

# Liability for Negligent Healthcare Clinical Risk Management in the United States and Germany

**Dissertation** im  
Studiengang  
Rechtswissenschaften vorgelegt  
von  
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im Januar 2023  
an der Juristischen Fakultät der Universität Passau

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Tag der Disputation: 27. Oktober 2023

## **Acknowledgements**

My completion of this dissertation was only possible because a great many people offered their guidance, support, and encouragement throughout this journey, which included mothering a toddler, a global pandemic, and two transatlantic moves. To them, I am forever grateful.

I would like to thank my Supervisor, Professor Dr. Jörg Fedtke, who originally encouraged me to go to Germany to engage in academic research and graciously hosted me at the University of Passau Faculty of Law. It was there that I began this academic endeavor. Professor Fedtke offered not only an economically viable opportunity for me as a young mother to remain in Passau as a PhD researcher, but he supported me from abroad when I returned to the US in the final stages of my PhD studies. I am also very grateful to the other members of my committee, including my committee chair, Professor Dr. Brian Valerius, and my second assessor, Professor Sara Gerke. Professor Gerke has been an incredible mentor to me.

I would also like to thank the Alexander von Humboldt Foundation for selecting me for the German Chancellor Fellowship Program. This experience sparked my interest in academic research and teaching. But more than that, it provided me with a lifelong global network and a cultural education that serves as a bedrock for my work as a comparative lawyer. Most importantly, it gave me friends whom I cherish and rely on still.

I am incredibly grateful to the Lawyering Program at New York University Law School for taking a chance on me. My time there provided me with valuable experience as a law teacher and legal researcher. My NYU colleagues, especially Britta Redwood, Edith Beerdsen, Tyler Rose Clemons, Brandon Johnson, Faraz Sanei, Haiyun Damon-Feng, and Dorien Ediger-Soto, provided excellent feedback during my dissertation drafting, and I am forever indebted to them for slogging through many pages on a topic outside of their own areas of interest.

On a personal level, I owe a huge debt of gratitude to my husband René and son Rainier, both of whom not only endured being dragged around the world but did so with great élan! René was a constant source of support and comfort, delivering food and water to my desk, proofreading chapters, fetching migraine medication, and generally holding down the fort for 6 years! To my dear Rainier, you have always been an inspiration, and I hope that this achievement someday inspires you!

I want to thank my family in Louisiana. My parents, Dawn Deogracias and Martin Nunez, and my siblings, Amber Nunez, Dorothy Nunez, and Martin Nunez, who, from day 1, never once questioned my life choices or my ability to succeed. You are all rock stars. My in-laws, and especially my mother-in-law, Kathleen Duffoure (who proofread my entire dissertation!), have been another constant source of encouragement and support. Finally, my grandmother, Barbara Deogracias, passed away in May 2023 and never got to see me become a doctor, but there is no one who would have been prouder. I miss her enormously and dedicate this entire endeavor to her.

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## Table of Abbreviations

AHRQ	Agency for Healthcare Research and Quality
APS	German Coalition for Patient Safety ( <i>Aktionsbündnis Patientensicherheit</i> )
ÄZQ	German Medical Center for Quality in Medicine ( <i>Ärztliches Zentrum für Qualität in der Medizin</i> )
BGB	German Civil Code ( <i>Bürgerliches Gesetzbuch</i> )
BGH	German Federal Court of Justice ( <i>Bundesgerichtshof</i> )
CIRS	Critical Incident Reporting System
CMS	Centers for Medicare and Medicaid
CRM	clinical risk management
DHHS	Department of Health and Human Services
EAHC	European Commission and the European Agency for Health and Consumers
EUNetPaS	European Union Network for Patient Safety
FMEA	failure modes effect analysis
FTA	behaviour fault tree analysis
HAS	French National Authority for Health
IfPS	Institute for Patient Safety ( <i>Institut für Patientensicherheit</i> )
IOM	Institute of Medicine
NQF	National Quality Forum
OECD	Organization for Economic Co-operation and Development
OLG	Higher Regional Court ( <i>Oberlandesgericht</i> )
PaSQ	European Network on Patient Safety and Quality of Care
PPACA	Patient Protection and Affordable Care Act
PRG	Germany's Patients' Rights Act ( <i>Patientenrechtegesetz</i> )
PSMLI	Patient Safety and Medical Liability Initiative
PSO	Patient Safety Organization
PSQIA	Patient Safety and Quality Improvement Act
PSQCWG	Patient Safety and Quality of Care Working Group
PSWP	Patient Safety Work Product
QuIC	Quality Interagency Coordination Task Force
RCA	root cause analysis
VA	U.S. Department of Veterans Affairs
WAPS	World Alliance for Patient Safety

## Zusammenfassung

Die moderne Medizin, die darauf abzielt, den Patienten eine wissenschaftlich verlässliche und therapeutisch nützliche Behandlung zukommen zu lassen, entwickelte sich erst im späten neunzehnten Jahrhundert. Mit dem Erfolg und der Akzeptanz der medizinischen Praxis als zentrale gesellschaftliche Institution wandelten sich auch die Krankenhäuser von Häusern für Kranke und Sterbende zu Einrichtungen für Lehre, Forschung und Heilung. Moderne Krankenhäuser haben großen Einfluss darauf, wie und wo Patienten medizinisch behandelt werden. Sie kontrollieren auch die Organisation des Behandlungsprozesses innerhalb des Krankenhauses und können durch den Prozess des klinischen Risikomanagements (CRM) die Rate der medizinischen Fehler direkt beeinflussen.

CRM ist der Teilbereich des Risikomanagements, der sich mit der Verbesserung der Qualität und Sicherheit der Patientenversorgung befasst. Es kann das Risiko von Schäden durch medizinische Fehler verringern, indem es versucht, Mängel in den organisatorischen Prozessen, die sich auf nahezu jeden Aspekt der Patientenversorgung im Krankenhaus auswirken, zu identifizieren, zu bewerten und zu korrigieren. Effektives CRM macht eine Gesundheitseinrichtung zu einem selbstlernenden System, das den medizinischen Behandlungsprozess ständig verbessert. Eine erfolgreiche CRM-Strategie erfordert eine interdisziplinäre Zusammenarbeit von Organisationswissenschaft, Medizin und Recht. Zentraler Bestandteil dieser Strategie ist die Schaffung einer Organisationskultur der Sicherheit.

Der Gedanke, dass medizinische Fehler in erster Linie durch die Organisationskultur verursacht werden und besser verhindert werden können als durch die Handlungen der einzelnen Leistungserbringer, wurde durch den Bericht *To Err Is Human: Building a Safer Health System* des Institute of Medicine (IOM) aus dem Jahr 1999 populär gemacht. In diesem Bericht stützte sich das IOM auf die Organisations- und Fehlerforschung des Soziologen Charles Perrow und des Psychologen James Reason, um zu erklären, dass medizinische Fehler im modernen Gesundheitswesen, einem Hochrisikosystem, in erster Linie durch systemische Fehler und nicht durch Fehler einzelner Anbieter entstehen. Sie wies darauf hin, dass die im Gesundheitswesen vorherrschende Kultur der "Schuldzuweisung und Beschämung", die sich auf die Bestrafung einzelner Leistungserbringer konzentriert, ein Hindernis für systemische Verbesserungen und wirksame Strategien zur Reduzierung medizinischer Fehler darstellt. Um medizinische Fehler zu reduzieren, empfahl das IOM, dass Organisationen im Gesundheitswesen eine Sicherheitskultur entwickeln sollten, die es ermöglicht, organisatorische Mängel zu erkennen und zu beseitigen.

Der IOM-Bericht erregte die Aufmerksamkeit von Gesundheitssystemen auf der ganzen Welt, die sich daraufhin bemühten, medizinische Fehler durch organisatorische Verbesserungen zu verringern. Die Weltgesundheitsorganisation (WHO) hat seitdem ihre Mitglieder zur Zusammenarbeit ermutigt, um durch nationale und internationale Bemühungen die Patientensicherheit voranzutreiben. Auf der Grundlage des IOM-Berichts konzentriert sich die

WHO bei diesen Bemühungen auf systemische Verbesserungen und rät von individuellen Schuldzuweisungen ab. Die WHO bezeichnete freiwillige, anonyme und sanktionsfreie Fehlermeldesysteme als wichtiges Instrument für organisatorisches Lernen. Die Organisation für wirtschaftliche Zusammenarbeit und Entwicklung (OECD) erkannte ebenfalls die weltweiten Kosten medizinischer Fehler an und forderte die Gesundheitssysteme auf, sich auf die Prävention zu konzentrieren, indem sie eine Kultur der Patientensicherheit schaffen, die darauf abzielt, systemische Mängel aufzudecken und zu beheben. In Europa hat die Europäische Union der Patientensicherheit Priorität eingeräumt und mehrere internationale und nationale Maßnahmen zur Verringerung medizinischer Fehler eingeleitet. Dazu gehören Empfehlungen zur Stärkung und Information der Patienten, zur Verbesserung der Ausbildung und der Arbeitsbedingungen des Gesundheitspersonals, zur Umsetzung wirksamer CRM-Strategien, zur Erleichterung der Fehlerberichterstattung und des Lernens sowie zur Förderung der internationalen Zusammenarbeit durch Forschung zur Entwicklung systembasierter Strategien zur Patientensicherheit.

In Deutschland wurde die Patientensicherheit sowohl im Rahmen der EU-Patientensicherheitsstrategie als auch auf nationaler Ebene in Angriff genommen. Der Bericht der Gesundheitsberichterstattung des Bundes hat im Jahr 2001 das Problem der Behandlungsfehler in Deutschland quantifiziert und seinen präventiven Handlungsauftrag auf die Behebung von Organisationsdefiziten konzentriert. Die Etablierung einer Sicherheitskultur zur Vermeidung von Behandlungsfehlern in Deutschland wurde 2002 fortgesetzt, indem die neu gegründete Expertengruppe Patientensicherheit des Ärztlichen Zentrums für Qualität in der Medizin (ÄZQ) eine gemeinsame Strategie zur Fehlerberichterstattung und -analyse entwickelte. Im Jahr 2003 diskutierte der Sachverständigenrat für die Konzertierte Aktion im Gesundheitswesen in seinem halbjährlichen Gutachten die systemischen Ursachen medizinischer Fehler und regte systemische Lösungen an, zu denen auch der Einsatz von Fehlerberichten und -analysen gehört. Das Jahr 2005 war für die Patientensicherheit in Deutschland ein richtungweisendes Jahr. Das Aktionsbündnis für Patientensicherheit (APS) wurde gegründet, um einen interdisziplinären, praktischen Ansatz zur Lösung des Problems der medizinischen Fehler in Deutschland zu fördern. Durch die Bemühungen der APS begannen deutsche Gesundheitsorganisationen, sich an internationalen und nationalen Kampagnen zur Patientensicherheit zu beteiligen, um die Zahl der Verletzungen von Patienten im Gesundheitswesen zu verringern. Im Jahr 2005 wurde in Deutschland das Critical Incident Reporting System (CIRS) ins Leben gerufen, ein nationales anonymes Fehlerberichts- und Lernsystem, das organisatorische Mängel aufdecken und korrigieren soll. Im Jahr 2009 gründete das APS das Institut für Patientensicherheit (IfPS), das akademische Forschung zum Thema Patientensicherheit betreibt und Empfehlungen und Schulungen zur Vermeidung medizinischer Fehler anbietet. Im Jahr 2013 wurde in Deutschland das Patientenrechtegesetz (PRG) verabschiedet, um sowohl die Patientensicherheit zu verbessern als auch die Rechte der Patienten zu stärken. Das PRG schrieb die Einführung von Risiko- und Qualitätsmanagement sowie von Patientenbeschwerde- und Fehlermeldesystemen in Gesundheitseinrichtungen vor, was zu einem drastischen Anstieg der Fehlerberichterstattung als Präventionsstrategie in deutschen Krankenhäusern führte.



In den Vereinigten Staaten verabschiedete der Kongress 1999 den Healthcare Research and Quality Act, der eine neue Behörde, die Agency for Healthcare Research and Quality (AHRQ), damit beauftragte, die Ursachen für medizinische Fehler zu ermitteln und zu beheben. Die AHRQ finanzierte Projekte zur Verbesserung der Patientensicherheitskultur, zur Verringerung medizinischer Fehler und zur außergerichtlichen Beilegung von Ansprüchen aus medizinischen Kunstfehlern. Im Jahr 2005 verabschiedete der Kongress den Patient Safety and Quality Improvement Act (PSQIA), um die Patientensicherheit und die Qualität der Gesundheitsversorgung zu verbessern. Der PSQIA förderte die Entwicklung und den Einsatz von Patientensicherheitsorganisationen (PSOs), die organisatorische Leistung zur Verbesserung der Patientensicherheit analysieren. Kurz nach dem IOM-Bericht von 1999 begann auch die Joint Commission, die Krankenhäuser akkreditiert, ihre Regulierungsbemühungen auf Patientensicherheit und organisatorische Leistung zu konzentrieren. Im Jahr 2008 sprach sich die Joint Commission für eine "Null-Schaden"-Strategie aus, bei der ein systemischer Ansatz zur Prävention medizinischer Fehler auf der Grundlage einer hochgradig zuverlässigen Wissenschaft verfolgt wird. Im Jahr 2015 verabschiedete der Kongress den Patient Protection and Affordable Care Act (PPACA), der in seinen neuen Finanzierungs- und Vergütungssystemen der Qualität der Versorgung Vorrang einräumt. Im Jahr 2015 begann die Joint Commission, Kapitel zur Patientensicherheit in ihre Akkreditierungshandbücher für Krankenhäuser und andere Gesundheitsorganisationen aufzunehmen. Diese Kapitel sollen den Organisationen eine Strategie an die Hand geben, wie sie durch Systemverbesserungen und insbesondere durch die Einführung einer "fairen und gerechten Sicherheitskultur" das Endziel "Null Schaden" erreichen können.

