

THE PENNSYLVANIA STATE UNIVERSITY
SCHREYER HONORS COLLEGE

DEPARTMENTS OF BIOETHICS AND MEDICAL HUMANITIES, INTERCOLLEGIATE
PROGRAM AND PHILOSOPHY

THE MEDICAL ETHICS AND PUBLIC HEALTH FRAMEWORKS OF PEDIATRIC
ANTIBIOTIC PRESCRIPTIONS FOR SUSPECTED ACUTE OTITIS MEDIA

MYKAIHLA STERNICK
Spring 2020

A thesis
submitted in partial fulfillment
of the requirements
for baccalaureate degrees
in Philosophy and Biology
with interdisciplinary honors in Bioethics and Medical Humanities and Philosophy

Reviewed and approved* by the following:

Jonathan Marks
Director of the Bioethics Program
Thesis Supervisor and Honors Advisor

Brady Bowman
Associate Professor of Philosophy
Honors Advisor

Michele Mekel
Assistant Director of Bioethics
Faculty Reader

* Electronic approvals are on file.

ABSTRACT

This thesis aims to use public health ethics in conjunction with individualized medical ethics to find a solution to the ethical problem of the large number of unnecessary antibiotic prescriptions for pediatric patients, specifically those with acute otitis media (AOM), the common ear infection which resolves spontaneously in 80% of cases. The medical ethical tenets of beneficence and non-maleficence are questioned when antibiotics are prescribed inappropriately, though there are many factors that go into this including time constraints, emotional parents, and difficulty in diagnosing AOM definitively. In doing so, the larger issue of antibiotic resistance is brought to the surface. By understanding this as a public health intervention, it must be justified to ask physicians to lessen the amount of antibiotics that they prescribe, against what a parent may ask for. In AOM infections, antibiotics are many times a futile or harmful treatment, and thus rarely have a place as a treatment.

Public health ethics frameworks from Nancy Kass, Ross Upshur, The American Public Health Association, and the Nuffield framework were used to identify a reasonable, ethical solution. It was determined that the stakeholders, including the physician, the patient, the parent, the medical profession, the pharmaceutical industry, pharmacists, and the government are called to action to increase public education and awareness. Also included in the solution is a streamlined watchful waiting process, increased empathetic communication dealing with risks of antibiotics, implementation of stewardship initiatives, understanding of conflicts of interest or commitment, investment in the social contract, and increased research for alternative treatment options for AOM. This solution ethically preserves both the health of the patients and the reserve of antibiotics.

TABLE OF CONTENTS

LIST OF FIGURES	iii
ACKNOWLEDGEMENTS	v
Introduction.....	1
Chapter 1 Acute Otitis Media and Antibiotic Prescribing.....	3
Chapter 2 The Public Health Crisis: Antibiotic Resistance	13
Chapter 3 The Aims of Public Health and Medical Ethics.....	33
Chapter 4 The Frameworks.....	37
Chapter 5 The Solution	54
Conclusion	67
BIBLIOGRAPHY.....	69

LIST OF FIGURES

- Figure 1. A. Normal tympanic membrane. B. TM with mild bulging C. TM with moderate bulging. D. TM with severe bulging. Courtesy of Alejandro Hoberman, MD (Lieberthal, et al., 2013). 4
- Figure 2. Infographic explaining the methods of developing and spreading antibiotic resistance (amr.gov.au)..... 22
- Figure 3. Parental views (n=138) on various aspects of AOM including treatments and effects of antibiotics in a German study conducted by Kautz-Freimuth et al., in 2015 (Kautz-Freimuth et al., 2015). 62

ACKNOWLEDGEMENTS

I have so much gratitude for all of the wonderful people in my life who have helped me in completing this thesis. Many, many thanks...

Dr Marks and Dr Mekel for the hours that you have spent reading the following pages from the preliminary drafts to the final product, and the hours that you spent teaching me parts of your crafts.

Dr Bowman for so graciously taking the time to help me with the philosophical concepts included in this thesis.

To my Mom and Dad- I cannot articulate the unbounded gratitude I have for your constant love and support, for providing me with perfect examples of what it means to work hard, and for teaching me to be my own unrelenting force.

Emily Caldes for the guidance and initial inspiration for this project.

Fr Michael and Mr Machamer - It truly means so much to me that you both took the time to read this entire thesis with a critical lens.

To my friends for showing me more love and support than I could ever ask for, whether knowingly or unknowingly.

Julia Barbon- it's impossible for me to imagine embarking on this endeavor with anyone else. Thank you for never letting anything be boring, and always being ready to bat for me. After all, we love this place.

Introduction

It is indisputable that medicine was changed forever in 1929, with the discovery of Penicillin by Alexander Fleming (Aminov, 2010). But, like many things, we don't know what we have until it's gone, or in this case almost gone. Antibiotic resistance has become a public health crisis in which bacteria evolved to become resistant to treatments like antibiotics, thus rendering them ineffective. Health and medicine simply cannot afford a squandering of this influential agent. While this is an extremely pressing issue, there is a more individualized problem for children. It has also been proven that antibiotics can permanently alter the health of both children and adults. The effects of antibiotics, while sometimes not even effective at treating minor infections, such as an ear infection, withstand in the body for months, and can cause ailments that last a lifetime.

Acute Otitis Media is the most common infection in which antibiotics are prescribed to children (Canadian Pediatric Society, 1998). In a cohort of 4.6 million children diagnosed with AOM, greater than 60% were prescribed an antibiotic (McGrath et al., 2013), even though 80% of all AOM infections resolve spontaneously (Rosenfeld et al., 2003). The ethical problem embedded in continuing with such a high volume of antibiotic prescriptions for children has two aspects. The health of the child is put at risk when they are exposed to antibiotics, and in cases such as AOM with such a high rate of spontaneous recovery, there is rarely any benefit to exposing them to antibiotics. Also, with antibiotic resistant bacteria's prevalence increasing,

medicine must reduce the possibility of resistance developing further to ensure that harmful bacteria are still impacted by the use of antibiotics.

The most critical aspiration held for increasing the awareness of this crisis is for us to adopt a more inquisitive mindset in order to decrease prescriptions for antibiotics for unnecessary usage such as acute otitis media, in many observed cases. Healthcare is aware of this issue; however, they can do better to act. In focusing on acute otitis media in pediatric patients, the intent is to offer insight, by using public health and medical ethics, into the reason a parent would care most about not encouraging their child to take an antibiotic: the future health of their child. By addressing the proper use of antibiotics in acute otitis media in pediatric patients by adhering to biomedical ethics, an ethical by-product, preservation of the supply of antibiotics, is formed. Public health ethical frameworks will be analyzed to encompass the most ethical solutions to the issue of overprescribing antibiotics.

Preservation of the amount, frequency, and the potency of antibiotics would allow usage of antibiotics for those where it is a truly life or death scenario: For the mother of three who recently went into renal failure and is in sepsis; For the grandfather who is diabetic with a sustainably weak immune system and has been fighting pneumonia for three months and is praying not to catch an infection of any kind; For the 8 year old little girl with leukemia who must endure routine bone marrow aspirations and whose blood counts are so low she couldn't survive another infection. These situations represent millions of people. The CDC has estimated that 47 million unnecessary antibiotic prescriptions are prescribed each year, amounting to 30% of all antibiotics prescribed in a year (CDC, 2019a). Simply put, that's just too much.

Chapter 1

Acute Otitis Media and Antibiotic Prescribing

Introduction

Acute Otitis media is the bacterial infection of the middle ear but can also be co-infected by a virus. The most common and primary symptom associated with acute otitis media is otalgia, commonly known as an earache, and is often accompanied with hearing loss. Parental concern arises from an infant's sudden difficulty in sleeping and crankiness, while in older children, parental concern is triggered by symptoms including fever and nausea (Miyamoto, 2019). Acute otitis media (AOM) is diagnosed by presence of erythema (redness) and bulging of the tympanic membrane, a membrane that separates the middle ear from the inner ear, commonly referred to as the eardrum (Lieberthal et al., 2013). Figure 1 demonstrates classifications of tympanic membrane bulging severity. Ear infections are frequent among children and AOM is the leading condition for which antibiotics are prescribed to children under 12 years of age (Vaz et al., 2014 in MacGeorge et al., 2017).

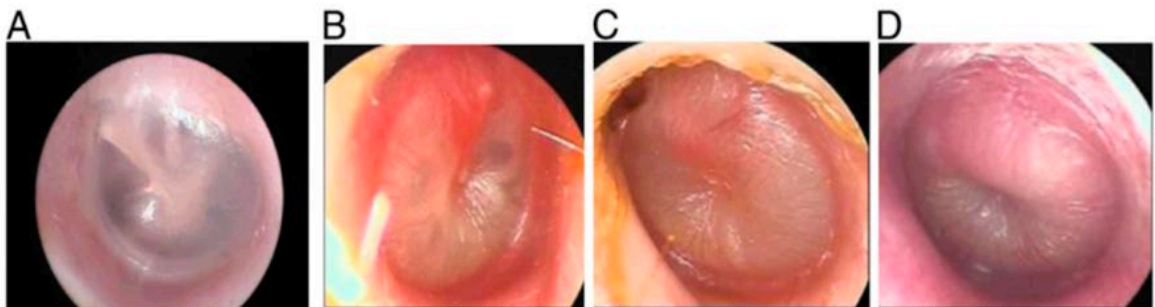


Figure 1. A. Normal tympanic membrane. B. TM with mild bulging C. TM with moderate bulging. D. TM with severe bulging. Courtesy of Alejandro Hoberman, MD (Lieberthal, et al., 2013).

Etiology

Bacterial acute otitis media (AOM) is characterized by rapid onset, inflammation, and effusion (presence of fluid behind the tympanic membrane). It is commonly caused by the bacterias *Escherichia coli*, and *Staphylococcus aureus* in neonates, *Streptococcus pneumoniae*, *Moraxella (Branhamella) catarrhalis*, and nontypeable *Haemophilus influenzae* in children under 14, and *S. pneumoniae*, group A β -hemolytic streptococci, *S. aureus*, and *H. influenzae* for those older than 14 (Miyamoto, 2019).

Otitis media with effusion (OME) is strictly of viral origin and must lack symptoms of bacterial infection (patient presents with no erythema or bulging of the tympanic membrane, no fever, and no otalgia) (MacGeorge et al., 2017).

Antibiotics are only effective in treating the bacterial infection. The microbiology of the infection can only be determined by invasively obtaining and culturing middle ear fluid via needle aspiration (Chonmaitree, 2006). The etiology of AOM is not easily determined, because both viruses and bacteria can be present. A study published in 2006 concluded from examining 79 children who have presented with otorrhea (ear ache) within a 48 hour window that bacteria was present in 92% of infections, a virus was present in 70% of infections, and both (bacteria and virus) were present in 66% of patients (Ruohola et al., 2006). From this it can be concluded that if antibiotics were prescribed as treatment for any of those children where AOM was not purely bacterial, the infection would not be cleared. If antibiotics were prescribed for the bacterial portion of a complex infection, the viral portion would still persist and could require its own treatment. However, both the viral and the bacterial infections can resolve on their own

(Handler, n.d.). It is estimated that prescriptions for antibiotics can be reduced for children and adolescents for nonsuppurative OM (no production of pus in the ear canal) by 100%, and suppurative infections by 10% (MacGeorge et al., 2017).

Though uncommon, there are complications that can occur from acute otitis media, and thus become the root reason for concern among parents. If the cause of OM is bacterial, the infection could spread locally to the inferior inner ear and result in other infections such as mastoiditis, petrositis, or labyrinthitis. Even more rarely, infection could spread to cause meningitis or a brain abscess. These infections would be identified by progressive symptoms including severe headache, confusion, neurological signs, and vertigo (Miyamoto, 2019). Because of these complications, it is especially important to offer appropriate treatment based on the physician's analysis and the presentation of symptoms. Health care professionals have developed and adapted guidelines, as they have for many conditions, to assist in diagnosis and treatment recommendations. These are known as Clinical Practice Guidelines.

Clinical Practice Guidelines

It is important to note that clinical practice guidelines are simply guidelines and are neither clinically nor legally binding for physicians to follow because they are not directives. They are put in place to ensure that patients are receiving quality care that is somewhat universal, but physicians are autonomously free to practice in any way they see fit. It is required that guidelines are updated regularly to represent advances in medicine and evolution of opinions (informedhealth.org). The American Academy of Pediatrics created "organizational principles to guide and define the child health care system and/or improve the health of all children" in their clinical practice guideline (Lieberthal, et.al., 2013). The introduction of these updated guidelines

in 2013 allowed more room for physician's discretionary judgement (MacGeorge et al., 2017). Clinical practice guidelines for acute otitis media are outlined in *Pediatrics*, the official journal for the American Academy of Pediatrics. The relevant key action statements from the 2013 clinical practice guidelines (CPGs) are as follows:

Statement 1A states that moderate to severe bulging of the tympanic membrane or new onset of an earache should be diagnosed with AOM. This is a stringent recommendation that had been amended since the last publication of CPGs. Statement 1B allows AOM to be diagnosed with mild bulging of the tympanic membrane that presents with either severe redness of the membrane, or recent onset of an earache (within 48 hours). This statement leads to overdiagnosis because of reporting bias on behalf of the parent. Statement 1C states that there must be middle ear effusion (liquid in the middle ear) to obtain the diagnosis of AOM. This guideline promotes use of extensive diagnostics, meaning use of two diagnostic tools that help provide a more definitive diagnosis: a pneumatic otoscope and tympanometer. These two tools are used to see the tympanic membrane's color, contour, and translucency, and to measure ear canal pressure, respectively. Key action statement 2 considers pain and recommendation to treat the pain. Acetaminophen and ibuprofen are recommended for mild to moderate pain based on effectiveness. Narcotics may be prescribed for moderate to severe pain, but this comes with significant risks. Naturopathic, homeopathic and home remedies can also be recommended, based on the physician.

The CPGs state that antibiotics are to be prescribed in severe AOM cases. This is classified by the following; the child is older than 6 months, and the symptoms include severe otalgia, otalgia for greater than 48 hours, and temperature over 102.2 F. Severe cases can be

bilateral or unilateral, meaning they can be present in both ears or one ear. These are cases when antibiotics are absolutely necessary. Antibiotics should be prescribed in non-severe cases of AOM only if the infection is bilateral, the child is between 6 and 23 months, and there are no severe symptoms (this includes mild ear pain for less than 48 hours, and temperature less than 102.2 F) (Lieberthal et al., 2013) The concept known as shared decision making is the method in which both the physician and the decision maker (in the case of minors, the decision maker is the parent or guardian) both contribute to making a medical decision. Elwyn et al. (2012) describe a three-step method in which the parent would be presented with a choice, given descriptions of each of the options, and then guided to help make a decision (Elwyn et al., 2012).

Shared decision making, between the physician and the parent, should be implored if the infection is non-severe, unilateral, and the child is between 6 and 23 months old. Shared decision making is also to be used if the infection is non-severe and the child is greater than 24 months old. They could recommend initial observation and treating symptoms. It is believed that there is only a small likelihood that antibiotics could offer any improvement of the symptoms. The physician must offer a mechanism for a follow-up conversation or visit. (Lieberthal et al., 2013).

