-utero.[12] WGS is currently used as a diagnostic tool to identify neurological and developmental conditions, and has the potential to be used for personality or affective disorders, which only expand upon the previous issues of conditions that are not treatable or fully understood.[13] The continuous development and focused research in genetics has led WGS and other screening techniques, such as exome sequencing, to be both a reliable diagnostic tool but also a way to develop effective therapies and gain an understanding of new disorders and areas of development. These technologies have the ability to assess almost every gene in the human genome, providing a great amount of information [14] Current research addresses in-utero WGS and interventions, emphasizing the need for solid recommendations and guidance to move forward.[15] The field of genetics continues to expand and with it societal and governmental regulations have appeared to help remedy the challenging ethical issues that arise and protect patients, both adult and children. These new technologies and expansions of the field will be discussed with the application of the enhanced model after the specific challenging ethical issues that arise within the field are addressed.

6.2.2 Ethical Issues and Dimensions

There are many challenging ethical issues throughout the field of genetics, with both adults and children, due to the levels of uncertainty and rapidly expanding panels of disorders that can be identified.[16] These expansions make interactions with children complex and challenging due to heightened issues, unclear decision making processes, and the future implications for the child associated with the nature of the screenings. Issues ranging from

parental authority and consent to the availability of therapies if a diagnosis is identified must be addressed on a regular basis.[17] In the future there is likely to be a large array of DNA-based tests to diagnose single-gene disorders and identify predispositions to genetically influenced disorders.[18] Testing and their results may offer medical or psychological benefits but additionally may harm the parent-child bonds or the child's understanding of self or even self-esteem. As identifiable disorders are found on a regular basis throughout the field of genetics, it becomes crucial to not only develop standards for what should be screened for, but a way for parents to work with physicians and the child, when possible, to determine what is best in specific instances. The potential exists to screen for not only diseases and disorders but also skills or even intelligence levels, emphasizing the need for a facilitated shared model. These issues of genetics are ethically troubling in themselves and when applying them to children the stakes are even higher.[19]

Currently in the United States, each state decides which disorders are part of newborn panels, leading to a great variance in testing.[20] Depending on the state, newborns are screened for 29-54 different conditions.[21] Additionally, since many individuals cross state lines to seek medical treatment and regularly travel throughout the country, it is difficult to know what a child has or has not been screened for at birth in the event that a physician needs to know for diagnostic purposes. These issues become much more troubling with the potential addition of whole genomic sequencing at birth, expanding the list of disorders screened to include many with limited therapies, if any, and others that do not develop until adulthood, or have uncertain clinical significance.[22] Some disorders that are screened for are not completely understood and lack effective treatments or options for the parents and child.[23] There are arguably other benefits to screening other than treatment including for the family to know about the condition and

prepare themselves, or even for society at large for planning or budget purposes or to gain more knowledge of diseases and inevitably increase the ability to treat them.[24] There are many benefits, however not all of those benefits are actual benefits of the child, making it difficult to determine if those benefits outweigh the possible harms posed to the child. Weighing benefits and burdens is additionally complicated by the actual results themselves. It is difficult to determine the likelihood that a child will develop a certain illness and when they test high enough for a "positive" result that will develop into the condition. Many tests give results that are not only positive or negative but give a probability that the child will develop the disease, making it challenging to decide what parents should be told and determine when the probability is meaningful.[25] With WGS, the fact that a child has a specific gene does not guarantee that they will develop the disorder. There are other factors, such as environment, that can be more of a marker for disorders, and combined with the genetic predisposition make the child more likely to develop a disorder, but still it is not guaranteed. For example, many with the genes for breast cancer, suspected Alzheimer's disease, and other conditions have never developed the diseases.[26] If a positive result has little bearing on whether the child will develop the disorder, there is not a strong argument for it to be part of screening panel, but arguments are made on the other side that if it has any bearing parents should be able to prepare for the chance that the child will develop the disorder. The fact that lifestyle or environment in many instances can combine with a genetic predisposition make a decent argument for telling people what they have the genes for, however there are many other issues that arise with that and the potential for abuse or the misuse of information. Determining if there is an actual benefit to the child when testing for untreatable illnesses, or when giving percentages with unclear meanings, is very challenging.[27] An additional component of this is the duties of physicians in this, since it becomes their job to

counsel and provide information to the patient and his or her family.[28] Primary care physicians are given the task of delivering the news of abnormal results and the outcome of these tests in general, seemingly being asked to predict the future, and discuss rare disorders that they may not have experience with, to parents who are scared and confused. False positives or abnormal results lead to parental stresses, impacts on the parent-child relationship, and perceptions of the child's health making it necessary that these results are followed up with, and in a meaningful way once the physician has interpreted the result.[29] A recent study found that after counseling, many parents had inaccurate information about a disease from their PCP and those who received false positives had heightened stress levels over a year after the mistake.[30] Another study found that both providers and genetic counselors, involved in many cases with genetic screening, were concerned that they were unable to give enough information to parents and that the patient may experience stress, anxiety, discrimination, or future impacts without access to the appropriate details.[31] Issues of accuracy of test and diagnoses, the availability of meaningful therapies, and the potential benefits and burdens to the child all must be considered when determining what tests should be used with children.

Other major ethical issues impacting genetics include parental authority and informed consent.[32] Parents are given a great deal of autonomy when making decisions for their children, but in order for parents to give valid informed consent, they must be able to not only understand the therapies and potential outcomes but weigh the benefits and burdens for their child in the specific case and situation. Many parents want, and believe they have the right, to know everything they can about their child, while others do not want these details. The ethical issue here is that the decision should not be what the parents want to know, but what the child would want to know since the parents are making the decision for the child. Consent is challenging for

many reasons but the major elements impacting and making consent challenging are a lack of parental understanding, information that may or may not be meaningful and beneficial to the child and family, and follow up on the results and information found with regard to access to providers, their time, and information that is meaningful and understood to them When used therapeutically, many genetic studies currently in practice tell parents that they will only have access to the results that would impact their child's current suspected illness. For example, they would not tell parents the child has the BRCA gene when they are looking for a diagnosis for neurological problems.[33] This becomes more complex when the family also has minimal history of breast cancer, leading to grey areas of both parental authority and their right to know. With current newborn screening, one of the major issues is a lack of information given to parents about the process, what they are screening for, and follow up and communication after the tests.[34] Even in instances where details are given, due to how much the family is going through during the birth of a child, they do not comprehend everything that is going on, and a little prick is not likely to appear significant to parents. In addition, after they leave the hospital unless the child receives a positive result they typically do not hear anything more.[35] There are many lessons to be learned from newborn screening when looking to expand whole genomic sequencing and finding more information.

The final major issue of genetics reviewed is privacy and future implications of the results on the life of the child. Issues of privacy are prevalent throughout the field of genetics and will only become larger with the expansion of WGS.[36] With newborn screening, issues range from the storage of the bloodspot and genetic information, to who has access to it and whether tests and research can be done on it without parental consent.[37] These determinations are crucial because once the child is found to have something, it cannot end there, as this is a diagnosis the

child and his or her family will have to deal with the rest of their lives.[38] There are also many burdens to knowing that a child has something, especially since these can go with the child for the rest of their lives and impact insurance, life decisions, employment opportunities, and the potential access to therapies and resources. Privacy is a very large issue that will require governmental regulations and oversight in the future as genetics expands.[39] When determining the spectrum of disorders tested for, there are advocates for testing everything to strictly regulating and only test for those with current affective therapies.[40] The American Society of Clinical Oncology recommends that genetic testing be offered when the patient has a personal or family history, the test can be adequately interpreted, and the results are meaningful in that they will impact medical care or lifestyle decisions. [41] Overall, there are many ethical issues throughout the field of genetics and these become exponentially larger with the expansion and potential addition of WGS to screening panels and the increased use as a diagnostic tool. The next section will look specifically at how the enhanced shared model facilitates decision making processes for parents, physicians, and the child to determine what should be screened for in different instances, as it cannot be the same across the board for each case and each child, however much guidance is needed.

6.2.3 Application of the Model to facilitate the DM process

Shared decision making is common in pediatrics however it is not evident that parents have enough support to be appropriately involved in a meaningful way balanced with the roles of the child and clinicians. A decision making model does not exist to facilitate the discussions that will occur with the expansions of the field of genetics, specifically whole genomic sequencing. In this section, the enhanced shared model will be applied to two different cases considering the

utilization of WGS. In the first case, the child's family has a history of the illness that they would like to screen for, however there is not anything that could be immediately done with the information obtained. The other case concerns a child with an unidentified disorder; the parents would like to use WGS for diagnostic purposes, however they are requesting additional tests be part of the panel, specifically tests for a disorder that the child does not have a family history of., For each case, the child will be evaluated and their appropriate level of involvement will be determined. After this evaluation of the child, the decision to be made will be classified and the specific duties and obligations of all involved will be outlined. Finally, the overall recommendations and proposed outcome will be developed, including policy suggestions and enhanced duties and tools will be discussed, and overall how the two cases should be handled differently.

6.2.3.1 Cases and Enhanced Shared Decision Making

To fully demonstrate the utilization of the enhanced shared decision making model, two children will be evaluated for genetic testing using the enhanced model to determine whether or not they should be screened and if so, what should be included in the panel. The child in the first case is an 11 year old female with a family history of breast cancer, among other cancers. Her aunt and grandmother both had breast cancer and were diagnosed at ages 17 and 42 respectively. Her parents want to have her screened before she enters puberty to know if she carries the gene so they can be prepared and make a decision that is best for their family. The second child is a 14 year old female who does not have a history of breast cancer, however is being screening for a possible neurological disorder that physicians have not been able to diagnose and believe WGS will help with. In this case, the parents have requested that she be screened for the BRCA gene

as they had a close family friend who recently died from breast cancer and they are worried about their daughter and would like to be able to prepare and take all prevention methods possible to avoid their daughter having to go through that. In both instances the parents are requesting additional information and the screening of their daughter for the breast cancer gene. It is important to note that the identification of this gene does not necessarily mean that the child will develop the cancer, just that there is a heightened chance. Breast cancer is treatable, not curable, however not until symptoms arise in most cases. Many argue that the knowledge could lead to earlier detection through the utilization of more regular exams, either by the child herself or a medical professional, however outside of that there are not clear next steps if the gene is identified. Additionally, it can be argued that if the only outcome would be preventative screenings, such as regular exams, that the child should do those regardless of having the information in order to protect the child from an incorrect diagnosis.

There are many ethical issues connected to both cases that will be worked through as the overall enhanced model is applied. The first step in the process of facilitated shared decision making is the evaluation of the child by either the physician or other qualified medical professional. This individual must look at the child's ability to understand and comprehend, make decisions, weight benefit and burden, think about his or her future, their perception of risk, and overall susceptibility to peers or family.[42] While assessing capacity, physicians must take into account their emotional status, cognitive abilities, language and communication skills, and social functioning.[43] Similar to adult medicine, physicians must share as much or as little as the child needs to understand, and adjust how they share it based on the child and what he or she needs to know. In these two cases, the children are approaching, if not already, adolescents as they approach adulthood. The most challenging group of children to assess is adolescents as

they are in an undefined place, not clearly children but also not yet adults of 18, and can likely play a much larger role than other age groups. Adolescents need to be the stewards of their care in any way that they can, and allowing them to participate in treatment decisions acknowledges their self-determination and helps enhance their developing capacities to make decisions, facilitating their growth into autonomous adults.[44] There is a great need to determine the developmentally appropriate involvement of adolescents as they approach adulthood and are in the process of gaining capacity rapidly.[45] In both of these cases as the children are older, they are both able to participate in the decision making processes, however the physician must work with the child to determine the exact level of involvement in correlation to where they fall on the spectrum of decision making capacities and their overall abilities to comprehend. Just as adults and parents who make decisions for children, children making their own decisions must be able to understand the options, including the medical complexities, future implications that these screenings have, and overall the benefits and burdens associated.[46] For the child with the strong family history, they must understand the potential negative impacts of not being screened now, if they physician thinks they exist, and the benefits of identifying a disposition to cancer early. For the child without the family history it must be explained what would happen if they were identified to have the BRCA gene.

