The Spread of Antibiotic-Resistant Bacteria through Medical Tourism and Transmission Prevention Under the International Health Regulations

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The Spread of Antibiotic-Resistant Bacteria through Medical Tourism and Transmission Prevention Under the International Health Regulations

Tamara L. Hill*

Abstract

Medical tourism—travel by healthcare patients to a foreign location for medical treatment—is a growing industry. Healthcare is nationally regulated in every country, and difficulties arise where legal remedies and standards vary between a medical tourist’s resident and destination country. Antibiotic-resistant bacteria, which are typically limited to healthcare settings and close community quarters, have predictable risk factors. These predictable risk factors generally reduce concern regarding healthcare-associated strains in the medical community because hospitals can set admission and contact policies to reduce the spread of healthcare-associated strains. As medical tourism increases, however, the spread of healthcare-associated antibiotic-resistant bacteria infections is also likely to increase because patients are more likely to be exposed to hospitals and healthcare settings in different countries. Patients may thus spread their infections to facilities around the world. One recently discovered antibiotic-resistant strain of bacteria has shown evidence of fast international spread due to connections with medical tourism.

There are a number of possible solutions to the public health and economic implications of the rapid spread of existing and potential antibiotic-resistant bacteria. These solutions include: containment strategies implemented by the World Health Organization (WHO) under the International Health Regulations 2005 (IHR); race-to-the-top strategies that do not require state intervention at any level, where patients seek out hospitals that best manage infectious disease; containment procedures utilized by individual countries to prevent incoming infections, similar to the classical IHR regime; and information-forcing regimes at either national or international levels, which can supplement any of the other three regulatory and economic solutions by instituting reporting requirements on individual states. To date, the

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WHO has never used the IHR to make recommendations regarding antibiotic-resistant bacteria. This Comment discusses the growth and practices of medical tourism, the development and spread of antibiotic-resistant bacteria, and compares the attributes of antibiotic-resistant bacteria to the attributes of previously declared pandemic diseases. This Comment proposes that the application of the IHR to antibiotic-resistant bacteria spread through medical tourism is consistent with the language of the IHR and concludes that the IHR offers the most efficient and potentially effective method of combating transmission of antibiotic-resistant bacteria.

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I. Introduction

Medical tourism—travel by healthcare patients to a foreign location for medical treatment—is a growing industry.1 Broadly, medical tourism may refer to all travel for healthcare, but the most typical definition focuses particularly on international medical tourism, which is travel between countries for medical treatment. This definition does not include healthcare provided to foreign tourists that is incidental to travel for other purposes, such as business or recreation. Many patients travel abroad for medical treatment due to significant cost savings, to utilize procedures not approved for treatment in their resident countries, or to exercise control over healthcare where public or private

1 Deloitte Center for Health Solutions, Medical Tourism: Update and Implications 3 (Oct 26, 2009), online at http://www.deloitte.com/assets/Dcom-UnitedStates/Local%20Assets/Documents/us_chs_MedicalTourism_102609.pdf (visited Apr 8, 2011) (“Barring any tempering factors such as supply constraints, resistance from health plans, increased domestic competition, or governmental policies, we project that outbound medical tourism could reach upwards of 1.6 million patients by 2012, with sustainable annual growth of 35 percent.”).
insurance plans provide limited treatment options. Healthcare is nationally regulated in every country, and difficulties arise where legal remedies and standards vary between a medical tourist’s resident and destination country. In particular, medical malpractice, safety certification and licensing, and privacy are recurring topics in medical tourism literature. Other ethical issues have been addressed by political organizations and the media, including lack of available care for residents of medical tourism destination countries or black market organ transplants.

However, not all of the repercussions of medical tourism are limited to those affecting only the patient, such as safety, cost, and liability. Antibiotic-resistant bacteria are typically limited to healthcare settings, and strains of antibiotic-resistant bacteria that spread outside of a healthcare setting, like community-associated methicillin-resistant staphylococcus aureus (MRSA), provoke more concern, since healthcare-associated strains have predictable risk factors. These predictable risk factors generally reduce concern regarding healthcare-associated strains in the medical community because hospitals can set admission and contact policies to reduce the spread of healthcare associated strains. As medical tourism increases, however, the spread of healthcare-associated antibiotic-resistant bacteria infections is also likely to increase, because patients are more likely to be exposed to hospitals and healthcare settings in different countries and thus spread their infections to facilities around the world. Exposure without patient knowledge, language barriers, and

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Such patients are attracted by the lower costs of procedures in less-developed countries, the opportunity to avoid their home country's health care rationing ... the need for a procedure still under regulatory review in their home country, or a belief in the healing potential of alternative procedures or medicines such as laetrile.


3 See, for example, Sanjiv N. Singh and Robert M. Wachter, Perspectives on Medical Outsourcing and Telemedicine—Rough Edges in a Flat World?, 358 New Eng J Med 1622, 1622 (2008) (“In this article, we explore some of the critical regulatory, legal, and policy issues surrounding healthcare.”).


inconsistent healthcare regulation and hospital policies reduce the predictability of transmission. One recently discovered antibiotic-resistant strain of bacteria, named New Delhi metallo-beta-lactamase (NDM-1), has shown evidence of fast international spread due to connections with medical tourism.6

This Comment will discuss possible solutions to public health and economic implications of the rapid spread of existing and potential antibiotic-resistant bacteria. Possible solutions include: containment strategies implemented by the World Health Organization (WHO) under the International Health Regulations 2005 (IHR); race-to-the-top strategies that do not require state intervention at any level, where patients seek out hospitals that best manage infectious disease; containment procedures utilized by individual countries to prevent incoming infections, similar to the classical IHR regime; and information-forcing regimes at either national or international levels, which can supplement any of the other three regulatory and economic solutions by instituting reporting requirements on individual states.

Although this Comment considers the IHR to be a possible solution to the problem posed by antibiotic-resistant bacteria and transmission through medical tourism, the WHO has never used the IHR to make recommendations regarding antibiotic-resistant bacteria.7 The only specific mention of antibiotic-resistant bacteria in the IHR appears in Annex 2, which contains a flow chart with questions as a decision instrument for classifying pandemic outbreaks.8 The Annex 2 chart poses a number of questions, and each must be answered in the affirmative to qualify for pandemic recommendations.9 The question of high public impact is explicitly answered as to antibiotic resistance; antibiotic-resistant bacteria are considered to have a high public health impact.10 Since transmission of healthcare associated strains of antibiotic-resistant bacteria is limited to

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6 Kate Kelland and Ben Hirschler, Scientists Find New Superbug Spreading from India, Reuters (Aug 11, 2010), online at http://www.reuters.com/article/idUSTRE67A0YU20100811 (visited Apr 9, 2011) (“At a global level, this is a real concern,’ [Timothy] Walsh, from Britain’s Cardiff University, said in telephone interview. ‘Because of medical tourism and international travel in general, resistance to these types of bacteria has the potential to spread around the world very, very quickly.”).
7 The WHO recognizes antibiotic-resistant bacteria as a health problem, but due to the slow spread of antibiotic-resistant bacteria outside the healthcare setting, has not considered it in light of pandemic outbreaks. See, for example, World Health Organization, Antimicrobial Resistance, Fact Sheet No 194 (Media Centre Feb 2011), online at http://www.who.int/mediacentre/factsheets/fs194/en/ (visited Apr 9, 2011).
9 Id.
10 Id at 44.
exposure in healthcare or close community settings,\(^\text{11}\) however, the other requirements for pandemic recommendations are not met.\(^\text{12}\)

This Comment is organized as follows: Section II discusses the growth and practices of medical tourism, including current state- and self-regulatory measures. Section III.A discusses the appearance and spread of antibiotic-resistant bacteria, including both MRSA and NDM-1, and their public health and economic ramifications. Section III.B compares the attributes of antibiotic-resistant bacteria to the attributes of infectious diseases that historically presented sufficiently great danger of transmission to warrant action under the IHR or its predecessor documents. This section analyzes the dangers presented by different types of diseases and addresses the difference between pandemic-type diseases and healthcare-associated diseases, particularly in light of global travel and other factors affecting modern disease transmission. Section IV considers application of the IHR to antibiotic-resistant bacteria spread though medical tourism; it also explains the development of the current IHR and its historical focus on pandemic-type diseases. Section V provides a textual analysis of the IHR by applying the IHR’s language to antibiotic-resistant bacteria and its rapid spread through medical tourism. Section VI.A considers potential response measures under the IHR, including both temporary and standing recommendations. This section also addresses recommendations previously issued under other pandemic situations, including the recent H1N1 pandemic and the SARS influenza, in order to determine if the WHO would be likely to consider issuing recommendations that would adequately respond to the growing problem of antibiotic-resistant bacterial diseases. The remaining part of Section VI analyzes alternatives to IHR recommendations, including the possible results of an unregulated medical tourism market, industry self-regulatory efforts, individual national regulation, and international regulation by multilateral treaty or by the WHO beyond the measures contemplated by the IHR.