Während der IOM-Bericht externe Faktoren, einschließlich des Rechtssystems, als Einflussfaktoren auf die Patientensicherheit in Gesundheitseinrichtungen identifiziert, unterschätzt das IOM die Fähigkeit des medizinischen Haftungssystems, die Bemühungen der Branche um Patientensicherheit zu behindern. Zwar sollte das Rechtssystem die Unternehmen zu Investitionen in die Vermeidung von medizinischen Fehlern durch einen Systemansatz ermutigen, indem es Fehler "kostspielig" macht, doch die entscheidende Frage lautet: Von wem werden diese Kosten aufgenommen? Da sowohl das amerikanische als auch das deutsche Arzthaftungssystem in erster Linie auf die Handlungen einzelner Leistungserbringer im Gesundheitswesen und nicht auf Organisationen abzielt, besteht eine Diskrepanz zwischen den Stellen, die für die Vermeidung medizinischer Fehler durch Systemgestaltung verantwortlich und in der Lage sind (Gesundheitsorganisationen), und den Personen, die für medizinische Fehler rechtlich verantwortlich gemacht werden (einzelne Leistungserbringer). Damit das System der Arzthaftung die Bemühungen der Gesundheitsbranche um die Vermeidung medizinischer Fehler durch organisatorische Verbesserungen unterstützt und nicht behindert, muss es eine reale Bedrohung durch die gesetzliche Haftung für Gesundheitseinrichtungen bieten, die die modernen CRM-Standards nicht einhalten.

Sowohl in den USA als auch in Deutschland gibt es ein auf Fahrlässigkeit basierendes medizinisches Haftungssystem, obwohl beide Länder in unterschiedlichen Common Law- bzw. Civil Law-Systemen arbeiten. Das Recht der medizinischen Fahrlässigkeit basiert in beiden Rechtssystemen in erster Linie auf Richterrecht, obwohl das deutsche PRG einen Teil

der bestehenden Rechtsprechung zu medizinischen Behandlungsfehlern kodifiziert hat. Ein weiterer Unterschied für die medizinische Haftung in den beiden Rechtssystemen ist der Vorrang des Deliktsrechts in den USA im Vergleich zum Vertragsrecht in Deutschland. Nichtsdestotrotz gelten in beiden Rechtsordnungen ähnliche Rechtsnormen für die Entscheidung von Arzthaftungsfällen. Dies lässt sich im Großen und Ganzen auf den pragmatischen Interaktionismus zurückführen oder konkreter auf die Tatsache, dass die Grundsätze der Fahrlässigkeit in beiden Ländern sowohl für deliktische als auch für vertragliche Ursachen von Arzthaftungsfällen gelten.

Auf Fahrlässigkeit basierende Systeme erlegen den Akteuren, die ein mangelhaftes Verhalten an den Tag legen, eine Haftung auf. Infolgedessen zielen die medizinischen Haftpflichtsysteme sowohl in den USA als auch in Deutschland darauf ab, sowohl eine Entschädigung für durch mangelhaftes Verhalten verursachte Schäden zu gewähren als auch die Akteure von mangelhaftem Verhalten abzuhalten. In Deutschland tritt die Entschädigungsfunktion des Arzthaftungssystems für Opfer von Behandlungsfehlern hinter die Entschädigung durch das starke deutsche Sozialversicherungssystem zurück. In den Vereinigten Staaten wird die entschädigende Rolle des Arzthaftungssystems als unzuverlässig, ineffektiv und ineffizient kritisiert.

Was die Rolle des Arzthaftungssystems bei der Abschreckung von unerwünschtem oder mangelhaftem Verhalten betrifft, so erkennen beide Rechtssysteme die Abschreckung als legitimes Ziel des Systems an. In den USA zielt das Deliktsrecht im Allgemeinen darauf ab, von fahrlässigem Verhalten abzuschrecken und die Zahl der Unfälle zu verringern, und als Unterabschnitt des Deliktsrechts zielt das Recht der medizinischen Fahrlässigkeit auch darauf ab, medizinische Fehler zu verhindern, indem Gesundheitsdienstleister davon abgehalten werden, akzeptable Behandlungsstandards zu unterschreiten. In Deutschland beinhaltet die Kombination von Vertrags- und Deliktsrecht zur Bewertung der medizinischen Haftung unter Verwendung des Fahrlässigkeitsstandards implizit auch das Ziel der Abschreckung. Darüber hinaus haben sowohl die Bundesärztekammer als auch der deutsche Gesetzgeber die Abschreckung bzw. Fehlervermeidung ausdrücklich als treibende Kräfte hinter dem deutschen Arzthaftungssystem anerkannt.

Ob die verschuldensabhängige Haftung tatsächlich abschreckend wirkt und Unfälle verhindert, ist seit langem Gegenstand einer interdisziplinären Debatte. Die ökonomische Theorie des amerikanischen Deliktsrechts und das Modell der ökonomischen Effizienz im deutschen Deliktsrecht lassen den Schluss zu, dass die Haftung für fahrlässiges Verhalten, das zu Verletzungen führt, andere davon abhält, dasselbe Verhalten in Zukunft an den Tag zu legen. Nach der ökonomischen Theorie des Deliktsrechts werden rationale Akteure haftungsauslösendes Verhalten zu ihrem eigenen wirtschaftlichen Vorteil vermeiden. Das deutsche Deliktsrecht beruht auf einer ähnlichen Theorie, die davon ausgeht, dass Gerichte organisch Sorgfaltsstandards schaffen, indem sie den sozialen Nutzen einer Tätigkeit gegen die Kosten von Präventivmaßnahmen abwägen, und dass die Akteure ihr Verhalten entsprechend anpassen, um den sich entwickelnden Sorgfaltsstandards zu entsprechen.

Rechtsrealisten sind der Ansicht, dass Faktoren außerhalb des Deliktssystems für nicht fahrlässiges Verhalten und Unfallverhütung verantwortlich sind. Andere Rechtswissenschaftler vertreten die Auffassung, dass das Deliktssystem zwar abschreckend wirken kann, dass aber seine derzeitige Organisation die Fähigkeit des Systems zur Verhaltensänderung beeinträchtigt. Priest macht dafür unter anderem die verschuldensunabhängige Haftung verantwortlich, die die Akteure unabhängig von ihrer Fähigkeit, Schäden zu vermeiden, rechtlich zur Verantwortung zieht. Latin behauptet, dass das Deliktsrecht nicht auf "problemlösende Akteure" abzielt, die am ehesten in der Lage sind, Unfälle zu verhindern. Shumans psychologischer Ansatz für das Deliktsrecht besagt, dass sich das Verhalten als Reaktion auf das derzeitige Deliktsrecht nicht ändern wird, weil nicht alle Akteure rationale Entscheidungsträger sind, und dass, selbst wenn sie es wären, die erforderliche Gewissheit der Bestrafung für mangelhaftes Verhalten durch das Deliktsrecht fehlt.

Die derzeitigen medizinischen Haftpflichtsysteme in den USA und in Deutschland haben, obwohl sie Abschreckung als Ziel anerkennen, wenig Erfolg bei der Verhinderung von medizinischen Fehlern gehabt. Die Beziehungen zwischen den einzelnen Leistungserbringern im Gesundheitswesen und ihren Patienten unterscheiden die Beklagten bei medizinischen Fehlern von den Tätern, so dass potenzielle wirtschaftliche Beweggründe im Allgemeinen weniger ins Gewicht fallen. Da das Wohlergehen der Patienten für die einzelnen Leistungserbringer im Allgemeinen Vorrang hat, unabhängig von der möglichen Haftung, führt die emotionale und berufliche Konsequenz, als Beklagter in einem Arzthaftungsfall genannt zu werden, nicht zu einem besseren, sichereren Verhalten, sondern eher zu einer defensiven Medizin. Defensivmedizin hat bestenfalls keine Auswirkungen auf die Patientensicherheit, schlimmstenfalls erhöht sie die Rate der medizinischen Fehler. Da es sich bei der defensiven Medizin um eine Verhaltensänderung als Reaktion auf die Deliktshaftung handelt, bezeichnen Mello und Studdert sie als "mutierende Abschreckung".

Das System der Arzthaftung ist auch nicht in der Lage, ärztliche Kunstfehler zuverlässig zu identifizieren, was es zu einer schlechten Informationsquelle dafür macht, warum medizinische Fehler auftreten und wie sie in Zukunft verhindert werden können. Infolgedessen wird das System der Arzthaftung von den einzelnen Leistungserbringern im Gesundheitswesen häufig als willkürlich angesehen, so dass es nicht die erforderliche Sicherheit bietet, um eine abschreckende Wirkung zu erzielen. Doch selbst wenn das System der Arzthaftung erfolgreich gegen individuelle Fahrlässigkeit vorgehen würde, wäre die Auswirkung auf die medizinische Fehlerquote wahrscheinlich vernachlässigbar, da die Ausrichtung der Präventionsbemühungen auf aktive Fehler von Einzelpersonen, die am Ende der Prozesskette auftreten, nicht die organisatorischen Mängel beheben wird, die den Verletzungsverursachenden Fehler überhaupt erst verursacht haben. Schlimmer noch, die unerkannten organisatorischen Mängel werden wahrscheinlich auch in Zukunft zu ähnlichen Verletzungen führen. Schließlich führt das medizinische Haftungssystem nicht nur zu einer defensiven Medizin, sondern auch dazu, dass die Leistungserbringer aus Angst vor rechtlichen Konsequenzen zögern, die systemischen Ursachen medizinischer Fehler zu melden und zu diskutieren.

Das medizinische Haftungssystem muss auch als gerecht empfunden werden, ein Attribut, das die Auswirkungen auf das berücksichtigt, was die Gesellschaft als wertvolle Wirtschaftstätigkeit ansieht. Bislang haben sowohl die USA als auch Deutschland die vorgeschlagene Einführung einer verschuldensunabhängigen Arzthaftung abgelehnt und sich stattdessen für die Beibehaltung des auf Fahrlässigkeit basierenden Systems entschieden. Die Reformbemühungen in beiden Ländern befassen sich mit Themen wie außergerichtliche Streitbeilegung, Screening-Panels und Schadensersatzobergrenzen, um die steigenden Prämien für Arzthaftpflichtversicherungen, die Verschlechterung des Arzt-Patienten-Verhältnisses und die Abneigung von Ärzten, in risikoreichen Fachgebieten zu praktizieren, einzudämmen. Mit diesen Reformen wurde versucht, der - ob zutreffend oder nicht - herrschenden Meinung entgegenzuwirken, dass das medizinische Haftpflichtsystem ungerecht ist.

Um eine wirksame Reform der Arzthaftung in einem auf Fahrlässigkeit basierenden System zu erreichen, sollten die Bemühungen darauf abzielen, einen Paradigmenwechsel herbeizuführen, der das Arzthaftungssystem mit dem organisationsorientierten Systemansatz für medizinische Fehler in Einklang bringt, der in der Gesundheitsbranche verwendet wird. Die Verlagerung der Haftung von einzelnen Leistungserbringern auf Organisationen des Gesundheitswesens verspricht, das Ziel des medizinischen Haftungssystems, nämlich die Abschreckung, besser zu erreichen und gleichzeitig Hindernisse für die Fehlerprävention in der Gesundheitsbranche zu beseitigen. Wenn sich das medizinische Haftungssystem auf die organisatorischen Akteure konzentriert, die am meisten für medizinische Fehler verantwortlich und in der Lage sind, diese zu verhindern, und deren Verhalten am ehesten durch die Kosten einer Haftung abgeschreckt wird, kann das medizinische Haftungssystem eine entscheidende Rolle bei der Vermeidung künftiger medizinischer Fehler spielen.