After the child has been evaluated, that understanding must be translated into a role for the child in the process. Before it can be directly translated and applied to the cases though, the decision itself must be evaluated as capacity is decision specific. In these two cases, physicians evaluate the two patients and work with them to determine if they understand the procedure, the information the sequencing can provide, and what can be done with that information. In both cases, more than one option exists leading to a shared decision making model, however there is a

wide range of ways that a shared model can be executed with more or less involvement from the parties involved depending on the individuals and decision to be made. In the first case, the decision is whether the child with history should be screened or wait until she is old enough to make her own decision and continue normal monitoring and prevention methods, such as annual exams, and in the second, it is not whether or not to screen, since they are already for another reason, but what information they should receive. Both cases bring up issues of parents authority and the ability of parents to request things for their children that they may believe they have a right to know. Discussions and details of the options for each scenario and outcome can be used to evaluate the expected benefits and burdens for the child, which must be taken into consideration before determining the involvement of the parents and physicians.

Once more than one option has been identified as appropriate or feasible, the decision needs to be classified along Kon's continuum of shared decision making ranging from completely patient driven to paternalistic physician driven, where the level of involvement correlates to the complexity of the decision. The roles of parents and physicians fluctuate based on the decision and overall the expected benefit and burden to the child, more so than that of the child which most strongly relies on their overall capacity and ability to be decision makers. The first case with a family history is less complex than the decision to screen for additional conditions in the second with a more anticipated benefit, however both fall towards the side of heavy physician involvement due to the fact that there are many nuances to the BRCA gene, including what type of history should be looked for before making recommendations to screen or not. Additionally both cases provide minimal initial impacts and burdens to the child due to the minimal impacts of the sequencing, but have the potential to have greater impacts to the child's future. Depending on the outcome, and future utilization, storage, or access to this information,

the potential exists that the child could be denied a job or medical insurance, or forced into higher insurance premiums due to the results of these test, rather than the diagnosis of the disorder. It additionally could impact the self-identification or self-esteem of the child as she grows into an adult. The benefit and burden must be taken into consideration when determining where the decision falls on spectrum and expected decision making model utilized.

In the first case, Whitney's discussed clinician directed or patient controlled decision making model would be the outcome, where the clinician's recommendation is given and either accepted or refused and he or she accepts their decision because there is substantial medical evidence and societal recommendations, and both decisions are justifiable. In relation to Weir's expert and negotiated models, the first case would fall more into the expertise category where the physician should give all appropriate information and then work with the parents and child through the decision making process, leaving the final decision up to them.[47] In this case, the benefits are moderate due to the increased susceptibility due to the established family history and the family has outlined what they would do if the result was positive. The burdens are present and should be worked through, however they are not enough to allow for the physician to potentially override the parental rights or refuse the request.

In the second case, where there is not significant clinical evidence for screening of the child, the negotiated model will be the outcome with the physician being not only a facilitator but also key stake holder involved in the decision making process. In the second scenario Whitney's clinically controlled model may be the outcome as well because it may come down to the insistence of the physician depending on the clinical evidence. This is the expected outcome due to the fact that there is not medical evidence to suggest benefits exist for the child. Exposing the child to the potential burdens is not justified for a child who does not have a genetic history,

especially when no therapy exists until symptoms are present.[48] Making this decision for the child undermines her future autonomy to either know or not know, and without a good reason, such as a strong family medical history, it should be left up to the child to decide once she is an adult. In both cases, the physician must encourage and elicit the involvement of the child with thoughtful and probing questions to help them work through uncertainty and reach a decision.[49] Physicians have a very crucial role in this process and must provide all information that they can in ways that the parents and child will understand. Parents have obligations to give accurate medical history to physicians and advocate for their child when necessary. Additionally, parents legally have to give consent since the child is not an adult and it is not the legal decision of the physician. It is in the physician's hands to evaluate the family history and advocate for the child's interests, while leading the decision making processes. Outside of the roles already mentioned, the overall process must be additionally guided by regulations about what can and cannot be tested for or divulged after the test is over, however due to the uncertainty surrounding the genetic sequencing for diagnostic purposes, the relevant stake holders together work through what they would or would not want to know from the test. The ASCO recommends genetic testing when history suggests a genetic susceptibility and only in settings of pre- and post-test counseling which include discussions of prevention methods and possible risks and benefits of cancer early detection.[50] Without meaningful treatment options or next steps if a positive result is found, there is not tremendous benefit to allowing for the test. By classifying the decision in a clear way and relating that to the overall involvement of parents and physicians, in combination with that of the child, the physician is able to confidently know that he or she should be more heavily involved in the process or work to empower parents to take on a bigger role, leading to better decisions and courses of action for pediatric patients.[51]

6.2.4 Recommendations

Overall the model leads to proposed interactions between the child, physician, and parents to work through the proposed options and feel empowered in their roles. Depending on the medical evidence and benefits and burdens of the available options, the involvement of the physician can be limited or increased, giving parents more or less control to work with their child and make a decision. With the high level of scientific evidence and understanding needed there will unlikely be cases of genetic screening with minimal physician involvement, however when both options are valid, the parents and child, in a way determined to be meaningful to him or her, should be given the ability to make decisions. In practice, it is likely that a genetic counselor will be involved with the physicians in the many complex discussion with the parents and child.[52] When there is clinical evidence in one direction, or a lack of information, the physician, or other relevant medical professionals, must be more involved and in many instances either insist on or refuse genetic screening. Additionally, governmental regulations and oversight will be needed as more conditions and disorders can be screened for to facilitate these situations. These decisions have a tremendous potential to impact the futures of many children and families, only to grow larger as time goes on, necessitating oversight. There are strong recommendations from the ASCO and other cancer organizations about the screening of those with a family history, however as panels expand, there should be more governmental regulations and education available to the general public.

There are many challenging decisions to be made within the field of pediatric genetics and parents, physicians, and the child need a facilitated model in which to make decisions and overall decide on courses of treatment and what information they can request and inevitably

learn about the child. There are many unknown impacts that this information can have on the entire life of the child, and the decisions surrounding them cannot be made lightly. The information that can be found impacts the child and parents in many ways including stress and anxiety, barriers to the parent-child relationship, and labeling the child for the future. The enhanced model allows for the child to be involved to the highest level that they are capable with other relevant stake holders to the appropriate degree based on the decision to be made and the options that are available. Outside of the model, there is a need for education of all involved in decision making processes, including additional physician education to enable them to facilitate these processes.[53] Before decisions are made, parents and the child should be separately educated on their roles in the process and empowered as decision makers. Evidence has shown that being a good decision maker can be taught, and attempts should be made to teach these skills before decision making processes.[54] Other areas that deserves additional research and attention is the development of tools to enhance decision making processes and inevitably government oversight and regulations to ensure that the information that is collected of children is safe and cannot be used negatively to harm them in the future.

6.3 Neurotechnologies

Similar to the field of genetics, neuroscience has grown tremendously in recent years and has the potential to expand at a much faster rate in coming years.[55] These expansions have led to much controversy and challenging issues that must be addressed within the field of medicine, specifically more challenging when applied to children.[56] This section will first look at the history and expansion of neuroscience as well as the new therapies that are available. There has been tremendous growth, with new processes identified on a regular basis that impact

understandings of the brain including emotions, cognition, and normal brain activity and function to use to diagnose conditions of the brain. Initially neuroscience will be examined with regard to children, addressing some of the unique issues that arise within pediatric medicine, specifically with the addition of neuroscience, and the immense possibility of diagnostic and therapeutic advancement. Following that, the developments and growth of the field will be elaborated in more detail followed by the emergence of the field of neuroethics as a specialty field of medical ethics. After the overview and background sections, the ethical issues will be explained including privacy and safety, incidental findings, prediction, enhancement, and uncertainty, all leading to overall challenging best interests determinations and unclear roles of all involved in care decisions. The final section will then apply the decision making model to two cases. The first case is of a child with suspected autism and the other is of a family who would like to enhance the cognitive capacities of their child. For each case, the decision will be evaluated, the proposed roles and responsibilities of each of the parties involved will be fully outlined, and the process of weighing benefit and burden will be explained within the new model, followed by recommendations and guideline suggestions.

6.3.1 History and Expansion

Advancements in the field of neuroscience have led to the creation of numerous therapies and diagnostic tools that have the potential to be utilized regularly throughout the field of medicine in coming years.[57] Over the past few decades there has been tremendous growth in areas of functional neuroimaging, brain mapping, and psychopharmacology leading to opportunities for more accurate assessments, diagnoses, customized treatments, and even possible enhancements of capacities. These interventions are surrounded by ethical issues and

heightened emotions due to the fact that many associate concepts of the self, free will, and even personhood with the brain.[58] These interventions bridge many unknown areas and shed light on processes that many do not want to believe are actually genetic or hardwired into the brain. New techniques for monitoring and manipulating brain functions are developing rapidly but it is not clear how these things should be used together.[59] It is currently not known how all of the different systems of the brain interact, or what a particular brain abnormality can predict about an individual, and it is further unknown how intervening in these systems can affect the beliefs, desires, intentions and emotions that constitute the human mind.[60] It is argued that doctors are able to use a brain scan to analyze the development of a child's brain and track possible psychological or developmental disorders after a simple five-minute scan.[61] This leads to questions of defining normality and then what is even able to be done with those results.[62] These interventions and scans are thought to be especially helpful in the monitoring and treating of patients with psychiatric and developmental disorders. A functional MRI also offers ways to analyze how different parts of the brain work together functionally. By comparing data with standardized models of how the brain functions or how a specific disease develops a variety of new clinical insights becomes available and it can be seen how the child's brain is out of sync with the normal developmental curve. This approach could enable treatment before the onset of symptoms and help physicians track the results of clinical trials of new therapies. Technological advancements of neuroscience, just as those of other fields of medicine, bring with them both new possibilities and new problems to address. The field of neuroethics looks specifically at resolving these issues so the positive outcomes of the technology can be utilized, with pediatric neuroethics focusing on the enhanced issues that arise with the addition of children.[63] The development of a new field of ethics specifically for neuroscience highlights the fact that there

are many pressing and unique issues of the field, and recently a sub-specialty of that, pediatric neuroethics has emerged to deal with how these complex issues apply to children.[64]

There are many challenging ethical issues within pediatrics and neuroscience individually, but when they overlap, even more are created with very high stakes and tremendous implications for the child and his or her family and future. It is one thing to allow adults to take risks, participate in new treatments or therapies, and even to choose controversial therapies that many not have clear benefit, but a completely different thing for parents to make these decisions for their children.[65] New technologies that can be utilized on children for both therapeutic and non-therapeutic benefits such as brain scans it is not clear if parents can make such a choice for their child, and if they can it is not clear how the decision should be made.[66] Developments of neuroscience have great potential to diagnose and even treat disorders of the brain, many of which impact children tremendously. A lack of effective therapies is a major problem but neuroscience has begun opening doors for these ranging from new techniques and methods for assessment and diagnosis, treatment, and potentially even fixing some of them, however it is still in the early stages. There is a lack of evidence about what neurological interventions can do, and even less about what it should be doing, which leads to many ethical issues, which will be addressed in the following section.