II. MEDICAL TOURISM

Until the late twentieth century, medical tourism existed primarily as a tool for people of economic means to obtain high-quality medical care.\(^\text{13}\) As

\(^{11}\) Klevens, 298 J Am Med Assoc at 1763 (cited in note 5).

\(^{12}\) IHR at 45–46 (stating three questions in addition to the public health risk, one of which must be answered in the positive to be eligible for recommendations under the IHR (cited in note 8). To date, the WHO has never considered any antibiotic-resistant bacteria as a pandemic for regulation under the IHR.

\(^{13}\) See Terri, 29 W New Eng L Rev at 422–23 (cited in note 2) (discussing the term “medical tourism” as applying to “travel of patients from less-developed countries seeking superior health care in industrialized countries”).
healthcare costs in certain countries have increased and the availability of
treatment in countries with universal healthcare systems has decreased,
a new type of medical tourism developed.\textsuperscript{14} This new form of medical tourism
allows patients who cannot afford or are not eligible to receive medical
treatments in their home countries to travel internationally for medical
treatment.

Many factors have contributed to the development of the medical tourism
industry. The US serves as an example of a country with expensive, privatized
healthcare and insurance, which drives the medical tourism industry with un-
under-insured patients looking for high quality, affordable healthcare.\textsuperscript{15} Medical
tourists from the UK may travel for treatments for which the time delay for
available treatment in the UK is lengthy.\textsuperscript{16} In other situations, medical tourists
may travel from countries with either public or private healthcare systems in
order to obtain treatments not approved in their home countries or for
transplant procedures in destination countries with different systems of organ
distribution.\textsuperscript{17} Some medical tourism may occur when patients travel to
countries with public healthcare systems, hoping to obtain treatments funded
by the government.\textsuperscript{18}

A. Current and Projected State of the Medical Tourism
Industry

The exact number of patients traveling internationally for medical
treatment is unknown, although a number of provider countries and consulting
firms have made estimates of the numbers. In 2003, approximately 350
thousand patients traveled from industrialized nations to developing countries
for healthcare.\textsuperscript{19} In 2007, approximately 750 thousand American patients

\textsuperscript{14} See id ("Today, however, it is more likely that the journey is reversed, as patients travel from
industrialized countries to less-developed nations."). See also Thomas R. McLean, \textit{The Global
patients care more about avoiding bankruptcy and the ability to purchase convenient healthcare
services.").

\textsuperscript{15} See generally, \textit{The Globalization of Health Care: Can Medical Tourism Reduce Health Care Costs?}, Hearing
before the Special Committee on Aging, 109th Cong, 2d Sess (2006).

\textsuperscript{16} See Terry, 29 W New Eng L Rev at 423 (cited in note 2) (discussing patients who travel to avoid
healthcare rationing in their home countries).

\textsuperscript{17} Mark S. Kopson, \textit{Fight or Flight: Medical Tourisms Implications for Providers and Plans} §3(B), American

\textsuperscript{18} See Terry, 29 W New Eng L Rev at 427 (cited in note 2) (discussing problems that arise when
medical tourists look to destination countries to fund their healthcare).

\textsuperscript{19} Michael D. Horowitz and Jeffrey A. Rosensweig, \textit{Medical Tourism—Health Care in the Global
Economy} (The Physician Executive Nov 1, 2007), online at
traveled abroad for medical treatment. And in 2004, India provided medical treatment for about 1.18 million foreign patients and Thailand provided medical treatment for 1.1 million foreign patients. Another study by global consulting firm McKinsey & Company indicated that in 2008, only between 60 thousand to 85 thousand patients traveled abroad specifically for medical treatment. However, the study excluded patients traveling for outpatient care and travelers to contiguous countries, which may explain the comparatively low estimate. The potential for industry growth, however, receives universal agreement. McKinsey estimated a potential US market of 500 thousand to 700 thousand medical tourists, if insurance providers offered foreign healthcare options. Deloitte predicted a potential upper bound on the US market of 1.6 million medical tourists seeking healthcare outside of the US by 2012.

The statistics of destination hospitals show that medical tourism is a large industry on an international scale. Numerous countries promote medical tourism specialties such as cosmetic surgery, and others offer comprehensive vacation packages that combine medical treatment with recreational activities. Bumrungrad, one of the largest providers of medical tourism services in Thailand, provided healthcare services for 400 thousand international patients in 2010. Frost & Sullivan, a consulting firm, estimates the current international medical tourism market to be worth $78 billion. It estimates that approximately 3 million patients traveled internationally for healthcare in 2010.


20 Harish Baliga, Medical Tourism is the New Wave of Outsourcing from India, India Daily (Dec 23, 2006), online at http://www.indiadaily.com/editorial/14858.asp (visited Apr 9, 2011).
21 Horowitz and Rosensweig, Medical Tourism (cited in note 19).
23 Kopson, Fight or Flight at §1 (cited in note 17).
24 Ehrbeck, Guevara, and Mango, Mapping the Market (cited in note 22).
25 Deloitte Center for Health Solutions, Medical Tourism: Update and Implications at 3 (cited in note 1).
28 Id.
B. Accreditation and Other Current Regulatory Methods

Safety is an important factor to patients traveling internationally for medical treatment. Currently, no single, authoritative international healthcare accreditation body exists. Certain accreditation bodies are prominent in different geographical regions. In the US, the Joint Commission International, a sector of a US non-profit accreditation organization, has accredited over 300 international healthcare facilities. In the UK and EU, the Trent Accreditation Scheme, recently reorganized as QHA Trent, provides accreditation to international hospitals. The Australian Council on Healthcare Standards International also provides accreditation services to international hospitals. Other accreditation bodies operate in different regions.

The WHO has recognized the need for accrediting bodies in order to ensure healthcare safety, but it has not advocated for a single, unified accreditation board or standard. Since accreditation is part of a holistic approach to medical treatment, encompassing not only medical treatment standards but also ethical considerations and medical research, the lack of a unified standard is reasonable. Instead, the WHO works with the Joint Commission International and other bodies to ensure safety and quality in international healthcare.
Commission International to promote patient safety standards through its Collaborating Centre.\(^\text{34}\)

Currently, no country prohibits medical tourism by law. Many countries provide advisory information to citizens traveling for medical tourism.\(^\text{35}\) The WHO recognizes the need for additional research into the medical tourism industry,\(^\text{36}\) but has not provided advisory information beyond the information generally available nationally.

III. ANTIBIOTIC-RESISTANT BACTERIA

Certain diseases have historically been the target of international concern. Over 150 years ago, countries agreed that diseases such as cholera could not be competently managed on a national scale, and as new diseases have emerged and medical science has improved, international regulation of infectious diseases has broadened.\(^\text{37}\) Although antibiotic-resistant bacteria have spread internationally, they are not highly communicable outside a healthcare setting. However, with the rise of medical tourism, antibiotic-resistant bacteria may spread between healthcare facilities across international borders when patients receive follow-up care in their home countries. This additional mechanism for spreading disease makes antibiotic-resistant bacteria more closely resemble the types of infectious diseases that qualify as pandemic diseases under the current International Health Regulations.

A. Attributes and Examples of Antibiotic-Resistant Bacteria

As antibiotics became the prevalent method for combating infectious disease, resistance to antibiotic treatment began to arise in certain bacterial


The Spread of Antibiotic-Resistant Bacteria

strains. Bacteria develop resistance naturally, but this development occurs more quickly when antibiotics are introduced to kill the bacteria. Bacteria with no resistance die, and bacteria with genetic mutations that fight the antibiotic survive, increasing the presence of the genetic mutation when the surviving bacteria reproduce. Bacteria also pass genes by conjugation, which allows antibiotic-resistant genetic mutations to pass through bacterial populations more quickly. Overuse of antibiotics, which means use of the drugs when not medically necessary, and underuse, which concerns noncompliance with treatment and inadequate dosages, accelerate the development of resistance.