These Clinical Practices Guidelines rely on using antibiotics as the primary treatment for AOM infections. When antibiotics are deemed necessary by the provider, the initial treatment is amoxicillin, at doses of 40-45 mg per kilogram every 12 hours for children under the age of 14, and 500 mg every 8 hours for those over the age of 14. Patients should receive amoxicillin unless they have been prescribed amoxicillin in the past 30 days, they have amoxicillin allergies, or when the patient has seen no improvement with their prescribed dosage of amoxicillin. The provider may prescribe other antibiotics in these cases including Cefdinir, Cefuroxime, Cefpodoxime, and Ceftriaxone at varying dosages. Finally, in cases where the bacteria of the

infection have developed antibiotic resistance, the guidelines for antibiotic prescriptions dictate use of Amoxicillin/clavulanate, preferably, and in other cases, Ceftriaxone and Clindamycin (Miyamoto, 2019). It is important to understand the mechanism by which antibiotics produce results.

Antibiotics work by killing bacteria by interfering with the cell wall or slowing the growth of bacteria. Thus, they are ineffective at treating any ailment that is not caused by bacteria. This falsifies the common misconception that antibiotics are effective in treating viral infections which are caused by a virus. Antibiotics can come in multiple forms, including capsules, creams, sprays, drops, and injections, but are most commonly prescribed for AOM in an ingestible form (National Health Service of the United Kingdom, 2019). The commonly known side effects of ingested antibiotics include nausea, vomiting, diarrhea, and allergic reactions, along with less commonly known and more long-term effects that will be discussed in detail (National Health Service of the United Kingdom, 2019). Antimicrobial drugs describe a larger class of agents that kill a wider classification of microorganisms and include antibiotics.

Antibiotics are not always effective as treatment for ailments that they are believed to treat, including AOM. In a comparative study analyzing 13 randomized control trials (RCTs) including 3401 children and 3938 cases of AOM (some children presented with recurrent AOM) conducted in high income nations, it was concluded that 24 hours after the start of treatment, regardless of the treatment being antibiotics or a placebo, 60% of the children had recovered. Those treated with antibiotics had no reduction in pain in the following 24 hours after the beginning of treatment. Not only did antibiotics fail to reduce the number of children with late AOM recurrences as compared to those with the placebo, they were associated with patients showing increased adverse effects such as vomiting, diarrhea, or rash (Venekamp et al., 2015).

Because of these adverse effects, exploration of natural and homeopathic treatments, which have been used for hundreds of years, has demonstrated the possibility of treatment. The clinical practice guidelines only briefly mention these alternative or complementary treatments currently, but with increasing research, they are proving to be a promising and valuable option.

Alternative and complementary medicine

Physicians could also express the existence of alternative treatment options. These options would relieve the infection and pain caused by the infection in a safe way with less risk of side effects to the child and the health of the public who could be exposed to resistant bacteria. The American Academy of Pediatrics supports the finding that approximately 80% of all AOM infections will resolve on their own within 3 days (Rosenfield et al., 2003), but many times it can be beneficial for the physician to offer some sort of action for the parent to take that will do no harm. It is crucial that any suggestion for homeopathic or natural based medicine be presented with compelling evidence and a clinical focus to counter the skeptical perspective that it is placebo based (Bell & Boyer, 2013). Bell and Boyer state that prescribing antibiotics is presumably pursued because physicians “wish to do something rather than nothing while the child is in distress” (Bell & Boyer, 2013). In cases where AOM is on the border between possibly benefitting from antibiotics and not, most pediatricians opt to prescribe (Bell & Boyer, 2013). This happens in cases of AOM with partially viral etiology as well, where an antibiotic would have no effect on the virus. A randomized control trial examined 75 children, with otalgia and bulging of tympanic membrane for less than 36 hours. The children were split into groups with homeopathic treatment and a placebo treatment. There was a statistically significant

decrease of symptoms after 24 hours and 64 hours for the group receiving homeopathic treatment (Jacobs et al. in Marom et al., 2016).

Homeopathic remedies offer a near perfect alternative. Homeopathy acts on the assumption that when given the proper environment and materials, the body can be stimulated into inducing its “own adaptive healing processes” (Bell & Boyer, 2013). While it is suggested that low dose NSAIDs (non-steroidal anti-inflammatory drugs), such as acetaminophen or ibuprofen, can be prescribed or purchased, there are risks associated with their use that make it worth offering other options to parents. “Evidence-based advantages for homeopathy include lower antibiotic fill rates during watchful waiting in otitis media, fewer and less serious side effects, absence of drug-drug interactions, and reduced parental sick leave from work” (Bell & Boyer, 2013). Side effects associated with acetaminophen include risk of asthma and possible liver damage, while ibuprofen can put the child at risk for gastrointestinal bleeding and ulcers (Bell & Boyer, 2013).

Homeopathic medicines are still regulated by the Food and Drug Administration (FDA, 2020) and are associated with better results, both financially and medically. There are online introductory resources for physicians interested in discovering the benefits of homeopathic remedies (Bell & Boyer, 2013). Homeopathic medicine also proves more cost-effective. A study examined 499 children with acute upper respiratory infections for 6 months. Those receiving homeopathic treatments had lower medical costs and the children's parents were forced to take significantly less sick time (Trichard et al. in Bell & Boyer, 2013).

Some common homeopathic remedies for AOM include Belladonna, Chamomilla, Silica, and colloidal silver (Marom et al., 2016). A study by Sarrell et al. (2001) concluded that Otikon ear drops, which are olive oil based and contains *Allium sativum* (garlic), *Verbascum thapsus*

(great mullein), *Calendula flores* (calendula), and *Hypericum perforatum* (St John's-wort), was just as effective as anaesthetic ear drops for reducing pain in a cohort of 103 children between 6 and 18 years old (Sarrell et al., 2001). Wustrow et al found that in a population of 390 children diagnosed with AOM and aged 1- 10 years old, half were given a homeopathic remedy (*Echinacea purpurea*, *Sambucus nigra*, *Sanguinaria canadensis*, and *Chamomilla recutita*), and only 14.4% were given antibiotics following (Wustrow et al., 2004). Sinha et al. (2012) found that in comparing a group of children (n=81) who were treated with homeopathy and those treated conventionally, none of those who had homeopathic treatment needed further antibiotic treatment, while 97.5% of the conventionally treated group did (Sinha et al., 2012). It is assumed that in this study, those receiving an antibiotic were still prescribed the antibiotic unnecessarily, as the infection likely would have self-cleared.

Other less invasive treatments that have been examined specifically for AOM treatment include vitamin D, probiotics and acupuncture. Vitamin D levels were found to be significantly reduced in a cohort of children with recurrent acute otitis media (84 children with recurrent AOM and 108 healthy controls). After providing a vitamin D supplement to the group with vitamin D deficiency, the occurrence of AOM dropped significantly after 1 year (Cayir et al. in Marom et al., 2016). Probiotics help to balance microbiota levels in the gastrointestinal tract when ingested orally, thus increasing the strength of the immune system. There is limited data on the effect of taking oral probiotics specifically for AOM in children. However, the benefits of probiotics for overall immune health are more widely accepted and they are considered a promising area of research for acute otitis media treatment and prevention (Marom et al., 2016). Acupuncture is a lesser studied area of otitis media treatment, but in canine studies, recurrent otitis media was successfully treated after one year. Researchers also found that antibiotic

treatment's effect was enhanced by concurrently using acupuncture (Sanchez-Araujo and Puchi in Marom, 2016).

Chapter 2

The Public Health Crisis: Antibiotic Resistance

THE ETHICAL ISSUE

The main ethical issue coming into question is whether it is ethical to restrict antibiotic prescriptions for children with suspected acute otitis media where there is uncertainty in the necessity of antibiotics. There are instances when antibiotics are unnecessary and inappropriate, instances of appropriate but still not necessary, and instances of necessary. This is the distinction that needs to be made in each pediatric presentation of acute otitis media. Unnecessary antibiotic use increases the likelihood of developing and spreading resistance.

The ethical dilemma can be narrowed into two parts: First, the individualized medical ethical issue for each patient when antibiotics are prescribed unnecessarily, in which the physician is breaching their duty to do no harm to the patient, and second, the widespread issue of the impact that unnecessary prescriptions have on the public and the environment. Embedded in this issue are many stakeholders with different and relevant motives. These stakeholders include the physician, the patient, the parent, the medical profession, the pharmaceutical industry, and the government.

The issue of antibiotic resistance has been labeled a crisis by the World Health Organization in 2013 (Assistant Secretary for Health, 2020). Following a report calling on international agencies to act in the interest of public health, the World Health Organization (WHO), citing Amina Mohammed, UN Deputy Secretary-General and Co-Chair of the UN Interagency Coordination Group (IACG), states “Antimicrobial resistance is one of the greatest threats we face as a global community. This report reflects the depth and scope of the response

needed to curb its rise and protect a century of progress in health. It rightly emphasizes that there is no time to wait and I urge all stakeholders to act on its recommendations and work urgently to protect our people and planet and secure a sustainable future for all.” (World Health Organization, 2019). If antibiotics continue to be used in an uncontrolled manner, the UN Ad hoc Interagency Coordinating Group on Antimicrobial Resistance estimates that, by 2050, drug-resistant diseases could be the cause of 10 million deaths (World Health Organization, 2019). Because of this, it is important to understand the methods in which resistance forms and spreads.

ANTIBIOTIC RESISTANCE

Antibiotic resistance first forms in a single organism. Because of evolutionary techniques, bacteria have developed ways to combat antibiotics designed to kill bacteria (CDC, 2020). Had this evolutionary defense mechanism not evolved, the bacteria that could be killed by antibiotics would have become extinct. Once these organisms have developed resistance to the drug that would have inevitably killed them, they became capable of multiplying and spreading throughout the host environment and beyond (CDC, 2020).

Baym et al. (2016) explains that most first-generation antibiotics have already been deemed ineffective. Although modifications of the antibiotic compounds have increased longevity of these drugs, the time limit on this extended effectiveness is nearing its end (Baym, et al., 2016). Scientists are now using genomics to alter gene expression and map mutations of certain bacteria, thus creating “anticipatory diagnoses” (Baym et al., 2016). Such diagnostics are intended for physicians to have better access to information that aids them in prescribing the proper antibiotic that would be most effective to combat development of resistance (Baym et al., 2016).

The WHO recognizes the interdependence of humans, bacteria, animals and food supplies and how they are all impacted by resistance, thus calling on a ‘one health’ paradigm. The critical recommendations include: “[1.] a call to prioritize national action plans to scale-up financing and capacity-building efforts; [(2.)] put in place stronger regulatory systems and support awareness programs for responsible and prudent use of antimicrobials by professionals in human, animal and plant health; [(3.)] invest in ambitious research and development for new technologies to combat antimicrobial resistance; [(4.)] urgently phase out the use of critically important antimicrobials as growth promoters in agriculture” (World Health Organization, 2019). The goal of these recommendations is to express the kairos of the situation and raises the question of human autonomy in decision making with effects past the scope of our own health.

THE ‘ONE HEALTH’ PARADIGM

The ‘One Health’ paradigm argues that humans, non-humans, and the environment are interconnected ontologically, epistemically, ethically, and methodologically (Beever & Morar, 2018). A ‘one health’ framework by FAO et al. suggests that “a number of sub-sectors and stakeholders are often involved and interconnected” (FAO et al. in Beever & Morar, 2018). However, Beever and Morar argue that the term ‘interconnected’ simply isn’t strong enough because it is underdefined. Rather, they assert that the actual relationship we all have is interdependent. To differentiate interconnectedness and interdependence, they state that when a whole is constituted by its parts, it is interdependent (Beever & Morar, 2018).

“It seems as though it is in the nature of the organs of an organism to play the role they play as parts of that organism—their nature seems to derive from the nature

of the organism ... At the same time, there is much intuitive force to the idea that an organism depends on its organs just as other complex wholes exist in virtue of the parts that compose them. Whilst the organs of an organism derive their nature from the organism, the organism requires its organs in order to exist and to be that organism. Metaphysical interdependence offers a way to reconcile these competing intuitions” (Naomi Thompson in Beever & Morar, 2018).

Kriti Sharma clarifies that these are not simply independent objects acting cohesively (Kriti Sharma in Beever & Morar, 2018), but they are “inextricably linked” (Beever & Morar, 2018). They believe that the human microbiome is proof of a unifying concept for health, using distinguished ideas of interconnection and interdependence between human, animal and environment. (Beever & Morar, 2018).

THE MICROBIOME

It can be argued that the health of an individual stems from their microbiome. The major area of the body that is impacted by antibiotics is the microbiome, and more specifically, the digestive tract. This is where the majority of the microbiome resides (Beever & Morar, 2018). Schneider and Winslow, citing a definition in Cho and Blasner, define microbiota as the “microbial organisms that constitute the microbiome, which is “the totality of microbes, their genetic function, and the milieu in which they interact.” (Schneider & Winslow, 2014). The metagenome is “the genetic information of a complex population-- typically from microbes in an environment or host niche sample-- that is constituted by the genome -- of many individual organisms” (Schneider and Winslow, 2014). This is an important shift in which science now

recognizes our genomes, the DNA which constitutes our basic level of being, to include these microorganisms. We depend on these microbes physically and genetically. With these definitions in mind, it is difficult to comprehend the host of organisms that are living inside our bodies. Humans provide them with shelter and energy, while they aid in our survival. A healthy individual is host to hundreds of trillions of bacteria (Schneider & Winslow, 2014). The dynamic relationship between the host human and the microorganisms blurs the lines of what constitutes an individual human and creates the need for the term “holobionts.” Holobionts are wholes that function as a single entity, while still relying on smaller parts to form an interdependent relationship (Schneider and Winslow, 2014). Because microbiota that help human’s health flourish are bacteria, they are susceptible to the detrimental effects of antibiotics. This means that taxonomic diversity can be greatly decreased in the gastrointestinal tract. In a study by Relman et al. (2008), three patients were prescribed ciprofloxacin and their microbiota was examined after the course of the antibiotics. One third of the flora was lost, and even after six months, multiple types still did not recover (Relman et al., in Cully, 2019). Specifically, the role of the digestive tract microbiota is to aid in digestion and absorption of nutrients, indicatively those that cannot be absorbed without microbes. If we are not able to absorb nutrients properly, the human body will become deficient in many areas, causing imbalances, which can lead to a plethora of health ailments. “[M]icroorganisms . . . have a profound influence on human physiology and nutrition and are crucial for human life” (Blaser et al., 2013 in Schneider & Winslow, 2014). With context of the ethical issue, it is important to understand that this mutualistic relationship cannot benefit the host when the microbes are under attack by a drug. The strained relationship can cause damage: “A very surprising finding has been that disruption of the homeostasis between the microbiota and the host . . . has a more important role than host genetics in the development of a

range of diseases, such as inflammatory bowel disease, obesity and type 2 diabetes” (Blaser et al., 2013 in Schneider & Winslow, 2014).

The results of this dysbiosis extend far into the future of a child’s health. Correlations were found between antibiotic use and development of irritable bowel syndrome (IBS), increased risk of eczema, asthma, and allergies (Neuman et al., 2018). Multiple studies found a positive correlation between antibiotic use and weight gain in children. Recent developments discovered a negative influence by antibiotics on the central nervous system development and function, as well as behavior modulated by the nervous system (Neuman et al., 2018). In a 2017 study that examined 526 children who have taken antibiotics, a higher number of symptoms that relate to depression and ADHD were identified by the age of 11. Higher behavioural difficulties were identified in children aged 3.5 and 7 (Neuman et al., 2018).