6.3.2 Ethical Issues and Dimensions

The utilization of neurotechnologies with pediatric patients is accompanied by the ethical dilemmas associated with their use in adult medicine, magnified exponentially, like other therapies of adult medicine applied to pediatrics.[67] New technologies in the field of neuroscience have greatly increased the number of ethical issues as well as the magnitude of those that already

existed. The opportunities and implications of neurotechnologies greatly impact the roles of parents and physicians and emphasizes a need for a shared role. Advancements in neuroscience have led to new possibilities and opportunities to diagnose or even predict, treat, and potentially enhance capacities.[68] The major ethical component that will be elaborated here include the tremendous levels of uncertainty leading to challenges of the assessment and diagnosis by the physician, issues determining the best interests of the patient, and problems with informed consent and comprehension.[69] Additional ethical dimensions that must be discussed that greatly impact decision making processes and are problematic include privacy of the information that is found and incidental findings that were not initially looked for.[70] The final area of issues that will be addressed greatly impact the future of the child and include issues of prediction and enhancement potential of the new technologies.[71] All issues relate to the overarching issue of uncertainty associated with these new interventions of neuroscience.

The new neurotechnologies discussed, including brain scans, can be utilized with children for diagnostic, therapeutic, and other non-therapeutic reasons. Brain scans specifically have great potential for the future including definitive assessment by correlating the scan with certain behaviors.[72] However because brain scans are newer technology they are accompanied by great levels of uncertainty and providers are challenged with the task of assessment and evaluation of the child and his or her condition, leading to the overall diagnosis with and utilization of the scans. Due to levels of uncertainty, providers and clinicians utilizing them are challenged with accurate assessment. The uncertainty and unknown associated with them can lead to over-interpreting or reading too much out of results from a study or the possibility of finding something else that is not being looked for at that time.[73] If it is not clear what the physician is looking for, it makes finding it and identifying it challenging, if not in many cases,

almost impossible. Additionally, since not all aspects of the brain are understood, in many cases they can only determine that the scan is normal or abnormal, not explicitly what that means. If it is found that the child has an abnormal brain scan but the clinician cannot link the abnormality to a specific disease or disorder it is unclear what that means for the child or how this will impact his or her future. Assessment with new technologies and interventions is very challenging for providers as they do not want to label the child or inaccurately diagnose them, but they also want to identify the problem and more than that find a way to treat or even cure it, which is accomplished by continuing research and utilization of the technology in practice.[74]

Another challenge is how to deal with incidental findings when utilizing new these new neurotechnologies.[75] If clinicians are looking to diagnose a possible developmental disorder and decide to use a brain scan, for instance, and then during the analysis a psychological disorder is found, it is not clear how that finding should be handled. They were not looking for the second disorder, and regardless of whether or not the developmental disorder is found, the role of the physician in dealing with the incidental finding is not clear. Additionally, due to this being new there is a great potential that what is found incidentally may or may not be fully understood. Since all children develop differently and at unique paces it is hard to define "normality" and develop standards to use to compare scans and define abnormalities.[76] If there is not an accepted normal, there is the potential that physicians will begin to look for something that is wrong or make sense of the functions they view as outside of normal. These findings, either intentional or incidental in nature, carry with them a great deal of importance and weight as they can impact the child in many ways, including those that could be prevalent throughout the child's life, impacting their future. These diagnoses have the possibility to be attached to the child leading to them being labeled, treated differently, denied benefits (such as enrollment into competitive

schools or medical insurance for presumed pre-existing illness), and even subjected to low self-esteem or additional stress.[77] It is possible that the information from the scan will be used in negative ways that could lead to problems later in life such as negative treatment or labeling of the child if this information becomes a means of describing him or her in society, the family, or even to themselves.[78] Disorders of the brain carry with them a lot of weight and implications that must be taken seriously and considered before utilizing the technology or specific intervention.

Outside of diagnostic or therapeutic interventions, these neurotechnologies could also be utilized for possible enhancements.[79] If it is found that a therapy can identify and treat a specific developmental disorder, it is possible that interventions could be used to enhance the capacities of those who are at or above the normal level, just as they could bring those below the level to a more normal capacity. As technology progresses, these possibilities continue to grow and the opportunities for enhancement tremendously increase. In the near future, parents will likely request enhancements for their children but with that come even more ethical dilemmas and issues ranging from justice to the rights of the child. New technologies within the field of neuroscience have increased the burden on the physician of these patients both in obtaining informed consent, and potentially to refuse to provide treatment when inappropriately demanded or if it is of uncertain benefit.[80] These neurological interventions make the basic components of decision making exponentially harder with the fact that they are new, changing, and filled with tremendous levels of uncertainty. Physicians cannot fully outline what will happen or be found in each instance, challenging the processes of weighing and balancing benefits and burdens. The impacts to the child are complex with therapies for the brain. Additionally there are great barriers to comprehension and overall understanding of the child patient and the parents.[81] Inevitably, these issues come down to consent, specifically what parents should consent to, who

should be involved and have a voice in the process, and how they should all work together to make decisions. Consent is very challenging with gaps in knowledge, comprehension barriers, and high levels of disparity between clinicians and patients and their parents. It is unclear how knowing that a child has a significant chance of developing something that is untreatable and not preventable will impact the child, their family, or society in general, emphasizing the need for the enhanced shared decision making model which will be developed in the next sections.

6.3.3 Application of the Model to Facilitate the Decision Making Process

There are many ethical issues that arise when making decisions to utilize new interventions of neuroscience. These technologies are surrounded with great levels of uncertainty ranging from the evaluation or interpretation of results and the diagnostic intervention and likely outcomes of intervention. The immediate impacts of the therapies themselves are not fully understood and it is unclear how to handle incidental findings that may arise while looking for something important or justified. Additionally there is great potential that the interventions will impact the entire life of the child due to carrying a label or diagnosis that may or may not be understood and has the potential to carry with it a social stigma that could hinder the child within society.[82] Neurobehavioral disorders are relatively common and these therapies have a substantial impact on both the individuals who have them and those who interact with them, and improved treatment could have significant benefits for all involved.[83] Disorders of the brain in children can be extremely burdensome to not only the child but also to his or her parents and entire family, adding additional dimensions and ethical issues to consider.[84] With interventions of the brain, the patient is often much more vulnerable than the typical child patient due to an abnormality, developmental delay or disorder, or an affective

disorder necessitating the intervention. All of these things make the decisions made about the use of neurotechnologies challenging for parents. This section will specifically look at the cases of a child with suspected autism, whose parents would like to have the physician screen for the disorders. The second case concerns a child whose parents are requesting cognitive enhancements with a pharmacological drug. For both cases, the facilitated shared decision making model will be applied offering recommendations at the end for potential policies, guidelines, and tools to enhance decision making processes.

6.3.3.1 Cases and Enhanced Shared Decision Making

In order to demonstrate how the enhanced model alleviates many ethical issues associated with neurotechnological interventions with children and facilitates decision making processes with parents, physicians, and the child him or herself, this section will apply the model to two unique cases. The first case involves a 6 year old male patient with suspected autism who has had difficulty communicating properly and relating to others for several years, if not his whole life.[85] His parents noted fine motor skill impairments at a young age but nothing ever came of the observations or comments they mentioned to their pediatrician. In this case, the physicians are proposing the use of a brain scan to assess if the child has autism and if he does, attempt to identify the degree and severity. Although treatments are most effective for cases of autism identified at a young age, there is still a great potential that things could be done for him, in addition to the parents overall just being able to understand and better take care of their son.[86] The second case is a 15 year old male previously diagnosed with childhood ADHD. When he was diagnosed, the physician prescribed medication to increase his attention and he was on the medication for several years, but stopped before entering into high school. He is able to perform

and concentrate in school, however not to the level of his two siblings who are at the top of their classes.[87] This has led his parents to request the utilization of medicine to increase his concentration and overall enhance his performance since the medication was able to enhance his performance and focus in the past.

The first step of the enhanced, shared model is the evaluation of the child. In the first case, the child is only 6 years old and has communication and social barriers. Evaluation is challenging with neurological disorders as levels of uncertainty surrounding the brain, there is a great potential for misinterpretation or an inaccurate assessment of the child. Developmental stages must be taken into consideration, including their emotional status, cognitive abilities, language and communication skills, and social functioning, all of which are limited in the case of the first child.[88] The physician must still evaluate the child, however the young child will not be able to meaningfully participate in the decision making process. This does not mean that the child should be excluded, however he should only be brought in to explain what is going on and the final decision once it is made. With the second child, he is an adolescent and definitely should be involved in all decision making processes, acknowledging his self-determination and ability to be a steward of his own care.[89] In both cases more than one reasonable option exists, leading to an instance of shared decision making. Looking at the complexity of the decision and the medical evidence we can apply Kon's continuum of shared decision making to both of the cases and then determine the involvement of all stakeholders.

In the first, because there is not strong clinical support for the use of brain scans, the physician needs to be highly involved in the decision making processes. On the other hand, since there is not tremendous evidence that a diagnosis for autism can be found this way, and additionally, that there are therapies that exist if a diagnosis is achieved, the parents must be

involved and their opinions weighed as heavily as the physician. Due to the young age of the child in the first case, the parents and physicians must work together to make the decision of whether or not to scan the child, talking through all benefits, burdens, and potential outcomes including uncertainty of results and what to do if incidental yet unrelated things are identified during the scan. The benefits and burdens are not easily accessed due to the impacts that the results could have on the future of the child, and unforeseen burdens that could come with those results. Parents, as the legal decision makers for the child, must work with physicians to make a decision that not only upholds the autonomy of their family, but the future autonomy of the child, making benefit burden analysis crucial, as well as discussions of options and paths to take for each potential outcome. Without a clear path if a positive result is found, it is not clear that intervention is justified, emphasizing the role of the physician to not only understand what could happen if varying degrees of positive or negative results are found, but accurately explain that to the parents to fully understand what they would or would not want to do in both cases. In this case the rights of the parents must be held in balance with those of the child, where the physician must be an advocate for the current and future interests of the young child who cannot adequately represent them. Parents attempt to represent their children and do what is best for them, however they are in a very challenging place and will not be able to accurately and adequately do this in all cases, making the more neutral role of the physician so crucial with young children.