Increased global trade and travel are recognized by the WHO as factors that increase the spread of infectious disease and necessitate an increase in global use of antibiotics. Antibiotic use is different in every country and depends on a large number of factors, including the regulatory environment. Regulatory environments that may promote the development of antibiotic infections are: the ability to obtain antibiotics without a prescription, including availability though internet purchase; lack of quality control for available drugs; and patients that lack funding to pay for full treatment courses. Hospitals are particularly sensitive to the dangers of antibiotic resistance, since they have a combination of infection-susceptible patients and high rates of antibiotic use.

Two types of antibiotic-resistant bacteria serve as representative examples of the dangers of widespread antibiotic resistance: MRSA and NDM-1.

1. Emergence, spread, and economic costs of MRSA.

The spread of MRSA since its emergence in the UK in 1961 illustrates the important role that increased global trade and travel play in the spread of antibiotic-resistant traits in bacteria. In addition to emergence through high rates

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41 Id at 56.

42 Id at 3 (“Antimicrobial use . . . is influenced by an interplay of the knowledge, expectations and interactions of prescribers and patients, economic incentives, characteristics of the health system(s), and the regulatory environment.”).

43 Id at 21–23.

of antibiotic use,\textsuperscript{45} patients have transmitted MRSA strains internationally through contact in healthcare settings. The development of MRSA strains is often characterized as national or international; the similarity of international MRSA strains indicates that transmission occurred through patient contact in healthcare settings.\textsuperscript{46} At first, scientists believed that methicillin resistance developed in a single strain and all MRSA strains developed from the initial bacteria. Later studies show that MRSA types have developed independently.\textsuperscript{47} Although the origins of MRSA are not precisely known, one study has indicated that some major MRSA strains are genetically related, and the most successful genetic mutations have created families of resistant bacteria.\textsuperscript{48} This dual method of emergence and transmission indicates that MRSA may be effectively fought by ensuring both preventing development of new strains through effective use of antibiotics, and by preventing the spread of existing infections.

The economic costs of MRSA are high. US statistics provide an example of how MRSA affects a healthcare system. In 2003, almost two-thirds of hospital staphylococcus aureus infections in intensive care units were antibiotic resistant.\textsuperscript{49} These hospital MRSA infections cause patients to require longer hospital stays for infection treatment and increase the mortality rate. Additional


This effort [to prevent evolution and transmission of MRSA] . . . focuses on effective antimicrobial treatment of infections, use of narrow spectrum agents, treatment of infections and not contaminants, avoiding excessive duration of therapy, and restricting use of broad-spectrum or more potent antimicrobials to treatment of serious infections when the pathogen is not known or when other effective agents are unavailable.

\textsuperscript{46} See Mark C. Enright, et al, \textit{The Evolutionary History of Methicillin-Resistant Staphylococcus aureus (MRSA), 99} Proceedings of the National Academy of Sciences of the USA 7687, 7687 (May 21, 2002), online at http://www.pnas.org/content/99/11/7687.full.pdf+html (visited Apr 9, 2011) ("Many studies have characterized MRSA isolates from individual hospitals or countries and have identified strains that appear to be well adapted to the hospital environment, are established in several hospitals within a country, or have spread internationally (epidemic MRSA, EMRSA).”).

\textsuperscript{47} Id.

\textsuperscript{48} Id:

The origins of the major MRSA clones are still poorly understood. Kreiswirth et al. proposed that all MRSA es were descended from a single ancestral S. aureus strain that acquired \textit{mecA}, but more recent studies show that some MRSA es are very divergent, implying that \textit{mecA} has been transferred between S. aureus lineages. The data from MLST can be used to probe the evolutionary and population biology of bacterial pathogens and to predict ancestral genotypes and patterns of evolutionary descent within groups of related genotypes.

\textsuperscript{49} Kleven, et al, 298 \textit{J Am Med Assoc} at 1763 (cited in note 5) ("The proportion of hospital-onset S aureus infections that were methicillin-resistant reached 64.4\% in US intensive care units in 2003.").
and more intensive treatment increases economic healthcare costs. Infections from methicillin-susceptible staphylococcus aureus (MSSA) increased median hospital stay costs for patients (MSSA infections are more difficult to treat than average bacteria, but do not have complete antibiotic resistance), and MRSA infections tripled the hospital stay costs. The Center for Disease Control (CDC) relies on studies estimating the frequency of MRSA infections in the US at approximately 0.03 percent, causing over 90 thousand infections and almost 20 thousand deaths in 2005. At two hospitals, MRSA infections raised costs by $240 thousand annually. In 2005, the excess costs of MRSA on the US healthcare system have been estimated as high as $9.5 billion, excluding patient costs of pain and lost economic value for time spent in the hospital.

Although the US numbers are high, MRSA infection rates and costs vary widely across nations. The UK has one of the highest MRSA infection rates in Europe, and the British National Audit Office estimated that in 2000, nine percent of hospital patients acquired MRSA infections. Statistics for other EU countries show a much lower incidence rate.

50 Id ("In the hospital, MRSA infections are associated with greater lengths of stay, higher mortality, and increased costs.").
51 John J. Engemann, et al, Adverse Clinical and Economic Outcomes Attributable to Methicillin Resistance among Patients with Staphylococcus aureus Surgical Site Infection, 36 Clinical Infectious Diseases 592, 592 (Mar 1, 2003) ("Median hospital charges were $29,455 for control subjects, $52,791 for patients with MSSA SSI, and $92,363 for patients with MRSA SSI (P .001 for all group comparisons). Patients with MRSA SSI had a 1.19-fold increase in hospital charges (P = .03) and had mean attributable excess charges of $13,901 per SSI compared with patients who had MSSA SSIs.").
52 Klevens, et al, 298 J Am Med Assoc at 1769 (cited in note 5) ("We estimate that 94 360 invasive MRSA infections occurred in the United States in 2005; these infections were associated with death in 18 650 cases. The standardized incidence rate of invasive MRSA for calendar year 2005 was 31.8 per 100 000 persons.").
53 Engemann, et al, 36 Clinical Infectious Diseases at 597 (cited in note 51) ("During the cohort period, among patients with S. aureus SSI, methicillin resistance was responsible for a total excess cost of $240,289 per year at the 2 study institutions.").
54 Eili Klein, David L. Smith, and Ramanan Laxminarayan, Hospitalizations and Deaths Caused by Methicillin-Resistant Staphylococcus aureus, United States, 1999–2003, 13 Emerging Infectious Diseases J 1840, 1844 (Dec 2007), online at http://www.cdc.gov/EID/content/13/12/pdfs/1840.pdf (visited Apr 9, 2011): Several studies have estimated that antimicrobial drug–resistant infections increase death, illness, and direct costs by 30%–100%. Estimates of the excess cost of an infection with MRSA compared with an infection with methicillin-sensitive S. aureus range from $3,000 to $35,000. This suggests that MRSA cost the healthcare system (patients and hospitals) an extra $830 million–$9.7 billion in 2005, even without taking into account indirect costs related to patient pain, illness, and time spent in the hospital.
55 Rory Clements, What is the Truth About the MRSA Superbug?, Mail Online, online at http://www.dailymail.co.uk/health/article-157079/What-truth-MRSA-superbug.html#ixzz19XFV0b5 (visited Apr 9, 2011); see also Lizette Alvarez, British Hospitals
2. Recent emergence of NDM-1 and its spread through medical tourism.

In 2010, a study in The Lancet medical journal reported the emergence of a new antibiotic-resistant bacteria strain called NDM-1.\(^{56}\) This strain of antibiotic resistance is particularly dangerous because it is resistant even to treatments reserved as last resorts, making the strain difficult to combat.\(^{57}\) The Lancet study linked the emergence of NDM-1 to both the over- and under-use of antibiotics. The WHO has endorsed The Lancet results by issuing a press release acknowledging the necessity of measures to prevent the spread of NDM-1.\(^{58}\)

The subsequent spread of NDM-1 to other countries highlights the changes brought by medical tourism to the spread of antibiotic-resistant bacteria. After release of The Lancet study, the US CDC announced that three cases of NDM-1 had been found in the country, “all from patients who received recent medical care in India, a country where people often travel in search of affordable healthcare.”\(^{59}\) These three cases were the first reports of NDM-1 cases in the US. Because the new antibiotic resistance was discovered during routine testing


\(^{57}\) See Johann D.D. Pitout, The Latest Threat in the War on Antimicrobial Resistance, 10 The Lancet Infectious Diseases 578, 578 (Aug 11, 2010), online at http://www.thelancet.com/journals/laninf/article/PIIS1473-3099(10)70168-7/fulltext# (visited Apr 10, 2011) (discussing development of resistance to carbapenems, which are often the last line of effective treatment available for bacterial infections resistant to multiple drugs).