In beiden Rechtssystemen wird die zivilrechtliche Haftung für medizinische und organisatorische Fehler auf der Grundlage eines auf Fahrlässigkeit basierenden Systems beurteilt, das darauf abzielt, unangemessenes Verhalten zu verhindern und geschädigte Patienten zu entschädigen. Medizinische Fahrlässigkeit liegt vor, wenn die Verletzung einer gesetzlichen Pflicht oder Verpflichtung zu einer Verletzung des Patienten führt. In den USA entsteht die gesetzliche Pflicht oder Verpflichtung gegenüber dem Patienten in Verbindung mit der Arzt-Patienten-Beziehung. In Deutschland sind die Leistungserbringer im Allgemeinen durch den Behandlungsvertrag und das deutsche Deliktsrecht dazu verpflichtet, Patienten nicht fahrlässig zu behandeln. Um eine rechtliche Verpflichtung des Leistungserbringers gegenüber dem Patienten festzustellen, prüfen die US-Gerichte in erster Linie deliktische Pflichten, während die deutschen Gerichte sich auf die durch den Behandlungsvertrag begründeten Beziehungen konzentrieren. Dennoch untersuchen beide Rechtssysteme das Verhalten der einzelnen Leistungserbringer, um festzustellen, ob ein Behandlungsfehler vorliegt, und beide Rechtssysteme erkennen Theorien der stellvertretenden Haftung für Ärzte und Gesundheitseinrichtungen an, die fahrlässige Leistungserbringer beaufsichtigen oder beschäftigen. Darüber hinaus erkennen beide Rechtssysteme an, dass Organisationen des Gesundheitswesens organisatorische Fehler begehen können, indem sie Patienten direkt und unabhängig voneinander Schaden zufügen.

Angemessenes Verhalten im Zusammenhang mit der medizinischen Behandlung durch einen einzelnen Leistungserbringer umfasst die von der Ärzteschaft festgelegten Standards. Beide Gerichtsbarkeiten wenden objektive Sorgfaltsstandards an, die sich am Stand der medizinischen Wissenschaft zum Zeitpunkt des mutmaßlichen Fehlverhaltens orientieren, aber dennoch flexibel genug sind, um die Umstände des jeweiligen Einzelfalls zu berücksichtigen. Folglich halten beide Rechtsprechungen Ärzte zwar an einen objektiven, auf Kompetenz basierenden Behandlungsstandard fest, der sich am aktuellen Stand der medizinischen Wissenschaft orientiert (z. B. die richtige Medikamentendosis), sie passen den Behandlungsstandard jedoch an die dem Arzt zur Verfügung stehenden Mittel an (z. B. Zugang zu einem bestimmten bildgebenden Gerät). Für die Feststellung eines Verstoßes gegen den anwendbaren Behandlungsstandard ist in beiden Rechtsordnungen in der Regel das Gutachten eines Sachverständigen erforderlich. Während amerikanische Gerichte jedoch auf das Erfordernis eines Sachverständigengutachtens zur Feststellung des Behandlungsstandards verzichten können, verlangen deutsche Gerichte zwar ein Sachverständigengutachten, können aber die Meinung des Sachverständigen zum anwendbaren rechtlichen Behandlungsstandard außer Acht lassen.

Um festzustellen, ob ein Verstoß gegen den Sorgfaltsstandard eine medizinische Verletzung hinreichend verursacht hat, wird in beiden Rechtsordnungen geprüft, ob der Verstoß die alleinige Ursache für die Verletzung war. Darüber hinaus verlangen beide Rechtssysteme, dass zwischen dem Verstoß und dem daraus resultierenden Schaden ein hinreichender Zusammenhang besteht, damit die Auferlegung der Haftung gerecht und angemessen ist. In den USA muss der Schaden eine vernünftigerweise vorhersehbare Folge des Verstoßes sein, während die strengere Angemessenheitstheorie in Deutschland ~~nur~~ verlangt, dass der Verstoß "allgemein geeignet" ist, den Schaden des Patienten herbeizuführen. Außerdem ist es in keiner der beiden Rechtsordnungen erforderlich, dass das fahrlässige Verhalten die einzige Ursache für eine Schädigung ist, und ein Schädiger wird im Allgemeinen nicht von der Haftung befreit, wenn es sich um gleichzeitige oder aufeinander folgende Ursachen handelt.

Wenn eine Verletzung der Sorgfaltspflicht zu einer Verletzung des Patienten führt, umfasst der ersetzbare Schaden sowohl wirtschaftliche Schäden, einschließlich berechenbarer Schäden wie medizinische Kosten und entgangener Lohn, als auch nichtwirtschaftliche Schäden, einschließlich Schmerzen und Leiden und Verlust der Lebensfreude. Die Rechtsprechung unterscheidet sich in mehreren Aspekten des Schadenersatzes für medizinische Verletzungen. Inhaltlich ist der Verlust der Chance auf ein besseres Ergebnis in den USA ein erstattungsfähiger Schaden, in Deutschland jedoch nicht. Was die Höhe des Schadenersatzes angeht, so werden die deutschen Schadenersatzleistungen von den hohen Schmerzensgeldern amerikanischer Geschworener in den Schatten gestellt, auch wenn in einigen US-Gerichtsbarkeiten der Schadenersatz bei ärztlichen Kunstfehlern begrenzt ist. Was die Form betrifft, so zahlen amerikanische Gerichte im Allgemeinen Pauschalbeträge für künftige wirtschaftliche Schäden, während Deutschland sich für vierteljährliche Renten entscheidet. Auf politischer Ebene bietet Deutschlands starkes Sozialversicherungssystem ein Maß an Schutz für die menschlichen Grundbedürfnisse, einschließlich Gesundheitsfürsorge

und Wohnraum, das die Abhängigkeit von Schadensersatzzahlungen durch das Rechtssystem als Sozialversicherung, wie sie in den USA gesehen wird, verringert.

Für die Haftung bei Organisationsfehlern gilt derselbe Fahrlässigkeitsrahmen; da die Organisation jedoch technisch gesehen keine Medizin ausübt, werden Organisationsfehler nach anderen Normen für gesetzliche Pflichten und Behandlungsstandards behandelt. Beide Rechtsprechungen stimmen darin überein, dass moderne Krankenhäuser direkt gegenüber den Patienten verpflichtet sind, die medizinische Behandlung im Krankenhaus zu organisieren. In den Vereinigten Staaten kann eine Organisation direkt haftbar gemacht werden, wenn sie es versäumt, kompetente Ärzte auszuwählen und zu beschäftigen, geeignete Einrichtungen und Geräte zu unterhalten, Mitarbeiter zu schulen und zu beaufsichtigen und geeignete Protokolle und Verfahren anzuwenden. Auch im deutschen Recht sind verschiedene organisatorische Pflichten anerkannt, darunter Pflichten zur Organisation und Überwachung von Personalplänen, zur Beaufsichtigung und Anleitung von Mitarbeitern, zur Schaffung einer Organisationsstruktur für die Aufnahme von Patienten sowie organisatorische Fehler in Bezug auf Einwilligung, Dokumentation, Hygiene und Sicherheit sedierter Patienten. Der für Gesundheitsorganisationen in den USA geltende Behandlungsstandard ergibt sich in erster Linie aus einer Kombination von staatlichen und behördlichen Zulassungs- und Akkreditierungsstandards sowie den eigenen Standards und Vorschriften der Organisation. In Deutschland erfordert der organisatorische Sorgfaltsstandard angemessene Anstrengungen zur Sicherstellung einer qualitativ hochwertigen medizinischen Versorgung und zur Beseitigung von Fehlern gemäß den anerkannten Standards in der Medizin. Trotz eines sich ausweitenden Rechtsrahmens für organisatorische Fahrlässigkeit in beiden Rechtsordnungen hat sich das Gesetz in diesem Bereich nie auf die Verantwortung der Gesundheitsorganisation konzentriert, medizinische Fehler mit CRM zu verhindern.

In beiden Gerichtsbarkeiten verlangen die Standard-Beweisregeln von den Klägern, dass sie die für den Nachweis ihrer Ansprüche erforderlichen Elemente nachweisen. Ein Unterschied in den Beweisregeln ist der Beweisstandard, nach dem die Kausalität bestimmt wird, wobei in den USA ein "angemessener Grad an medizinischer Gewissheit" [by a preponderance of the evidence] und in Deutschland ein strengerer Standard der "vollen richterlichen Überzeugung" gilt. Es gibt einige Umstände, unter denen die Beweislast des Klägers, dass der Beklagte gegen die Sorgfaltspflicht verstoßen hat, reduziert oder aufgehoben wird. In den USA gilt nach dem Grundsatz *res ipsa loquitur* für den Kläger eine Fahrlässigkeitsvermutung, die vom Beklagten widerlegt werden muss. In Deutschland dient das Konzept der "voll beherrschbaren Risiken" dazu, die Beweislast für Fahrlässigkeit (oder deren Fehlen) auf den Beklagten zu verlagern. Das deutsche Recht verlagert auch die Beweislast für den Kausalitätsnachweis in Fällen von Anfänger- oder groben Fehlern.

Die primäre Beweisquelle in Fällen von ärztlichen Kunstfehlern sind die medizinischen Behandlungsunterlagen des Klägers. In beiden Rechtsordnungen haben Patienten das Recht, ihre eigenen Krankenakten zu erhalten, indem sie diese direkt beim beklagten Anbieter anfordern. In Deutschland haben Patienten, die einen Behandlungsfehler vermuten, außerdem einen Rechtsanspruch auf Unterstützung durch ihre Krankenkasse, die auch die Beschaffung

von Krankenakten umfassen kann. Beide Rechtsordnungen erlauben es den Parteien auch, im Laufe eines Rechtsstreits gegenseitig Unterlagen anzufordern, obwohl die deutschen Vorschriften zur vorprozessualen Offenlegung konservativer sind als die in den USA und den Zugang zu Dokumenten stärker einschränken. Die konservative Offenlegungspraxis in Deutschland ist in erster Linie auf die Anerkennung des Rechts auf Selbstbelastungsfreiheit sowohl im straf- als auch im zivilrechtlichen Kontext zurückzuführen. Schließlich bemühen sich beide Rechtsordnungen um die Vertraulichkeit von Dokumenten und Informationen, die zur Verbesserung der Pflegequalität verwendet werden, indem sie diese von der Offenlegung ausnehmen. Ein zuverlässigerer Schutz der Bemühungen einer Organisation um die Verbesserung der Patientensicherheit ist jedoch entscheidend für die Schaffung einer rechtlichen Verpflichtung für Organisationen zum Risikomanagement im Gesundheitswesen.

Damit in beiden Arzthaftungssystemen ein rechtlicher Grund für eine Klage wegen fahrlässigem CRM entstehen kann, müssen die Gesundheitsdienstleister zunächst eine rechtliche Pflicht oder Verpflichtung gegenüber den Patienten haben, CRM durchzuführen. Deutsche Rechtswissenschaftler sind der Meinung, dass eine rechtliche Verpflichtung zu CRM, auch wenn sie von der Rechtsprechung nicht ausdrücklich anerkannt wird, als eine Erweiterung der bestehenden Organisationspflichten von Gesundheitsorganisationen angesehen werden kann. Diese Erweiterung wird ihrer Ansicht nach durch das allgemeine Fahrlässigkeitsrecht, die bestehende Rechtsprechung zu Organisationspflichten und die bestehenden Verpflichtungen von Produktherstellern zur Risikovermeidung im Produkthaftungsrecht gestützt. In den USA gibt es eine vergleichbare Grundlage für die Feststellung einer CRM-Pflicht, da (1) die medizinische Haftung in beiden Rechtsordnungen auf ähnlichen fahrlässigkeitsbasierten Prinzipien beruht, (2) die Rechtsprechung in beiden Rechtsordnungen bestehende Sorgfaltspflichten für Organisationen im Gesundheitswesen in ähnlicher Weise anerkennt und (3) das Produkthaftungsrecht in beiden Rechtsordnungen den Herstellern ähnliche Risikomanagementpflichten auferlegt. Infolgedessen unterstützen die bestehenden medizinischen Haftpflichtsysteme beider Länder die Feststellung einer Verpflichtung zur CRM für Organisationen im Gesundheitswesen.

Sobald Organisationen des Gesundheitswesens nach dem Arzthaftungsrecht für die Durchführung von CRM verantwortlich sind, muss es Sorgfaltsstandards geben, nach denen diese Verantwortung beurteilt wird. Damit die Auferlegung der Haftung für fahrlässige CRM eine wirksame Abschreckung darstellt, sollten die Sorgfaltsstandards sowohl angemessen als auch vorhersehbar sein. Auch hier haben deutsche Rechtswissenschaftler bereits einen Rahmen für die Ausgestaltung von Sorgfaltsmaßstäben für CRM erwogen. Dieser Rahmen basiert auf einem bestehenden CRM-Prozess, der in der Gesundheitsbranche international anerkannt ist und in vier Phasen des Risikomanagements unterteilt werden kann: Risikoidentifizierung, Risikoanalyse, Risikobewertung und Risikokontrolle. Die Risikoidentifizierung erfordert von den Gesundheitsorganisationen die Einführung von Systemen zur Aufdeckung von Systemmängeln. Freiwillige Fehlermelde- und Lernsysteme sind ein entscheidender Teil des Risikoidentifizierungsprozesses. Die Risikoanalyse dient dazu, die Ursachen und Auswirkungen der ermittelten Risiken zu ermitteln, um besser zu verstehen, warum Risiken auftreten und wie sie verhindert oder minimiert werden können. Die Risikobewertung

bestimmt die Wahrscheinlichkeit und den Schweregrad eines jeden Risikos, so dass die Risiken für den Risikokontrollprozess priorisiert werden können. Die Risikokontrolle erfordert, dass Organisationen des Gesundheitswesens Maßnahmen zur Risikoprävention entwickeln, umsetzen und überwachen. Es gibt verschiedene Methoden für die Durchführung jeder Phase des CRM-Prozesses, die dem Sorgfaltsstandard entsprechen und deren Auswahl von der Größe und den Ressourcen der Gesundheitseinrichtung und/oder der Art der ermittelten spezifischen Risiken abhängen kann.