In the second case, the decision is not as complex resulting in a much more balanced, shared process, with a strong role of the adolescent child. Although it is not as complex, the physician still has a large task and must not only present all medical options, benefits, burdens and possible harms, but also work to ensure that the medications utilized would be medically

necessary for the child and that the decision that is made is guided by legal regulations and in the medical best interests of the child. The physician, parents, and child must all work together to outline the options and what actions they would take depending on the results. In cases of enhancement and drugs with children, depending on the legal context, there are different regulations in place guiding the decisions that can and cannot be made. There are interventions that can be done with children at a young age that have the great potential to not only impact their whole lives but possibly change outcomes, limit or increase the number of jobs or insurance the child can receive, and be used as a means of describing the child. Children do not fully understand the implications or impacts that decisions they may make or want to do not have on their entire lives, making the role of adults crucial in the process, but it is also very important that the adolescent child be heard and have a large role in the overall decision making process. Privacy and uncertainty of the interventions, both of which have unknown future impacts, are two of the major issues impacting decision making processes. Neurotechnologies are an area where it is likely that government regulations will expand. As more enhancements are developed and possible, normally aimed at those in need or who are below average, there are more and more possibilities that the enhancements will be used to enhance the abilities of those who do not necessarily need them, leading to the need for physician guidance and government regulations and oversight. This model helps facilitate decision making processes around the use of these new interventions, defining the appropriate roles of all involved based on the levels of uncertainty and options for the child, but legal regulations provide additional context and guidance that may eventually limit the authority of parents in more ways. Parents must give valid consent in order for their children to participate in a therapy, but without full understanding that is not possible, emphasizing the involvement of the physician and need for a more structured

model that ensures comprehension, understanding, and overall the appropriate involvement of all parties.[90]

Overall, the utilization of Weir and Whitney's models, guiding the enhanced shared decision making model, parents, physicians and children can work to make good decisions about the utilization of neurotechnological interventions.[91] In the first case, Whitney's discussed clinician directed or patient controlled decision making model should be the outcome, where the clinician's recommendation is given and either accepted or refused. At this point the parents make the decision and the physician will accept the parent's decision because there is substantial medical evidence and societal recommendations, making both decisions justifiable and reasonable options. In relation to Weir's expert and negotiated models, the first case would fall into the expertise category where the physician should give all appropriate information, including all scientific evidence and expected outcomes, and work with the parents through the decision making process, leaving the final decision up to them.[92] In this case if they decided to use the brain scan there would be additional considerations to review, however these considerations would be after the initial decision had been made and could use the same negotiated models. For the second case, because there is not tremendous immediate evidence that the medication is medically necessary, the physician must guide the discussions in more of an expert model, and potentially fall into the area of Kon's continuum where the physician must insist on something that they know is best. In this case, they must include the child and work with both parents and the child, but inevitably, the physician will have more of the needed scientific knowledge. The enhanced shared decision making model helps address issues of uncertainty, unclear benefit and burden, the lack of therapies, and potential future implications for the child while respecting the rights and authority of parents, the role and obligations of the

physician or other clinicians, and the central and important role of the child in his or her own care and decisions.

6.3.4 Recommendations

Neurotechnologies bring with them the possibility to enhance and help the lives of many patients, offering diagnoses or treatment for situations previously unable to treat, but also create challenging decisions that must be made with caution and extra attention must be paid to potential burdens on the patient, outcomes, and long term impacts that these decisions have on the child. Similar to the genetics cases, when there is strong clinical information, the physician must be involved to supply the data and evidence, however the parents and child can be more in control of the decisions. When there is limited evidence, or the request has questionable benefits, the physician must be more involved and inevitably more in control than the parents or child. Physicians must also be transparent in what is and is not known about the particular intervention, which is difficult with new neurotechnologies and interventions that have very high levels of unknown and uncertainty. There is great potential for these technologies, both therapeutic and diagnostic, however they are not completely proven at this time, meaning the physicians must not only be highly involved, but they also must be honest, work hard to ensure comprehension of all involved, and advocate for the child. In cases of neurological issues the child may be even more vulnerable than in other cases due to decreased capacity or the effects of the neurological or developmental disorders, necessitating increased attention to not exploit the child.

The specific scenarios discussed with neurotechnologies are hypothetical, as a brain scan is not a definitive way to diagnose autism nor are there pharmacological drugs guaranteed to

enhance cognitive capacities and brain function, however such products exist on the market for both of these cases, necessitating regulation and oversight, and emphasizing the fact that the field is constantly changing and in need of a decision making model that is flexible. Therapies or diagnostic tools should not be available to the general public until they have undergone extensive testing and research, which will be looked at in the following section specifically with regard to research with neurotechnologies, but even then, there will be a need for oversight and control to a degree. Additionally, this field has seen a great number of consumer products that fall outside of the scope of medical practice, which physicians must be aware of as many patients will use them or want to.[93] The enhanced shared decision making model elaborated enables parents to work with physicians depending on the decision to be made, options available, and the levels of uncertainty involved. These are all components that vary from situation to situation, but additionally can be assessed in all situations, leading to appropriate decision making. With this model, stakeholders are involved in a way that makes the most sense for the decision to be made and incorporates the child in a meaningful way, acknowledging their future autonomy, enabling them to grow into successful adults who are involved in their medical care.

6.4 Clinical Research

Research is a controversial area of medicine that has led to the development and refinement of therapies for many diseases and disorders.[94] It has also led to refined understanding of the human body and health. Physicians have come a long way and it was not an easy road to get here as we did not always know what we do now and conditions previously thought of as incurable or a death sentence are becoming manageable if not curable.[95] The growth of the past however is not without its ethical missteps as progress was not always made

in the best ways.[96] Research is especially challenging with children as researchers and clinicians must work with emotional parents and non-autonomous children to serve the overall good of medicine. This section will outline the emergence of research with children highlighting the expansion and development of research within the fields of genetics and neurosciences. Then the regulations that impact research including governmental oversight, review boards, and issues of consent and assent will be discussed since they greatly impact decision making processes and outline what can and cannot be done. Regulations also appeared in light of the troubling start research had in the past, and an emphasis has been made on protecting the child, as it has in other areas of society.[97] Following the development of the expansion of the field and the overarching issues, the specific ethical issues that make decision making challenging in the current model will be elaborated. Following this, the enhanced decision making model will be applied to two research cases, one of an infant and genetic research and the other at an adolescent with a possible, unidentifiable neurological disorder. Overall it will be argued that the new model facilitates smoother decision making and enables all stakeholders to work together to come to the best decisions, while enhancing the understanding of all involved.

6.4.1 Expansion of Research with Children

Research has been a central component in the developments and advancements of and successes within the fields of genetics and neuroscience.[98] Research is an area full of new technologies, both for therapeutic and diagnostic purposes. Clinical research has many ethical issues, especially when it involves human subjects, needed before the general public can utilize therapies. Research with children is possibly the most troubling area of development for the current decision making models as it encompasses the issues of both genetics and neuroscience,

highlights the vulnerable status of children, makes it possible that they will be exploited, and makes issues of therapeutic and non-therapeutic interventions immediately more troubling. There are many legal and ethical issues associated with vulnerable populations such as children, especially those with genetic, neurological, or developmental abnormalities making conducting pediatric research challenging.[99] Children cannot be isolated from research, as they then would not have protections and good medical care available to them, however they are vulnerable and not of legal consenting age so there are many additional considerations that must be taken.[100]

Historically, clinical research has exploited vulnerable and underserved populations, which has led to increasing regulation and oversight, and initially, the exclusion of children.[101] Over time they were included in research but just as all other areas of medicine, when children are involved there are additional ethical issues to consider, heightened stakes, and the need for enhanced models of consent and decision making. As the care of children developed into its own field a need for research and the development of therapies and drugs specifically for children emerged. Children are both vulnerable subjects who need protection from research risks and "therapeutic orphans" who have been denied access to the benefits of research.[102] The long term tradition of protecting children, extending to not include medical research was recently shifted when the US created mandates promoting the inclusion of children in clinical research.[103] The development of lifesaving cures for terminal childhood diseases depends on the advancement of pediatric research even though children are vulnerable.[104] Translating knowledge gained from scientific advances in biology, genetics, and neuroscience into treatments for children is possible only through research.[105] Children cannot be ignored from research, as they have been before, because they themselves need treatments, therapies, and inevitably drugs but because they are children more issues must be considered. If new advances

are not tested or studied with or on children, then they will be blindly used on them without knowing exactly how it will work in a child.[106] Children are developing and changing at a much more complex rate than adults, and things that would not be issues for adults may be for children, and –on the other side, things that may not be issues for children are with adults; adults and children cannot be lumped together and treated the same necessitating research to flush out those differences and fully understand how they must each be treated

Research exists in all fields of medicine ranging from the use of ibuprofen with infants to identify what it can treat to trials to determine the correct dose for different weights.[107] Currently more than 1900 clinical trials are approved for children with more each day as technologies are developed. Many advancements have been made in the areas of genetics and neuroscience that have great ethical issues in and of themselves, placing parents in very difficult positions. Research in these areas is necessary in order to be able to utilize the developments and advancements of these areas throughout society and impact the general population, but to get to that stage research must be done with these technologies with high levels of uncertainty and many complicated and unknown elements. Within the field of genetics, whole genomic sequencing is becoming much more prevalent and researchers have identified many new disorders that can be or can possible be identified through WGS.[108] WGS has immense potential to be used as a diagnostic and potential screening tool, however there are many concerns and ethical issues associated with this utilization. Whole genomic and exome sequencing have the potential to change the field of medicine with diagnostic potential, leading to the hope that disorders that were untreatable or diagnosed in the past will one day be understood and even treatable.[109] With this potential however comes a large burden on parents and physicians to together determine what should and should not be tested for, and how to handle additional results

that are found. Additionally, the complex nature of genetics leads to a large responsibility placed on physicians, or other involved clinicians such as geneticist to educate parents before the child is sequenced and then review the results and counsel them once they are identified,[110]

Within the field of neuroscience there are therapies and technologies that are currently being researched and this number is only going to grow in the near future as advancements are being made and more processes of the brain are being understood. Some of the most promising and controversial developments of neuroscience with ongoing research studies include functional neuroimaging, brain mapping, psychopharmacology, and enhancement opportunities with the potential to impact behavior, personality, and consciousness.[111] Many researchers have identified brain processes that are related to experiences and concepts such as free will, agency, moral judgment, self and personality, while others are utilizing brain scans to diagnose pediatric disorders such as autism or ADHD.[112] New techniques for monitoring and manipulating brain functions are developing rapidly but it is not clear how all of the different systems of the brain interact, or what a particular brain abnormality can predict about an individual, and it is further unknown how intervening in these systems can affect the beliefs, desires, intentions and emotions that constitute the human mind This approach could enable treatment before any onset of symptoms and help physicians track the results of clinical trials of new therapies. Pediatric brain scans are not currently being used throughout medicine, but this is potentially where things are going with care for children, along with genetic screening, which are the two areas of focus for the cases at the end of this section. Much research and effort is being spent in these two areas to develop tools that will accurately identify and treat childhood illnesses and inevitably improve the lives of children and their families.[113] As science and technology progress, more research trials will be necessary to appropriately include and treat childhood illnesses and disorders,

making an enhanced shared model necessary for parents to utilize with the physicians and child, when possible, to do what is best but not automatically exclude them from all research. This necessity to include them additionally leads to another need for guidelines and regulation for research from legal entities. Because this is such an expanding area of medicine that has tremendous levels of uncertainty, regulations are needed in addition to an enhanced model.