\(^{58}\) World Health Organization, WHO Urges Countries to Take Measures to Combat Antimicrobial Resistance (Media Centre Aug 20, 2010), online at http://www.who.int/mediacentre/news/releases/2010/amr_20100820/en/index.html (visited Apr 10, 2011) (“An article published in The Lancet Infectious Diseases on 11 August 2010 identified a new gene that enables some types of bacteria to be highly resistant to almost all antibiotics. The article has drawn attention to the issue of AMR, and, in particular, has raised awareness of infections caused by multi-drug resistant bacteria.”). The Indian government, however, disputes this contention. See, for example, Ulterior Motives Could be Behind Superbug Claim: India, Hindustan Times (Aug 13, 2010), online at http://www.hindustantimes.com/Ulterior-motives-could-be-behind-superbug-claim-India/Article1-586370.aspx (visited Apr 10, 2011) (interviewing the Indian Minister of State for Health and arguing that multinational pharmaceutical companies funded the study, which ignored the prior universal presence of the NDM-1 bacteria).

\(^{59}\) Kelland and Hirschler, Scientists Find New Superbug Spreading from India (cited in note 6).
at the CDC, it is likely that NDM-1 was not in the US prior to these three cases.\footnote{Centers for Disease Control and Prevention, \textit{Detection of Enterobacteriaceae Isolates Carrying Metallo-beta-Lactamase—United States, 2010}, 59 Morbidity and Mortality Wkly Rep 750, 750 (Jun 25, 2010) (reporting identification of NDM-1 in three 2010 cases during routine testing and alerting clinicians to possible NDM-1 infections in patients who received recent medical care in India or Pakistan).}

\textit{The Lancet} study focused on NDM-1 cases in India, Pakistan, Bangladesh, and Britain. The study found that “several of the British NDM-1 positive patients had traveled recently to India or Pakistan for hospital treatment, including cosmetic surgery.”\footnote{Kelland and Hirschler, \textit{Scientists Find New Superbug Spreading from India} (cited in note 6).} Discovery of the NDM-1 strain was reported in August 2010, and the three US cases were reported shortly afterward. By November 2010, additional European cases had been reported. A scientist at the European Centre for Disease Prevention and Control (ECDC) announced that seventy-seven cases of NDM-1 had been reported in thirteen countries between 2008 and 2010.\footnote{Kate Kelland, "\textit{Super Superbug} NDM-1 Spreads in Europe, Reuters (Nov 17, 2010), online at http://www.reuters.com/article/2010/11/17/us-superbug-ndm-idUSTRE6AG1AJ20101117 (visited Apr 10, 2011).}

The ECDC reported that “[a]mong 55 cases with recorded travel history, 31 had previously traveled or been admitted to a hospital in India or Pakistan and five had been hospitalised in the Balkan region.”\footnote{Marc J. Struelens, et al, \textit{New Delhi Metallo-beta-lactamase 1—producing Enterobacteriaceae: Emergence and Response in Europe}, 15 Eurosurveillance 1, 1 (Nov 18, 2010).} The ECDC concluded that NDM-1 has been spreading across Europe and is linked to both a history of healthcare abroad and nosocomial (or healthcare-setting acquired) transmission.\footnote{Id.} The ECDC expressed particular concern regarding transmission across national borders:

Carbapenemase-producing strains [NDM-1 bacteria] have been the cause of country-wide epidemics of healthcare-associated infections in Greece, Israel, the United States (US), several Latin American countries and China, and of local outbreaks in Poland and Italy. These epidemic strains ... have been shown to spread when carried by patients who are transferred between hospitals. Such introductions into healthcare systems across country borders have led to international epidemics by secondary local or regional transmission.\footnote{Id.} There is heightened concern regarding international transmission in light of the fact that recent medical care appeared to be a significant factor, not just medical care in another country at any prior point in time. “Most patients with recent travel had been hospitalized in a foreign country during the 30 days prior
to the detection of NDM-1.” Transmission of antibiotic-resistant bacteria through patient travel between healthcare settings is a new development, driven by the increase in global travel and trade. NDM-1 exemplifies the potential dangers of international spread.

B. Attributes of Antibiotic-Resistant Bacteria Compared to Attributes of Other Pandemic Infectious Diseases

Antibiotic-resistant bacteria have not historically been considered pandemic infectious diseases, since they are not communicable via airborne transmission like influenzas and other highly contagious infectious diseases. Additionally, the methods of preventing transmission and containing infections for antibiotic-resistant bacteria differ from the methods used for pandemic-type diseases.

1. Risk factors for infection and transmission of antibiotic-resistant bacteria compared to other infectious diseases.

Most antibiotic-resistant bacteria, like MRSA, primarily exist in healthcare settings. “The most common health care risk factors among cases with [healthcare associated] infections [are] a history of hospitalization, history of surgery, long-term care residence, and MRSA infection or colonization.” Community-associated cases, which are not as common as healthcare-associated infections, typically have risk factors common with institutional settings such as schools, athletic facilities, and jails. These risk factors include: “close skin-to-skin contact, openings in the skin such as cuts or abrasions, contaminated items and surfaces, crowded living conditions, and poor hygiene.” Notably, transmission requires direct skin-to-skin contact or surface contamination, but antibiotic-resistant bacteria do not tend to survive for more than a few minutes on contaminated surfaces. Without long periods of transmission through surface contamination or airborne transmission, antibiotic-resistant bacteria do not tend to spread rapidly outside healthcare or institutional settings. Casual contact, such as hugging, is usually acceptable for visitors of an infected patient, as long as contact with the wound site is avoided.

Pandemic outbreaks, on the other hand, are more often associated with infectious diseases with transmission methods that are more difficult to monitor.
and control. The 2009 H1N1 influenza, which was declared a pandemic by the WHO, "transmitted through: [d]roplet exposure of mucosal surfaces by respiratory secretions from coughing or sneezing; [c]ontact, usually of hands, with an infectious patient or [contaminated surface] followed by self-inoculation . . . ; and [s]mall particle aerosols in the vicinity of the infectious individual." In addition to rapid transmission contact factors, other attributes make the influenza virus particularly susceptible to rapid population spread. "Influenza viruses are notorious for their rapid mutation and unpredictable behaviour."71

Medical tourism provides a tool of rapid transmission across international borders for antibiotic-resistant bacteria that did not exist before this century. Although pandemic outbreaks have many factors that make them prone to rapid transmission, the introduction of a cross-border transmission factor for diseases that are particularly resistant to treatment may be especially dangerous.

2. Containment and transmission prevention methods for antibiotic-resistant bacteria compared to pandemic-type infectious diseases.

Since antibiotic-resistant bacteria spread by different methods than pandemic-type infectious diseases, it follows that the methods for containing and preventing transmission of antibiotic-resistant bacteria differ from the methods for containing pandemic-type infectious diseases.

The most common transmission prevention method for healthcare-associated MRSA is hospital screening policies. These policies generally require the hospital to request information before admission regarding the patient's exposure to certain high-risk healthcare settings, such as intensive care units.72 In the Netherlands, hospital preadmission questionnaires, which typically ask about exposure to healthcare settings and previous MRSA infections, also ask if the patient has been treated in a foreign hospital.73 "In the Dutch opinion, all foreign hospitals are considered suspected for harboring MRSA."74 Once the


73 Johan H.T. Wagenvoort, et al, *Once MRSA, Always MRSA? Setting up a Hospital Preadmission Questionnaire*, 21 Infection Control & Hospital Epidemiology 251, 251 (April 2000).

74 Id.
initial risk for exposure is determined, hospitals provide various levels of isolation to prevent transmission. New methods of preventing transmission of antibiotic-resistant bacteria include: "antibiotic control...; selective digestive decontamination to reduce endogenous infections in high-risk, critically ill patients; or more widespread use and promotion of hand antiseptics rather than conventional hand washing to prevent cross-infections." These infection containment methods illustrate the low risk of transmission without direct contact. Containment methods for antibiotic-resistant bacteria are largely dependent upon hospital rules and practices.