Schließlich muss ein rechtlicher Klagegrund für CRM ein Gleichgewicht zwischen der Vertraulichkeit, die erforderlich ist, um eine Sicherheitskultur in Organisationen des Gesundheitswesens zu etablieren, die für den Erfolg von CRM entscheidend ist, und der Transparenz des CRM-Prozesses, die erforderlich ist, um sicherzustellen, dass Organisationen des Gesundheitswesens für fahrlässige Praktiken zur Verantwortung gezogen werden können, herstellen. Um die Vertraulichkeit zu gewährleisten, die die Sicherheitskultur ermöglicht, die für ein funktionierendes CRM-System entscheidend ist, sollten die Gerichte einen Offenlegungs- und Beweisschutz für Dokumente und Informationen bieten, die im Rahmen des CRM-Systems entwickelt wurden und sich auf einzelne Vorfälle beziehen und einzelne Anbieter identifizieren. Um sicherzustellen, dass Patienten bei fahrlässigen CRM-Praktiken von Organisationen über einen realisierbaren Klagegrund verfügen, sollten die Gerichte einem Paradigma der Lastverteilung folgen, das: (1) eine Fahrlässigkeitsvermutung aufstellt, wenn die Verletzung des Klägers aus einer CRM-Aktivität resultiert, die vollständig unter der Kontrolle der Organisation steht; und (2) die Beweislast umkehrt (oder eine gesetzliche Vermutung anwendet), wenn es um die Frage der Verursachung im Falle grob fahrlässiger CRM-Aktivitäten geht. Einige Varianten dieser Beweisregeln sind für die erfolgreiche Entwicklung der Pflicht zum Risikomanagement entscheidend.

Zusammenfassend lässt sich sagen, dass eine CRM-Pflicht für Organisationen des Gesundheitswesens ein entscheidender Aspekt der Prävention von medizinischen Fehlern ist, da sie unsicheres Organisationsverhalten verhindern, die Kultur der Patientensicherheit verbessern kann, indem sie die Angst der einzelnen Leistungserbringer vor Beschämung, Schuldzuweisung und Sanktionen im Rahmen des gesetzlichen Haftungssystems abbaut, und die Praxis der defensiven Medizin eindämmt, indem sie die Haftung zu einem zuverlässigeren Indikator für verletzungsverursachendes Organisationsverhalten macht. Die Gerichte, die über Klagen wegen fahrlässigen Risikomanagements entscheiden, müssen jedoch Beweismittel und Beweisregeln als Instrumente einsetzen, um das empfindliche Gleichgewicht zwischen der Vertraulichkeit, die für die Aufrechterhaltung einer Sicherheitskultur in Organisationen des Gesundheitswesens erforderlich ist, und der Transparenz, die erforderlich ist, um Organisationen des Gesundheitswesens für fahrlässiges CRM zur Rechenschaft zu ziehen, herzustellen. Auch wenn das medizinische Haftpflichtsystem nicht die treibende Kraft für die Prävention medizinischer Fehler sein kann und soll, so sollte es doch die akzeptierten Normen für die Fehlerprävention im modernen Gesundheitswesen stärken und zumindest die Präventionsbemühungen der Branche nicht behindern. Ein gut ausgearbeiteter Klagegrund für das Risikomanagement wird dazu beitragen, das medizinische Haftungssystem sowohl in den



USA als auch in Deutschland besser mit dem systembasierten Ansatz der Gesundheitsbranche bei organisatorischen Fehlern in Einklang zu bringen.

# 1. Introduction

## 1.1 Background

Two long-held convictions lie at the heart of this dissertation. First, the maxim of *primum non nocere*, which articulates the fundamental bioethics principle that doctors are obliged “first, to do no harm.”<sup>1</sup> Second, the proverb *errāre hūmānum est*, meaning “to err is human,” popularized by Alexander Pope in *An Essay on Criticism* and reinvented by the Institute of Medicine (IOM) to express that everyone, even doctors, make mistakes.<sup>2</sup> What follows from these notions are legal questions about who bears responsibility for medical mistakes that cause patient harm. The easy answer and the one historically adopted by the medical liability systems in both the United States and Germany is that the individual healthcare provider who made the mistake is primarily responsible.<sup>3</sup> This answer, however, ignores the complexities of the modern healthcare delivery system. It ignores the fact that beyond the faces of doctors and nurses lies an intricate and complex organization, one that has the capacity to induce and ability to reduce medical errors that harm patients through the design of its organizational systems.<sup>4</sup>

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<sup>1</sup> See Christine Harrison, *Primum non nocere is only the beginning*, 12(5) Paediatrics Child Health 379, 379 (2007) (“‘First do no harm’ is considered one of the primary ethical principles of medical practice.”).

<sup>2</sup> Alexander Pope, *An essay on criticism* (1711); Inst. of Medicine [IOM], *To Err Is Human: Building a Safer Health System* (Linda T. Kohn et al. eds., 2000) (1999), available at <https://www.nap.edu/catalog/9728/to-err-is-human-building-a-safer-health-system>.

<sup>3</sup> See Michelle M. Mello & David M. Studdert, *The Medical Malpractice System: Structure and Performance*, in *Medical Malpractice and the U.S. Health Care System* 12–13 (William M. Sage & Rogan Kersh eds., 2006) (physicians are primary targets of medical malpractice claims in the U.S.). See also Wolfgang Voit, *Entsprechung und Abweichungen nach deutschem Arzthaftungsrecht* [Equivalence and deviations according to German medical liability law], in Peter Jabornegg, Reinhard Resch & Otfried Seewald, *Haftungsfragen im System der Leistungserbringung des Krankenversicherungsrechts* [Liability issues in the health insurance law claims management system] 23-24 (2006) (F.R.G) (noting that despite the ability to find organizations directly liable for patient injuries, in practice, physicians will remain primary litigants in medical malpractice cases). See generally Interview with Hermann Liebermeister, German physician and retired member of the Saarland medical arbitration body, in Frankfurt, Germany (Mar. 7, 2017), available at [www.medriskreport.com](http://www.medriskreport.com) (discussing the inability of medical arbitration boards to consider organizational fault because legal system is focused on personal faults of individual doctors); Interview with Jana Hassel, a plaintiffs’ medical malpractice attorney, in Berlin (November 2017), available at [www.medriskreport.com](http://www.medriskreport.com) (explaining that organizational errors are rarely considered in medical malpractice cases); Bundesärztekammer, *Statistische Erhebung der Gutachterkommissionen und Schlichtungsstellen für das Statistikjahr 2020* [Statistical survey of the expert commissions and arbitration boards for the statistical year 2020], available at [https://www.bundesaerztekammer.de/fileadmin/user\\_upload/\\_old-files/downloads/pdf-Ordner/Behandlungsfehler/Statistische\\_Erhebung\\_2020\\_neu.pdf](https://www.bundesaerztekammer.de/fileadmin/user_upload/_old-files/downloads/pdf-Ordner/Behandlungsfehler/Statistische_Erhebung_2020_neu.pdf) (last visited Oct. 29, 2022) (statistics compiled for the purpose of helping identify causes of medical errors showing no findings of organizational errors, presumably because the expert commissions and arbitration boards do not consider organizational errors) (F.R.G).

<sup>4</sup> See generally IOM, *supra* note 2.

Because this amorphous organization does not have hands to hold a scalpel that inadvertently nicks a muscle or eyes to misread a medication order, it generally escapes blame and legal liability for medical errors that ultimately manifest through an individual provider's actions. But modern error prevention research proves that design defects in a healthcare organization's systemic processes play a prominent role in medical errors.<sup>5</sup> More importantly, healthcare organizations, through the process of clinical risk management (CRM), have the ability and the responsibility to identify and cure those error-inducing system design defects.<sup>6</sup> Further, blaming individual providers for medical errors while ignoring the deep-seated systemic deficiencies in healthcare organizations is not an effective error prevention strategy.<sup>7</sup>

While the IOM's 1999 report *To Err Is Human: Building a Safer Health System* ignited a paradigm shift that led the healthcare industry to approach medical error prevention with an organizational, rather than individual, focus, that same shift has not occurred in either the American or German medical liability systems, where individual providers remain the primary targets in medical malpractice litigation.<sup>8</sup> This continued focus on individual providers in the medical liability system negatively impacts patient safety in two significant ways.

First, it decreases safety culture within healthcare organizations by discouraging individual providers from speaking about medical errors, encouraging the practice of defensive medicine, and discouraging doctors from treating complicated patients. The threat of litigation is one well documented cause of the culture of silence – reluctance to discuss medical errors – in both the U.S. and Germany.<sup>9</sup> In contrast, legal policies that encourage healthcare providers to discuss medical errors both internally and with their patients can promote safety culture, facilitate organizational learning, and decrease medical errors.<sup>10</sup>

Additionally, the practice of defensive medicine, in which providers overprescribe medical care to patients to avoid potential lawsuits, puts patients at additional risk of harm simply because they are undergoing additional, often unnecessary, medical treatment.<sup>11</sup> Danielle Ofri

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<sup>5</sup> See *id.* at 2.

<sup>6</sup> World Health Organization [WHO], WHO Multi-professional Patient Safety Curriculum Guide, 63 (2011), available at <https://www.who.int/publications/i/item/9789241501958> (discussed in Topic 6: Understanding and managing clinical risk).

<sup>7</sup> See IOM *supra* note 2, at 55-56.

<sup>8</sup> See sources cited *supra* note 3.

<sup>9</sup> See Kai Loewenbrück et al., *Disclosure of adverse outcomes in medicine: A questionnaire study on voice intention and behaviour of physicians in Germany, Japan and the USA*, 30(3-4) *German J. Hum. Res. Mgmt.* 313-314 (2016); Mello & Studdert, *supra* note 3, at 28-29.

<sup>10</sup> See generally Mindy Nunez Duffourc, *Filling Voice Promotion Gaps in Healthcare Through A Comparative Analysis of Error Reporting and Learning Systems and Open Communication and Disclosure Policies in the United States and Germany*, 44 *Am. J.L. & Med.* 579 (2018).

<sup>11</sup> Danielle Ofri, *When We Do Harm: A Doctor Confronts Medical Error* 142-143 (2020) (discussing negative impact of defensive medicine on patient safety); see Mark Stauch, *The Law of Medical Negligence in England and Germany: A Comparative Analysis* 131-132 (2008) (regarding the widespread assumption that the practice of defensive medicine occurs in Germany and claims that

explains how additional imaging, a common defensive medicine practice, can lead to kidney damage, cancer, and false positive diagnoses.<sup>12</sup> She further notes that, “even knowing doctors win most cases doesn’t assuage the terror or reduce the aggressive over-testing and overtreatment from defensive medicine.”<sup>13</sup> Another provider response to medical malpractice lawsuits, or the mere threat thereof, that ultimately inures to the detriment of patients is reluctance to treat complicated illness.<sup>14</sup> Ofri recounts such a response by a psychiatrist who endured, and ultimately won, a five-year medical malpractice lawsuit that destroyed her personally and professionally after one of her patients committed suicide.<sup>15</sup> More than half of doctors who had been sued, and 40% who only feared being sued, reported that malpractice fears affected their patient care.<sup>16</sup> Christiane Goldbach agrees that when medical errors are equated with the personal failures of an individual physician, the physician feels attacked and assumes a defensive position.<sup>17</sup>

The second reason that the continued focus on individual providers in the medical liability system negatively impacts patient safety is that the system fails to act as an effective legal mechanism for creating and enforcing standards that promote systemic improvement in healthcare organizations. As Ofri points out, the reaction of British doctors following a highly publicized criminal conviction of a physician after a patient death was that the legal system was used as a “weapon to scapegoat doctors for the shortcomings of the entire medical system.”<sup>18</sup> The ability of the tort system to ignite change is one of its strengths; however, when the system has the wrong targets in its crosshairs, it can hinder, rather than promote, societal improvement. As long as the medical liability system serves as a public forum for scapegoating individual providers, it will not be an effective catalyst for systemic improvement within the healthcare system. Instead, a medical liability system that is completely misaligned with the industry’s systems-focused error prevention efforts will negatively impact patient safety. William Sage observed, “patient safety has yet to improve measurably in the five years since the first IOM report, in part because medical liability and patient safety mechanisms do not yet work hand in hand.”<sup>19</sup>

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malpractice litigation undermines trust and confidence in the physician-patient relationship); Thomas L. Hafemeister & Joshua Hinckley Porter, *The Health Care Reform Act of 2010 and Medical Malpractice Liability: Worlds in Collision or Ships Passing in the Night*, 64 S.M.U. L. Rev. 735, 741-42 (2011) (discussing the practice of defensive medicine and rising insurance premiums in the U.S.).