6.4.2 Guidelines for Research with Children

There is a great deal of regulation and oversight that exists within the fields of genetic research with children.[114] Research in general is subjected to a lot of regulation from review boards, however even more so when the research subjects are children. Children are not just "little adults" as they were once thought and they cannot be treated as such. In addition, because of their exceptional vulnerability, the structure of research methods are crucial because children must not be exploited or abused. During the Nazi regime children were used as guinea pigs for research leading to the Nuremberg code which appears to suggest an absolute prohibition of pediatric research stating "the voluntary consent of the human subject is absolutely essential. This means that the person involved should have the legal capacity to give consent."[115] In the 1970s, the United States developed regulations that allow advances and the participation of children in research while protecting them from unnecessary and uncompensated risks and discomfort.[116] Current US regulations are there to provide additional protections for children participating in research, however there will always be risks.[117] Children require additional safety measures due to their limited capacity to give informed consent and vulnerable status, but well-designed and well-regulated research with children is needed to improve children's health, and pediatric ethics can work with doctors and researchers to help ensure that this happens.

Children are in a unique position in that they must be protected while also advocated for so they are appropriately and meaningfully included in not just research, but also the decision process to select to enter into the study so they are not exploited or taken advantage of.

Children have been exploited for research in the past, but this cannot be held as a reason not to continue and pursue more research with children, it merely argues that extra precautions must be taken into consideration to adequately protect them.[118] Society is obligated to protect children from excessive risk to foster their development and grow into competent, autonomous adults, but also need to allow for enough research for the best interests of children as a population, and not prevent parents from being parents and making decisions for their children.[119] The United Nations and the US have both commented on pediatric research through addresses and legislation, offering some ways to potentially enhance the process so it is more ethical and not as burdensome to children. The UN Convention on the Rights of the Child adopted in 1989 articulated several considerations that pediatric research must follow to improve results and limit the exploitation of children.[120] The Convention stated that children's views should be given and taken into consideration in medicine, including with new treatments and therapies. However, it did acknowledge that research with children raises additional ethical questions. Children and parents must be given details about the purpose and nature of the research, the methods and timing, in addition to the possible harms, benefits, and outcomes.[121] Beyond the basics, doctors must also work with patients and their families to explain the concepts, such as consent, and give as much information as possible.[122] Children should be given a leaflet to explain the research in their native language as well as talk directly to the researcher and encourage the child to ask questions because the children themselves must be informed. In the last 15-20 years, there has been tremendous growth in research with children,

the reporting of children's own views and experiences, formal pediatric research ethics committees and ethics training for pediatric research.[123] There is a need for change and continued development in the current system, and the UN Convention gives some good starting points. It is argued that the current research model does not adequately protect children from harmful and useless research nor promote their participation and interests overall, but that does not mean it should be stopped. Additional regulations from the Department of Health and Human Services, the Food and Drug Administration, the Children's Health Act of 2000, and pediatric review boards give additional regulations and protections for children emphasizing the importance of adequately protecting children in research.[124] All research studies should be subject to evaluation by research ethics committees and review boards to minimize risks and ensure that ethical guidelines are followed.[125] Additionally there must be a focus on the interests and unique elements of children. Despite these regulations and attempts to protect children and their best interests, many ethical issues and problems still exist, which will be looked at in the following sections.

6.4.3 Ethical Issues

Ethical issues are prevalent throughout medical research, and become more complex with children, leading to tremendous oversight and regulation within the field. There is a need for balance between protecting children and reducing harms while respecting and involving them in necessary research.[126] There are many ethical issues of pediatric research, some new and unique to research and others that are present throughout pediatrics but become more challenging research including consent, autonomy, comprehension of the child, vulnerability, and possible exploitation The issues that will be highlighted here and directly addressed by the enhanced

shared decision making model in the following section are issues assessing and determining the developmental capacity of the child, which makes the already challenging elements of consent, assent, and refusals of children extremely difficult. Other issues prevalent in research with genetics and neurotechnologies, include the comprehension of parents, burden on physicians to explain to parents and the child, and the therapeutic misconception, which all make it challenging to assess benefit and burden for the child.[127] The issues discussed in relation to both genetics and neuroscience are present here, heightened by the fact that they are part of clinical research placing the child and his or her parents in a vulnerable place. Research in and of itself complicates aspects of the decision making process specifically informed consent, including the assent or dissent of the child and comprehension levels to fully understand and give informed consent. Additionally the unclear outcomes and potential for the research subject to not even receive the therapy, benefits and burdens are challenging to weigh.

A central issue to research is the ability to give and receive accurate informed consent.[128] Consent processes are extremely important throughout clinical research, adult and pediatric, due to the fact that the participant must understand what he or she is participating in and all potential outcomes.[129] Research, unlike therapeutic interventions, do not guarantee results, effectiveness, or even that the participant will receive the treatment being tested. In order to participate, consent, or assent in the case of a child, must be given after the physician explains the potential outcomes, side effects, and burdens in addition to the general research processes themselves, which most are not familiar with. This is challenging for children because in order to give assent or possible dissent, physicians must assess their capacity to make decisions, which is challenging because with genetics or neurotechnologies, these children many times have developmental or other severe disorders.[130] Since children cannot give formal consent, regulations require that

both parental permission and the assent of the potential child subject before they are enrolled in a research trial to protect the child from unreasonable risk but also recognize the child as a person.[131] In order for research to be valid, the trials themselves and consent processes must follow strict ethical guidelines and valid consent must be obtained and present for all participants.[132] Research subjects must understand what they are signing up for and all of the possible outcomes, however the research studies in this area are complicated and there are many barriers to comprehension and a large burden on the physician and researcher to explain all options.

Parental comprehension of the proposed therapy impacts consent processes within pediatric research, and research processes in general, and the potential outcomes. This impacts consent, as in order for consent to be valid, parents and the child must fully understand the options, benefits and burdens, and inevitably what he or she is consenting to. With research, the benefit cannot always be best interests because sometimes the child does not stand much of a chance of receiving a benefit but other children do, and other factors that come into play are altruism, compensation to parents or child, the maintenance of hope, or even confusion coming from the therapeutic misconception that anything offered will be of benefit.[133] In order for assent to be meaningful, the child must understand the intervention of the research study, voluntarily choose to undergo the procedure, and communicate this choice to the researcher.[134] In a study of 200 IRBs, by A. Whittle et al, 2004, only half of the IRBs required investigators to determine if children were capable of assent, and when they were it was primarily based on an age rather than capacity assessment.[135] Refusals of children are additionally troubling and many argue that children who have been deemed to be competent should be able to refuse therapies, potentially even those that are in his or her best interests, however if interventions will protect the child from

harms, there are arguments to be made to override this, however with clinical research since nothing is certain, these cases are rare.[136] Even in these instances, efforts should be made to persuade them rather than immediately just overriding their decision to respect them as persons.

Research poses additional complexity for parental consent and comprehension due to the therapeutic misconception. The therapeutic misconception refers to the problem created when providers offer therapy to patients, that may or may not have benefit to them, and the patient perceives such a benefit based solely on the fact that the provider offered them the intervention.[137] In research, in addition to the complex treatment options and unique terms to research, such as randomization of placebo, many times parents assume that there is therapeutic benefit to be gained from the study.[138] Despite these recommendations, 58% of the surveyed IRBs would enroll a child who was incapable of assent in a non-beneficial study even if the children who are capable could be enrolled instead.[139] Additionally, when asked about the payment of children, 46% believe that it sometimes or always acceptable to offer incentive payments to children, and more than one third thought it was acceptable to offer payment to the parents. There are regulations in place to help protect children however none of them are tremendously specific because it depends on the child, the study itself and what the intervention is, and the overall circumstances. The enhanced facilitated shared decision making model addresses these issues and elaborates how to include the child based on the specific decision and attempts to further open lines of communication to help the other issues. The following section will apply the enhanced shared decision making model to two pediatric research cases and look at how this model enhances the process and facilitates the involvement of all necessary individuals and allows for the best decisions to be made for children.

6.4.4. Application of the Model to Facilitate the DM Process

There are challenging ethical issues to overcome within the area of research, especially when it comes to interventions within the fields of neuroscience and genetics utilized with children. Research is a key component of medicine that leads to the development and utilization of new therapies and interventions, however research with children in areas of new technologies with great levels of uncertainty, unknown outcomes, and future implications must be considered carefully. Before developments of these fields can be used by the general public they must undergo extensive research to prove their efficacy and safety. This section will apply the facilitated shared decision making model to cases of research in the areas of neurotechnologies and genetics to demonstrate how this model alleviates many of the challenging ethical issues and outlines the roles of all involved in the process. In each of the following cases, the enhanced shared model will be applied to guide and structure decisions, help decision makers determine what information should be revealed, and when, including relevant aspects that should be taken into account and those that should not. The first case is of a male infant with parents requesting that he be part of a genetic research study to sequence the child's genome. In this case the child is not sick nor does he have an illness. In the second case, the child is an adolescent with an unidentified neuro-affective disorder. His parents would like to enroll him in a research study to try to identify the disorder but this brings up issues of other information that is available with the sequencing. All steps of the process will be elaborated in both cases to show that the model facilitates decision making processes and addresses the many ethical issues.

6.4.4.1 Cases and Enhanced Shared Decision Making

The enhanced shared decision making model facilitates decisions surrounding the enrollment of children into research trials and will be specifically analyzed with the application of the model to two cases, one within the field of neuroscience and the other in genetics. This application will show that the enhanced model is needed to overcome the many ethical issues parents must overcome and work through when making decisions to enroll their children in clinical research studies. The first case that will be analyzed involves an infant boy whose parents are requesting that he be part of a genetic research study where the researchers want to sequence the infant's genome. Whole genomic sequencing does not involve a complicated medical procedure and is very straightforward for the actual sequencing, however the unknowns here involve the accuracy of the genetic disorders or traits currently identifiable and what the researcher will or will not tell parents, and further what parents have a right to know or request to know about their child. Benefits and burden analysis is not easy because it is unclear what the sequencing will identify and what actions could be taken on the findings. The second case is of a 12 year old male with a neuro-affective disorder whose parents want to enroll him in a research study to see if it is a genetic condition. In this case, the child has a disorder that they want to use sequencing to identify to better treat the child, but while performing the basic sequencing the parents and researchers will have access to an abundance of information about the child, leading again to issues of what can and will be done with the results that are found. In both cases there are multiple options available, leading to situations of shared decision making involving the parents, physician, and in the second, the child.

To work through many of the ethical issues and complex roles of the decision makers, the enhanced shared decision making model will be applied to each case to outline the proposed roles and the inevitable recommended outcome. The first element of the enhanced shared

decision making process is to assess the child, who is in this case both the patient and potential research subject. Determining competence for research is similar to competence for other areas of medicine and decision making; the child must show that he or she can understand the information given to them including the proposed therapy, treatment, and details of their own condition or illness, so they can give assent or dissent.[140] The first child is a newborn so there is not anything to assess as he is not of capacity to be involved in decisions. This does not mean that his interests should be excluded, but that the child cannot be involved in the process. The second child has a neuro-affective disorder so he is likely not able to meaningfully participate, however the physician must still evaluate him and determine if there is a way to include him or pieces that he may be able to comprehend. The physician must be sure to evaluate the important elements of capacity that are relevant to the specific decision at hand since capacity should be decision specific, not absolute. Beyond the evaluation of the capacity of the child, competency and understanding are crucial to parental consent. Parents must fully understand what they are agreeing to for their child, therapeutic or not, which is very difficult in cases of new technologies surrounded by great levels of uncertainty. This comprehension barrier and the assessment of compromised children places a large burden on the physician. The model however, by forcing the physician to first analyze the child, keeps the focus on the child as the central component of the decision.