For pandemic-type infectious diseases, "[t]he infectious characteristics of pandemic influenza will not be known until after it emerges. Consequently, infection control plans will have to be adapted to the current knowledge of transmission and updated as new information becomes available." However, transmission typically occurs via "airborne, droplet, or contact transmission." Standard precautions against these types of transmission include:

The use of gloves and facial protection by healthcare workers when providing care to coughing/sneezing patients. Hand hygiene before and after patient contact, and after removing gloves... performed either by using an alcohol-based hand rub or by washing hands with soap and water... Standard operating procedures to handle and disinfect patient care equipment, patient rooms, and soiled linen; prevent needlestick/sharp injuries; and address environmental cleaning, spills-management, and handling of waste.

These types of precautions illustrate the difficulties in containing pandemic-type infectious diseases outside of the hospital setting, where contact with infected persons might include coughing and sneezing or casual contact, but is less likely to include direct contact with infected abrasions. In a hospital setting, healthcare workers have access to gloves, facial protection, and handwashing facilities. Outside the hospital setting, individuals may not have access to these types of tools to prevent transmission. However, the extensive transmission prevention procedures required for pandemic-type infectious diseases show that current containment methods may be economically costly.

75 Id.
76 Andreas F. Widmer, Hugo Sax, and Didier Pittet, Infection Control and Hospital Epidemiology Outside the United States, 20 Infection Control & Hospital Epidemiology 17, 20 (Jan 1999).
78 Id.
79 Id (parentheses omitted).
IV. APPLICATION OF THE IHR TO ANTIBIOTIC-RESISTANT BACTERIA

In order for the IHR to provide a possible solution to the problem of transmission of antibiotic resistant bacteria transmission through medical tourism, the regulations must first apply to the problem. The WHO’s jurisdiction over international public health is broadly written, but the WHO has traditionally limited application of its jurisdiction in light of political, social and economic concerns. The general history and purpose of the IHR indicate that it should be applied to an international health problem of high social and economic concern, like transmission of antibiotic-resistant bacteria through medical tourism. In addition, the regulatory language literally applies to the situation as well.

A. The History of the IHR

The IHR evolved out of international concern regarding sanitation and environments conducive to diseases with danger of international spread. Previous regulations included only a limited list of diseases, including cholera, yellow fever, and plague, but the IHR has since expanded to broad language encompassing a range of different diseases. As David Fidler explains:

[The] WHO widened the risks the revised IHR would cover to include more than infectious diseases. The first indication of this move [came] in February 2001, when WHO discussed in its IHR revision progress report how [the WHO’s Global Outbreak Alert and Response Network] could be designed to “provide information on noncommunicable diseases and environmental, chemical or nuclear risks.”

Fidler’s explication of the history, development, and purpose of the IHR provides a useful basis for examining their application to antibiotic-resistant bacteria.

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80 Lindsay F. Wiley, Moving Global Health Law Upstream: A Critical Appraisal of Global Health Law as a Tool for Health Adaptation to Climate Change, 22 Georgetown Int'l Env't L. Rev. 439, 461 (2010) (“Although the World Health Assembly [...] (the governing body of the WHO) has notably broad legislative and regulatory powers under the WHO Constitution, it has generally refrained from using them.”).

81 Fidler, 4 Chinese J Int'l L at 328–29 (cited in note 37).

1. Expansion from member state reporting requirements to regulatory structure.

The IHR has expanded from information-dissemination requirements with no regulatory structure, allowing individual states to protect themselves, into a single set of international rules, allowing states to cooperate in order to pursue protection from international disease transmission in the most efficient and effective possible method. "The classical regime pursued protection against the international spread of infectious diseases through international legal obligations requiring that (1) States notify other countries about outbreaks of specified diseases; and (2) [States] maintain adequate public health capabilities at points of disease entry and exit."\(^{83}\) The classical regime was designed to give minimal interference into national affairs. "The goal [of the classical regime] was to structure State responses to infectious disease outbreaks in other countries so that States could protect themselves from disease importation and spread in ways that were scientifically effective and the least restrictive of trade and travel possible."\(^{84}\) Of particular concern were diseases spreading from Asia and Africa to Western states. The two presumptions implicit in the classical regime were that individual states were capable of structuring state regulations that would prevent disease transmission, and that each state was the best decision-maker regarding the balance of economic restrictions in exchange for disease transmission prevention.

\textit{a) The 1948 WHO Constitution.} In 1948, the WHO Constitution was adopted, and its language drastically changed the setting for application of international regulation to infectious disease transmission.

The procedural changes effected by the WHO Constitution created the possibility for [the] WHO to adopt one set of international legal rules to replace the patchwork of international sanitary conventions and to revise and amend such rules efficiently in response to changes in scientific or other factors. In addition, the WHO Constitution’s ‘opt out’ technique would help ensure that the single set of rules would be widely applicable in the international system.\(^{85}\) This change allowed the WHO to broaden its regulations beyond simple reciprocal information reporting requirements and to provide a set of reciprocal standard regulations to all countries that opted in to compliance. Significantly, the constitutional expansion also allowed reporting information from parties other than the Member State.\(^{86}\) "[T]he new IHR contain[ed] a vision of

\(^{83}\) Id at 329 (parentheses omitted).
\(^{84}\) Id at 330.
\(^{85}\) Fidler, 4 Chinese J Intl L at 332–33 (cited in note 37).
\(^{86}\) Id at 346.
integrated governance for global public health because the proposals connect public health objectives with principles and norms found in international law on trade, human rights, environmental protection and security.”

b) The shift from International Sanitary Regulations to a health-based regulatory approach. Prior to the adoption of the IHR, the classical regime relied upon sanitary regulations to control infectious disease. “The International Sanitary Regulations (ISR), adopted in 1951, were based on an approach to the legal control of infectious disease that dated back to at least the mid-nineteenth century.” Since infectious diseases tended to emerge in countries with poor sanitary conditions, industrialized nations could protect themselves from pandemics by controlling travel and trade at their own national borders. “For more than a century, the notification requirements that triggered an international response (primarily relying on travel and trade restrictions to control the spread of disease) were applicable only to a short list of named infectious diseases, principally cholera, plague, and yellow fever.” The three diseases included in the ISR were the known diseases at the time that now best fit the pandemic-type infectious disease model. “The list shifted slightly with the adoption of the ISR in 1951 and a series of minor revisions, and the ISR were retooled as the IHR in 1969, but the basic approach remained the same.” As medical knowledge regarding infectious disease grew, and more pandemic-type infectious diseases were discovered, the ISR expanded to include more diseases for possible national restrictions.

After the ISR began expanding to include additional diseases, the WHO adopted the original version of the International Health Regulations. The original regulations adopted the classical regime of reporting and national regulation, which also became ineffective:

[For a variety of reasons, the IHR became largely irrelevant to the realities of infectious disease control in practice. Rapid increase in the speed of travel and trade made quarantine and isolation provisions far less effective, and advances in medical technologies, especially the development of antibiotics and vaccines, required a fundamentally different approach to fighting disease. Later, several new developments left [the] WHO looking flat-footed, as many criticized its lack of leadership on new threats to health. These issues included the emergence of HIV/AIDS as one of the worst pandemics in history, the growing burdens of other infectious diseases like malaria and tuberculosis, and the proliferation of biological weapons.]

87 Id at 343.
89 Id.
90 Id.
91 Id.
These problems led to a revision process of the IHR.

2. Expansion from a limited to expansive definition of the term “disease.”

The WHO entered into a ten-year process of negotiation to develop a new version of the IHR. The WHO adopted the revisions in 2005. The revised IHR was put into force in 2007. “The new IHR’s purpose is ‘to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks and which avoid unnecessary interference with international traffic and trade.’” Although the purpose of the new IHR was similar to the purpose of the original ISR, it contained an important change in focus. The inclusion of broad language applying “to all ‘public health emergencies of international concern,’ include[d] not only infectious disease outbreaks, but also chemical and radio-nuclear events and perhaps other threats to health as well.” This broad language, although typically interpreted as an expansion beyond solely the threat of disease, also means that the IHR applies beyond just the traditionally presented pandemic-type diseases and the influenza virus outbreaks that are often declared pandemics (such as SARS or H1N1 influenza). The WHO further clarified that “[a] ‘public health emergency of international concern’ is defined as ‘an extraordinary event which is determined ... : (i) to constitute a public health risk to other States through the international spread of disease; and (ii) to potentially require a coordinated international response.’” In particular, “[d]isease’ is defined quite broadly as ‘an illness or medical condition, irrespective of origin or source, that presents or could present significant harm to humans.’” The historical development of the IHR indicates that it is meant to be interpreted broadly, and the current use of the term “disease” is meant to include antibiotic-resistant bacteria.