<sup>12</sup> Ofri, *supra* note 11, at 142-143.

<sup>13</sup> *Id.* at 143.

<sup>14</sup> *Id.* at 144.

<sup>15</sup> *Id.* at 143-144.

<sup>16</sup> *Id.* at 144.

<sup>17</sup> Christiane Goldbach, Risikomanagementsysteme im Krankenhaus nach dem Patientenrechtegesetz: Sozialrechtliche Pflicht und haftungsrechtlicher Standard [Risk Management Systems in Hospitals According to the Patients’ Rights Act: Obligation under Social Law and Standard under Liability Law] 129 (2014) (F.R.G).

<sup>18</sup> Ofri, *supra* note 11, at 143.last

<sup>19</sup> William M. Sage, *Malpractice Reform as a Health Policy Problem*, in *Medical Malpractice and the U.S. Health Care System* 30 (William M. Sage & Rogan Kersh eds., 2006).

Overall, the traditional approach to focusing liability for injuries caused by medical errors on individual healthcare providers is an outdated approach that fails to consider the complexities and intricacies of modern healthcare delivery systems. Crucially, this approach ignores the well-established role that system design defects play in medical errors and the ability of CRM to detect and correct those defects. This dissertation argues that liability for negligent CRM would help bring the healthcare organization into focus and align the medical liability system with the systems-focused error prevention efforts occurring in the healthcare industry.<sup>20</sup>

## 1.2 Significance of the Research

Systems-focused error prevention efforts are internationally recognized in the healthcare industry, and industry efforts to identify and correct organizational defects through the process of CRM are well established in the U.S. and Germany.<sup>21</sup> However, in both countries, there is no clear corresponding liability for healthcare organizations who fail to engage in systems-based learning through the process of CRM.<sup>22</sup> Although both jurisdictions do recognize organization-based theories of liability,<sup>23</sup> liability for negligent CRM has not been explicitly recognized by courts in either jurisdiction to date.<sup>24</sup> German legal scholars, recognizing this gap in liability for healthcare organizations, have written in support of finding liability for negligent CRM under existing tort law; however, there is no corresponding discussion in the American legal literature.<sup>25</sup> This dissertation fills that gap with a comparative analysis of medical negligence law in the U.S. and Germany through the international lens of modern medical error prevention science and policy to articulate a legal basis and sketch the evidentiary framework for tort liability based on negligent CRM.

## 1.3 Methodological Approach

Examining liability for negligent healthcare CRM in the United States and Germany required a comparative and interdisciplinary research approach. Applied comparative law as a research

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<sup>20</sup> See Goldbach, *supra* note 17, at 129-30.

<sup>21</sup> See WHO, *supra* note 6; Matthias Briner et al., *Assessing hospitals' clinical risk management: Development of a monitoring instrument*, 10:337 BMC Health Serv. Res. (2010), available at <https://bmchealthservres.biomedcentral.com/articles/10.1186/1472-6963-10-337>; European Commission, DG Health and Consumer Protection, Patient Safety – Making it Happen! Luxembourg Declaration on Patient Safety (2005), available at [https://ec.europa.eu/health/ph\\_overview/Documents/ev\\_20050405\\_rd01\\_en.pdf](https://ec.europa.eu/health/ph_overview/Documents/ev_20050405_rd01_en.pdf).

<sup>22</sup> Goldbach, *supra* note 17, at 49-51. A Westlaw search for cases in the U.S. recognizing a legal cause of action for negligent risk management in medical malpractice revealed no relevant cases.

<sup>23</sup> See Dieter Giesen, *International Medical Malpractice Law: A Comparative Law Study of Civil Liability Arising from Medical Care* 58-59 (1988) (noting the emergence of broader vicarious liability doctrines as well as expanded causes of action for direct organizational liability).

<sup>24</sup> See *supra* note 22 and accompanying text.

<sup>25</sup> Goldbach, *supra* note 17, at 46-49 (“although there is no uniform picture of the RM obligation in the literature, the number of affirmative voices is successively increasing”).

method is useful for examining different legal systems for similarities and differences to uncover new or different approaches to a common legal issue.<sup>26</sup> To understand how CRM might be integrated into the medical liability system in both jurisdictions, I conducted a micro-comparison of obligations in private law as applied to medical injuries in both the United States and Germany, which centered primarily on medical negligence, but which also involved intersecting or overlapping issues of contract law, social law, regulatory law, and product liability law.<sup>27</sup> Instead of applying a single comparative law methodology, I used a number of methodological research tools.<sup>28</sup> I used an analytical approach to examine the basic legal concepts and rules that govern medical liability in both jurisdictions including duties and obligations in private law, standards of care, causation, proof, and fairness. I used a structural approach to examine the fundamental principles underlying the medical liability systems, as a subset of tort law, in both jurisdictions. I used a historical approach to understand the differences and similarities of the two medical liability systems rooted in different legal systems (common v. civil law). I used a law-in-context approach to examine the larger social impacts on the medical liability systems in both countries, including the evolution of medicine as a profession and the role of hospitals, malpractice reform, patients' rights, and medical error prevention policy. Finally, though primarily focused on legal questions involving liability for medical injuries, I used an interdisciplinary approach to understand the interaction between law, medicine, and organizational science.<sup>29</sup>

## 1.4 Chapter Overview

Here in Chapter 1, I provide the background, significance and methodology for this research.

I begin in Chapter 2 by discussing the development of modern medical error prevention and risk management within the healthcare industry as a reaction to the modern system of healthcare delivery in Western societies, a development that affects healthcare in both the U.S. and Germany. I outline the paradigm shift in thinking about medical errors ignited in 1999 by the IOM's *To Err is Human* report, which applied the organizational and error research used in other high-risk industries to the healthcare system. This shift fueled the development of an international approach to error prevention in the healthcare industry using an organizational, rather than individual, focus. I discuss how, although the IOM recognized legislative and regulatory actions as external factors influencing patient safety efforts in the healthcare industry, its limited attention to medical liability system's influence on error prevention was a critical oversight. I conclude that the medical liability system can influence the success of industry error prevention efforts by holding healthcare organizations responsible for preventing errors through the process of CRM.

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<sup>26</sup> See Jan Kropholler, *Comparative Law, Function and Methods*, in *Encyclopedia of Disputes*, in *Encyclopedia of Disputes* Installment 52-58 (Rudolf L. Bindschedler, et al. eds. 2009).

<sup>27</sup> See *Id.*

<sup>28</sup> See Mark Van Hoecke, *Methodology of Comparative Legal Research*, LaM (December 2015), DOI: 10.5553/REM/.000010.

<sup>29</sup> See Giorgia Guerra, *An Interdisciplinary Approach for Comparative Lawyers: Insights from the Fast-Moving Field of Law and Technology*, 19(3) *German Law Journal* 579, 589 (2018).

In Chapter 3, I introduce the general legal structures for the American and German medical liability systems under which a healthcare organization's liability for negligent CRM would be situated. Although, at the outset, there appear to be major differences in the two systems stemming from the Common/Civil law system distinction and Tort/Contract law distinction in the jurisdictions' approaches to medical liability, I show that, in practice, these differences have little consequence on the systems' operation, both of which are centered on the concept of negligence. Next, I identify the goals of the American and German negligence-based medical liability systems to include compensation and deterrence, and more generally, fairness. I highlight differences in the compensatory roles of the American and German medical liability systems, but focus on the shared goal of deterrence, because, like the process of CRM, it seeks to prevent errors. Next, I discuss how the perception of fairness (or unfairness) triggered by an increase in medical malpractice claims influenced the medical liability landscape and triggered debates about medical malpractice reform in both countries, both of which chose to retain negligence-based systems. I conclude that if these negligence-based medical liability systems recognize liability for negligent CRM, they will compliment, rather than inhibit, the healthcare industry's error prevention efforts because the liability systems' deterrence goals will better align with the industry's systems-based approach to medical error prevention.

In Chapter 4, I discuss how claims of medical negligence operate in both the American and German medical liability systems. First, I outline the legal elements for establishing medical malpractice in the U.S. and Germany, including causes of action based on treatment and organizational errors. Next, I discuss the rules of proof applicable to medical malpractice claims, noting differences in the jurisdictions' standards of proof, but similarities in the general rules assigning the burden of proof to the plaintiff. Additionally, both jurisdictions have mechanisms to modify general burden of proof rules in medical malpractice cases — the U.S. through the doctrine of *res ipsa loquitur* and Germany through the burden of proof rules codified in the Patients' Rights Act. Regarding evidence of malpractice, the primary source of proof is the plaintiff's medical treatment record, which both jurisdictions grant plaintiffs a legal right to obtain. Additionally, both jurisdictions apply some evidentiary protections to documents in medical malpractice cases that focus on hospital activities outside of the individual plaintiff's medical treatment. I conclude by observing that although neither country has recognized or established a framework for liability based on a healthcare organization's negligent CRM, including such liability under the existing rules for proving medical negligence is not only possible, but crucial to achieving the systems' deterrence goals.

In Chapter 5, I propose a legal framework for liability based on negligent CRM under the current medical liability systems in both countries. This framework is guided by the German legal academic discussion finding a legal obligation to CRM under German law. First, I discuss how German legal scholars support finding liability for negligent CRM as an extension of existing organizational liability under Germany's general negligence laws and by comparing legal obligations of manufacturers in product liability law to legal obligations of healthcare organizations in medical negligence law. Applying this German analytical framework to the U.S., I opine that liability for negligent CRM is also supported in the U.S. under general tort

law, organizational negligence law, and product liability law. Second, I sketch parameters for defining legal standards of care for CRM by relying on the work of German legal scholars in this area. Standards of care for CRM flow directly from the internationally accepted CRM process, which is organized in four phases: risk identification; risk analysis; risk assessment; and risk control. Finally, I propose legal proof rules that balance the confidentiality required to carry out patient safety activities and the transparency necessary to hold healthcare organizations responsible for negligent CRM. The rules manifest in two parts: first, in discovery and evidentiary protections for CRM activities that require confidentiality to sustain safety culture in healthcare organizations, and second, in burden-shifting rules informed by Germany's Patients' Rights Act that ensure injured patients have a viable cause of action against organizations for negligent CRM.



## 2. Risk Management in Modern Medicine

The problem of medical errors in today's healthcare system is shaped by modern medicine's success in treating and curing medical conditions and the emergence of the modern hospital as a complex system that organizes the medical treatment process. As a result, the ability to solve the problem of medical errors requires an understanding of organization and error prevention science as applied to the modern provision of healthcare, a high-risk venture. CRM is designed to prevent medical errors in healthcare systems by focusing on identifying, analyzing, and curing deficiencies in the organizational treatment process. While this systems approach to medical error prevention is accepted in both American and German healthcare industries; neither legal regime has yet to recognize CRM as an important aspect of medical liability.

### 2.1 Modern Medicine and the Modern Hospital

For most of medicine's 3,500-plus-year history, it did not provide a reliable or effective response to human illness.<sup>30</sup> Medical historian, Roy Porter, noted that the Greek word *pharmakos* referred to remedies and poisons alike and observed, "[t]hat double idea – death and the doctors riding together – has loomed large in history."<sup>31</sup> As late as the eighteenth century, therapeutic medicine was highly unsuccessful and, in many cases, positively harmful.<sup>32</sup> In 1714, English poet, Matthew Prior wrote, "The Remedy Worse than the Disease,"

I SENT for Eatcliffe; was so ill,  
That other doctors gave me over :

He felt my pulse, prescrib'd his pill.  
And I was likely to recover.

But, when the wit began to wheeze,  
And wine had warm'd the politician,

Cur'd yesterday of my disease,  
I died last night of my physician.<sup>33</sup>

Even when it was not positively harmful, the physician's work focused primarily on providing patients with comfort, not cures.<sup>34</sup> And even when eighteenth century advancements in biomedical science began to show promise for improving public health, medical treatment itself

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<sup>30</sup> Frederick G. Kilgour, *Modern Medicine in Historical Perspective*, 50.1 Bulletin Med. Libr. Ass'n 42, 49, 54-55 (1962).

<sup>31</sup> Roy Porter, *The Greatest Benefit to Mankind: A Medical History of Humanity*, at 218 (Kindle ed. 1997) (ebook).

<sup>32</sup> *Id.* at 5136.

<sup>33</sup> Matthew Prior, *The Remedy Worse Than the Disease* (1714).