After the assessment of the child, the boundaries and roles of the physician and parents is then defined based on the options available, evidence for the outcomes, and the level of uncertainty. Both of these treatment decisions are complex, however in the second case, there is more of a medical reason for the intervention, although both are questionable since the amount of therapeutic interventions that could come from them are unknown. The complexity of both

decisions would lead them to fall on the physician led side of Kon's continuum of shared decision making. Additionally, Weird and Whitney's models can be utilized to guide the decision making by classifying them as both clinician directed and expertise. In these cases, the physician should give his or her recommendations and work with another physician and within the legal parameters to guide parents to make decisions and include children in research that will not only respect the rights of the parents but also the current and future interests of the child. In cases of research it is crucial that an outside physician be involved to lead as the principal researcher is not always the ideal advocate for the child and the parents do not always have the ability to understand or know what questions to ask. The child in the first case is very young so it will likely only be the parents working with the physician(s), and researchers to make a decision in a clinician directed, expertise model. In these cases it is possible that parents will look to other family members for support or even turn to advocacy or parental support groups for guidance or advice, but those sources do not have a legal say and can only impact decision making processes in ways that parents allow them to. The same should be the outcome in the second situation, however in this case the child may have more of a role depending on the severity of its impairment and the outcomes of the clinical competency assessment. Regardless of ability to comprehend and give consent or assent, in the second case, the patient must be included, even if his opinion does not carry much weight. Overall with research, especially in the areas of neurotechnologies and genetic interventions, the role of the outside, non-research related physicians is crucial as they will be the ones who have the knowledge and medical background to fully explain the case to the parents and child, and work them through the process with the involvement of the researcher. The enhanced model allows for the classification of the

decision in a streamlined way based on the number of options and complexity, allowing all to know their roles in the process and be empowered to participate.

6.4.5 Recommendations

There are many legal and ethical issues associated with vulnerable populations such as children, especially those with suspected neurological or genetic disorders, making conducting pediatric research problematic.[141] By following the enhanced shared decision making model, parents and physicians are able to work in a meaningful way together and incorporate the child into the process to enable them to be in control of their medical care and inevitably lives. Children must be empowered to be stewards of their healthcare, and this model helps facilitate this growth and ensure that they are include and their voice is heard before they are entered into a study.[142] Additionally, it is recommended that in cases of research, the patient's PCP or other primary physician, not involved in the research study, be around to support the family and overall guide them through the decision making process. Review boards exist to ensure that research follows ethical guidelines, standards, and does not exploit patient or their families, however in current practice there are many things that occur on a regular basis that are not considered ideal, such as payments to parents of children and only considering the age of the child when determining if they can give assent or refuse enrollment, making it not only necessary that a decision making process be streamlined, but that a physician not involved in the research study be involved in these processes and work with the child and parents to make decisions. By involving a physician who is not part of the study, the parents and child are able to get a better full picture of the research study so they can make the best decision and weight the benefits and burdens in a meaningful way.

Additionally, research is a very good candidate for the utilization of enhancement tools to facilitate the decision making process and overall communication processes.[143] A great deal of research has been devoted to learning about how parents and children learn and best comprehend information, which can then be developed into communication tools. These tools need to facilitate the growth of the relationship between the child, physician, and parents, but also work to ensure comprehension. Comprehension and complexity of information are important issues throughout all areas discussed in this chapter, more complicated by research since the technology used is not well understood and there are components of research in and of itself that parents or decision makers do not routinely comprehend, such as the concept of a placebo. It has been found that many parents do not know what they are consenting to and that they assume there is a benefit to their child, regardless of the fact that the forms they signed outlined that this was not the case. The therapeutic misconception is prevalent throughout research and parents, or patients in general, believe that there is a benefit due to the fact that a medical professional, with the goal of helping patient and making them better, is proposing the intervention. There is a great need for new ways of communicating and bridging the educational gaps present between researcher and clinician and patients, including the child and his or her parents. Overall there is a great need for enhancements within the field of pediatric research, but the enhanced shared model is a good starting point to help parents, physicians, and children identify their roles in the process and inevitably determine which trials they should or should not be part of.

6.5 Conclusion

Over the past few decades there has been tremendous growth in the areas of genetics and neuroscience, including and led by clinical research trials in both of those areas. With these

advancements come great levels of uncertainty and many complicated decisions that parents, as the legal decision makers, must make for their children. There is a need for the enhanced model to facilitate decisions and enable the best decisions to be made for children with the utilization of new technologies. Tremendous expansion in the fields of neuroscience and genetics, both with growing numbers of new technologies and interventions available makes it crucial that physicians have a structured way to work with parents and incorporate the child into the process at a level that is appropriate, and advocate for the involvement if necessary. It is crucial that the child, parents, and physicians work together in a meaningful way to make decisions about the utilization of these new and expanding technologies. Additionally, the cases reviewed within each area of medicine emphasize that the most complex and controversial cases are those with older children, as determining their level of involvement is one of the central pieces to the decision making process, enabling them to be involved in the current decision and further enabling them to become and grow into good decision makers in the future. Many mature minors have more capacity than adults with diminished capacity allowed to make decisions, making it not only important that they are involved, but relevant and optimal. It is important to note that all decisions cannot easily be classified as decisions since all patients are different, however they can be when the patient and situation are taken into consideration.[144] For instance, all decisions of whether or not to use a brain scan to determine if the child has ADHD cannot be made in the same way, using the same type of shared decision making, as the capacity of the child has not been taken into account, nor have the circumstances of the family or any outside impacts. A good physician knows that they must explain things to the patient in ways meaningful to them in order to enable them to be good decision makers.[145] By identifying the type of decision to be made, specifically if there is more than one reasonable option, and

understanding that there are different, yet specific types of decision making that can occur, it is possible for the roles of the physicians and parents to be added to the decision making model in addition to the already determined developmentally appropriate role of the child and ideally, the selection of the best course of action for the child.

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Chapter 7 – Conclusion

Shared decision making occurs throughout the field of medicine each day as physicians work with patients to make medical decisions about treatment and courses of care. This process becomes challenging when the patient loses the ability to make a decision and someone else must step in to do so on his or her behalf. When the patient is a child, he or she by definition does not have the ability to make medical decisions, and therefore the parents, or legal guardians, must be involved and make the decisions for the child patient. There is not a current model for parents to use to make decisions for their children that adequately incorporates all relevant stakeholders or supports the new and continuously emerging technologies present throughout pediatric medicine. The objective of this dissertation is to present a new model that better facilitates decision making processes for decisions in pediatric medicine. The enhanced shared decision making model offers more support and guidance for all involved while emphasizing the central role of the child, as the patient, where possible.

Chapter 2 reviewed the relevant background, including the history and development of pediatric medicine. It was argued that pediatric medicine developed out of adult medicine, creating problems for pediatric patients since they were not initially treated different than adults. Pediatric medicine was not always a medical specialty due to the fact that children were not always seen as children, but rather as miniature adults. However, over the past few centuries, an increased focus has been placed on the period of childhood and ideas of childhood.[1] Over time, children were acknowledged as different from adults, and as a central piece of the family, vulnerable and innocent, and in need of protections.[2] These ideas led to the UN Convention for the Rights of a Child, giving children a legal voice, as well as child labor laws and other societal mechanisms.[3] As it was realized that children were different from adults in numerous ways it

became evident that they were in need of specialized medical care.[4] In the initial phases of pediatric medicine, children were treated the same way as adults, and many of the regulations, practices, and delivery methods from adult healthcare were directly applied, such as limited visiting hours of parents.[5] New regulations, practices, and understandings were needed specifically for the medical care of children. One area where there is a need for new understandings is with regard to the goals of pediatric medicine as they are in fact different than those of adult medicine.[6] Additionally, the ethical issues with children and their families are different from those in adult medicine and cannot be handled in the same manner. In pediatrics, respect for the patient, rather than autonomy is more significant, involving both protection of the vulnerable child and respectful listening to the voices of the key stake-holders, specifically the child and parents or guardian(s).[7] The professional goals of physicians are also different as pediatricians must not only work with their patients to select both the right and good course of action, but instead primarily with their patient's parents.[8] Within pediatrics, the child patient relies completely on adults, specifically parents and doctors, to define what is right and good for them.[9] Goals of pediatrics are complex and include protecting the child and furthering his or her best interests, protecting the child from unjustified harms in regard to medical interventions, and showing respect for family autonomy.[10] Pediatric medicine has many unique issues and problems such as heightened emotions, decisions with potentially higher stakes and longer impacts, and making decisions for someone else, specifically one's own child. In response to these unique challenges, considerations, and goals, a special area of ethics was developed. Pediatric ethics emerged out of the realization that issues within pediatric medicine are not only different but must be handled in way that is not similar to adult medicine. Pediatric medicine emerged as they were given a place in society, however there is still a great need for

developments in the field, not only of science, but also of ethics and inevitably a decision making model. The medicine, ethics, or decision making processes of adult medicine cannot be used as a model for those within pediatrics, and it is crucial that pediatric medicine has its own standards and models in order for the roles of the family, child, and society to be balanced while providing the best care for the child.

Chapter 3 developed the dimensions of medical decision making and the complicated area of surrogate decision making. There are models that guide surrogate decision making, substituted judgment and best interests, however neither apply to pediatrics. In most cases of adult medicine patients make their own treatment decisions based on respect for autonomy.[11] In the past, physicians made treatment decisions for patients, however over time, this paternalistic approach changed to the patient centered, personal autonomy based model of today, allowing the patient to make decisions for him or herself through a process of informed consent.[12] Informed consent enables patients to make decisions based on their own values and goals, ranking options according to personal standards rather than those of the physician. Decisions made by others are more challenging in that the person making the decision cannot know for certain the decision the patient would make, leading to the creation of ethical standards to guide surrogate decision makers, substituted judgment and best interest, both of which are patient-centered.[13] Substituted judgment focuses on executing the wishes of the patient, while best interests asks the surrogate to select the course of action that will most benefit the patient overall. The substituted judgment model, as the ideal model, asks surrogates to make the decision or choice that would mirror that of the patient if he or she would be able to make decisions, specifically to act as a "substitute" for the patient.[14] This model requires a lot of knowledge of the patient and this model is used in combination with the best interests model, asking the surrogate decision maker to weight the

potential benefits and burdens of each available option and determine the "best" course of action.[15]

There are many problems with the substituted judgment and best interests models in practice, including giving too much power to or placing too much of a burden on families, who may or may not be reliable sources of information about the patient.[16] Additionally both are seemingly impossible to execute as defined in practice, and regardless of the decision-making model utilized, decisions will typically be made in a shared effort. Shared decision making (SDM) involves an exchange of information between the medical team and the patient or surrogate where they each work together, share knowledge, and express preferences and negotiate the treatment plan, ideally reaching an option most consistent with the patient's personal wishes.[17] Decision making is complex in adult medicine, especially when a surrogate is involved, and it becomes even more so when the patient is a child, an individual who has never had decision making capacity, making the application of adult decision making models challenging if not impossible.[18]

Dimensions of autonomy, decision making capacity, and informed consent make the decision making process with children more challenging since these concepts do not directly apply to children in the same way that they do in adult medicine. In pediatrics, parents or guardians are typically given the legal authority to make decisions for their child, however the child must be involved in the process in a way that they are capable. Capacities necessary for decision-making include communication, the ability to understand information, reasoning and deliberation, and the ability to have and apply a set of values or conception of the good, all of which are challenging to assess in children.[19] Despite the fact that it is challenging to assess, it is crucial that they are included to the level they are able to be decision makers, and additionally

apply concepts of assent or possibly consent when available.[20] The child, as the patient, should be the center of the decision making process, however there are many individuals with large responsibilities in pediatric decision making, specifically the parents or guardians, physicians, and even society. Parents, as the legal decision makers and those thought to know the child better than others, will be looked at next.[21] Physicians also have obligations to the child as his or her doctor, and additionally to the family.[22] Within pediatrics, parents and physicians are many times thought of as co-fiduciaries, both having strong obligations to the child patient.[23] Finally, society has a role in ensuring that the child's well-being is protected.[24] There are many stakeholders in pediatric medicine and the opinions and conceptions of all parties must be balanced. Although the parents legally have the final say and authority to make the child's medical decisions, ethically this is not sufficient for the best decision to be made and there is a need for a model that incorporates and acknowledges all parties.