B. The Purpose of the IHR

According to the WHO, the IHR serves two main goals: the development of a framework for coordination of public health emergencies of international concern and improvement of every nation’s ability to manage public health

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93 Id at 463.
94 Id.
The Spread of Antibiotic-Resistant Bacteria

threats.\textsuperscript{95} The innovations under the revised IHR reflect their broad purpose, including:

(a) a scope not limited to any specific disease or manner of transmission, but covering "illness or medical condition, irrespective of origin or source, that presents or could present significant harm to humans"; (b) State Party obligations to develop certain minimum core public health capacities; (c) obligations on States Parties to notify [the] WHO of events that may constitute a public health emergency of international concern according to defined criteria; (d) provisions authorizing [the] WHO to take into consideration unofficial reports of public health events and to obtain verification from States Parties concerning such events; (e) procedures for the determination by the Director-General of a "public health emergency of international concern" and issuance of corresponding temporary recommendations, after taking into account the views of an Emergency Committee; (f) protection of the human rights of persons and travellers; and (g) the establishment of National IHR Focal Points and WHO IHR Contact Points for urgent communications between States Parties and [the] WHO.\textsuperscript{96}

The IHR is meant to encompass all types of diseases, regardless of method of transmission. In addition, allowing unofficial reports of public health events for notification prevents member states from limiting the definition of disease via their own reports. Instead, the IHR places discretion in the hands of the WHO and its Director-General to determine whether a disease qualifies as a public health emergency and issue recommendations to member states. This expanded purpose and retained discretion allow "the IHR [to] remain firmly rooted in a security-based justification for international cooperation with respect to health."\textsuperscript{97} Despite the broad language, the purpose of the IHR focuses more heavily on security, which makes prevention of emergence and transmission of infectious disease incidental to, though a necessary part of, the purpose of the IHR. For antibiotic-resistant bacteria and medical tourism, this purpose makes it likely that the WHO will balance both the public health factors and the economic benefits and risks of the medical tourism industry in combination with antibiotic-resistant bacteria.


\textsuperscript{96} IHR at 1–2 (cited in note 8). See also Bradly J. Condon and Tapen Sinha, \textit{The Effectiveness of Pandemic Preparations: Legal Lesson from the 2009 Influenza Epidemic}, 22 Fla J Int'l L 1, 4 (2010) ("The IHR (2005) expanded disease coverage, notification requirements, and the sources of information that the WHO can use regarding disease outbreaks.").

\textsuperscript{97} Wiley, 22 Georgetown Int'l Envir L Rev at 462 (cited in note 88).
C. Implementation of the IHR, Including General Enforceability and Effectiveness

Prior to the revisions of the IHR, the WHO’s regulatory structures for controlling infectious diseases were legal failures:

As early as the late 1960s, WHO officials and other commentators expressed frustration about the lack of IHR compliance by [member states]. One expert asked, “[I]s there much sense in the maintenance of rules if they are not observed—if they are disregarded or more or less systematically broken—without any consequences for those who deviate?”

This concern regarding implementation affected the development of the revised IHR and continues to affect the WHO’s decisions regarding the declaration of public health emergencies and the appropriate temporary and standing recommendations. Since “[member states] routinely violated their obligations to notify WHO of outbreaks of diseases subject to the [IHR] and to refrain from applying unwarranted measures to the trade and travel coming from countries suffering such outbreaks,” the WHO is using the revised IHR not only to attempt to change the prior system for regulating public health emergencies, but also to ensure that member states adequately comply with an international public health regulatory structure. As such, it is unlikely that the WHO will embrace regulating antibiotic-resistant bacteria and issuing recommendations to combat their international spread unless member states believe compliance is in their own best interest.

D. Application of the IHR

Application of the IHR has exposed flaws in the regulatory structure. The SARS pandemic, which occurred in 2002 and 2003, exposed the WHO to potential problems, but since the outbreak occurred before revisions were complete, many of the problems led to changes in the revision process. The 2009 H1N1 pandemic provides the best example of application of the revised IHR. Problems arose during H1N1, including the lack of financial assistance to implement the IHR in developing countries and the lack of effective recourse for asymmetrical travel and trade restrictions.

1. Significant new reporting compliance with the IHR.

Although Mexico did not report the H1N1 outbreak as soon as it began, due to the similarity in symptoms to seasonal influenza, it reported suspected

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98 Fidler, 4 Chinese J Intl L at 335 (cited in note 37).
99 Id at 335–36.
100 Condon and Sinha, 22 Fla J Intl L at 30 (cited in note 96).
cases quickly.\textsuperscript{101} Such compliance with IHR regulation is an example of how the revised IHR has encouraged countries to comply with reporting requirements by providing incentives like reciprocal reporting requirements and symmetrical travel and trade restrictions.\textsuperscript{102} Modern technology increases incentives for countries to comply with reporting requirements by making it more likely that the information will be internationally communicated regardless of the government decision. If the outbreak is not initially reported by the state, the government risks receiving bad press alleging inadequate monitoring of outbreaks or even suppression of information.

2. The WHO’s declaration of a pandemic and issuance of recommendations.

The WHO was willing both to declare a pandemic and issue recommendations during the H1N1 outbreak, reassuring member states and commentators who were concerned that the WHO would be hesitant to do so due to possible non-compliance.\textsuperscript{103} However, a significant number of countries—from different parts of the world and with varying levels of economic development—chose to ignore the WHO DG’s recommendations in introducing trade and travel restrictions. In contrast to the reporting obligation, the WHO DG’s recommendations are not binding. This suggests that non-binding recommendations might not prove effective in minimizing the economic damage caused by disproportionate trade and travel restrictions.\textsuperscript{104}

Many countries made the unsupported assumption that the H1N1 virus originated in Mexico, despite a similar number of cases in the US. These countries responded by issuing asymmetrical travel and trade restrictions against Mexico.

3. Non-compliance with symmetrical travel and trade restrictions.

Despite its willingness to declare a pandemic and issue recommendations, “the WTO was remarkably slow to address the disproportionate trade restrictions, despite being the international organization with jurisdiction over such matters.”\textsuperscript{105} Since reporting requirements are still open to national delay based on detection, maintaining incentives to report remains important.

\textsuperscript{101} Id at 5.
\textsuperscript{102} Id at 11.
\textsuperscript{103} Id at 12 ("[W]hile some might like to see a faster response, this contradicts prior speculation that the WHO DG would be unwilling to issue recommendations.").
\textsuperscript{104} Condon and Sinha, 22 Fla J Intl L at 12 (cited in note 96).
\textsuperscript{105} Id at 17.
“Reducing the risk of disproportionate trade restrictions would enhance economic incentives to comply with surveillance requirements.”\textsuperscript{106}

Overall, the H1N1 pandemic provides encouraging evidence that the IHR may be used to control transmission of antibiotic-resistant bacteria. Though the host country may not be likely to report an outbreak, other countries are likely to comply with reporting requirements, since discovery of new antibiotic-resistant bacteria in patients that have recently traveled to other countries for medical care would not damage the reporting country’s reputation or result in economic sanctions through travel or trade restrictions. Likewise, the WHO has shown its willingness to declare a pandemic and issue recommendations. If the WTO and the WHO continue to respond slowly to asymmetric recommendations between states, as during the H1N1 pandemic, countries are likely to use asymmetric response restrictions, since antibiotic-resistant bacteria are likely to affect only localized areas if they are reported before widespread transmission.

V. \textbf{TEXTUAL APPLICATION OF THE IHR TO CONTAINMENT OF ANTIBIOTIC-RESISTANT BACTERIA INFECTIONS}

The WHO clearly intended to include antibiotic-resistant bacteria in its definition of disease. This intention is evidenced by the statement of purpose in the explanatory foreword to the IHR, the broadly constructed definition of terms, the guiding principles of interpretation provided by the WHO, and the recommendations permissible under the IHR.

A. Statement of Purpose

The WHO created its broad definition of disease in part to ensure that a restricted definition would not become obsolete as new diseases were discovered. “By not limiting the application of the IHR (2005) to specific diseases, it is intended that the Regulations will maintain their relevance and applicability for many years to come even in the face of the continued evolution of diseases and of the factors determining their emergence and transmission.”\textsuperscript{107} The IHR explicitly states that “[t]he purpose and scope of these Regulations are to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade.”\textsuperscript{108} The purpose does not limit itself to certain classes or types of disease, and the only limitations placed on prevention

\textsuperscript{106} \textit{Id} at 3.
\textsuperscript{107} IHR at 2 (cited in note 8).
\textsuperscript{108} \textit{Id} at 10.
measures are designed to ensure that there is in fact a risk and that the response taken is economically proportionate to that risk. Under the purpose of the IHR, the requirements for classifying antibiotic-resistant bacteria as an applicable disease are: that it might spread internationally, which is likely, considering the growth of medical tourism; that a risk exists, which is supported by the high cost of antibiotic-resistant infections; and that the recommended measure must be proportionate to the risk.