Children’s microbiomes are subject to more profound detrimental impacts from antibiotic use due to their limited microbiota diversity in taxonomy and dynamic nature (Neuman et al., 2018). Even small factors such as change in environment and dietary alterations create large shifts in microbiota, demonstrating this vulnerability of their microbiomes. Antibiotics are not usually able to be tailored to combat specific bacteria. In addition, it is unknown as to what is the specific bacterial agent responsible for the infection. As a result, broad spectrum antibiotics are often prescribed that can further contribute to the imbalances between “good” and “bad” bacteria. This information is an important consideration for both the parents and physician. The physician has a specific duty to the singular patient.

INTERCONNECTEDNESS OF MICROBIOMES

Microbiomes are impacted by surrounding microbiomes of other humans. It is no surprise that hospitals are one of the highest concentrated locations for antibiotic resistance genes. Because of this, those who occupy hospitals regularly have a higher risk for acquiring resistant bacteria that inhabit their microbiomes. This is important for children because any household cohabitating with a family member who consumes antibiotics can spread resistance to the children. For example, patients with chronic infections must consume repetitive doses of antibiotics and are subject to developing resistance. This can happen by horizontal gene transfer (HGT), in which the specific resistance gene is inserted to a non-resistant bacterium, rendering it resistant (Kraemer et al., 2019). A “superbug,” a term that has been coined in the medical realm, describes bacteria that has become extensively resistant, such as *Staphylococcus aureus* (MRSA). It is believed that bacteria contain integrons, which are genetic structures that transfer resistance genes using HGT (Kraemer et al., 2019).

It is also no surprise that those who may be living with someone who consumes antibiotics regularly, such as roommates, significant others, or family members, can also be impacted by antibiotic resistance gene spreading. A study conducted in four New York City hospitals examining the transmissibility of specific bacterial infections found that patients were 4.82 times more likely to have been exposed to pathogens causing subsequent infections with similar antibiotics resistant profiles from their roommate (compared to controls, who were similar but uninfected patients) (Cohen et al., 2018). These results show that antibiotic resistance can be spread to those who are living in close proximity to an infected person (Cohen et al., 2018). As it turns out, there are other indirect methods of contracting resistance that are farther removed from the actual act of prescribing.

AIRBORNE AND ENVIRONMENTAL SPREAD

It is not well known by society that antibiotic use and resistance can be spread by air, the environment through water sources, and food. This imposition on the delicate balance of the ecosystem, has implications on all forms of life. Kraemer et al. (2019) explains that there are two mechanisms which can lead to resistance in bacteria. One mechanism that can cause resistance is *de novo* arising of mutations. This has accrued more attention because of anthropocentric origins. The second method occurs when the genes for resistance are already present in the environment and they are implemented into their genome (Kraemer et al., 2019). These genes can then be transferred to other bacteria that they come in close contact with using integrons and horizontal gene transfer (HGT), during which the bacteria can gain new genetic information by three methods: take up genetic information from the environment, directly transfer genetic information from bacteria to bacteria, or be infected with a virus that contains genetic information (Burmeister, 2015).

This is the same mechanism that is used by bacteria in all ‘hotspots.’ These hotspots include hospitals, animal feeding operations, aquaculture operations, and wastewater treatment plants. Stemming from hospitals and homes, ~70% of consumed antibiotics can transfer through the digestive system, be excreted through urine, and enter into the sewage system while still maintaining their same potency as when they lay dormant in the prescription bottle (Kraemer et al., 2019). Along with these antibiotics, bacteria (antibiotic resistant bacteria, ARBs) that contain genes coding for antibiotic resistance and the genes themselves (antibiotic resistant genes, ARGs) can also enter the water system. Humans rely on wastewater treatment to purify the water enough to remove both the bacteria, the antibiotics, and the genes. Because of the contact that antibiotics have with other bacteria in this environment, they can continue to cause development

of resistance and spread resistant genes through HGT (Kraemer et al., 2019). Fortunately, the genes are removed efficiently from water supplies. However, because of varying degrees of stringency in the purification processes based on material and location, antibiotics, ARBs, and ARGs are not removed well from biosolids. Biosolids are typically buried in landfills which can contaminate runoff water and could potentially be used for fertilizer (Kraemer et al., 2019). Crops and grazing livestock are then subject to consumption of antibiotic resistance generating agents.

Livestock can also be impacted by overuse of antibiotics, as 80% of all the US's supply of antibiotics are for veterinary use (Ventola in Kraemer et al., 2019). Livestock are commonly injected with antibiotics to promote growth and treat infections (Kraemer et al., 2019). The livestock waste containing ARBs then flows into water supplies. Antibiotic resistant bacteria can be present on poorly cooked livestock food, and on fruits and vegetables that are poorly washed, as irrigation water is likely not purified at all (CDC, 2019d).

Fish farms are also commonly pumped with antibiotics directly to prevent infections and promote growth. One study found that individuals with increased contact with livestock have had an increased risk of developing antibiotic resistance, such as farmers, livestock and fish handlers, and veterinary workers (Hanselman, Levy, & Price in Kraemer et al., 2019).

In a study by Li et al. (2018), the air of 19 cities across the globe were analyzed for 30 antibiotic resistance genes that are resistant to seven antibiotics. They concluded that available antibiotics, which are prescribed and used, correlate to a varying distribution of airborne antibiotic resistance genes (Li et al., 2018).

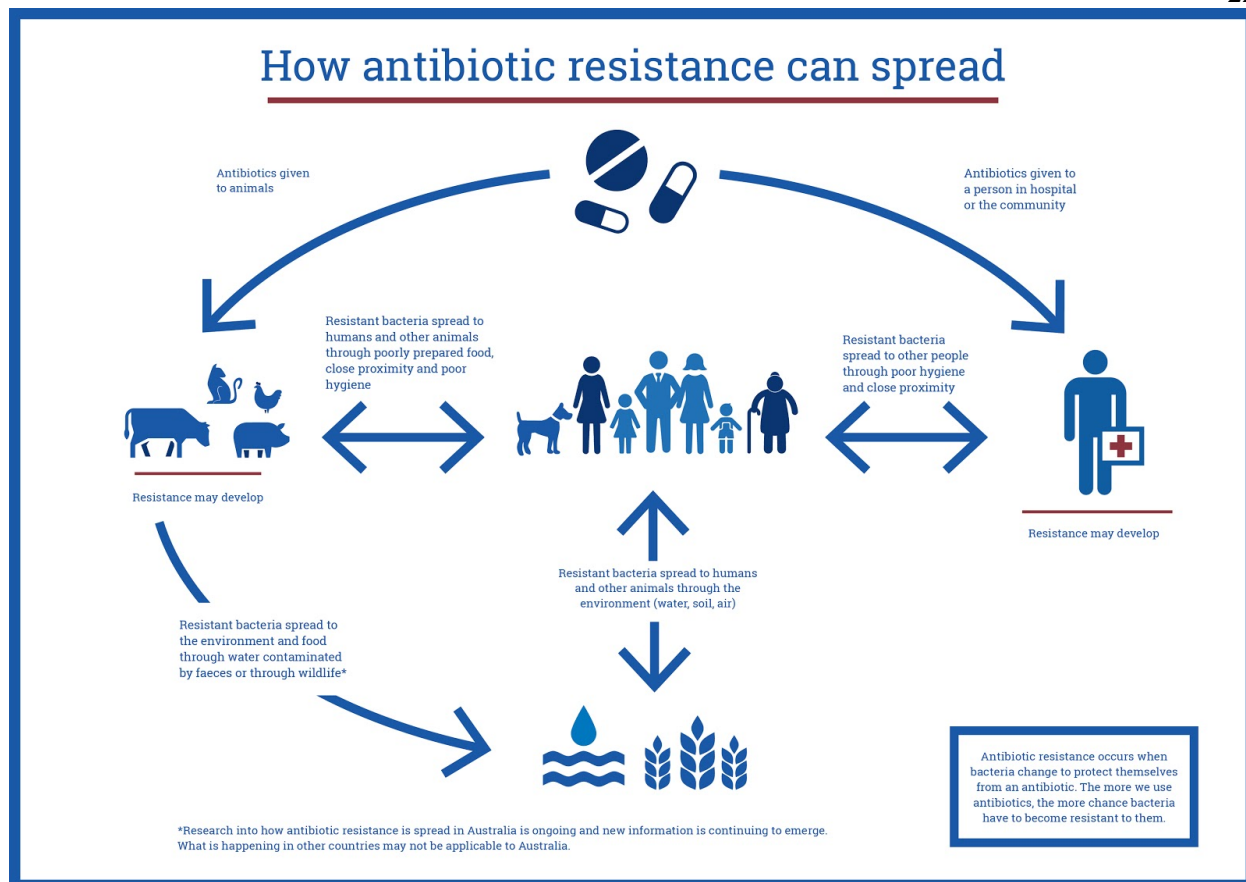


Figure 2. Infographic explaining the methods of developing and spreading antibiotic resistance (amr.gov.au)

STAKEHOLDERS

The stakeholders in the situation include the most obvious: the minor patient, the minor patient's parents, the physician, and the public. It is true that these stakeholders likely have the same intention, ensuring the continued or re-found health of the patient. However, they may have differing opinions on how to attain this goal. The patient likely cares the most about the relief of pain and has less of a concept of what infections are or how antibiotics treat them. The healthcare provider is also likely aware of the distress of their parents and may or may not empathize with the worry of their parents or guardian. Other stakeholders include the medical profession, the pharmaceutical industry, pharmacists, and the government, which includes public health agencies.

The Physician

Gillon explains that beneficence and non-maleficence are often grouped together because in aiming to help the patient, there is always a risk that the physician may put the patient at risk (Gillon, 1994). Because of this, the Hippocratic ethical obligations that a physician possesses aim for a “net medical benefit” with more benefits than harm. In this case, causing harm would be refusing to prescribe antibiotics when they are absolutely necessary, and could result in serious complications. It is a duty of the physician to avoid undue harm by only prescribing antibiotics when necessary because of the adverse effects to the microbial population in the host. Though these can be conflicting duties, it is up to the physician’s discretion to use their expertise to make an informed diagnosis, recommendation, and choice to prescribe or not to prescribe. Though this may deprive the parent the ability to make a treatment decision, it relies on scientific and clinical data to form recommendations for treatment. This includes information that the patient or surrogate decision maker (parent) is not totally responsible to understand beyond the scope of the child.

The physician has a conflict of commitment created by institutional design. A conflict of commitment differs from a conflict of interest (Marks, 2020). A conflict of interest is defined as “circumstances that create a risk that professional judgments or actions regarding a primary interest will be unduly influenced by a secondary interest” (Institute of Medicine Committee on Conflicts of Interest in Medical Research, Education, and Practice, 2009). A conflict of commitment focuses on a conflict between two professional obligations, rather than a professional obligation and a secondary interest, such as a financial interest (Werhane & Doering, 1996). Pediatricians report seeing, on average, 75 patients per week within an average 45-hour work week (AAP, 2012). Even if all of the 45 hours were spent working with patients (which they are not), that would

only allow for a little more than one half hour with each patient. In this time, they need to speak with the patient and parent, examine and diagnose the patient, educate the patient and the parent, and complete the documentation for the visit. It seems that the most dispensable part of the equation is education, and thus why it seems to falter. It is faster to agree to the antibiotic prescription, write a script, and send the pair on their way (Mekel, 2020). Thus, I find lack of time to fuel a conflict of commitment. The physician must complete a duty to preserve the health of the patient, but also complete other duties required by the profession with only so much time to do so (Werhane & Doering, 1996).

The Parent

The parent is known as the surrogate decision maker, meaning that since the child is a legal minor and deemed incompetent to make their own decisions, they must have someone to do so on their behalf (Beauchamp & Childress, 1994). The parent can have three aspects that cause them to worry. They are: 1. the care of their child, 2. information that they think they know (meaning, improper use of antibiotics), and 3. their emotional state of mind which they may not be aware is impacting their decisions. This third conflict may rise to the forefront unknowingly, and also may mitigate the parents own personal wellbeing (Mekel, 2020). The ethics of care theory, pioneered by Carol Gilligan, emphasizes interdependence through empathetic relationships. This theory claims that the mother of a child has a strong moral calling for responsibility and care to others, including to their own child. She has the responsibility to care for her child's basic needs, alleviate their pain, and sustain their basic capabilities. It prioritizes values of empathy and relatedness, and so, when the physician appeals to these values, they could more likely gain the trust of the mother (University of Amsterdam ComScience, 2017).

Parents, among others, consider the long-term effects of the situation to be the primary concern. This could include both long term effects of ear infection or the long-term effects of antibiotics on the child's gastrointestinal tract, development, and metabolism. It is a fact that AOM can also have a viral aspect. Because children have narrower eustachian tubes, they are more susceptible to develop ear infections than adults (Weill Cornell, 2017). It is also important to consider the possibility of recurring ear infections and other infections due to weakening of the immune system with decreased microbiota diversity and function.

A longitudinal study followed 296 parents of children 3 years or younger who were diagnosed with 2 or more acute otitis media infections in the past 6 months to assess the attitudes of antibiotic prescribing for their infections (Bien et al., 2000). The concerns of the parents were stated as follows: 75% were worried about continued pain and symptoms, 72% were worried their child would not recover, 63.5% were worried the child could develop hearing loss, and 38% were worried about the cost of future appointments (Bien et al., 2000). Parents also were aware and worried about the potential adverse effects of the antibiotics (62%) and 63% expressed concern of the antibiotic effectiveness decreasing with increasing use (Bien et al., 2000). This does not mean that they applied the worries to the matter at hand. They may be solely looking for their child to be out of discomfort. The medical community cannot allow this standard protocol of 'no-questions-asked' prescribing, caused by time crunches on both the parental and medical professional ends. In later chapters, I will explain that most of these concerns do not have a scientific basis, and thus, are only emotionally charged concerns. It has been shown that antibiotics do not aid in pain management. Most infections have both viral and bacterial origin, thus making the antibiotics ineffective at treatment of the whole infection. Under watchful waiting protocol, if the symptoms did not improve in the following 2-3 days, they would have

been given access to a prescription for antibiotics. According to MacGeorge et al., watchful waiting is “a treatment strategy for childhood OM that involves providing caregivers with an antibiotic prescription (or the ability to access one) but advising that it not be utilized unless the child’s symptoms worsen or do not improve in a specified period of time, such as 48 hours” (MacGeorge et al., 2017).