The model of adult medicine, substituted judgment and best interests were argued to be insufficient for pediatric medicine for many reasons, primarily that they do not address the unique or different dimension of pediatric medicine. Substituted judgment is not typically relevant with children because they have never had the capacity for decisions, or fully developed personal beliefs and values, which is the basis of this model.[25] The best interest standard, on the other hand, requires that parents select the best treatment for their child after weighting potential benefits and burdens of each option, selecting the therapy with the maximum benefits and minimum burden.[26] Some of the issues and problems with this standard include that it is subjective, places a large burden on parents already in a difficult position, does not ensure understanding, or does not give the child or physician a clear role. Neither the best interests nor the substituted judgment models are sufficient for pediatric decision making, however elements

of these standards are incorporated into the enhanced model since the inevitable goal is to make the best decision for the child patient in a given setting.

Chapter 4 focused on the scientific developments and advancements in areas of genetic screening, neurotechnologies, and clinical research. All three fields have experienced tremendous growth in the last 10-15 years, leading to the creation of numerous challenging and complicated ethical issues. Genetic screening with children began initially with newborn screening for the easily identifiable and remedied PKU. Over time, the panel has steadily increased to include anywhere from 20-54 conditions, some of which have no therapies.[27] The American Society of Human Genetics and The American Academy of Pediatrics believe that testing for disorders without therapies should be limited, however, there are arguable benefits other than therapy, such as planning for the future or identifying subjects for research, making it unclear if it is in the child's interests to be screened or not.[28] Deciding what should and should not be screened for becomes a much bigger issue with the decreasing costs of whole genomic sequencing (WGS), and the possible detection of a multitude of diseases, and can be utilized at birth or later in life.[29] Genetic testing is becoming an important diagnostic tool in medicine, making discussions of determining benefit and burden crucial.[30] The next area of advancements addressed is neurotechnologies, examining the emergence and utilization of interventions within neuroscience such as functional neuroimaging, brain mapping, psychopharmacology, and potential enhancement opportunities with the potential to impact behavior, personality, and consciousness.[31] In the last decade tremendous technological advancements have been made, leading to new possibilities and opportunities to diagnose or even predict, treat, and potentially enhance capacities.[32] Many physicians believe that they can analyze the development of a child's brain and track possible psychological or developmental disorders after a simple five-minute

brain scan or functional MRI (fMRI), to identify and treat psychiatric and developmental disorders, possibly even before the onset of symptoms.[33] Neuroimaging with children is accompanied by all the ethical dilemmas associated with neuroimaging adults, enhanced due to their status as children.[34] It is not clear what therapies physicians should offer parents, or how parents are to make decisions for their children.[35] The final area of growth is pediatric research, and was specifically addressed with the growing number of research trials for genetic screening and the use of neurotechnologies with children. New technologies create the possibility for parents to enroll their children in trials both with and without therapeutic benefits, but it is not clear if they can make such a choice for their child, and if they can, it is not understood how they should decide.[36]

Many ethical issues that accompany the new technologies render decision making challenging and inevitably the models of adult medicine insufficient. The new technologies make the ethical issues prevalent throughout all areas of pediatrics more complicated and additionally add unique dimensions. Some of these basic yet more complicated dimensions include barriers to comprehension, emotional distress of the family, assumed benefit because therapy is offered (specifically the therapeutic misconception), overall impacting parental consent. Consent is troubling with regard to pediatric research because it is not clear if the consent of the family carries the same weight as in other areas of pediatric medicine and if parents can consent to risky research. Other issues are caused when disorders are identified that cannot be treated because with whole genomic sequencing (WGS) it will be possible to screen for specific diseases, but also identify risk factors for multi-genetic diseases, carrier status for many autosomal recessive conditions, adult-onset conditions, or those with uncertain clinical significance.[37] Other challenging issues include uncertainty, privacy, and future implications of

findings in children. There is a lack of evidence of what neurological interventions can do or exactly what the identification of a mutation means, and even less about what it should be doing.[38] Additionally these expanding technologies bring with them concerns of privacy and possible future implications of information discovered with the technological interventions and impacts on the child and family.[39] There is a very real possibility that the information from the scan will become a means of "describing" the child, which makes the issue of privacy of the information tremendously crucial and problematic and additionally emphasize the need that decisions to treat and utilize these interventions be considered in light of both current and future outcomes.[40] Overall, decision making in the light of the new technologies is extremely difficult and here is a need for a new model that accommodates the enhanced ethical issues and all of the stakeholders appropriately.

In chapter 5 the enhanced shared decision making model is developed specifically for children to address the issues of the expanding technologies of genetics, neuroscience, and pediatric research. Ideally, a shared model should be based on the medical facts, some understanding of the patient and his or her values, beliefs, and autonomous wishes (if the patient is not making his or her own decisions), and a general idea of what is "best" for the patient both personally and medically.[41] This works well in adult medicine, however this is not possible with children because they are not and have never been autonomous with fully developed values and beliefs of their own, necessitating an enhanced model. The enhanced model presented incorporates the goals of pediatric medicine, facilitates the numerous roles of stakeholders in decisions made in the treatment of children, and additionally places the child, as the patient, at the center of the model, with regard to participation and current and future interests that are weighed. The goals incorporated were (1) beneficence and non-maleficence, (2) respect for

family autonomy, (3) respect for the future autonomy of the child, and (4) promoting the current and future interests of the child.[42] The stakeholders include parents, as legal decision makers in most instances, the physician, with professional and legal duties to uphold, the child, who is the patient, and even society. All are trying to overcome barriers of the new technologies, including uncertainty and unclear benefit and burden to the child, to overall advocate for and do what is best for the child patient. Each of the appropriate stakeholders and goals have an important role in the enhanced model because each must be met in order for the model to be acceptable and actually facilitate decision making with new technologies.

The enhanced model begins with the evaluation of the child patient as the central component. Children are at a stage in life where they are developing the capacities needed for making medical decisions and including them has many benefits, making it crucial that the child be involved in any way possible, for both the end resulting medical treatment and the future of the child as an autonomous individual. During the initial step of the process, the capacities of the child are evaluated, including their developmental stage, comprehension, and communication abilities. Following the assessment of the child, the medical decision to be made is evaluated and classified utilizing the medical scenarios outlined by Whitney et al, 2008 and Kon's continuum of shared decision making. Whitney et al, 2008 discuss situations where (1) there are no medical alternatives, and patient preferences are irrelevant, so no shared process occurs and (2) those where there are several options and potential disagreement arises, where shared decision making occurs. Whitney and colleagues classify the second group as when agreement is not met, yet even in instances where agreement is realized, this category deserves extra attention with regard to new technologies. This is where pieces from the negotiated and expertise models of Weir et al, 2011 and Kon, 2010's continuum of shared decision making ranging from completely patient

driven to paternalistic will be elaborated, connecting the level of involvement with the complexity of the decision. After the level of involvement of the child has been determined and the decision has been classified, decision making can begin at the appropriate level of involvement from all stakeholders. The overall goal is for the patient, family, and caregivers to work together in a process of education and support enabling collaborative decision making, and ideally mutual influence while taking into account both current and future interests of the child as well as communitarian claims such as the protection of others from harm or the preservation of public goods, which may override those of parents.[43]

Overall, the enhanced facilitated shared decision making model allows for parents, physician, and children to work together in a meaningful decision making process. It is necessary that the child is included in the decision making process, which is why he or she is evaluated as the first step of the process. Physicians must assess the developmental capacities of the child, looking further than their age, and determine the appropriate level of involvement that the child should have in the process. After that, the decision itself must be fully understood so that the appropriate level of shared decision making can be identified and all decision makers can participate in the process in a meaningful way that acknowledges their duties and responsibilities, fully enabling them as decision makers. The enhancements discussed in the last few sections provide additional details for ways to improve decision making processes and fully enable children and parents to be decision makers, and ensure that physicians can properly coordinate the interactions. Structured education, discussions of justice and access to resources, and the creation of tools to enhance communication between physicians and parents, and the overall understanding of parents can greatly add to the decision making process. There is a great need for continued development in these areas to put the facilitated model to use and overall

enhance communication. In the proposed model, enhanced education of both parents and physicians is accomplished through a more structured decision making process that emphasizes the relationship between them as well as placing a burden on physicians to not only ensure understanding but to work with parents to make decisions.[44] The final component of the enhanced model is the justified outside impacts, discussing how society, among other potential outside impacts, has a stake in the decisions made for children in many instances. This enhanced model enables parents, children, and physicians to work together to make decisions in light of the tremendous uncertainty of the fields of genetics and neuroscience and the expanding number of research studies. The new suggestions and enhancements address the goals of pediatric medicine, incorporate all relevant stakeholders, as well as accommodate the new technologies.

Chapter 6 then applied the enhanced shared model to scenarios of the expanding technologies of genetics, neuroscience, and pediatric research. The first section presented the background and history of genetics as it applies to children, developing from newborn screening panels to the increasing use and accessibility of whole genomic sequencing. As the field has expanded, recommendations have attempted to keep up, establishing guidelines and suggestions to protect the needs and interest of the child, however there are still tremendous ethical issues and challenging decisions to be made. The ethical issues of genetics that necessitate an enhanced shared model include the spectrum of disorders screened for, consent models, privacy, and different policies and procedures in each state and the problems created by those differences. When determining the spectrum of disorders tested for

There is not clear guidance to identify what should and should not be tested for, as many advocate for the testing of all that is possible or requested while others believe it should be strictly regulated and only test for those disorders with current therapies available to the child.[45]

This determination is crucial as once the child is found to have a mutation, it cannot end there since this is a diagnosis the child and his or her family will have to deal with the rest of their lives. Many parents want to know everything they can about their child, while others do not, but the bigger ethical issue is whether or not they get to make that decision for their child. These issues become much more troubling with the potential addition of whole genomic sequencing at birth, by expanding the list of disorders that can be tested for, many of which have limited therapies available, if any, do not develop until adulthood, or have uncertain clinical significance.[46] Beyond these issues of privacy, there are issues with the storage of the bloodspot and genetic information, who has access to it, and whether test and research can be done on it without parental consent.[47] Currently in the United States, each state decides each of the previous issues, leading to more problems because many people cross state lines to see physicians or move, leading to problems such as knowing what the child was or was not tested for.[48] The enhanced model was then applied to two cases of genetic testing, specifically where the decision was about the utilization of whole genomic sequencing and if so, what should be included in the panel. Case one was of a child with a family history of breast cancer and the second is of a child without such history, however both sets of parents are requesting the sequencing of their child's genome. For each case, the child was evaluated first and their role in the process was established. Following this, the decision to be made was discussed and classified along Kon's continuum of shared decision making to identify the necessary involvement of the parents and physician. Kon's continuum ranges from completely patient driven to paternalistic physician driven, where the level of involvement correlates to the complexity of the decision in light of the ethical issues, medical facts, and levels of uncertainty

to determine the appropriate balance of the physician and parents for the overall facilitation of the decision.