<sup>34</sup> Stauch, *supra* note 11, at 3.

was still extremely risky.<sup>35</sup> In the early nineteenth century, patients had less than a fifty percent chance of benefiting from medical treatment.<sup>36</sup>

The nineteenth and twentieth centuries' rapid advances in preventive medicine, surgery, and treatments for endocrine, metabolic, and infectious diseases birthed modern medicine.<sup>37</sup> Medical treatment for thyroid disease exemplifies how advancement in medical science began to translate to success in medical therapy. In 1875, doctors believed that the thyroid was useless and removed the gland from diseased patients. By 1940, however, thyroid function was well understood, and treatment was primarily non-surgical.<sup>38</sup> According to Eliot Freidson, the scientific developments of the late-nineteenth century established a foundation for medicine as a "true consulting profession" that, for the first time, offered its users an advantage over services provided by other healing professions.<sup>39</sup>

With the increased success rate of modern medicine, public expectations for medicine began to change. Porter observed that "[t]he more medicine seemed scientific and effective, the more the public became beguiled by the allure of medical beneficence, regarding the healing arts as a therapeutic cornucopia showering benefits on all, or, like a fairy godmother, potentially granting everybody's wishes."<sup>40</sup> Twentieth century medicine made the provision of healthcare an economic and political endeavor, prompting Porter to compare modern medicine to "the military machine or the civil service."<sup>41</sup> Medicine expanded its objectives from providing reactionary healing to becoming a central figure in society, bringing with it the promise of a holistic approach to societal health.<sup>42</sup> According to Porter, "[m]edicine in mass society inexorably became inseparable from economics, central and local administration, the law, the social services and the media."<sup>43</sup> It is from this place in society that medicine is judged today, against its twentieth century promises to prevent the unpreventable, treat the untreatable, and cure the incurable. Nevertheless, medicine has chosen to assume this heroic role in modern society, and with that choice comes great responsibility and the corresponding potential for great liability.

The development of the modern hospital is, of course, entwined with that of modern medicine. Just as doctors historically had little success as healers, hospitals had little success as healing institutions. Until the middle of the nineteenth century, hospitals housed mentally ill, poor, diseased, dying, and homeless populations and served as learning institutions for medical

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<sup>35</sup> *Id.* at 2.

<sup>36</sup> *Id.* at fn 7.

<sup>37</sup> Kilgour, *supra* note 30, at 49, 54.

<sup>38</sup> *Id.* at 49, 50-51.

<sup>39</sup> Eliot L. Freidson, *Profession of Medicine* 12-13 (1970).

<sup>40</sup> Porter, *supra* note 31, at 12238-12239.

<sup>41</sup> *Id.* at 12204.

<sup>42</sup> *Id.* at 12324-12325, 12281-12283.

<sup>43</sup> *Id.* at 12960-12961.

students, but they rarely improved patients' medical conditions.<sup>44</sup> To the contrary, in many instances, hospital conditions were responsible for patient deaths. Porter provides a glimpse of eighteenth-century hospitals:

Pivotal to the public provision of health-care facilities was the hospital, but it was also perhaps the nub of the problem. Nominally a site of recuperation, it became a spreader of disease. Hospitals took many forms and served many functions. In France, the *hôpital général*, an institution similar to the English poorhouse, sheltered beggars, orphans, vagabonds and prostitutes, together with the sick and mad. The Paris *Hôtel Dieu* was a healing institution, but had an atrocious reputation as a hotbed of infection . . . Similar developments occurred in North America . . . Hospitals provided treatment, food, rest and convalescence, but they restricted themselves to complaints that would respond to treatment, excluded infectious cases and, in any case, could treat only a fraction of the sick. Their effects were consequently somewhat slight.<sup>45</sup>

Medical camps for injured soldiers had a similar reputation, and their unhygienic conditions were responsible for more soldier deaths than battle injuries.<sup>46</sup> In 1854, during the Crimean war, Florence Nightingale linked poor sanitation practices at a British medical camp in Turkey to poor recovery rates.<sup>47</sup> Following Nightingale's insistence on better hygiene, lighting, diet, and activity, the death rate for injured soldiers in the camp decreased from 42% to less than 3%.<sup>48</sup> After the war, Nightingale continued to advocate for better hospital conditions in both civilian and military hospitals.<sup>49</sup> Nightingale's work exposed the risks associated with institutional conditions, separate from the inherent risk of medical treatment itself or the poorly skilled healthcare provider.

The medical achievements of the nineteenth and twentieth centuries transformed the purpose and organization of hospitals. Advances in surgery, made possible by anesthetics and antiseptics, required operating rooms and post-surgical care in hospitals.<sup>50</sup> In addition, hospitals became the homes of teaching and research institutions. American hospitals grew exponentially in the nineteenth century — from two in 1800 to five thousand by 1914.<sup>51</sup> Porter noted that

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<sup>44</sup> Max E. Valentinuzzi & Ron Leder, *The Modern Hospital in Historical Context*, in 31st Annual International Conference of the IEEE EMBS 1089 (2009).

<sup>45</sup> Porter, *supra* note 31, at 5878-5881, 5906-5907, 5910-5911, 5912-5913.

<sup>46</sup> Valentinuzzi & Leder, *supra* note 44, at 1090.

<sup>47</sup> *Id.*

<sup>48</sup> *Id.*

<sup>49</sup> *Id.*

<sup>50</sup> Kilgour, *supra* note 30, at 49.

<sup>51</sup> Porter, *supra* note 31, at 7479-7482.

hospitals were “fast becoming the headquarters of medicine.” For a physician practicing during this time, the transformation of hospitals was readily observable over the course of a medical career: “[a]ll over the world the very name ‘hospital’ suggested pestilence or insanity; few people would go voluntarily to such a place, no matter how well equipped it was for doing routine work efficiently. Today, almost everybody with any illness at all serious wishes to go there.”<sup>52</sup>

Modern hospitals are complex organizations with elaborate infrastructures, bureaucracies, policies, procedures, and budgets.<sup>53</sup> They maintain identities separate from those of the providers they house, and they play a direct role in the delivery of healthcare. The U.S. News & World Report’s 2018 hospital rankings by specialty features, among others, Mayo Clinic, Johns Hopkins, Cleveland Clinic, and University of Texas MD Anderson Cancer Center — hospitals that have become household names.<sup>54</sup> In 1957, a New York Court of Appeals rejected the argument that modern hospitals merely provide facilities for healthcare providers to treat patients noting that “the person who avails himself of ‘hospital facilities’ expects that the hospital will attempt to cure him, not that its nurses or other employees will act on their own responsibility.”<sup>55</sup> Hospitals too recognize their influence on patients and actively develop and maintain their identities through the practice of reputation management. It works. Patients in both the U.S. and Germany confirm that reputation is an important consideration when choosing a hospital.<sup>56</sup> In addition to influencing patients’ provider choices, hospitals’ systems design and operation affect patient care. Crucially, hospitals’ risk management efforts, or lack thereof, can have a direct impact on medical error rates within the organization.

## 2.2 Clinical Risk Management in Healthcare

Healthcare institutions face a broad array of risks relating not only to the provision of healthcare treatment, but also to financial, managerial, and external activities.<sup>57</sup> Andrea Pauli defines risk in healthcare using the following formula:  $R$  (risk) =  $P$  (probability of a negative event occurring) x  $L$  (consequences of the negative event).<sup>58</sup> For jurists, this definition of risk has an unavoidable connection to American Judge Learned Hand’s definition of negligence, which he describes as occurring when  $B$  (the burden of preventing an accident) is less than  $P$  (the

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<sup>52</sup> *Id.* at 7479-7482.

<sup>53</sup> *Id.* at 12212-12219.

<sup>54</sup> US News & World Report, *Best Hospitals by Specialty National Rankings*, <https://health.usnews.com/best-hospitals/rankings> (last visited Jan. 2, 2022).

<sup>55</sup> *Bing v. Thunig*, 143 N.E.2d 3, 8 (N.Y. 1957).

<sup>56</sup> Werner de Cruppé & Max Geraedts, *Hospital choice in Germany from the patient’s perspective: a cross-sectional study*, 17:720 *BMC Health Serv Res.* 2 (2017), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5683328/>; Katie Johnson, *The Link Between Patient Experience and Hospital Reputation*, National Research Corporation Research Brief, Feb. 2014, at 2.

<sup>57</sup> See Andrea Pauli, *Risikomanagement und CIRS als Gegenstand der Krankenhaushaftung [Risk management and CIRS as subject of hospital liability]* 49 (2013) (F.R.G.).

<sup>58</sup> *Id.* at 49.

probability of the accident) multiplied by L (the magnitude of the loss).<sup>59</sup> The inextricable connection between the definition of risk itself and liability for risks that materialize in healthcare must be observed, because as Ofri unenthusiastically points out, some level of risk acceptance is necessary.<sup>60</sup> Ofri compares the risk/benefit analysis involved with a daily activity like crossing a busy street to get a fresh bagel (the chance and degree of harm associated with being hit by a car and the necessity of breakfast) with the dozens of medical decisions made hourly by healthcare providers “trellised across the dizzying intricacies of the human body.”<sup>61</sup> Nevertheless, however imperfect risk management efforts are at eliminating patient harm, reasonable efforts to identify and eliminate risks that can injure patients should be standard operating procedure in healthcare organizations.<sup>62</sup>

Clinical risks are those specifically related to the quality and safety of patient care.<sup>63</sup> Managing clinical risks occurs at the organizational level through the process of CRM.<sup>64</sup> CRM is defined “as all structures, processes, instruments and activities that enable hospital employees to identify, analyze, contain and manage risks while providing clinical treatment and patient care.”<sup>65</sup> CRM seeks to eliminate risk of patient harm by identifying, analyzing, and taking measures to prevent activities and processes that have the potential to harm patients during the treatment process.<sup>66</sup> Effective CRM “integrates both proactive and reactive approaches and frames the hospital as a system, instead of focusing on individuals and their potential for committing errors.”<sup>67</sup> As demonstrated by the graphic below, CRM is an iterative self-learning process.

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<sup>59</sup> U.S. v. Carroll Towing Co., 159 F.2d 169, 173 (2d Cir. 1947).

<sup>60</sup> Ofri, *supra* note 11, at 220.

<sup>61</sup> *Id.*

<sup>62</sup> Briner et al., *supra* note 21 (“Risks associated with patient care can never be completely eliminated, therefore, clinical risk management plays a crucial role in enabling hospitals to enhance patient safety”).

<sup>63</sup> See Pauli, *supra* note 57, at 49.

<sup>64</sup> *Id.* at 51.

<sup>65</sup> Briner et al., *supra* note 21.

<sup>66</sup> WHO, *supra* note 6, at 163.

<sup>67</sup> Briner et al., *supra* note 21.



Image: Adapted from Government of Western Australia Department of Health Clinical Risk Management [https://ww2.health.wa.gov.au/Articles/A\\_E/Clinical-risk-management](https://ww2.health.wa.gov.au/Articles/A_E/Clinical-risk-management)

Hart describes medical treatment as only one element in the broader medical treatment process.<sup>68</sup> While medical treatment is carried about by individual medical providers and governed by medical standards, he distinguishes the medical treatment process as, “the organisational and institutional framework within which the medical treatment is carried out.”<sup>69</sup> This process is governed by interdisciplinary standards guided by medicine, law, and organizational science.<sup>70</sup> In order to effectively prevent medical errors, CRM must look beyond medical treatment to the broader treatment process to develop an interdisciplinary organizationally-focused error prevention strategy.<sup>71</sup> In the Luxembourg Declaration on Patient Safety, the EU Commission found that “[a] precondition for risk management is an open and trusting working environment with a culture that focuses on learning from near-misses and adverse events as opposed to concentrating on individual ‘blame and shame’ and subsequent punishment.”<sup>72</sup> A 1999 report by the Institute of Medicine (IOM) became an important catalyst for shifting the international medical community’s focus from blaming individual providers for medical errors to creating an organizational culture of safety conducive to successful CRM.

<sup>68</sup> Dieter Hart, *Patientensicherheit nach dem Patientenrechtgesetz* [Patient safety under the Patients’ Rights Act], 31 MedR 159, 159-60 (2013).

<sup>69</sup> *Id.* at 160 (translated from German).

<sup>70</sup> *Id.*

<sup>71</sup> Briner et al., *supra* note 21.

<sup>72</sup> European Commission, *supra* note 21.

## 2.3 To Err is Human

In 1999, the IOM's *To Err Is Human: Building a Safer Health System* report became the seminal work for modern medical error prevention.<sup>73</sup> It debunked the myth that medical errors were caused solely by individual healthcare providers by recognizing what other high-risk industries did a decade before: "[t]he problem is not bad people; the problem is that the system needs to be made safer."<sup>74</sup> When the IOM issued its report, the idea that medical errors could be prevented by better-trained, more-skilled, and less-stressed healthcare practitioners permeated public opinion.<sup>75</sup> While organizational influences lingered in the background of this individual-focused perception, "[m]ost people view[ed] medical mistakes as an 'individual provider issue' rather than a failure in the process of delivering care in a complex delivery system."<sup>76</sup> Healthcare providers themselves, immersed in a culture that demands perfection, also associated medical errors with the actions and qualifications of individual healthcare providers.<sup>77</sup> The IOM attempted to shift the focus from individual failures to organizational failures not to excuse negligent provider actions, but rather to highlight and advocate for a new approach to preventing medical errors, one that had proven successful in other high-risk industries.<sup>78</sup>

The IOM heavily relied upon the research of sociologist, Charles Perrow, and psychologist, James Reason to explain why errors occur in the modern healthcare system.<sup>79</sup> Perrow's normal accident theory accepted that high-risk systems were accident prone.<sup>80</sup> According to Perrow, the level of risk inherent in a system depends upon whether it is (1) complex or linear and (2) tightly or loosely coupled.<sup>81</sup> Complex tightly-coupled systems present the highest risk.<sup>82</sup> Complexity is measured by the dependency of the systems' interrelated processes on one another.<sup>83</sup> In a complex system, when a single process fails, it causes the subsequent failure of several other dependent processes.<sup>84</sup> In addition, the more specialized those processes are, the more complex the system becomes.<sup>85</sup> Coupling refers to the amount of time the system can

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<sup>73</sup> IOM, *supra* note 2.