B. Definition of Terms

The defining terms are constructed so that antibiotic-resistant bacteria are included within their scope. The term "disease," as previously discussed, is defined broadly as "an illness or medical condition, irrespective of origin or source that presents or could present significant harm to humans."\(^{109}\) Disease, however, is not the only term that is broadly defined in order to maintain the wide scope of the IHR. Other terms are likewise defined broadly and therefore can easily be construed to include antibiotic-resistant bacteria within their scope.

First, the terms that apply directly to the type of disease and carriers are defined broadly enough to include antibiotic-resistant bacteria and medical tourist carriers. The term "affected" is defined to include infected persons who carry sources of infection or contamination,\(^{110}\) which would apply to medical tourists traveling across national borders with antibiotic-resistant infections. Similarly, an "ill person" is anyone "suffering from or affected with a physical ailment that may pose a public health risk."\(^{111}\) Using the term "physical ailment" instead of a more limited descriptor such as "infectious disease" makes clear that the WHO intended anything capable of causing physical illness to be actionable under the IHR. An infection is also broadly defined as "the entry and development or multiplication of an infectious agent in the body of humans and animals that may constitute a public health risk,"\(^{112}\) which also encompasses antibiotic-resistant bacteria.

The terms that describe the health threat and recommendations are similarly broad and are easily construed to include the threat of healthcare-associated antibiotic-resistant bacteria traveling internationally through medical tourism. The term "event" is similarly not limited to a single geographical and temporal event; instead, it "means a manifestation of disease or an occurrence

\(^{109}\) Id at 7.
\(^{110}\) Id at 6.
\(^{111}\) IHR at 8 (cited in note 8).
\(^{112}\) Id at 8.
that creates a potential for disease."\textsuperscript{113} Unlike pandemics, which develop, spread, and peak quickly, with definite geographical boundaries defined by patients showing symptoms, new antibiotic-resistant bacteria may not be discovered quickly and their spread may be more difficult to locate, since symptoms may not occur until after travel. The term “public health risk” means “a likelihood of an event that may affect adversely the health of human populations, with an emphasis on one which may spread internationally or may present a serious and direct danger.”\textsuperscript{114} This definition includes antibiotic-resistant bacteria, since they directly threaten health, though not all strains will present the same degree of danger.

The term “public health emergency of international concern,” used frequently in the IHR, means “an extraordinary event which is determined, as provided in these Regulations: (i) to constitute a public health risk to other States through the international spread of disease [and] (ii) to potentially require a coordinated international response.”\textsuperscript{115} The broad definition has only two requirements: first, that a disease be capable of spreading across national borders, as antibiotic-resistant bacteria are through medical tourism; and second, that a coordinated international response be required, meaning that individual state restrictions would either be inadequate or less efficient to prevent the spread of the disease. Since a country already affected by a particular antibiotic-resistant strain of bacteria would have little incentive to report or contain antibiotic-resistant bacteria without international reciprocity, the IHR provides efficient grounds for such compliance.

C. Guiding Principles of Interpretation of the IHR

The WHO provides guiding principles for interpreting the IHR:

1. The implementation of [the IHR] shall be with full respect for the dignity, human rights and fundamental freedoms of persons. 2. The implementation of [the IHR] shall be guided by the Charter of the United Nations and the Constitution of the World Health Organization. 3. The implementation of these Regulations shall be guided by the goal of their universal application for the protection of all people of the world from the international spread of disease. 4. States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to legislate and to implement legislation in pursuance of their health policies. In doing so they should uphold the purpose of [the IHR].\textsuperscript{116}

\textsuperscript{113} Id at 7.
\textsuperscript{114} Id at 9.
\textsuperscript{115} IHR at 9 (cited in note 8).
\textsuperscript{116} Id at 10.
These principles comport with the idea that antibiotic-resistant bacteria are an appropriate subject for regulation under the IHR. Allowing member states to regulate medical tourism and antibiotic-resistant bacteria independently would lead to asymmetrical travel and trade regulations, particularly against developing nations. Member states would target developing nations because the factors that increase the probability of developing new antibiotic-resistant bacteria\textsuperscript{117} are more prevalent where less funding and education is available for healthcare. In addition, regulation by individual states would not help develop infrastructure in developing nations to prevent over- and under-use of antibiotics. Preventing development of antibiotic-resistant bacteria where it originates is the containment method most consistent with the IHR's guiding principle of protecting all people from disease.

D. Reporting Requirements

The IHR provides a detailed flow chart and descriptive information to help member states determine what diseases qualify for reporting. Initially, member states must maintain the “capacity to detect, assess, notify and report events”\textsuperscript{118} and report to the WHO “essential information includ[ing] the following: clinical descriptions, laboratory results, sources and type of risk, numbers of human cases and deaths, conditions affecting the spread of the disease and the health measures employed.”\textsuperscript{119} Using the chart and information, member states must report all qualifying events to the WHO\textsuperscript{120}

Applying the attributes of antibiotic-resistant bacteria to the flow chart leads to the conclusion that antibiotic-resistant bacteria capable of international spread through medical tourism likely qualify for regulation under the IHR. First, antibiotic-resistant bacteria have a serious impact on public health,\textsuperscript{121} as evidenced by the high economic costs of treatment of MRSA in affected countries.\textsuperscript{122} In addition, indication of treatment failure, including new or emerging antibiotic resistance, is explicitly given public health impact under the IHR flow chart. Second, antibiotic resistance is unusual or unexpected, especially when new resistant strains develop.\textsuperscript{123} Third, antibiotic-resistant bacteria pose a significant risk of international spread, since medical tourists are a highly mobile

\textsuperscript{117} See Section III.A.
\textsuperscript{118} IHR at 10 (cited in note 8).
\textsuperscript{119} Id at 40.
\textsuperscript{120} Id at 12, 43–46.
\textsuperscript{121} Id at 43–46.
\textsuperscript{122} See Section III.A.1.
\textsuperscript{123} IHR at 45 (cited in note 8).
population likely to travel internationally while infected. Therefore, the medical tourism industry is an appropriate area for international regulation, since medical tourism is by its nature an area involving a high degree of international travel. Also, the NDM-1 case shows that emergence of new antibiotic-resistant bacteria generates requests for more information by foreign officials and the international media. The satisfaction of these factors under Annex 2 makes emergence of a new antibiotic-resistant bacteria in an area of medical tourism reportable under the IHR.

The incident is also reportable if the confluence of factors would meet the overall requirements of a public health emergency. In determining whether an event constitutes a public health emergency of international concern, the Director-General shall consider: (a) information provided by the State Party; (b) the decision instrument contained in Annex 2; (c) the advice of the Emergency Committee; (d) scientific principles as well as the available scientific evidence and other relevant information; and (e) an assessment of the risk to human health, of the risk of international spread of disease and of the risk of interference with international traffic. This more general assessment is even more likely to lead to the conclusion that the emergence of new antibiotic-resistant bacteria in an area of medical tourism is reportable, since it incorporates the more general purpose and guiding principles of the IHR.

E. Other Sources Support the Idea of a Public Health Emergency to Include Antibiotic-Resistant Bacterial Infections

Scientific research supports the contentions that antibiotic-resistant bacteria are no longer difficult to transmit and are best controlled within individual healthcare environments. The prevalence of community-associated MRSA and difficulty distinguishing it from healthcare-associated MRSA illustrate the potential development of antibiotic-resistant bacteria and the need to prepare for newly emerging methods of transmission, like medical tourism.

Control of community-acquired [antibiotic-resistant bacterial] infection (coming from all sources that do not include healthcare facilities) and risk communication (the provision of information and prevention guidance to the general public) are keys to preventing amplification of contagions in the population likely to travel internationally while infected.
community at the residential and broader community levels. Research shows
that secondary, bacterial infection (co-infection) complications, exacerbated
by influenza-induced immune system suppression, were the primary cause
of death during the 1918 influenza pandemic. This challenges the utility of
viral vaccination programs, and should result in a shifting of present
pandemic planning.\textsuperscript{129}

The presence of potential additional transmission methods demonstrates that
considering the risk of antibiotic-resistant bacteria as a pandemic or as a co-
infection to a viral pandemic is essential to proper pandemic planning, which is
the goal of the IHR.