The decision making framework was next applied to cases of neurotechnology. There has been tremendous growth in the field of neuroscience, developing new interventions and therapies for children which brought with them many ethical issues and dimensions, including privacy and safety, incidental findings, prediction, enhancement, and uncertainty, all leading to overall challenging best interests determinations and unclear roles of all involved in care decisions, creating difficult decisions that must be made.[49] Neuroscience is unique in that there is a field of ethics that has developed specifically for the field, neuroethics, however even within that there are not accommodations made for children, necessitating the enhanced model. The enhanced model was then applied to two pediatric cases about the utilization of neurotechnologies and the decision of what to do. Neurotechnologies bring with them the possibility to enhance and help the lives of many patients but decisions must be made with caution and extra attention must be paid to potential burdens on the patient, outcomes, and long term impacts that these decisions have on the child. The first case involves a 6 year old male with suspected autism who has difficulty communicating properly and relating to others and physicians are proposing the use of a brain scan to assess if the child has autism and if he does, attempt to identify the degree and severity. The second case is a 15 year old male previously diagnosed with ADHD and treated with medication, however now that he is older the doctor has taken him off of the medication. His parents are requesting the utilization of medicine to increase his concentration and overall enhance his performance. The first step in the application of the enhanced model is the evaluation of the child. This is exponentially more challenging in cases where neurotechnologies are proposed as they are typically suggested for children, and patients in general, with disorders

or conditions of the brain, many of which have diminished levels of capacity or overall development and comprehension. After the evaluation of the child, the decision to be made itself is classified with the review of the medical facts, uncertainty, and potential benefits and risks. Once the decision was classified, it was then related to Whitney's models to elaborate the appropriate involvement of the physician and parents, in addition to the pre-determined level of involvement of the child.

The final technology is pediatric research and the two cases looked at were for research specifically with current research of brain scans and whole genomic sequencing. Clinical research, similarly to the field of medicine in general, started as a field focused on adults. As it was applied to children new regulations and processes were put into place, but many ethical issues are still present including issues of consent/assent, the comprehension of parents, and the therapeutic misconception will be analyzed, emphasizing the difficulty in assessing the actual benefit and burden within pediatric research.[50] The enhanced model was then applied to two cases. The first case that has been analyzed involves an infant boy whose parents are requesting that he be part of a genetic research study where the researchers want to sequence the infant's genome. The second case is of a 12 year old male with a neuro-affective disorder whose parents want to enroll him in a research study to see if it is a genetic condition. In this case, the child has a disorder that they want to use sequencing to identify to better treat the child, but while performing the basic sequencing the parents and researchers will have access to an abundance of information about the child, leading again to issues of what can and will be done with the results that are found. In each of these cases the enhanced model was applied to show how parents and physicians should be working together to ensure understanding, weigh benefit and burden, and ultimately make a decision about a specific intervention. The model guided and structured the

decisions, shed light on what information should be revealed, and when, including relevant aspects that should be taken into account and those that should not.

There is a need for the enhanced model to facilitate decisions and enable the best decisions to be made for children with the utilization of new technologies. Tremendous expansion in the fields of neuroscience and genetics, both with growing numbers of new technologies and interventions available makes it crucial that physicians have a structured way to work with parents and incorporate the child into the process at a level that is appropriate, and advocate for the involvement if necessary. It has been noted by many researchers that there is a great need for future research and studies to be done with physicians and parents making medical decisions, specifically regarding cases of new technologies to accurately create and implement a model for shared decision making, however this enhanced model is an example of a way for this to begin. The new model facilitates smoother decision making and enables all stakeholders to work together to come to the best decisions, while enhancing the understanding of all involved. Depending on the medical evidence and benefits and burdens of the available options, the involvement of the physician can be limited or increased, giving parents more or less control to work with their child and make a decision. With the high level of scientific evidence and understanding needed there will unlikely be cases of genetic screening with minimal physician involvement, however when both options are valid, the parents and child, in a way determined to be meaningful to him or her, should be given the ability to make decisions. When there is clinical evidence in one direction, or a lack of information, the physician must be more involved and in many instances either insist on or refuse genetic screening. Additionally, governmental regulations and oversight will be needed as more conditions and disorders can be screened for to facilitate these situations. There is a need for more research additionally to look at the steps of

the current decision making processes of parents, to properly integrate the enhancements and decision aids. Decision aids are crucial to facilitating the new decision model, and have been found very valuable by many researchers, and are a component of this enhanced model. Despite the need for more research to fully integrate this model, and increased costs associated, it will best facilitate the decisions that surround the enhanced ethical issues of new technologies.

Notes to Chapter 7

[1] Devettere, *Practical Decision Making*, 105-106.
[2] Aries, *Centuries of Childhood*, 285.
[3] Brodie, "Overview of Health Promotion," 5-6; Vardin and Brody, *Children's Rights*.
[4] Alderson and Morrow, *The Ethics of Research with Children*, 179.
[5] Vessey, "Overview of Responses of Children," 103.
[6] Mercurio, "Pediatric Ethics Committees," 88.
[7] Kodish, *Research with Children*, 280; Ross, *Children, Families, and Health Care Decision Making*, loc 400.
[8] Donovan and Pellegrino, "Virtues," 7-8.
[9] Lipstein et al., "What Is Known about Parents' Treatment Decisions?," 248.
[10] Kodish, *Research with Children*, 280.
[11] Walker, "Respect for Rational Autonomy," 354; Kelly, *Medical Care at the End of Life: A Catholic Perspective*, 37; Parker and Dickenson, Cambridge medical ethics, 276.
[12] Kon, "Shared Decision-making Continuum," 903-904; V. Arnason et al., "Informed Consent," 106 – 107.
[13] Devettere, *Practical Decision Making*, 132-133.
[14] Beauchamp and Childress, *Principles of Biomedical Ethics*, 136-138; Devine, *Good Care*, 256.
[15] Buchanan and Brock, *Deciding for Others*, 122-123; Devettere, *Practical Decision Making*, 133; Beauchamp and Childress, *Principles of Biomedical Ethics*, 138.
[16] Buchanan and Brock, *Deciding for Others*, 121.
[17] Fiks et al., "Shared Decision-making and Health Care Expenditures," 99; Kon, "Shared Decision-making Continuum," 903.
[18] Post et al., *Handbook*, 68.
[19] Buchanan and Brock, *Deciding for Others*, 218.
[20] Parker and Dickenson, *Cambridge Medical Ethics*, 213; Buchanan and Brock, *Deciding for Others*, 229.
[21] Donovan and Pellegrino, "Virtues," 8.
[22] Parker and Dickenson, *Cambridge Medical Ethics*, 222.
[23] McCullough, "Contributions of Ethical Theory," 18.
[24] Devettere, Practical Decision Making, 132; Post et al., *Handbook*, 71.

[25] Devine, *Good Care*, 136-137; Kelly, *Medical Care at the End of Life: A Catholic Perspective*, 40.

[26] Beauchamp and Childress, *Principles of Biomedical Ethics*, 138; Kopelman, "Using the Best-Interests Standard in Treatment Decisions for Young Children," 23-26.

[27] Pellegrino et al., *Moral Focus of Newborn Screening*, 7; Moyer et al., "Expanding Newborn Screening," 37.

[28] Rhodes, "Why Test Children," 614; Tarini and Goldenberg, "Newborn Screening in the Genomics Era," 384.

[29] Bennet et al., "Newborn Screening for Metabolic Disorders," 324-325; Williams, "Public Health Genomics," 132; Cornel et al., "The Promises of Genomic Screening," 74-75.

[30] Clayton, "Genetic Testing in Children," 246-7; Wertz et al.," Genetic Testing for Children," 877.

[31] Fuchs, "Ethical Issues in Neuroscience", 602; Illes, "Medicine, Neuroscience, Ethics, and Society," 34-35 ; Farah, "Monitoring and Manipulating Brain Function," 36.

[32] Illes and Bird, "Neuroethics: A Modern Context for Ethics in Neuroscience," 511.

[33] Pederson, "Brain Scans May Track Childhood Psychological Disorders." Illes, "Neuroethics in a New Era of Neuroimaging," 1739.

[34] Hinton, "Ethics of Neuroimaging in Pediatric Development," 455-457.

[35] Racine et al., "Evidence BasedN," 23-24 ; W Rae et al., "Pediatric Psychology," 28.

[36] Racine et al., "Evidence Based Neuroethics," 23-24 ; Illes, "Medicine, Neuroscience, Ethics, and Society," 41-42 ; Fuchs, "Ethical Issues in Neuroscience", 602-603.

[37] Bennet et al., "Newborn Screening for Metabolic Disorders," 326; Rhodes, "Why Test Children," 613; Williams, "Public Health Genomics," 135.

[38] Racine et al., "Evidence Based Neuroethics," 23-26; Illes, "Medicine, Neuroscience, Ethics, and Society," 41-42.

[39] Williams, "Public Health Genomics," 136.

[40] Hinton, "Ethics of Neuroimaging in Pediatric Development," 461.

[41] Frosch and Kaplan, "Shared Decision Making in Clinical Medicine," 287-289; Emanuel and Emanuel, "Four Models," 2222-2223.

[42] Emanuel and Emanuel, "Four Models," 2224.; Beauchamp and Childress, *Principles of Biomedical Ethics*.

[43] Post, *Handbook*, 67; Baines, "Medical Ethics for Children," 143; Lown et al., "Mutual Influence in Shared Decision Making," 161.

[44] V. King et al., "Perceptions of Shared Decision Making," 636.

[45] Tarini and Goldenberg, "Newborn Screening in the Genomics Era," 383-384.; Duffner, "Newborn Screening for Krabbe Disease." 245-248; DeLuca et al., "Parents' Experiences of ExpandedN Screening Evaluations," 56-58.

[46] Bennet et al., "Newborn Screening for Metabolic Disorders," 325-326.

[47] Moyer et al., "Expanding Newborn Screening," 33-34; Bennet et al., "Newborn Screening for Metabolic Disorders," 325.

[48] Tarini and Goldenberg, "Newborn Screening in the Genomics Era," 383-384.

[49] Illes et al., "Practical Approaches to Incidental Findings in Brain Imaging Research," 385–386 and 388-389.

[50] Weir et al., "Ethical Decision Making," 53; Barfield and Church, "Informed Consent," 21.

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