<sup>74</sup> *Id.* at 5, 49.

<sup>75</sup> IOM, *supra* note 2, at 42 (citing a study finding that the public associates medical errors with provider incompetence, carelessness, stress, and exhaustion).

<sup>76</sup> *Id.* at 43.

<sup>77</sup> *Id.* at 22.

<sup>78</sup> *See id.* at 4-5. The IOM concluded that like other complex tightly-coupled systems, the healthcare system is error-prone. *Id.* at 60.

<sup>79</sup> *See id.* at 51-66 (relying heavily on the work of Charles Perrow and James Reason to explain why accidents happen).

<sup>80</sup> *Id.* at 57.

<sup>81</sup> *Id.* at 58.

<sup>82</sup> *Id.*

<sup>83</sup> *Id.* at 59.

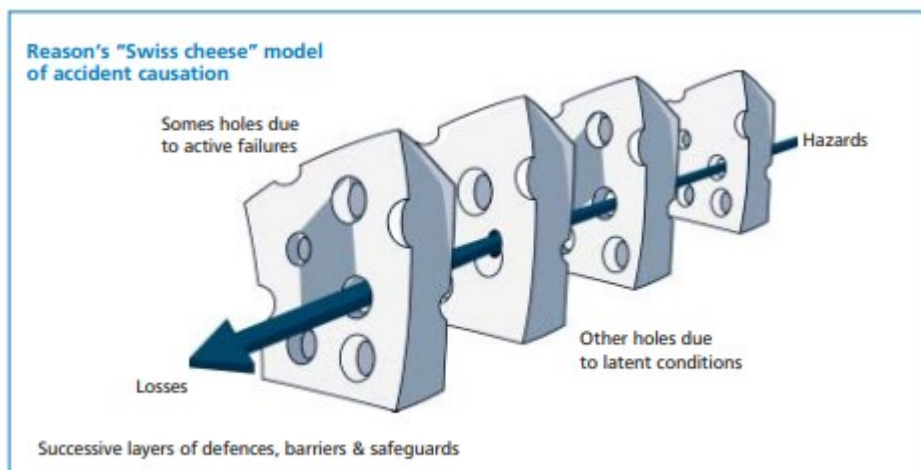
<sup>84</sup> *Id.*

<sup>85</sup> *Id.*

tolerate between processes and the flexibility of the systems' process order.<sup>86</sup> Tightly-coupled systems have fixed-order processes that occur in rapid succession.<sup>87</sup>

The IOM defines a "system" as "a set of interdependent elements interacting to achieve a common aim."<sup>88</sup> Healthcare systems encompass everything from a large regional multispecialty healthcare delivery system, to a hospital specialty unit, to a single operating room, all of which are interdependent.<sup>89</sup> This interdependence combined with the specialization of healthcare delivery makes healthcare systems complex.<sup>90</sup> In addition, because there is little buffer between the "dependent processes and sequences" in healthcare systems, they can be classified as tightly coupled.<sup>91</sup> The IOM concluded that like other complex tightly-coupled systems, including aviation and nuclear power plants, healthcare systems are error-prone.<sup>92</sup>

James Reason's Swiss Cheese Model describes how active failures and latent conditions, represented as holes in Swiss cheese, can align to cause an accident and result in damage.<sup>93</sup>



Source: Reason JT. *Managing the risks of organisational accidents*, 1997 [14].

Active failures include the easily recognizable individual actions that are usually temporally connected to the resulting damage.<sup>94</sup> Latent conditions include system design, structure, oversight, and maintenance problems that can unexpectedly combine to cause or induce a subsequent active error.<sup>95</sup> Because latent conditions occur earlier in the process chain, they are

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<sup>86</sup> *Id.*

<sup>87</sup> *Id.*

<sup>88</sup> *Id.* at 52.

<sup>89</sup> *Id.*

<sup>90</sup> *Id.* at 58.

<sup>91</sup> *Id.* at 59.

<sup>92</sup> *Id.* at 60.

<sup>93</sup> James Reason, *Human error: models and management*, 320 *BMJ* 768, 769 (2000).

<sup>94</sup> *Id.* at 769.

<sup>95</sup> *Id.*



more difficult to identify than damage-causing active failures.<sup>96</sup> In addition, hindsight bias can also conceal latent errors.

Hindsight bias means that things that were not seen or understood at the time of the accident seem obvious in retrospect. Hindsight bias also misleads a reviewer into simplifying the causes of an accident, highlighting a single element as the cause and overlooking multiple contributing factors. Given that the information about an accident is spread over many participants, none of whom may have complete information, hindsight bias makes it easy to arrive at a simple solution or to blame an individual, but difficult to determine what really went wrong.<sup>97</sup>

Recognizing that active errors do not occur in a vacuum but rather within a complex system, is critical not only for understanding why an error occurred, but also for developing successful error-prevention strategies.

Although human error is admittedly the cause of most accidents, these errors can often be prevented by better system design.<sup>98</sup> Reason explains that, “[w]e cannot change the human condition, but we can change the conditions under which humans work.”<sup>99</sup> He further provides the following analogy to illustrate the systems approach to preventing errors: “active failures are like mosquitoes. They can be swatted one by one, but they still keep coming. The best remedies are to create more effective defences and to drain the swamps in which they breed. The swamps, in this case, are the ever present latent conditions.”<sup>100</sup> The IOM, adopting Reason’s theory of accident causation, concluded that latent errors pose the greatest threat to patient safety.<sup>101</sup> As a result, punishing individuals who commit active errors is not an effective way to prevent future errors, because (1) the active error can be caused or induced by a specific combination of latent errors that is unlikely to repeat, and (2) failing to address the latent errors allows them to accumulate making the system more error-prone.<sup>102</sup>

Central to the success of a systems approach to medical error prevention is the development of a culture of safety within the healthcare organization itself.<sup>103</sup> The IOM found that, “[h]ealth care organizations must develop a culture of safety such that an organization’s care processes

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<sup>96</sup> See *id.* at 769; IOM, *supra* note 2, at 65.

<sup>97</sup> IOM, *supra* note 2, at 53.

<sup>98</sup> See IOM, *supra* note 2, at 65.

<sup>99</sup> Reason, *supra* note 93, at 769

<sup>100</sup> *Id.*

<sup>101</sup> IOM, *supra* note 2, at 65.

<sup>102</sup> See *id.* at 55-56.

<sup>103</sup> See *id.* at 14.

and workforce are focused on improving the reliability and safety of care for patients.”<sup>104</sup> This culture of safety stands in stark contrast to the culture of blame that historically prevailed in healthcare.<sup>105</sup> Replacing a culture of blame with a culture of safety enables healthcare systems to become highly reliable.<sup>106</sup> According to high reliability theory, high-risk organizations can overcome their proclivity for accidents by maintaining an organizational culture that enables identification and elimination of organizational defects through the process of CRM.<sup>107</sup>

## 2.4 The Response to *To Err is Human*

*To Err is Human* forced the healthcare industry worldwide to prioritize patient safety.<sup>108</sup> It also ignited a paradigm shift in the way healthcare researchers approached patient safety.<sup>109</sup> According to a study that evaluated the effects of the IOM report on patient safety publications, pre-report publications focused on medical malpractice, while post-report publications focused on organizational culture.<sup>110</sup> The study’s authors noted that, “the IOM report has changed the very nature of the patient safety conversation from focusing on dispensing blame to improving systems.”<sup>111</sup>

### 2.4.1 The International Response

The World Health Organization (WHO) first addressed patient safety on a global scale at its 2002 World Health Assembly.<sup>112</sup> Noting that avoidable adverse events were a significant cause of human suffering, it passed resolution WHA55.18 on “Quality of care: patient safety” urging member states “to pay the closest possible attention to the problem of patient safety.”<sup>113</sup> Since then, the WHO has leveraged its global network to bring together all stakeholders in the healthcare industry for the purpose of improving patient safety and managing healthcare risks.<sup>114</sup> In 2004, it launched the World Alliance for Patient Safety (WAPS) to unite Member

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<sup>104</sup> *Id.*

<sup>105</sup> *See id.* at ix, 157, 179.

<sup>106</sup> *See id.* at 57.

<sup>107</sup> *See id.*

<sup>108</sup> *See* H. T. Stelfox et al., *The “To Err is Human” report and the patient safety literature*, 15(3) *Qual. Saf. Health Care* 174 (2006), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2464859/> (finding that that IOM’s report “stimulated research and discussion about patient safety issues”).

<sup>109</sup> *See Id.* at 104.

<sup>110</sup> *Id.* at 176.

<sup>111</sup> *Id.* at 177.

<sup>112</sup> WHO, *Resolutions*, <https://www.who.int/teams/integrated-health-services/patient-safety/policy/resolutions> (last visited Jan. 2, 2022) (“The global need for quality of care and patient safety was first discussed during the World Health Assembly in 2002.”).

<sup>113</sup> WHO, WHA55.18, *Quality of care: patient safety* (May 18, 2002), [https://apps.who.int/gb/archive/pdf\\_files/WHA55/ewha5518.pdf?ua=1&ua=1](https://apps.who.int/gb/archive/pdf_files/WHA55/ewha5518.pdf?ua=1&ua=1).

<sup>114</sup> *See generally* World Alliance for Patient Safety [WAPS], *Patient Safety: Making Healthcare Safer* (WHO 2017), available at <https://apps.who.int/iris/handle/10665/255507>.

States and pool their resources to advance an international patient safety agenda.<sup>115</sup> Like the IOM, the WAPS accepts that most adverse events are caused by organizational and systemic deficiencies and recommends preventive measures that change the system instead of those that target individual practices or products.<sup>116</sup> At its inception, the WAPS framed the international task of improving patient safety as follows:

Enhancing the safety of patients includes three complementary actions: preventing adverse events; making them visible; and mitigating their effects when they occur. This requires: (a) increased ability to learn from mistakes, through better reporting systems, skillful investigation of incidents and responsible sharing of data; (b) greater capacity to anticipate mistakes and probe systemic weaknesses that might lead to an adverse event; (c) identifying existing knowledge resources, within and outside the health sector; and (d) improvements in the health-care delivery system itself, so that structures are reconfigured, incentives are realigned, and quality is placed at the core of the system. In general, national programmes are built around these principles.<sup>117</sup>

In 2005, the WHO launched its first Global Patient Safety Challenge, an initiative to identify a patient safety risk and collaborate with international leaders to propose solutions.<sup>118</sup> The Challenges have thus far addressed infections, surgery risks, and most recently, medication safety.<sup>119</sup> In 2005, the WHO also released its draft guidelines for adverse event reporting and learning systems. These guidelines identify voluntary error reporting as a valuable tool for organizational learning and error prevention.<sup>120</sup> The WHO continues to promote error reporting and learning systems by providing tools that facilitate error reporting and analysis such as the Minimum Information Model for Patient Safety and updated guidelines for reporting and learning systems.<sup>121</sup>

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<sup>115</sup> WHO, *World Alliance for Patient Safety* (Oct. 27, 2024), <https://www.who.int/news/item/27-10-2004-world-alliance-for-patient-safety#:~:text=The%20World%20Alliance%20for%20Patient%20Safety%20was%20launched%20in%20Washington,%2C%20Dr%20Mirta%20Roses%20Periago> (last visited Jan. 2, 2022).

<sup>116</sup> WHO, *World Alliance for Patient Safety, Forward Programme 3-4* (Oct. 2004), *available at* [https://www.who.int/patientsafety/en/brochure\\_final.pdf](https://www.who.int/patientsafety/en/brochure_final.pdf).

<sup>117</sup> *Id.* at 4.

<sup>118</sup> See generally Claire Kilpatrick, et al., *WHO First Global Patient Safety Challenge: Clean Care is Safer Care, Contributing to the training of health-care workers around the globe*, 7(2) *Int'l J. Infection Control* (2010), *available at* <https://www.ijic.info/article/view/6515>.

<sup>119</sup> WAPS, *supra* note 114, at 5.

<sup>120</sup> WAPS, *WHO Draft Guidelines for Adverse Event Reporting and Learning Systems: From Information to Action* (WHO 2005), *available at* <https://apps.who.int/iris/bitstream/handle/10665/69797/WHO-EIP-SPO-QPS-05.3-eng.pdf>.

<sup>121</sup> WAPS, *supra* note 114, at 11.