The Public

Society persists as a stakeholder by supporting the public health viewpoint which emphasizes the cruciality of managing and possible hope of reversing the impact of antibiotic resistance. Society is composed of many individuals, who are also parts of many different groups in society. Individuals familial roles, education, and personal values can cause aligned or conflicting interests regarding public health. It can be the case that members of society only have interest in their own and their family’s health with no regard for the health of the public. It may also be the case that an individual has more interest in the health of the public than individual patient-physician interactions. Because of these overlapping publics, there may be conflict of opinions in many medical situations where public health plays a part because of competing interests. One may say that in this case, self-interest and the public interest are in opposition, making it a “tragedy of the commons,” as Porco et al claim (Porco et al., 2012). A “tragedy of the commons” is when individuals overuse a shared resource, and ultimately lead to its destruction that results from the conflicting interests of the individuals and the public. A classic example is grazing livestock. Cattle owners are incentivized to increase grazing, but in the end, the livestock will not have anywhere to graze because of the depleted resource (Porco et al., 2012). However, I disagree with the claim that antibiotic overuse for AOM infections is an

example of the tragedy of the commons. When the overuse of antibiotics is considered a tragedy of the commons, it is not considered that it is in the best interest of the individual to limit their consumption of antibiotics for their health. These antibiotics are not usually required for the resolving of AOM infections and can cause more harm to the child's health than benefit. While an individual overuse has brought us to our current situation of antibiotics resistance, the incentives of the individual must be considered. They are incentivized by a lack of information that would lead individuals to change their minds about demanding antibiotics. In the case of AOM, the interests of the public and of individuals align. Both benefit from reducing antibiotic prescriptions because of lessening the prevalence of health risks caused by antibiotics and lessening the risk of bacteria developing resistance to antibiotics.

The rapid evolution of resistance in the bacteria, and the rapid life cycle of bacteria allows them to multiply quickly while expressing resistance genes and spread even more rapidly. It is a great concern that the genes causing resistance can be passed on to people that have not even taken antibiotics in their recent medical history.

The Medical Profession

The medical profession has interest in this situation because of their duty as practicing physicians. The empirical claim is that physicians value the tenets of medical ethics and by taking the Hippocratic oath, agree to protect the wellbeing of their patient (beneficence) and do no harm (maleficence). But the normative claim, which revolves around what they in fact value is different. Though it may still be the wellbeing of their patient primarily, physicians are exposed to practices that may undermine health and well-being. There are financial ties, specifically to pharmaceutical industries, that may influence the judgement of the physicians. For example, small gifts and gestures or drug samples from pharmaceutical companies to physicians

can impact their judgement (Institute of Medicine, 2009). Because of these influences, the trust that a patient or parent of the patient may have in the physician is lessened.

These conflicts of interest between the pharmaceutical company and the medical profession can lead the public to question healthcare professional's integrity while making medical judgements (Institute of Medicine, 2009). The Physician Charter on Medical Professionalism, a charter developed to prioritize medical ethics by the American Board of Internal Medicine (ABIM, n.d.) claims that "medicine's contract with society... demands placing the interests of patients above those of the physician..." (ABIM in Wellie, 2011). Wellie argues that the medical profession is best understood in the context of the social contract. Social contract theories rest on the premise that in the medical realm, there are two parties: the medical profession and the public. Each party obtains their own benefits.

Philosopher Thomas Hobbes's social contract "arises from the plainly egoistic realization that a truce is more likely advantageous than a battle among equals" (Wellie, 2012). But in the case of physician's, it is an altruistic goal, with no real self-interest in considering solely serving others. This motivation is speculative, depending on each physician. It must be noted that physicians do have self interest in their financial gain, but the profession as a whole is based on the premise that physicians are meant to be healers who serve others. Wellie states that the social contract is invoked "as justification for linking profession to social responsibility" (Wellie, 2012), but also that there can be other sources of social responsibilities, thus "the goals, values, and norms are internal to the practice" (Wellie, 2012). With this, I agree. Physician's only have a duty to the public based on the social contract, when the interests of the public and the individual patient align. Physician's should not be tasked with another duty of extensively considering the public health implications of each medical decision they make based on the social contract. That

is not to say the physician does not have any interest in public health, only that it is not their duty to protect the health of an overarching society.

Physicians have a duty to their patient in the case of AOM. It is in the interest of both the patient and, secondhandedly, the public for the physician to ethically refrain from prescribing antibiotics. Physicians gain trust of their patients because they act with the consideration of the health of their patients primarily, not because of an entering into the social contract.

The medical profession is not limited solely to the physicians, as it extends to nurses, nurse practitioners, physician's assistants, and technicians. Interestingly, studies have shown that the frequency of antibiotic prescriptions prescribed by nurse practitioners (NP) and physician assistants (PA) are higher compared to physicians. A study, conducted during the years 2006-2011 examining the differences in volume of prescriptions, found that PAs and NPs prescribed antibiotics 5% more in all visits, and 7% more in acute respiratory tract infections, which includes AOM (Sanchez et al., 2016). The conclusion of this study was that NPs and PAs should be targeted for intervention and increased education to reduce inappropriate use of the drug (Sanchez et al., 2016). It is important to note that the word inappropriate was used, rather than necessary. This distinction indicates that the influx of prescribing is due to uncertainty in instances when the antibiotics could be necessary, but on the other hand, the infection could likely resolve on its own.

The Pharmaceutical Industry

The pharmaceutical industry has a large stake in this ethical dilemma. Since 2017, eight antibiotics have been developed. Only two of them contain novel chemical scaffolds, while the other six are derivatives of existing antibiotics (World Health Organization, 2019b). Even if new antibiotics are developed and integrated into clinical practices, it is only a band-aid on a larger

issue that will continue to progress unless the issue is fixed at its root. At first glance, this seems like it would be an issue that the pharmaceutical industry would not care much about. They would not object to the overuse of their product, nor would they object to a greater increase in revenue. If this overprescribing continues, antibiotics will be ineffective in treating anything and they may not be prescribed at all. Antibiotics are a finite resource. Thus, it is beneficial for the pharmaceutical industry to aid in the combat of this crisis for the future wellbeing of all. This is part of the industries' interaction with the social contract theory that they have entered in. The premise of all social contracts is: "social arrangements among people are just when and because they have been freely agreed-upon by those participating in the arrangements" (Wellie, 2012), stating that they are theoretically used to make clear an unspoken agreement. Healthcare professionals prescribe the drugs made by pharmaceutical companies, and individuals consume the drugs because they think it will treat their ailment. Individuals and industry enter the social contract because of their self-interest, and they are willing to give up some of their self-liberties to obtain greater liberties (D'Agostino et al., 1996). Pharmaceutical companies use this contract to their advantage to increase the units of drugs that they can sell, because patients trust their physicians. The breach in trust can come between the pharmaceutical industry and the medical profession, especially when a physician, who is the middleman in the contract between industry and consumer, is unknowingly influenced to prescribe drugs which includes antibiotics. The solution is twofold; it is both ethical to restrict the antibiotics by providing education and guidance, and it is in their best interest to preserve the supply.

The Pharmacists

The Royal Pharmaceutical Society and the National Pharmaceutical Association (of Great Britain) present four key messages as necessary to express to those receiving antibiotic

prescriptions. They are “[(1.) Counsel patients on appropriate antibiotic use when prescribed; [(2.) Counsel patients on antibiotic resistance, as appropriate; [(3.) Counsel patients on adverse effects; [(4.) Recommend symptomatic therapy for non-vulnerable patients” (Fleming et al., 2011). These recommendations are upheld in multiple pharmaceutical publications, including *Pharmacy Today*, an official publication of the American Pharmacists Association. This publication cites Ruth Lynfield, MD, State Epidemiologist and Medical Director for the Minnesota Department of Health saying, “Pharmacists lend critical expertise to an antibiotic stewardship program because of their understanding of how antimicrobials work, the appropriate dosages and routes, and their toxicities and interactions. Pharmacists also know how antimicrobials are used in the healthcare system, what the available antimicrobials are, and how to fine tune the formulary” (Collins, 2012). Stewardship is defined by the World Health Report as “the careful and responsible management of the well-being of the population” (Kapoor et al., 2014), and is specifically, in the case of AOM treatment, with respect to management of the finite resource of antibiotics. This includes both responsible prescribing and patient education, tasks accomplished by physician and pharmacist. The pharmacist takes part in a later step of the medical process, and this education is within their scope of practice. The patient has already gotten the doctors approval, and now they are being told similar things by the pharmacist, which serves as a reinforcement of the same ideas. The pharmacist counsels the patient on proper use by using the mnemonic FRAIS; finish the course, regular intervals, after, with or before food, interactions, and side effects. (Fleming et al., 2011).

The Government

The government, specifically the Food and Drug Administration, has a vested interest also because they may be required to make the decision to mandate and regulate prescriptions of

antibiotics to pediatric patients with acute otitis media. The FDA has partnered with public health organizations such as the CDC to increase awareness, as well as encouraging development and approving new antibiotics and regulating antibiotic labels (FDA, 2019). The government can both educate the public on antibiotic resistance and reasons why antibiotics are usually not necessary for AOM. It would be beneficial for a subset of the government, The National Center for Complementary and Integrative Health (NCCIH, 2020), to aid in funding for alternative treatment research for acute otitis media, including homeopathic remedies. The government could provide incentives for implementation of education programs and incentives for hospitals and doctors to use and succeed with these programs.

Chapter 3

The Aims of Public Health and Medical Ethics

INTRODUCTION

As discussed in previous chapters, not only does antibiotic resistance risk eliminating the viability of antibiotics, a powerful health agent, but it can also adversely affect the health of the child. The reason for why the physician does not want to initially prescribe antibiotics must be understood and articulated thoroughly by the medical professional; the decision to watch and wait does not stem exclusively from an unempathetic perspective that is focused on public health only nor is it unempathetic to the parent of the pediatric patient. Rather, this balanced approach considers the patient at the fore, while accounting for the overarching ethical considerations of non-maleficence.

Public health and individualized patient care share the same goals of improving overall health, prevention of harm, and promotion of wellbeing. These approaches could diverge when faced with a universal concern such as antibiotic resistance crisis, propelled by antibiotics being prescribed unnecessarily. In this case, both medical ethics and public health aim to decrease the volume of antibiotics being prescribed in an ethical manner. This places the physician as a gatekeeper who owes a duty directly to a patient in terms of nonmaleficence and beneficence. This duty runs to the pediatric patient rather than the surrogate decision maker, the parent, who may have competing interests when demanding a medically unwarranted treatment which are often expressed in terms of dissatisfaction, urgency, and at times, anger toward medical professionals.

MEDICAL ETHICS

The American Medical Association's (AMA) Code of Medical Ethics, adopted in 1847, and based on the goals of medicine described in 5th century BC by Hippocrates has become the guiding oath for physicians. The overarching guideposts are to avoid causing harm, promote well-being and fostering this in a fiduciary relationship between physician and patient. The principles defined by the AMA include that "A physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights" (American Medical Association, 2016).

The four *prima facie* principles of biomedical ethics proposed by Beauchamp and Childress are central to ethical, practicing physicians. The principles are autonomy, beneficence, non-maleficence, and justice, and they must be balanced with no single principle being weighed more than another. Autonomy is based on the principle of respect for persons and requires 'informed consent' for which the patient must be presented with information to decide based on their own opinions (Beauchamp & Childress, 1994). In a case where the patient (or decision maker in the case of a minor) does not have the opportunity to make this decision, a certain degree of paternalism is evoked, where the physician makes the decision based on their expertise and professional opinion in order to keep the decision maker from inflicting unintentional harm to the patient. In the case of AOM and antibiotics, the cost-benefit ratio is so high in favor of benefit for most cases of AOM that paternalism can be justified. By using a paternalistic approach, the physician is acting with beneficence and non-maleficence, two principles of Beauchamp and Childress's principlism. These two principles reflect what's best for the

patient's health, and to do no harm to the patient, respectively (Beauchamp & Childress, 1994).

The most important distinction is to realize that by doing nothing a physician is technically not doing any harm, but they would be violating beneficence by not helping the patient.

The final principle of Beauchamp and Childress is justice, which states we must distribute medical services and goods fairly (Beauchamp & Childress, 1994). The fourth principle of justice is prevalent in two ways; distributive justice and intergenerational justice. Distributive justice is present due to the need to preserve and maintain the supply of a finitely effective resource (Beauchamp & Childress, 1994). There is also intergenerational justice, in which the pediatric patient who holds no legal decision-making power cannot make decisions based on their own self-interest, and thus, they rely on their parents to hold their best interest as the primary concern to make the decision. Medicine does not have duty to the public, only to the patient.

In the specific case of antibiotics, I argue that shared decision making should be restricted to physician's expertise to move more towards paternalism. Paternalism is defined as the "interference of a state or an individual with another person, against their will, and justified by a claim that the person interfered with will be better off or protected from harm" (Nuffield, 2007). When a parent demands antibiotics, as they do in some cases, the physician will make the decision, when medically warranted, to not prescribe in order to prevent the child from being exposed to risks associated with antibiotic use. In the case of pediatric patients, since the patient is a minor, there is an absence in autonomy for themselves that is granted to the parent surrogate decision maker. Even so, there is no case to be made in medicine for future or contraindicated treatments, such as antibiotics for most AOM infections.

Paternalism would give the physician the authority to prescribe fewer antibiotics. It seems that it is the opposite from *Jacobson v Massachusetts*, a public health case taken to the U.S. Supreme Court in which the individual fought against a forced administration of a vaccine (Gostin, 2005). Here, there is a role for strong paternalism with pediatric patients which gives medical professionals decision making authority for antibiotic prescribing based on their own judgement, expertise, and education. Public health and medicine have many tensions with each other, but in many cases, they may also align. Because it is an aim of medicine to protect the patient and an aim of public health to maintain the health of a society, it would be possible to restrict antibiotic prescriptions in order to protect the health of individuals, the health of the society, the antibiotic supply, and the health of ecology. Physicians understand that by accepting to uphold the AMA's code of ethics, they are agreeing to their duties in the social contract as professionals. There is reciprocity between the physician, the patient, society, and the profession and this is represented by the flexibility of the code to progress as society evolves (Wells, 2004). This reciprocity is key to the success of these relationships and is developed in the following chapter of public health frameworks.

Chapter 4

The Frameworks

Introduction

Four public health ethical frameworks have been chosen because of their appropriate application to the situation. Because restricting the use of antibiotics is in accordance with both the goals of medicine and the goals of public health, there is no conflict between medicine and public health here. I assert that the physician only has a duty to public health when the goals align with the goals for the individual patient. When it is appropriate, decisions such as this one benefit both the patient and the health of the public. Restricting antibiotic prescriptions preserves the health of the patient and also preserves the viability of the supply of antibiotics.

The following frameworks, which are Nancy Kass's framework, Ross Upshur's framework, the American Public Health Society's "Public Health Code of Ethics, and the Nuffield framework, work in concordance to offer a comprehensive public health framework that protects the wellbeing of patients, the public, and the environment. All of these ethical frameworks have a goal of safeguarding the interdependent health of all, with some being stronger than others in ways that I will expand upon.

1. NANCY KASS

Nancy Kass explains that bioethics is used by health policy makers to aid in the navigation of moral dilemmas such as those that can be posed in public health regulation scenarios, so that they do not impose on the rights of the individual extensively. In her framework, she relies on Beauchamp and Childress's principles of medical ethics (Kass, 2001).

She presents an analytical tool that consists of six questions, with an aim of improving the health of the public while simultaneously addressing injustices between an individual's medical care and the health of the public.

1. "What are the public health goals of the proposed program?"
2. How effective is the program in achieving its stated goals?
3. What are the known or potential burdens of the program?
4. Can burdens be minimized? Are there alternative approaches?
5. Is the program implemented fairly?
6. How can the benefits and burdens of a program be fairly balanced?" (Kass, 2001).