F. Potential Response Measures under the IHR

The IHR obligates member states to "develop, strengthen and maintain . . .
the capacity to respond promptly and effectively to public health risks and public
health emergencies of international concern."\textsuperscript{130} Thus, the response measures
under the IHR are limited to an individual state's ability to comply with the
recommendations. In addition, the WHO may only issue recommendations on
specific subject matters:

Recommendations issued by WHO to States Parties with respect to persons
may include the following advice: no specific health measures are advised;
review travel history in affected areas; review proof of medical examination
and any laboratory analysis; require medical examinations; review proof of
vaccination or other prophylaxis; require vaccination or other prophylaxis;
place suspect persons under public health observation; implement
quarantine or other health measures for suspect persons; implement
isolation and treatment where necessary of affected persons; implement
tracing of contacts of suspect or affected persons; refuse entry of suspect
and affected persons; refuse entry of unaffected persons to affected areas;
and implement exit screening and/or restrictions on persons from affected
areas.\textsuperscript{131}

Many of these recommendations apply to containment of antibiotic-resistant
bacteria, including review of travel history, review of medical or laboratory
information, and quarantine and isolation of affected travelers. These
recommendations may be either temporary or standing recommendations,
depending upon the temporal nature of the outbreak.


130 IHR at 15 (cited in note 8).

131 Id at 17.
1. Temporary recommendations.

To prevent antibiotic-resistance bacteria transmission, temporary recommendations, which are only applicable for a specific time period or during the duration of the outbreak, would be less useful than standing recommendations. Temporary recommendations "may include health measures to be implemented by the State Party experiencing the public health emergency of international concern, or by other States Parties, regarding persons, [etc.,] to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic." The WHO is likely to be more willing to issue temporary recommendations because of their nonpermanent nature. Since the IHR requires the WHO to consider the economic repercussions of any recommendations issued, restrictive recommendations are more likely to be temporary, allowing regular travel and trade to resume after the outbreak. For antibiotic-resistant bacteria, the risk of transmission would not diminish until the new bacteria were actually transmitted internationally—effectively making temporary recommendations into standing recommendations until the temporary recommendations fail.

2. Standing recommendations.

Standing recommendations have a greater likelihood of success than temporary recommendations in containing antibiotic-resistant bacteria over time, but the WHO may be more hesitant to issue them. Although the WHO has the same power to make standing recommendations as it has to make temporary ones, the requirement that the recommendations be the least restrictive possible makes standing recommendations less useful. Thus, potential standing recommendations would more likely be less restrictive, such as review of travel history and review of medical records. Since medical tourists (as opposed to travelers who receive emergency treatment abroad) usually have visas indicating the medical nature of their trips, standing recommendations of this nature would be minimally restrictive on travel. In addition, review would allow member states to conduct testing and provide treatment highly likely to prevent transmission in domestic hospitals, making this type of recommendation highly effective.

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132 Id at 16.
133 Id.
VI. ALTERNATIVES TO RECOMMENDATIONS UNDER THE IHR TO PREVENT TRANSMISSION OF ANTIBIOTIC-RESISTANT BACTERIA

The IHR is not the only tool to help contain antibiotic-resistant bacteria and monitor the medical tourism industry. Other possibilities include: forgoing a regulatory scheme and allowing patients to seek the best healthcare per cost, essentially creating a race-to-the-top scheme for medical tourism hospitals; purely information-forcing regimes that would cooperate with a race-to-the-top scheme; and the classical IHR regime of allowing individual countries to regulate containment procedures for incoming antibiotic-resistant bacteria.

A. No Regulatory or Information-Forcing Regime

If the WHO and individual countries forgo any regulatory or information-forcing regime, the results are likely to lead to widespread international transmission of new antibiotic-resistant bacteria. This type of regime would require methods of getting accurate information to patients regarding the presence of antibiotic-resistant bacteria at destination hospitals. In practice, countries with strong medical tourism industries have little incentive to release information regarding emergence of antibiotic-resistant bacteria in their own country. This leaves other methods of dissemination for this type of information, none of which is as efficient as member state reporting. Media dissemination, for example, is dependent upon both adequate scientific research in the affected country and adequate incentives to give the information to the media. For scientists receiving government funding or conducting research with government permission, there may not be adequate incentives to provide this information to the media as soon as the risk arises. Reporting by other countries would be similarly inefficient, given that countries would be motivated to report all emerging resistances as originating in other countries, even if the resistance had originated in their own. Ultimately, the information reported would be perceived as unreliable due to political motivations or would actually be unreliable.

Even if media attention and medical tourism facilitation agencies could provide sufficient information, patients would not necessarily choose a hospital in order to minimize the risk of spreading antibiotic-resistant bacteria to their home country. The patient’s determination of destination hospital would include a number of factors, most importantly cost, but the patient would also balance

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134 See Section II.
a number of risk factors, such as accreditation, malpractice remedies, and other patient-protective concerns. Patients will seek out destination hospitals that best manage the combination of these risk factors, and they may find an acceptable tradeoff between the risk of exposure to antibiotic-resistant bacteria in exchange for affordable cost or greater potential remedy for complications.

B. Information-Forcing Regimes Only at Either the National or International Level

The next step toward more regulatory structure offers little help. Even if a national structure exists to force accurate information at a national or international level, the same problems with patient choice structures arise. Even with accurate information, the patient would not have the proper incentive to choose medical treatment in a destination country with the lowest risk of spreading new antibiotic-resistant bacteria. Either some additional incentive or regulation would have to be in place to induce the patient to select a destination based on this concern or to require hospitals to screen medical tourists for exposure in countries with emerging antibiotic resistance.

In addition, the failure of the classical IHR regime illustrates another potential problem with attempting to enforce only reporting requirements. With no control over national responses, there is little state motivation to report...
emergence of new antibiotic-resistant bacteria. The prior International Health Regulations, before the 2005 revision, illustrated the problems with compliance with an information-forcing-only scheme.

C. National Containment Procedures to Prevent Transmission of Incoming Antibiotic-Resistant Bacteria

A third alternative structure for containment would be to use only national regulatory schemes, possibly in addition to an information-forcing scheme. It is possible that political concerns about travel and trade restrictions would create proper motivation to force accurate information regarding antibiotic-resistant bacteria, since countries with a high number of medical tourists but less economic benefit from the medical tourism industry would otherwise place overly restrictive regulations in order to protect themselves. This proposal most closely approximates the classical International Health Regulation scheme in place prior to the 2005 revision. The classical regime had a number of problems while in force:

[Public health experts raised questions about the substantive nature of the classical regime, indicating that the law no longer responded to public health reality. In 1969, for example, one expert noted that the IHR did not apply to many infectious diseases that posed similar risks of international spread as the diseases subject to the Regulations. Similarly, another expert argued in 1974 that the diseases subject to the IHR “are the pestilential diseases of the past”, implying that the IHR were backward-looking rather than geared to the infectious diseases the world faced in the present and future. These criticisms illustrated the extent to which WHO did not revise, update and modernize the classical regime through its innovative constitutional provisions.]

The foremost concerns of the classical regime were that accurate information would not be reported and that the diseases included in the classical regime were limited and did not include newly arising health concerns. However, national containment procedures would suffer from similar problems: namely, the individual states would not receive information soon enough to prevent transmission and, without that information, the national regimes would not update information quickly enough to screen for the most current health concerns.

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139 See Fidler, 4 Chinese J Intl L at 333–35 (cited in note 37) (discussing four principle factors that led to the “marginalization and stagnation” of the prior regulative scheme).

140 See Section IV.A.1.

141 Fidler, 4 Chinese J Intl L at 336 (cited in note 37).
VII. Conclusion

The threat of emerging antibiotic-resistant bacteria in combination with medical tourism creates a significant public health and economic threat to national healthcare and patients. Due to the broad revisions in 2005, the IHR both applies to the development of this new danger and provides sufficient and appropriate levels of control through recommendations of travel and trade restrictions. The text of the IHR encompasses antibiotic-resistant bacteria when transmission via medical tourism is considered. Other alternative measures of containment, including market incentives, national regulation and information-forcing regimes, would not adequately protect countries from transmission into healthcare environments. Containment of antibiotic-resistant bacteria transmission through medical tourism using the IHR comports with the history, purpose, and text of the IHR and fits into the jurisdiction of the WHO.