In focusing on the principles introduced in questions 1, 3, 5, and 6, it becomes obvious how they demonstrate the values and positive obligations of health care to the public. Question 1 addresses the motive behind the policy, and as Kass states, the goal for public health is not always seeking to solely reduce morbidity and mortality in every intervention. This goal aligns the health of the public and the individual. For example, an applicable intervention to the issue at hand is education (Kass, 2001). The intention behind education is to inform the public so that they understand the reasoning behind physicians making paternalistic decisions so that it no longer seems 'paternalistic.' Even if it is in the best interest of the child to not prescribe antibiotics, if the parent demands them, it is considered against the will of the surrogate decision maker and is then paternalistic. But, if a better education of AOM and risks of unnecessary antibiotic use were well presented, it would become clear that unnecessary antibiotic use is detrimental to the patient. This would likely allow the parent to see the benefits of having the child not consume antibiotics, and they would be able to make the decision willingly against the

prescription (at least right away, in watchful waiting decisions). The effectiveness of the program is already accounted for in weighing the cost and benefits.

Kass defines 3 categories of ethical burdens; risks to privacy, risks to liberty and self-determination, and risks to justice (Have et al., 2010). Risks to liberty and self-determination are the most prevalent in antibiotic prescribing for AOM in pediatric patients. Kass differentiates between a restriction of personal liberty to protect the individual, and a restriction of personal liberty to protect another individual, or multiple individuals. Because a patient or decision maker cannot ask for and receive a treatment that would be harmful to the child, there is no infringement on a decision-making right. If watchful waiting (the protocol in which an observational period is supposed to be utilized before antibiotics are consumed) is implemented, the physician will be assured that they made the proper decision. In waiting, it will be revealed that either the child did not need unnecessary antibiotics, or the infection progressed to a point where antibiotics may benefit the child. There is no infringement on any personal liberty. Restriction of antibiotic prescribing protects the health of the public for future use of antibiotic agents, and it protects the health of the child, in terms of their immune system, digestive system, metabolism, and even nervous system. In the case of antibiotic resistance, it is important to consider the importance; though it may seem insensitive for a physician to refuse prescribing an antibiotic initially when they do not see it fit, they would never, with sound judgement, refuse to prescribe in a situation where the patient is at a great risk or in medical danger. The goal is not to make antibiotics obsolete, only used in rare cases, and impose undue burdens on patients, but rather to restrict use to be *more* conservative.

Nancy Kass argues that public health has a duty to aid in balancing societal injustices. In this case, the largest societal injustice comes within the duty of the parent to the child, and the parent's role in society. Imagine a scenario in which a child is diagnosed with acute otitis media, with severe otalgia. The child is home from school, and miserable with pain, thus causing a parent, with duties as the caretaker of the child to remain at home as well, and to handle the child's pain. When watchful waiting is advised by the health provider, it is crucial that some sort of action is recommended to the parent, whether it be analgesics or homeopathic treatment to ensure that the child is relieved of pain, and the guardian is also relieved of possible guilt that could ensue after watching their child tolerate pain.

Finally, question 6 addresses the burdens and benefits which need to be balanced. Unfortunately for employed parents, it is difficult to be absent from work in the event of an ill child. But watchful waiting procedures could be changed so that the parent does not obtain the prescription directly after the office visit, but only after the observation period is expired, if the child has not improved or if their condition has worsened (Marks, 2020). I assume that the worry of the parent in this instance would be difficulty of contacting the physician's office again. Because of this, in order to minimize the burdens as question 4 suggests, the protocol must include a phone extension to reach a nurse who has access to and is privy to the case of the child diagnosed with suspected AOM in the event that the infection does not self-resolve. They would then be able to give the antibiotic prescription.

Nancy Kass's question-based framework is most useful for weighing the burdens and benefits of the decision, with regard to injustices to the patient, parent, and physician.

Though it speaks of burdens being minimized and a fair balance with questions, it does not explicitly state the implementation of a program that is least restrictive as a principle, nor does it speak of a reciprocity principle as Ross Upshur's does.

2. ROSS UPSHUR

Ross Upshur introduces four principles that justify public health intervention. He cites that Gostin differentiates between three types of ethics relating directly to public health; the ethics *of* public health, which are concerned with the trust that a physician is acting in the common good, ethics *in* public health, which deals with moral standings and tradeoffs between moral merits including those of clinical ethics, and ethics *for* public health, in which the main consideration is the value of health itself and prioritizes the interests of populations (Gostin in Upshur, 2002). While these three types all hold true, a physician acts with the health of his or her patient at the fore, and though it may benefit the public, that is not their duty to act upon.

These principles are the harm principle, the principle of least restrictive means, the reciprocity principle, and the transparency principle. The harm principle is stated by John Stuart Mill saying "The only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant" (Mill in Upshur, 2002). I disagree with this principle, as I believe, in the case of restriction of antibiotics, it is sufficient warrant for the good of the *patient* to be a limiting factor of a decision, while also acting with the good of the public. Paternalism is invoked in these situations when the parent demands a medically unwarranted treatment that would harm the child, and the physician may make a decision to not prescribe against the parents will. Because medicine and public health are acting in accordance with each other in this situation, the restriction acts beneficently for both entities.

The principle of least restrictive means states that the full power of the overarching authority should not be used except in extreme circumstances. “Education, facilitation, and discussion should precede interdiction regulation or incarceration” (Upshur, 2002). In the case of AOM, the healthcare industry along with organizations like the CDC have attempted to increase education and discussion, and health care providers have, assumingly, attempted to facilitate conversations that are considered ‘shared decision making.’ But this facilitation does not give enough authoritative power to the physician. The physician must use paternalistic means of care and treatment for minors with suspected AOM because of the failure to reduce antibiotic use in unnecessary situations. This use of paternalism and modified watchful waiting is the least restrictive means to restrict antibiotics, with the most restrictive being the mandating of antibiotics prescribing, which would significantly inhibit the physician’s right to exercise his judgement on a case by case basis. This would be a scenario like *Jacobson vs Massachusetts*, having been the most cited public health case in history, the findings of that case would need to be applied in an extreme scenario of the legal restriction of antibiotic prescribing. The court ruled in favor of the state and against the individual, Jacobson. The court set forth four guideposts to govern state police power. Police power is defined as “The fundamental right of a government to make all necessary laws. In the United States, state police power comes from the Tenth Amendment to the Constitution, which gives states the rights and powers ‘not delegated to the United States.’ States are thus granted the power to establish and enforce laws protecting the welfare, safety, and health of the public” (Legal Information Institute, n.d.) These four established standards are necessity, reasonable means, proportionality, and harm avoidance (Gostin, 2005). These state that the powers must not be arbitrary and must be based on a real threat. The actions must be sensible in ameliorating the danger, and it must not overreach too

invasively into personal autonomy. Finally, the power itself should not do any harm (Gostin, 2005). These findings are relevant because they would likely be the standards used if it became necessary to strictly mandate antibiotics.

Upshur also introduces the reciprocity principle, which, while similar to Kass's values expressed in question four in which she uses a question to ensure that the burdens should be minimized is more explicit and applicable to this scenario. This deals with the relationship between the parent or guardian of the minor and the public health agency. In the case of AOM, since the goals of medicine and public health are in synergy, the physician would act on behalf of public health as well as medicine. This is a duty-based principle that places an obligation on the providers to aid in the compliance of the ethical burden that may have been placed on the parent or guardian. When antibiotics are not immediately prescribed, the three largest costs that come to the parent are additional monetary costs of the analgesic or homeopathic remedy, time off from work, and the burden of trying to contact the physician's office again after the time spent waiting, should there be no improvement of the symptoms of AOM.

In weighing the burdens and benefits of the analgesic prescription, it seems that most parents would choose to relieve the suffering of their child, especially with data presented earlier indicating that in most cases where an antibiotic is prescribed, the pain is not relieved within the coming 24 hours (Venekamp et al., 2015). A study published in 2017 found that, considering the benefits of watchful waiting for the patient and the public, watchful waiting reduced health expenditures and was deemed cost effective (Sun et al., 2017). Sun et al. used incremental cost-effectiveness ratios (ICER) expressed in USD per disability-adjusted life year (DALY). They concluded, with their model using watchful waiting, that for every 1000 patients diagnosed with AOM, antibiotic prescriptions were decreased by 514 initially, and 205 fewer overall. This

resulted in decreasing the scenario by 14.3 DALYs and saved \$5573. They also stated that with AOM being a large burden regarding resources, one child with AOM can increase outpatient health care costs by \$314, increase office visits by 2, and increase prescription refills by 1.6x. The calculated cost of antibiotics was found to be \$54.67, a follow up was \$35, and analgesics without antibiotics was \$3.10. The cost of a day's work lost for the parent when antibiotics were immediately prescribed was found to be \$196.56, a day's work lost without antibiotics was \$63.78, and a day's work lost with watchful waiting \$34.99 (Sun et al., 2017). These costs were predicted using research literature, Medicaid data, and institutional costs (Sun et al., 2017). These findings are important to show the effectiveness of watchful waiting protocol as it is in place today, especially for anyone who may oppose watchful waiting.

In light of this information, the burden on the patient's guardian can further be reduced by ensuring a direct line to a health care provider that would have knowledge of the patient and be able to write a prescription for the antibiotics at that time. This would further level the reciprocity between the physician and the parent.

The final principle of Upshur's model is the transparency principle, which would ensure that all stakeholders are, in some way, though possibly very minimally, involved in the decision-making process, and that the process should proceed free of political influence and coercion (Upshur, 2002). In cases where paternalistic decisions need to be used, the parent does not have a large part in making any treatment decisions. The child has no legal right to make any decisions. By focusing on the medical care of the patient, the physician can be free from coercion by the parent's demands to restrict antibiotic prescribing, even though it second-handedly benefits the public as well.

The principle of least restrictive means, the reciprocity principle, and the transparency principle are the most important and applicable to this situation. I do not agree with the use of the harm principle here, because both medical ethics and public health ethics warrant this restriction of prescribing, therefore, the public health does not need to be prioritized over the health of the patient. While Upshur speaks about the relationship between the patient and the public, he does not speak about the relationship to the environment or mention the clear link due to interdependence of patient, public, and environment. The American Public Health Society does this.

3. AMERICAN PUBLIC HEALTH ASSOCIATION'S PUBLIC HEALTH CODE OF ETHICS

The American Public Health Association is an organization which aims to improve the health of the public by using their broad community of members and their advocacy with their influence on the federal government (APHA, n.d.). The most notable “core value” described by the APHA to my argument is Interdependence. “Public health practitioners and organizations have an ethical obligation to foster positive—and mitigate negative—relationships among individuals, societies, and environments in ways that protect and promote the flourishing of humans, communities, nonhuman animals, and the ecologies in which they live” (APHA, 2019). This code of ethics was adopted from a previously published code by the Public Health Leadership Society and has been absorbed by the APHA. But I believe the original code of ethics presents the argument for interdependence as a principle more explicitly in the following three principles:

“2. Public health should achieve community health in a way that respects the rights of individuals in the community.

9. Public health programs and policies should be implemented in a manner that most enhances the physical and social environment.

12. Public health institutions and their employees should engage in collaborations and affiliations in ways that build the public’s trust and the institution’s effectiveness. (Thomas et al., 2002).

The most crucial belief for the argument of antibiotic prescribing paternalism that is articulated clearly in this code of ethics is the concept of interdependence. Paternalism is the physician acting against the will of the parent for the patient, but to benefit the patient. By benefitting the patient’s health, their network of humans that they come into contact with is benefitted. This explains that all humans, through their relationships whether they be known in familial ways or lesser known in the sense of a community as a whole. Stephens et al. describes interdependence interestingly as the complement to autonomy, and it is emphasized in the second principle on the individual level, the ninth principle with relation to the environment, and twelfth principle of the code on an institutional level (Thomas et al., 2002).

Their relationship between autonomy and interdependence is thought provoking, in that autonomy is an ungrounded gift that we actually do not have a bounded right to. There is no denying that we are all connected, especially with biological science now on this side of the aisle. Though the patient is a minor and thus has no autonomy, and also has no warranted right to medically futile treatment, there is another sense of autonomy. The interdependence of humans also implies that when someone consumes antibiotics, people around them who have not consented to the effects of antibiotics are also impacted secondarily. Thus, the autonomy of surrounding humans is impacted. This raises implications for relational autonomy, which states

that we are not rational actors who are free from influence of other people. Megan Wright states that “patients want physicians to respect their values and not be overly paternalistic, but they also want physicians to assist with their decision-making” (Wright, 2017). We form an idea of ourselves through interactions with others, it only makes sense that we then make decisions in conjunction with influence of others. This includes physicians, family members, and the surrounding community. In the case of pediatric AOM, the child him/herself and the condition the child is in impacts the decision that the parent makes.

But, many times, autonomy is an illusion. Humans as patients are provided with the sense of agency to make decisions based on their own self-interest, yet we are constrained by a number of biases, most of which we are psychologically unaware of. In the case of ‘informed consent,’ where a patient or surrogate decision maker believes that they are making a decision, many times it would be more accurate to coin it ‘informed enough consent.’ (Wright, 2017, Wright, 2020). At that point in time, a patient does not have the breadth of knowledge or expertise of the pediatrician who is equipped to make a judgement based on clinical training and clinical guidelines. By having the opportunity to feel as though they are making a decision based on the information that has been provided to them, a patient or decision maker feels empowered and respected as an individual with rights. In this case, there is no place for the demand of antibiotics, as they are unnecessary in most cases. They do have the choice to use pain treatments or natural/homeopathic remedies. If antibiotic resistance continues to progress to a world where infections run rampant with no way of controlling outbreaks, we would likely lose all sense of autonomy and any right to consent in all aspects of healthcare.

These same sentiments hold true with respect to our relationship to the environment. The abuse of a powerful medical tool is constantly affecting the natural world in which we live. Not

only does this affect natural ecosystems, but cyclically returns to impact humans in ways that are still being discovered today.

The ethic of trust is presented by the APHA to ensure that physicians or public health agencies disclose necessary information, such as conflicts of interest, so that individuals are assured that health decisions are made free of coercion (APHA, 2019). Reciprocity is also acknowledged by the APHA, stating that it should be used as a guide in ethical decision making, but it is not in the Code of Ethics itself. The APHA argues “reciprocity obligates us to relieve, as much as reasonable, the burdens of adhering to public health policy” (APHA, 2019), meaning that in the case of pediatric AOM, the physician has an obligation to cooperate with the patient and parent to ensure that, when watchful waiting is used, the risk of the parent having any trouble obtaining the prescription if necessary is minimized.

4. NUFFIELD

The Nuffield stewardship model is concerned with valuing the individuality of persons and restricting infringement on these rights to only limitations that greatly increase the benefits to the public in an inverse relationship. This model does not hold true that the state “has the duty to enable” citizens leading healthy lives, while still aiming for the citizens to have healthy outcomes (Have et al., 2010). An example of a goal that would be supported by this model includes banning smoking in public places to minimize risk and maximize the health of society (Have et al., 2010).

“Concerning goals, public health programmes should:

- aim to reduce the risks of ill health that people might impose on each other;

- aim to reduce causes of ill health by regulations that ensure environmental conditions that sustain good health, such as the provision of clean air and water, safe food and decent housing;
- pay special attention to the health of children and other vulnerable people;
- promote health not only by providing information and advice, but also with programmes to help people to overcome addictions and other unhealthy behaviours;
- aim to ensure that it is easy for people to lead a healthy life, for example by providing convenient and safe opportunities for exercise;
- ensure that people have appropriate access to medical services; and
- aim to reduce unfair health inequalities” (Nuffield, 2007).

This model calls for special attention to children, which in the case of AOM and unwarranted antibiotics treatments is especially important. The effects that antibiotics can have on children can cause health ailments for the rest of their lives, and they are left vulnerable to surrogate decision making, with only hopes that the parent and physician have their best interest in mind. This model also prioritizes the environment and its impacts on humans, as well as the impact of human to human interaction, which briefly echoes interdependence. But what I find to be most important is their stewardship model.

The Nuffield stewardship model relies on an ‘intervention ladder’ in which increasing degrees of intervention are described, ranging from eliminate choice, restrict choice, guide choice through disincentives, guide choice through incentives, guide choices through changing the default policy, enable choice, provide information, do nothing or simply monitor the current situation “ (Have et al., 2010). At this point in time, this proposed solution would call for a balance between the elimination of choice and the restriction of choice. When the physician sees

that there is no benefit to prescribing antibiotics, there would be no shared decision making, and no choice. In watchful waiting, the physician disincentivizes the use of antibiotics by off putting the consumption until there is more evidence that they are necessary. The patient or the parent of the patient still has the option to have the child consume the antibiotics. They do not get the prescription until the waiting period has expired. The point of the program is to have the child only consume the antibiotics if they do not improve with time. Information is also to be provided, but that is not the sole intervention.

The Nuffield model acts by placing stewardship as an important aspect of both individual people and to society. The health-outcome-focused approach relies on being cost free and convenient, with no coercion from the state (Nuffield, 2007). This depends upon a certain degree of paternalism. There are many degrees of paternalism, with the most basic form defined as “interference of a state or an individual with another person, against their will, and justified by a claim that the person interfered with will be better off or protected from harm” (Nuffield, 2007). Weak paternalism advocates interference when people think their decision will result in beneficial ends, but they are incorrect and they may actually be harmed (Dworkin, 2002). A strong paternalism believes that people may have misinterpreted the consequences, and they need to have the decision made for them (Dworkin, 2002). The Nuffield model is strictly in opposition to coercion. So, it must be the case that a middle ground is found between hard paternalism and libertarian paternalism, where judgements on health are gently suggested, yet individuals can opt out (Nuffield, 2007). Nuffield raises the point that there are suggestions of a more lenient idea of paternalism to be applied. The solution is weak paternalism. Weak paternalism would say that parents of patients want the child with AOM to be healthy and

relieved of suffering, and they think antibiotics will help them achieve that. But they are wrong, so the physician will refrain from prescribing. This is exactly what I believe to be the case, and thus advocate for weak paternalism. The application of the stewardship model is now prevalent in organizations dealing with antibiotics, and is defined as “judiciously limiting antibiotic use to appropriate regimens, doses, durations, and administrations “ (Infectious Diseases Society of America in MacGeorge et al., 2017), since AOM is a large target for antibiotic reduction. Vaz et al. concluded that “any additional decline in antibiotic rates will likely be driven by changes in diagnosis and management of this common infection” (Vaz et al., in MacGeorge et al., 2017). A particular goal is to optimize antibiotic use in hospitals and outpatient centers while paying special attention to reduce contaminations, optimizing the dosage and choice of prescriptions, using attentive diagnostics in infections such as AOM, where uncertainty exists, and using clinical follow ups, otherwise known as watchful waiting (Le Saux, 2014).

Conclusion

This chapter has introduced four public health ethics frameworks that are mostly fit to address this situation. My recommendation calls for a cut and paste model of these frameworks to create one that is specific to examine the ethical decision to restrict the prescribing of antibiotics for pediatric patients with acute otitis media.

This model would be a principlism model which is based on the ideas of the questions, principles, and aspects of a code described. It would include weighing the burdens and benefits of the decision for each patient by the physician, which also would benefit public health (included in Kass’s framework), using the principle of least restriction (included in Upshur and similar to the intervention ladder of Nuffield), the reciprocity principle (Upshur), the

transparency principle (Upshur's principle and the ethic of trust by the APHA), the interdependence principles (principles 2, 9, and 12 in Public Health Leadership Society, and principle of the American Public Health Association), the focus on children and other vulnerable populations, and the stewardship model (Nuffield). Using these principles, considerations, and models would allow the physician to focus on their duty to the patient, while also effectively addressing the public health crisis of antibiotic resistance.

The model of principles would be as follows

1. The benefits and the burdens of the proposed public health restriction must be considered and balanced. This must be done in each medical case, by the physician, and in the wider implication for the health of the public, by a public health institution. In cases where public health goals and medical goals align, the physician may act on behalf of both public health and medicine.
2. The program must be implemented with the least restrictive means for each individual so that the burdens of the program are kept to a minimum. It should not require forceful authority to meet a public health goal. The highest degrees of intervention are reserved for the greatest threats to public health.
3. The reciprocity between public health and the public must be considered. There must be an equal and reciprocal relationship which assist the individual in complying with the public health goals.
4. Public health agents and those acting on behalf of public health (such as physicians), must be transparent in their methods and decisions, and disclose any conflict of interest that may undermine their efforts to preserve the health of the

public. This ensures that members of society trust those acting on behalf of their health

5. It must be considered that all humans, aspects of the environment, and industries of public health are linked interdependently. Because of this, all decisions made by human or industry must be made with the impact that they have on all three aspects in mind.
6. Children and vulnerable populations who are not able to make sound decisions on their own must be considered especially.
7. Stewardship must be considered to a high degree when dealing with allocation of limited resources. Public health and medicine are tasked with the preservation of these resources to maintain their viability.

Chapter 5

The Solution

The overarching question that must be addressed in this solution is to find what the scientifically and ethically sound methods of addressing otitis media are. While doing this, the goal must be to reduce the volume of antibiotics prescribed, while keeping in mind the health of the child and that the network of interconnectedness is insured. From the ethical frameworks examined in the previous chapters I have created a framework of ethical principles, that draws influences from segments of Nancy Kass's six questions, Upshur's principlism model, the Public Health Leadership Society's principlism model in conjunction with the American Public Health Association's Code of Ethics, and Nuffield's stewardship model may be particularly useful in answering the aforementioned question. When principles are referenced, they are referring to those of the model that I have proposed at the end of Chapter 4.

THE MEDICAL PROFESSION

The medical profession must adapt the most of all the situation's stakeholders in order to achieve an ethical solution to restrict antibiotic prescribing. These adaptations must then be put into practice by physicians. The Clinical Practice Guidelines, as introduced in Chapter 1, are updated regularly with input from a group of practicing physicians. I feel they need to be updated to become more stringent, and it is particularly necessary to remove shared decision making from the guidelines. In the guidelines, it is outlined when shared decision making should be used, but parents should not be tasked with making medical decisions based on the amount of information that they are presented with during the office visit with the physician (Lieberthal et al., 2013). The physician alone should decide: a.) whether antibiotics are necessary, based on the

severity of the infection and b.) in cases where they believe antibiotics are necessary, if they will prescribe them immediately, or use an observational period known as watchful waiting. The medical profession is tasked with weighing the burdens and benefits of the situation (Principle 1. Balance the burdens and benefits). This also implores implementation of the least restrictive means to reduce the volume of antibiotics prescriptions (Principle 2. Least restrictive means).

The watchful waiting procedure as it exists today must be changed. This would be the duty of the medical profession to ensure that the protocol is put into place to streamline the process. In conversation with me, Jonathan Marks proposed that in a circumstance where watchful waiting is used, the physician might not give the parent and patient the script for antibiotics, but rather would task a nurse to call the parent after a set observational period to follow up regarding the medical condition of the child, and to give the prescription for antibiotics if there is no improvement (Marks, 2020). While I agree that the parent should not be given the script immediately, I disagree with assigning the nurse the duty of calling the parent. This is for two reasons. First, so many AOM infections resolve on their own, it is very likely that the infection is beginning to or has resolved on its own. Second, it would be very difficult to implement because the nurse must find time in the busy schedule of their profession to add another time-consuming job.

The time conflict is a major issue in medicine. Physicians are expected to see a huge number of patients each day. This expectance is embedded in a conflict of commitment. Education programs, such as those that will be introduced in the following paragraph, could allow for more flexibility by beginning the education as soon as they walk into the office or hospital. Visual education materials, items for parents to read, and nurse education are all

methods which can relieve the pressure of the doctor to start and finish the education in a short office visit.

Many hospitals have implemented and had success with antimicrobial stewardship programs. The Johns Hopkins Hospital Antimicrobial Stewardship Program, established in 2001, expresses their mission “to ensure that every patient at The Johns Hopkins Hospital who needs antimicrobial therapy gets optimal drug choice, dose, duration and route of administration while minimizing resistance development and toxicity” (Hopkins Medicine, n.d.). With this program in place, they have developed a conglomeration of research projects relating to resistance, including PAUSE, which focuses on preventing antibiotic overuse. They have created presentations for medical professionals, in accordance with CDC guidelines, to educate professionals on diagnosis of common ailments such as pneumonia that include definitive indications of infection, common misconceptions, and statistics of improper antibiotic use that can be shocking to those who see pneumonia and antibiotic use as mundane, run of the mill topics. They have also created an algorithm dictating when to collect bacterial cultures, and thus, help to create opportunities for professionals, mostly nurses who become antibiotics stewards (Hopkins Medicine, n.d.). In doing so, education would be more widely spread, and this could lead to incentives for hospitals and physician groups to develop programs that could increase patient satisfaction and feelings of relief for parents of patients that their physician is part of a national initiative for responsible prescribing. This is entailed by the 7th principle of the created framework, which stresses the importance of stewardship in public health situations such as the antibiotic resistance crisis (Principle 7. Stewardship).

The American Medical Association has partnered with the CDC on the *Get Smart* campaign, which offers information about antibiotics and when they are appropriate (American Medical Association, 2015), but the program is not widely implemented. Implementation of this program, which offers educational resources, along with stewardship programs in hospitals and outpatient centers would increase the effectiveness of both programs.

THE PHYSICIAN

The duty of the physician in this scenario is to first do no harm, and by following the American Medical Association's Code of Ethics and adhering to the Hippocratic oath, they are agreeing to practice in an ethically sound manner with the individual pediatric patient having the utmost importance to them. In Beauchamp and Childress's model of principlism, all four principles of biomedical ethics are *prima facie*,¹ meaning that they are each binding unless one principle conflicts with another (Gillon, 1994). Cases such as pediatric AOM are unique situations in which the pediatric patients themselves do not have autonomy, and it is the parent or guardian who makes the decision. I argue that beneficence and nonmaleficence are the most important medical ethics principles that the physician must have in mind in this situation.

In applying these two principles by Beauchamp and Childress, the physician considers the health and wellness of the patient, regardless of what the parent may express, including disdain toward the physician. The gravity of the AOM infection and the patient's health in the future are of foremost importance, and their impact on the world around them as an integrated

¹ In contrast, autonomy is held to a higher degree than other principles in many medical decision-making processes of Western practices (Varelius, 2006)

part of society is included in this consideration as a positive ethical by-product. Understanding these aspects, the physician must consider the stringent policies for antibiotic prescriptions as described in the Clinical Practice Guidelines. These guidelines very explicitly outline the necessity of antibiotics in certain situations and when the decision is left to be decided by the medical professional. But they must be amended to no longer include shared decision making, which is an action for the greater medical profession.

In situations where antibiotics prescriptions are not explicitly recommended, it is recommended that shared decision making is no longer used. Watchful waiting must be prescribed along with a prescription for a low dose NSAID (non-steroidal anti-inflammatory drug) to aid in pain relief for the child and ease the mind of the parent or guardian. In some cases, if the physician supports the evidence, homeopathic or natural remedies may be recommended. In a study by Sun et al., results showed 231 patients, 93.5%, received an antibiotic prescription, but 143 of those patients, 57.9%, qualified for watchful waiting (Sun et al., 2017). The communication between the physician and patient is made more difficult by adding the third person, the parent or guardian. Because of this, the physician is tasked with being increasingly empathetic and increasingly explanatory of the condition (AOM), the treatment (watchful waiting), and why he or she does not advocate for antibiotics initially. They must do so using terminology that is easily accessible and understandable and leave room to welcome questions and concerns. Reassurance of the physician's peak concern for the wellbeing of the child could comfort the parent/guardian and lead to a more satisfied attitude following the visit. This is so that the physician is transparent and able to be trusted (Principle 4. Transparency). They cannot hide any conflict of interest that may undermine their decisions to preserve the health of the child, including financial ties to the pharmaceutical industry.

Because the guidelines state factually when antibiotics should be prescribed in order to reduce risk of further infection complications, by default, when the decision is made for watchful waiting, it would be very unlikely that the patient's condition progress severely to a state that would be more serious than AOM in the following few days of observation. This is already accounted for in the guidelines and the physician would see the necessity of the treatment at the time of examination. It would be very likely that the condition either begins to resolve on its own (no antibiotics necessary), or progresses minorly, in which case the parent would obtain the antibiotic prescription. It is crucial that at this point, the physician must express the consequences of antibiotic use at a critical developmental stage in the child's life, citing some of the risks that have been explained in the previous chapters. The parent will care primarily about the wellbeing of the child, their future, and their relief of pain at that time, and not about the health state of the public. It is not beneficial to express the concern of the public health antibiotic resistance crisis to the parent or patient, although it is implied. This could stir emotions and cause concern for the motive of the physician's decision. The decision is simply beneficial in multifaceted aspects. Because of this, there is no shared decision making, but education is of the utmost importance. (Principle 5. Interdependence). Though not explicitly expressed, the physician is acting with interest of all humans as well as the environment's best interest in mind.

Following the diagnosis and education, it must be explained to the patient and the system must be implemented that a nurse be made aware of the child's case and examination so that a parent or guardian has a direct line to a nurse who will be able to send a prescription for the antibiotics after the specified time period has passed for observation in the event that there is no improvement. This deals with reciprocity, which ensures that the parent is able to easily contact

with the physician's office and obtain the prescription for antibiotics if necessary (Principle 3. Reciprocity). Pediatricians, specifically, are tasked with being advocates for the health of their patients. Children must be paid special attention to, because of their vulnerability (Principle 6. Attention to children). They cannot make decisions for themselves, so they must rely on their parent or guardian to make the proper decision. In many cases, such as those where the parent demands unwarranted antibiotics, the parents fail to do so. The child resorts to reliance on the physician to keep their best interest as the most important aspect of their decision-making process.

Four of the proposed principles must be considered by the physician: 3. Reciprocity, 4. Transparency, 5. Interdependence, and 6. Special attention for children in decision making.

THE PARENT OR GUARDIAN

The parent or guardian of the child holds all decision-making power, legally deeming them the surrogate decision maker. In scenarios such as this one, it is understandable that emotions hold a huge stake in the discriminatory power of the parent. They want what is best for their child. They don't want them to be in pain, nor do they want them to be forced to endure awful side effects. On a more parent-centered note, many times, they do not want to be forced to miss a day of work. But many times, the wellness of the child is prioritized over their own personal wellbeing, attributing it to be a duty of parenthood. It is important that parents understand all the risks associated with antibiotic use that could impact their child for years to come, and also impact all forms of life that the child can come into contact with, whether directly, such as brothers, sisters, and classmates, or indirectly spread through air and water. It is

crucial that the physicians do their best to stress the fact that in the case of this child, antibiotics would be doing more harm than good.

Having a streamlined protocol in place for watchful waiting, this process would account for less annoyance for the parents being placed on hold and explaining the situation multiple times on the phone. For example, the process would ideally be as follows; a patient is diagnosed with AOM but prescribed to watch and wait. This would all be explained to the parent, and they would be given a direct extension to the phone nurse who would be able to do this for them. Parents should be encouraged to ask questions about antibiotics and ear infections, and there should be more information on this available as extra reading material from the pediatrician's office. Explicit education and directions are keys for success in allowing parents to express their emotional concerns as they are directed to the right decision which is based in science.

In one study, anonymous surveys were distributed to German parents of children between 2 and 7 years of age who attend a childcare facility. This study shows the margins where education can be beneficial for parents. Their findings are listed in the figure below (Kautz-Freimuth et al., 2015).

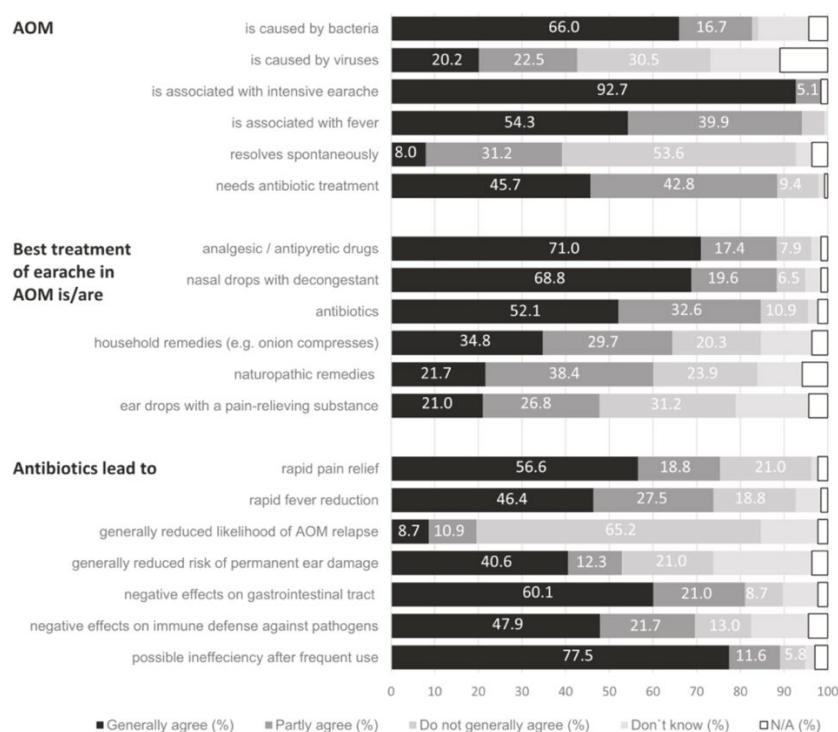


Figure 3. Parental views (n=138) on various aspects of AOM including treatments and effects of antibiotics in a German study conducted by Kautz-Freimuth et al., in 2015 (Kautz-Freimuth et al., 2015).

THE PHARMACEUTICAL INDUSTRY

The ethical duties of the pharmaceutical industry begin with more education. It is important for this industry to act on this crisis, because as time continues and the number of types of bacteria that have developed antibiotic resistance increase, the less effective their product becomes. If this continues as it is now, it is only a matter of time before there are no antibiotics that treat infections such as AOM. Even with new developments on novel antibiotics, the habits of over-prescribing and the lack of public knowledge will continue to burn through antibiotics stores. McCoy et al., in the article published in 2011 in *US Pharmacist* cites three reasons for the lacking development of new antibiotics; 1. lack of incentive due to the small number of units prescribed for a small number of days, 2. tendency for prescribers to save *new* antibiotics as last resort for bacterial infections and finally, 3. difficulty of conducting antibiotic

clinical trials (McCoy et al., 2011). Since the time of this article's publication, some advancements have been made, but certainly not enough to combat the crisis. All of these factors lead to low profit for pharmaceutical companies. The alternative of complete loss of profit due to ineffectiveness needs to be realized. The pharmaceutical industry is reputable for creating conflicts of interest, and because of this, the conflicts that are created must be transparent to preserve the trust that individuals place in physicians who prescribe the drugs pharmaceutical companies promote (Principle 4. Transparency).

PHARMACISTS

For this reason, pharmacists are also tasked with continuing their education program. This would cause pharmacists to reinforce the ideas that patients or parents of patients have already heard from their physician or provider. These stewardship initiatives are important for the preservation of antibiotics (Principle 7. Stewardship). Sara Cosgrove, MD, MS, Director of the Antimicrobial Stewardship Program at Johns Hopkins Hospital, is quoted "A pharmacist should work with the stewardship physician to get recommendations across and to make decisions about program priorities, as well as serve as a critical bridge to the pharmacy department. There are many pharmacists who aren't used to doing interventions and communicating directly with physicians, but the field needs to move in this direction," (Cosgrove in Collins, 2012). During counseling, the pharmacist should express the concern of proper use, possible side effects, long term side effects, and contribution to antibiotic resistance. This would only offer another line of defense, and also coincide with a collaboration between physician and pharmacist. As it exists in the timeline, the patient will already be in possession of the drug.

THE GOVERNMENT

It is crucial that the government provides funding for implementation of antibiotic stewardship programs (Principle 7. Stewardship). Primarily, the government can provide payments as an incentive for hospitals to implement these programs, such as the one that is used at Johns Hopkins (Hopkins Medicine, n.d.). Secondly, the hospitals can be rewarded for showing success with the programs. This would also be beneficial for the hospitals to collect data on antibiotic prescribing, not only for research, but to provide a sense of watchfulness over the prescribers. The physicians can then be awarded a higher pay for education of patients with AOM and antibiotics. In theory, an incentive program such as this could resemble Medicare and Medicaid programs that offer incentives for physicians to shift to electronic health record (EHR) technology (Kibbe, 2009). While this would be a Pay-for-Performance program, allowing the program to be developed alongside physicians with their widespread knowledge of the problem in the medical realm, would only enhance the acceptance of quality medicine. Implementation of a program such as this could standardize education that is offered to patients and parents of pediatric patients, leading to presentation of more complete and reinforced information, which could result in better patient satisfaction ratings for physicians.

A five-year plan has been developed by a government council titled PACCARB, Presidential Advisory Council Combating Antibiotic Resistant Bacteria, beginning in 2015, following an executive order, and including a milestone road map. The council includes members from Agriculture, Pharmacy, Biomedicine, Public Health, Veterinary Health, Healthcare, and Epidemiology (CDC, 2020b). This range of members from different background implies that the government realizes the importance of interdependence (Principle 5. Interdependence). The five goals for five years include slowing emergence and preventing

spread of resistance, strengthening ‘one-health’ surveillance, and accelerate research for new antibiotics as well as other therapeutics (American Medical Association, 2015).

These goals were announced as an executive order in 2015, reinforced in 2017 (CDC, 2019b). The government and the CDC have worked together on multiple projects including hosting and attending international forums, sequencing genomes of ARBs, and have strengthened surveillance efforts (CDC, 2019c). New antibiotics are being developed (CDC, 2019a), and international collaboration is in place (CDC, 2019c). Because of this, I believe incentives for adopting and having successful stewardship programs would be supported by the government, the medical profession, and physicians. While these initiatives are likely raising awareness and helping to fund research critical to antibiotic resistance, I believe the largest changes will be seen at more local levels, with education in hospitals and outpatient centers by physicians and medical professionals, who are the gatekeepers to control the volume of prescriptions.

In those same interactions, reducing prescriptions comes at a more personal level to the patient. These programs target antibiotic resistance education, while they could focus on personal level, educating people on adverse effects of unnecessary antibiotics that can cause no benefit. With this in mind, it is important to understand that antibiotic resistance is only half of the ethical issue being addressed. While it is very pressing to public health, medicine must also uphold its ethics to make sure antibiotics are not being prescribed that contradict a physician's aim to do no harm to the patient. Hospital and outpatient center stewardship programs would focus more on that aspect and what physicians are doing instead of prescribing antibiotics for AOM and similar infections. While it is less likely for allopathic physicians to resort to alternative or

complementary medicine, anecdotal evidence suggests that it is not impossible for them to do so.

The National Center for Complementary and Integrative Health (NCCIH), a branch of the U.S. Department of Health and Human Services, offers grants and research funding for researchers who believe to embrace their three main focuses; mind and body practices, natural products, and pain (NCCIH, 2020). Research on natural remedies for AOM has the potential to be included in that description. Bell and Boyer's analysis, cited in an earlier chapter, was funded by the NCCIH. I believe that there are areas of AOM treatment and prevention that can benefit from extended research that appeals to natural products, as described in Chapter 1. Parents, when presented with the data, would likely agree as well due to lack of risks associated with medication and cost effectiveness of natural products.

Conclusion

The ethical issue presented is twofold; it includes large scale antibiotic resistance, and harmful prescribing of unnecessary antibiotics. While the concept of antibiotic resistance has gained some attention in society, the multi-faceted problems that cause it and are caused by it must be bolstered to increase understanding. With this in mind, the health of children and families are also directly impacted everyday by unnecessary prescriptions of antibiotics. The large number of antibiotic prescriptions is not intended to place blame on physicians, who are fully aware of the resistance crisis, but may be blinded to the fact that they, perhaps unknowingly, can harm the patient by prescribing a drug that would provide no medical gain. By aiding physicians so that the burden of this education is not placed solely on them, they can spend valuable time catering to the needs of the patient in front of them, not any unwarranted demand of a parent. I believe the problem can be repaired most effectively at the level of the interaction; the physician must understand both the effects of antibiotics and when they are necessary. Once this is understood, they will focus on using the amended Clinical Practice Guidelines as a guide, refrain from using shared decision making by using the evolved watchful waiting protocol as often as possible, and work to reduce their prescribing for AOM. This should be incentivized by the government, aided by stewardship programs that increase education in both healthcare institutions and pharmacies.

With this solution as a restriction, the volume of antibiotic prescriptions must decrease, leading to children having fewer long-term health ailments which are rooted in unnecessary antibiotic use. The environment can recover from the bombardment of antibiotics and antibiotic resistant bacteria, and the public and health community can rest assured knowing that something

is being accomplished to preserve the limited supply of this invaluable drug. Without implementation of those restrictions, we can expect to appreciate the depletion of our antibiotic supply and a continued decline of the health of any child who is unknowingly subjected to consumption of antibiotics brought about by forced use on behalf of parents and futile use by the physician.

BIBLIOGRAPHY

- InformedHealth.org. (2006). What are clinical practice guidelines? Cologne, Germany: Institute for Quality and Efficiency in Health Care (IQWiG). Available from: <https://www.ncbi.nlm.nih.gov/books/NBK390308/>
- ABIM American Board of Internal Medicine. (n.d.). The Physician Charter. Accessed <https://abimfoundation.org/what-we-do/physician-charter>
- American Academy of Pediatrics Division of Health and Human Resources. (2012). Executive Summary, Periodic Survey of Fellows #81- Pediatricians Life and Career Experience. *Periodic Survey of Fellows*. Accessed https://www.aap.org/enus/Documents/surveys_periodic81_ES_PLACES.pdf
- American Medical Association. (2016). AMA Principles of Medical Ethics. Accessed <https://www.ama-assn.org/about/publications-newsletters/ama-principles-medical-ethics>
- American Medical Association. (2015). Action of the AMA House of Delegates 2015 Interim Meeting: Council on Science and Public Health Report 3 Recommendations Adopted. Accessed <https://aspe.hhs.gov/pdf-report/national-action-plan-combating-antibiotic-resistant-bacteria-progress-report-years-1-and-2>
- American Public Health Association. (2019). Public Health Code of Ethics.
- American Public Health Association. (n.d.). About APHA. Accessed <https://www.apha.org/about-apha>
- Aminov, R. I. (2010). A brief history of the antibiotic era: Lessons learned and challenges for the future. *Frontiers in Microbiology*. Doi:10.3389/fmicb.2010.00134.
- Assistant Secretary for Health. (2020). Presidential Advisory Council for Combating Antibiotic Resistant Bacteria. Accessed <https://www.hhs.gov/ash/advisory-committees/paccarb/about-paccarb/index.html>
- Australian Government. (2010, August 29). *How antibiotic resistance spreads*. [digital image]. Retrieved from <https://www.amr.gov.au/resources/infographic-how-antibiotic-resistance-can-spread>.
- Baym, M., Stone, L. K., & Kishony, R. (2016). Multidrug evolutionary strategies to reverse antibiotic resistance. *Science*, 351(6268). <https://doi.org/10.1126/science.aad3292>.

- Bell, I. R., Boyer, N. N. (2013). Homeopathic Medications as Clinical Alternatives for Symptomatic Care of Acute Otitis Media and Upper Respiratory Infections in Children. *Glob Adv Health Med.* 2(1). 32-43.
- Beauchamp, T. and Childress, J. (1994). *Principles of Biomedical Ethics*, Fourth Edition. Oxford.
- Beever, J., Moorar, N. (2018). The epistemic and ethical onus of 'One Health'. *International Association of Bioethics.* 33(1). <https://doi-org.ezaccess.libraries.psu.edu/10.1111/bioe.12522>
- Bien, J., Doyle, E., Kenney, B., Jones, E., Siegel, R., Muething, S., Brokaw, B., Lichtenstein, P., Gupta, K., Asmussen, L., Olson, L., (2000). Parental Attitudes about Antibiotics Use for Otitis Media. *American Academy of Pediatrics.* Accessed <https://www.aap.org/en-us/professional-resources/Research/Pages/Parental-Attitudes-about-Antibiotic-use-for-Otitis-Media.aspx>
- Burmeister A. R. (2015). Horizontal Gene Transfer. *Evolution, medicine, and public health*, 2015(1), 193–194. <https://doi.org/10.1093/emph/eov018>
- Canadian Society of Pediatrics. (1998). Antibiotic management of acute otitis media. *Paediatrics & child health*, 3(4), 265–270. <https://doi.org/10.1093/pch/3.4.265>
- CDC. (2020). Antibiotic/Antimicrobial Resistance (AR/AMR): How antibiotic resistance happens. *U.S. Department of Health and Human Services.* Accessed <https://www.cdc.gov/drugresistance/about/how-resistance-happens.html>
- CDC. (2020b). Presidential Advisory Council on Combating Antibiotic- Resistant Bacteria (PACCARB). *U.S. Department of Health and Human Services.* Accessed <https://www.cdc.gov/drugresistance/us-activities/paccarb.html>
- CDC. (2019a). Antibiotic Use in the United States, 2018 Update: Progress and Opportunities. *US Department of Health and Human Services.* Atlanta, Georgia.
- CDC. (2019b). Antibiotic prescribing and use in doctor's offices: Ear Infections. *U.S. Department of Health and Human Services.* Accessed <https://www.cdc.gov/antibiotic-use/community/for-patients/common-illnesses/ear-infection.html>
- CDC. (2019c). US Action to Combat Antibiotic Resistance. *U.S. Department of Health and Human Services.* Accessed https://www.cdc.gov/drugresistance/us-activities.html#anchor_1535643114550
- CDC. (2019d). Antibiotic Resistance and Food Safety. *U.S. Department of Health and Human Services.* Accessed <https://www.cdc.gov/foodsafety/challenges/antibiotic-resistance.html>
- Chonmaitree, T. (2006). Acute Otitis Media is Not a Purely Bacterial Disease. *Clinical Infectious Diseases.* 43(11). 1423–1425. <https://doi.org/10.1086/509329>

- Cohen, B., Liu, J., Cohen, A. R., & Larson, E. (2018). Association Between Healthcare-Associated Infection and Exposure to Hospital Roommates and Previous Bed Occupants with the Same Organism. *Infection control and hospital epidemiology*, 39(5), 541–546. <https://doi.org/10.1017/ice.2018.22>
- Collins, S. (2012). Working to Prevent Antibiotic Resistance. *Pharmacy Today*. (18)7. 7-8.
- Cully, M. (2019). Antibiotics alter the gut microbiome and host health. *Nature Milestones*.
- D'Agostino, F., Gaus, G. and Thrasher, J. (1996). Contemporary Approaches to the Social Contract. *The Stanford Encyclopedia of Philosophy* (Fall 2019 Edition), Edward N. Zalta (ed.), Accessed <<https://plato.stanford.edu/archives/fall2019/entries/contractarianism-contemporary/>>.
- Dworkin, R. (2002). Paternalism, in *Stanford Encyclopedia of Philosophy*, available at: <http://plato.stanford.edu/entries/paternalism/>.
- Elwyn, G., Frosch, D., Thomson, R., Joseph-Williams, N., Lloyd, A., Kinnersley, P., Cording, E., Tomson, D., Dodd, C., Rollnick, S., Edwards, A., & Barry, M. (2012). Shared decision making: a model for clinical practice. *Journal of general internal medicine*, 27(10), 1361–1367. <https://doi.org/10.1007/s11606-012-2077-6>
- Fleming, N., Barber, S., and Ashiru-Oredope, D. (2011). Pharmacists have a critical role in the conservation of effective antibiotics. *The Pharmaceutical Journal*. 287. 465.
- FDA. (2020). Homeopathic Products. U.S. Food and Drug Administration. Accessed <https://www.fda.gov/drugs/information-drug-class/homeopathic-products>
- FDA. (2019). Combating Antibiotic Resistance. U.S. Food and Drug Administration. Accessed <https://www.fda.gov/consumers/consumer-updates/combating-antibiotic-resistance>
- Gillon, R. (1994). Medical Ethics: Four Principles Plus Attention to Scope. *BMJ*. (309)184.
- Gostin, L. O. (2005). *Jacobson v Massachusetts* at 100 Years: Police Power and Civil Liberties in Tension. *American Journal of Public Health*. 95(4).
- Handler, S. (n.d.). Otitis Media with Effusion (OME). Children's Hospital of Pennsylvania. Accessed <https://www.chop.edu/conditions-diseases/otitis-media-effusion-ome>
- Hopkins Medicine. (n.d.). Department of Antimicrobial Stewardship. Accessed <https://www.hopkinsmedicine.org/antimicrobial-stewardship/>
- Institute of Medicine (US) Committee on Conflict of Interest in Medical Research, Education, and Practice. (2009). Conflict of Interest in Medical Research, Education, and Practice. Lo B., Field M.J., (Ed.). Washington DC. National Academies Press (US). Accessed <https://www.ncbi.nlm.nih.gov/books/NBK22926/>

- Kapoor, N., Kumar, D., & Thakur, N. (2014). Core attributes of stewardship; foundation of sound health system. *International journal of health policy and management*, 3(1), 5–6.
<https://doi.org/10.15171/ijhpm.2014.52>
- Kass, N.E. (2001). An ethics framework for public health. *Am J Public Health*. 91(11).1776-1782.
- Kautz-Freimuth, S., Redaelli, M., Samel, C., Civello, D., Altin, S. V., & Stock, S. (2015). Parental views on acute otitis media (AOM) and its therapy in children--results of an exploratory survey in German childcare facilities. *BMC pediatrics*, 15, 199.
<https://doi.org/10.1186/s12887-015-0516-3>
- Kibbe, D. C. (2009). A Physician's Guide to the Medicare and Medicaid EHR Incentive Programs: The Basics. *American Academy of Family Physicians*. Accessed
<https://www.aafp.org/fpm/2010/0900/p17.html>
- Kraemer, S. A., Ramachandran, A., Perron, G. G. (2019). Antibiotic Pollution in the Environment: From Microbial Ecology to Public Policy. *Microorganisms*. 7 (180).
doi:10.3390/microorganisms7060180
- Legal Information Institute. (n.d.). Police Powers. Accessed
https://www.law.cornell.edu/wex/police_powers
- Le Saux, N. (2014). Antibiotic stewardship in daily practice: Managing an important resource. *Canadian Journal of Infectious Diseases and Medical Microbiology*. 25.
<https://doi.org/10.1155/2014/359523>
- Lieberthal, A.S., Carroll, A.E., Chonmaitree, T. ... Tunkel., D. (2013). The diagnosis and management of acute otitis media. *Pediatrics*. 131 (3). 964-999. <https://doi.org/10.1542/peds.2012-3488>
- Li, J., Cao, J., Zhu, Y.-G., Chen, Q.-L., Shen, F., Wu, Y., . . . Yao, M. (2018). Global survey of antibiotic resistance gene in air. *Environmental Science and Technology*, 52(19), 10975-10984.
<https://doi.org/10.1021/acs.est.8b02204>
- MacGeorge, E.L., Caldes, E.P., Smith, R. A., Hackman N.M., & San Jose, A. (2017). Reducing unwarranted antibiotic use for pediatric acute otitis media: the influence of physicians' explanation and instruction on parent compliance with 'watchful waiting', *Journal of Applied Communication Research*, 45(3). 333-345, DOI: [10.1080/00909882.2017.1320575](https://doi.org/10.1080/00909882.2017.1320575)
- Marks, J., (2020). Phone Interview.

- Marom, T., Marchisio, P., Tamir, S. O., Torretta, S., Gavriel, H., & Esposito, S. (2016). Complementary and Alternative Medicine Treatment Options for Otitis Media: A Systematic Review. *Medicine*, 95(6), e2695. <https://doi.org/10.1097/MD.0000000000002695>
- McCoy, D., Toussaint, K., Gallagher, J. C. (2011). The Pharmacist's Role in Preventing Antibiotic Resistance. *U.S. Pharmacist*. 36(7). 42-49. Accessed <https://www.uspharmacist.com/article/the-pharmacists-role-in-preventing-antibiotic-resistance>
- McGrath, L. J., Becker-Dreps, S., Pate, V., & Brookhart, M. A. (2013). Trends in antibiotic treatment of acute otitis media and treatment failure in children, 2000-2011. *PloS one*, 8(12), e81210. <https://doi.org/10.1371/journal.pone.0081210>
- Mekel, M. (2020). Phone Interview.
- Miyamoto, M. (2019). Otitis Media (Acute). Retrieved from Merck Manual, Professional Version website <https://www.merckmanuals.com/professional/ear,-nose,-and-throat-disorders/middle-ear-and-tympanic-membrane-disorders/otitis-media-acute>
- ten Have, M., van der Heide, A., Mackenbach, J.P., de Beaufort, I.D. An ethical framework for the prevention of overweight and obesity: a tool for thinking through a programme's ethical aspects. *European Journal of Public Health*. 23(2). 299–305. <https://doi.org/10.1093/eurpub/cks052>
- National Center for Complementary and Integrative Health. (2020). <https://www.nccih.nih.gov/>
- National Health Service. (2019). Antibiotics. *The National Health Service of the United Kingdom*. Accessed <https://www.nhs.uk/conditions/antibiotics/>
- Neuman, H., Forsythe, P., Uzan, A., Anvi, O., & Koren, O. (2018). Antibiotics in early life: Dysbiosis and the damage done. *FEMS Microbiol Rev*, 42(4), 489-499. <https://doi.org/10.1093/femsre/fuy018>
- Nuffield Council on Bioethics. (2007). Public health: ethical issues. *Nuffield Council on Bioethics*. London, England.
- Porco, T. C., Gao, D., Scott, S.C., Shim, E., Enanoria, W. T., Galvani, A. P., Lietman, T. M. (2012). When Does Overuse of Antibiotics Become a Tragedy of the Commons? *PLoS ONE* 7(12): e46505. doi:10.1371/journal.pone.0046505
- Rosenfeld R.M., Kay D. (2003). Natural History of Untreated Otitis Media. *Laryngoscope*. 113(10):1645–1657. doi: 10.1097/00005537-200310000-00004.
- Ruohola, A., Meurman, O., Nikkari, S., Skottman, T., Salmi, A., Waris, M., Osterback, R., Eerola, E., Allander, T., Niesters, H., Heikkinen, T., Ruuskanen, O. (2006). Microbiology of Acute Otitis Media in Children with Tympanostomy Tubes: Prevalences of Bacteria and Viruses. *Clinical Infectious Diseases*. 43. 1417-22.

- Sanchez, G., Hersh, A., Shapiro, D., Cawley, J., and Hicks., L. (2017). Outpatient Antibiotic Prescribing among United States nurse practitioners and physician assistants. *Open Forum Infectious Diseases*. DOI: 10.1093/ofid/ofw168
- Sarrell, E.M., Mandelberg A., Cohen H.A. (2001). Efficacy of Naturopathic Extracts in the Management of Ear Pain Associated With Acute Otitis Media. *Arch Pediatr Adolesc Med*. 155(7):796–799. doi:10.1001/archpedi.155.7.796
- Schneider, G. W., Winslow, R. (2014). Parts and Wholes: The Human Microbiome, Ecological Ontology, and the Challenges of Community. *Perspectives in Biology and Medicine*. 57(2). 208-223. Johns Hopkins University Press. <https://doi.org/10.1353/pbm.2014.0016>
- Sinha M.N., Siddiqui, V.A., Nayak, C., et al. (2012). Randomized controlled pilot study to compare homeopathy and conventional therapy in acute otitis media. *Homeopathy*. 101(1):5-12.
- Sun, D., McCarthy, T.J., Liberman, D. B. (2017). Cost-Effectiveness of Watchful Waiting in Acute Otitis Media. *Pediatrics*. 139(4). DOI: 10.1542/peds.2016-3086.
- Thomas, J., Sage, M., Dillenberg, J., Guillory, V. (2002). A code of ethics for public health. *American Journal of Public Health*. 92(7).
- University of Amsterdam ComScience. (2017). Alternative Paradigms: Care Ethics and Feminist Ethics. UvA ComScience Microlectures. Accessed <https://www.youtube.com/watch?v=4iaCpAFypq8&t=5s>
- Upshur, R.E.G. (2002). Principles for the justification of public health intervention. *Canadian Journal of Public Health*. 93(2). 101-103.
- Varelius, J. (2006). The value of autonomy in medical ethics. *Medicine, health care, and philosophy*, 9(3), 377–388. <https://doi.org/10.1007/s11019-006-9000-z>
- Venekamp, R.P., Sanders, S.L., Glasziou, P.P., Del Mar, C.B., Rovers, M.M. (2015). Antibiotics for acute otitis media in children. *Cochrane Database of Systematic Reviews*. (6). DOI:10.1002/14651858.CD000219.pub4.
- Weill Cornell Medicine. (2017). What Can Cause Chronic Ear Infections. *Weillcornell.org*. Accessed <https://weillcornell.org/news/what-can-cause-chronic-ear-infections>
- Wellie, J.V.M. (2011). Social Contract Theory as a Foundation of the Social Responsibilities of Health Professionals. *Med Health Care and Philos*. 15:347–355 DOI 10.1007/s11019-011-9355-7
- Wells, A.L. (2004). Reevaluating the Social Contract in American Medicine. *Virtual Mentor*. 6(4). Doi:10.1001/virtualmentor.2004.6.4.oped2-0404

- Werhane, P. and Doering, J. (1996). Conflicts of Interest and Conflicts of Commitment. *Professional Ethics*, 4(3&4): 47–81.
- World Health Organization. (2019a). New report calls for urgent action to avert antimicrobial resistance crisis. Retrieved March 13, 2020, from World Health Organization website: <https://www.who.int/news-room/detail/29-04-2019-new-report-calls-for-urgent-action-to-avert-antimicrobial-resistance-crisis>
- World Health Organization. (2019b). Antibacterial agents in clinical development: an analysis of the antibacterial clinical development pipeline. Geneva. Licence: CC BY-NC-SA 3.0 IGO.
- Wright, M. (2020). Personal Interview. University Park, PA.
- Wright, M. (2017). End of Life and Autonomy: The Case for Relational Nudges in End-of-Life Decision-Making Law and Policy. *Maryland Law Review*. 77, (4) Available at SSRN: <http://dx.doi.org/10.2139/ssrn.3024949>
- Wustrow, T.P. (2004). Alternative Versus Conventional Treatment Strategy in Uncomplicated Acute Otitis Media in Children: A Prospective, Open, Controlled Parallel Group Comparison. *Int J Clin Pharmacol Ther*. 42(2).110-9.

ACADEMIC VITA
MYKAIHLA STERNICK
mykaihla@gmail.com

EDUCATION

Schreyer Honors College, Pennsylvania State University, University Park

Graduation- May 2020

Bachelors of Science in Biology with focus in Neuroscience

Bachelors of Arts in Philosophy

Honors and Minor in Bioethics and Medical Humanities

University of Sydney,

Sydney, New South Wales, Australia

February 2018- July 2018

PROFESSIONAL AND RESEARCH EXPERIENCE

Trauma Surgery Research

Pennsylvania State University School of Medicine

February 2020-

Schreyer Honors College Thesis

Pennsylvania State University

March 2019-

Biological Oceanography Research and Presentation at Penn State Undergraduate Exhibition

Puerto Rico, USA

April 2018

Shadowing Health Professionals

Pottsville and State College, PA

May 2017-

TEACHING EXPERIENCE

Mid-State Literacy Council, State College, PA

English as a Second Language Tutor

January 2019- May 2019

OTHER WORK EXPERIENCE

The Tavern Restaurant, State College, PA

Waitress

March 2019-

Crimson Academy for the Performing Arts, Pottsville, PA

Dance Choreographer and Instructor

June 2017-

COMMUNITY SERVICE

Patient Floor Volunteer

Mount Nittany Medical Center, State College, PA

January 2019-

AWARDS AND HONORS

Linda Brodsky Strumpf Trustee Scholarship in The College of the Liberal Arts

January 2020

Daniel and Elizabeth Hartnett Cwenar Trustee Scholarship

August 2018

Schreyer Ambassador Travel Grant

February 2018

Paterno Fellows Program

August 2017-

Phi Eta Sigma National Honor Society

August 2017-

Sol Lipton Scholarship

June 2016

Provost Scholarship

June 2016

EXTRACURRICULARS

Penn State THON Committee Member and Family Relations Liaison

November 2018-

Dance

2001-

CERTIFICATIONS

American Red Cross Adult and Child CPR/AED/First Aid certified