Other WHO patient safety initiatives include: (1) Global Ministerial Summits on Patient Safety, which promote patient safety at the political level; (2) the Global Patient Safety Network, which collects and shares evidence from international stakeholders to encourage development and maintenance of patient safety guidelines and best practices; (3) the Global Knowledge Sharing Platform for Patient Safety, which provides an online platform for sharing systemic analysis and response to adverse events; (4) patient safety education and training resources, including the Multi-professional Patient Safety Curriculum Guide and the Educational Councils Network; (5) checklists that minimize patient safety risks, including the WHO Safe Childbirth Checklist and the WHO Surgical Safety Checklist; (6) Patients for Patient Safety, which provides a patient advocacy network for patients and their families; and (7) the development of tools and metrics for measuring patient safety.<sup>122</sup>

The Organization for Economic Co-operation and Development (OECD) has also turned its attention to the global problem of medical errors.<sup>123</sup> In a 2017 working paper, the OECD estimated that the annual global health, financial, and economic costs of patient harm caused by treatment errors amount to trillions of dollars.<sup>124</sup> It also concluded that systemic and organizational changes were needed to prevent errors and reduce resulting patient harm.<sup>125</sup> Like the IOM, the OECD recognized that modern healthcare systems are complex and dynamic, and as a result, require complex and dynamic interventions to prevent medical errors.<sup>126</sup> These interventions, it argued, must take a systems perspective and focus on creating an organizational culture that fosters patient safety.<sup>127</sup>

In Europe, the European Commission Directorate-General for Health & Consumers has undertaken initiatives to promote patient safety and healthcare quality in the European Union. In 2005, the commission published the Luxembourg Declaration on Patient Safety recognizing the human and financial costs of patient injuries and placing patient safety high on the European Union's political agenda.<sup>128</sup> At the international level, the declaration recommended international collaboration to help policymakers understand and propose solutions for patient safety issues and the development of patient-safety-focused regulations and standards that govern the provision of medical goods and services.<sup>129</sup> At the national level, the declaration recommended patient empowerment including: giving patients access to records and information concerning their medical treatment; improving training and working conditions for

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<sup>122</sup> *Id.* at 7-16.

<sup>123</sup> Luke Slawomirskii, et al., *The economics of patient safety, Strengthening a value-based approach to reducing patient harm at national level*, OECD Health Working Papers, No. 96 (2017), available at [https://www.oecd-ilibrary.org/social-issues-migration-health/the-economics-of-patient-safety\\_5a9858cd-en](https://www.oecd-ilibrary.org/social-issues-migration-health/the-economics-of-patient-safety_5a9858cd-en).

<sup>124</sup> *Id.* at 6, 10, 19, 23, 49.

<sup>125</sup> *Id.* at 4, 29-30, 46-48.

<sup>126</sup> *Id.* at 29.

<sup>127</sup> *Id.*

<sup>128</sup> European Commission, *supra* note 21.

<sup>129</sup> *See id.*

healthcare professionals; promoting patient safety culture through risk management, quality assurance, and error reporting and learning; providing collaborative space for all stakeholders in the healthcare industry to discuss patient safety; and using technology to solve patient safety problems.<sup>130</sup> At the industry level, the declaration recommended collaboration to increase patient safety, promotion of patient safety culture in healthcare organizations, and improved communications with patients and families about medical errors.<sup>131</sup>

From 2008 through 2010, the European Commission and the European Agency for Health and Consumers (EAHC) funded the European Union Network for Patient Safety (EUNetPaS), a project initiated by the Patient Safety and Quality of Care Working Group (PSQCWG) and coordinated by the French National Authority for Health (HAS).<sup>132</sup> As the first patient safety project to include all 27 EU Member States, EUNetPaS's objectives were two-fold.<sup>133</sup> They included both collaborative international research and development of uniform systems and standards to improve patient safety as well as national networks focused on sharing patient safety information with all relevant stakeholders.<sup>134</sup> One main focus of EUNetPaS's collaborative efforts was to improve patient safety culture. It defined a "culture of safety" as "[a]n integrated pattern of individual and organisational behaviour, based upon shared beliefs and values that continuously seeks to minimise patient harm, which may result from the processes of care delivery."<sup>135</sup> Drawing from the IOM's finding that systemic deficiencies could only be improved by creating a safety culture in healthcare organizations, EUNetPaS sought to identify patient safety indicators that led to an improvement in patient safety culture.<sup>136</sup>

In 2009, the Council of the European Union issued a recommendation on patient safety, including the prevention and control of healthcare associated infections.<sup>137</sup> According to the recommendation, "[a] large proportion of adverse events, both in the hospital sector and in primary care, are preventable with systemic factors appearing to account for a majority of

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<sup>130</sup> *See id.*

<sup>131</sup> *See id.*

<sup>132</sup> Pauli, *supra* note 57, at 35; European Patients Forum, *EUNETPAS*, <https://www.eu-patient.eu/Projects/completed-projects/EUNetPaS/> (last visited Jan. 2, 2022).

<sup>133</sup> Pauli, *supra* note 57, at 35; Carita Linden-Lahti et al., *Facilitators and barriers in implementing medication safety practices across hospitals within 11 European Union countries*, 17(4) *Pharm. Pract.* (Dec. 4, 2019), available at <https://www.pharmacypractice.org/index.php/pp/article/view/1583/762>.

<sup>134</sup> *See* Pauli, *supra* note 57, at 35.

<sup>135</sup> The European Network for Patient Safety [EUNetPaS], *Use of Patient Safety Culture Instruments and Recommendations* 4 (2010) available at [https://pasq.eu/DesktopModules/BlinkQuestionnaires/QFiles/448\\_WP4\\_REPORT%20%20Use%20of%20%20PSCI%20and%20recommandations%20-%20March%20%202010.pdf](https://pasq.eu/DesktopModules/BlinkQuestionnaires/QFiles/448_WP4_REPORT%20%20Use%20of%20%20PSCI%20and%20recommandations%20-%20March%20%202010.pdf).

<sup>136</sup> EUNetPaS, *Patient Safety Culture Report: Focusing on Indicators* 4 (2010) available at <https://psnet.ahrq.gov/issue/patient-safety-culture-report-focusing-indicators>.

<sup>137</sup> Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections, 2009/C 151/01, available at [https://joint-research-centre.ec.europa.eu/system/files/2017-07/2\\_June\\_2009%2520patient%2520safety.pdf](https://joint-research-centre.ec.europa.eu/system/files/2017-07/2_June_2009%2520patient%2520safety.pdf).

them.”<sup>138</sup> The council’s recommendations on general patient safety issues mimicked those articulated in the Luxembourg Declaration and included: the development of national patient safety policies and programs; empowerment of citizens; establishment of error reporting and learning systems; patient safety education and training of healthcare professionals; implementation of a system for classifying and measuring patient safety; initiation of national and international collaboration and information sharing; and promotion of patient safety research.<sup>139</sup>

In 2012, the European Network on Patient Safety and Quality of Care (PaSQ) launched with funding and support from the European Commission’s Public Health Programme.<sup>140</sup> PaSQ seeks to support implementation of the Council’s recommendation on patient safety.<sup>141</sup> In 2014, the Council adopted conclusions on patient safety and quality of care asking member states to “intensify their efforts in implementing” the Council’s Patient Safety Recommendation.<sup>142</sup> In addition to the focus on implementing and strengthening patient safety measures, the conclusions called for the establishment of patient safety standards and guidelines.<sup>143</sup>

## 2.4.2 The Response in Germany

In addition to the role it played in the broader European efforts discussed above, the IOM’s 1999 report also sparked national interest in the systems approach to improving patient safety in Germany.<sup>144</sup> By 2001, the issue of medical errors was increasingly gaining the attention of both the German public and the healthcare industry.<sup>145</sup> The Federal Health Monitoring Report disseminated, for the first time, a statistical analysis of medical errors in Germany.<sup>146</sup> The report addressed the impact of organizational errors, finding that curing organizational deficits would have prevented a significant number of medical errors.<sup>147</sup> It also noted that organizational errors were becoming more prominent topics in medical malpractice proceedings.<sup>148</sup> Finally, the

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<sup>138</sup> *Id.* at Recital (4).

<sup>139</sup> *See generally* Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections, 2009/C 151/01, available at [https://joint-research-centre.ec.europa.eu/system/files/2017-07/2\\_June\\_2009%2520patient%2520safety.pdf](https://joint-research-centre.ec.europa.eu/system/files/2017-07/2_June_2009%2520patient%2520safety.pdf).

<sup>140</sup> PaSQ, *What is the Project About?*, <https://pasq.eu/Project/Project.aspx> (last visited Jan. 3, 2022).

<sup>141</sup> *Id.*

<sup>142</sup> Council conclusions on patient safety and quality of care, including the prevention and control of healthcare associated infections and antimicrobial resistance, Employment, Social policy, Health and Consumer affairs Council meeting Brussels, 1 December 2014, *available at* [https://www.consilium.europa.eu/uedocs/cms\\_data/docs/pressdata/en/lssa/145976.pdf](https://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lssa/145976.pdf).

<sup>143</sup> *Id.*

<sup>144</sup> Pauli, *supra* note 57, at 30.

<sup>145</sup> Martin L. Hansis & Dieter Hart, Gesundheitsberichterstattung des Bundes, Medizinische Behandlungsfehler [Health Reporting of the Federal Government, Medical treatment errors] (Robert Koch-Institut Issue 04/01) (2001) (F.R.G), *available at* <https://www.gbe-bund.de/pdf/Behand.pdf>.

<sup>146</sup> *See id.*

<sup>147</sup> *See id.*

<sup>148</sup> *See id.*

report echoed the IOM's call for a systems approach to medical error prevention, calling it "a task for society as a whole."<sup>149</sup>

In 2002, the German Medical Center for Quality in Medicine (*Ärztliches Zentrum für Qualität in der Medizin - ÄZQ*) established a Patient Safety Expert Group to address the problem of medical errors.<sup>150</sup> The group developed a plan to raise awareness for error prevention in the medical community, establish expert groups to discuss error management and prevention, develop principals and common data sets to use in error analysis, and improve quality assurance to address medical errors with a systems approach.<sup>151</sup> That same year, the Berlin Health Prize focused on projects that offered innovative approaches to medical error prevention.<sup>152</sup> The award's presenters, the Berlin Chamber of Medicine and the AOK public health insurer, sought to galvanize a culture of safety with the ability to identify and eliminate structural weaknesses in Germany's healthcare industry.<sup>153</sup>

In 2003, the German Advisory Council for Concerted Action in Healthcare included the topic of medical errors in its biannual report.<sup>154</sup> "The Council consider[ed] the analysis of conditions under which medical errors arise and the development and implementation of more effective and efficient prevention strategies to be a pillar of quality assurance in the health care system."<sup>155</sup> The report noted that errors were caused by failures in the many layers that comprise a complex healthcare delivery system, including at the individual, team, facility, and system levels.<sup>156</sup> It discouraged punishing individual providers for reporting errors and encouraged the establishment of sanction-free near-miss error reporting systems.<sup>157</sup> Interestingly, although the report found that error prevention was more important than patient compensation for damages caused by medical errors, it also viewed medical error claims to be a valuable source of information for reducing errors and encouraged healthcare providers to disclose medical errors to patients.<sup>158</sup>

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<sup>149</sup> *See id* (translated from German).

<sup>150</sup> Pauli, *supra* note 57, at 31.

<sup>151</sup> *See id*.

<sup>152</sup> Berliner Gesundheitspreis 2002, *Gesundheit Fehlervermeidung und Sicherheitskultur* [Berlin Health Award 2002, *Gesundheit Error Prevention and Safety Culture*], Das AOK-Forum für Politik, Praxis und Wissenschaft (Special ed. 5/2003) (F.R.G.), available at [https://aok-bv.de/engagement/berliner\\_gesundheitspreis/index\\_16472.html](https://aok-bv.de/engagement/berliner_gesundheitspreis/index_16472.html).

<sup>153</sup> *See id*.

<sup>154</sup> *See* Health Care Finance, User Orientation and Quality Report 2003 Summary 50 (Advisory Council for the Concerted Action in Health Care, Health Care Finance, 2003) (F.R.G.), available at [https://www.svr-gesundheit.de/fileadmin/Gutachten/Gutachten\\_2003/Kurzfassung\\_engl\\_2003.pdf](https://www.svr-gesundheit.de/fileadmin/Gutachten/Gutachten_2003/Kurzfassung_engl_2003.pdf).

<sup>155</sup> *Id*.

<sup>156</sup> *Id*. at 58-56.

<sup>157</sup> *Id*. at 57-61.

<sup>158</sup> *Id*. at 61.

According to Dr. Günter Jonitz, former President of the Berlin Chamber of Physicians, 2005 was “the year of patient safety in Germany.”<sup>159</sup> That year, the German Medical Assembly (*Deutscher Ärztetag*) unanimously declared that, “medical ethics and social responsibility of doctors in Germany are the foundation to take action on patient safety.”<sup>160</sup> The year 2005 also saw the birth of the German Coalition for Patient Safety (*Aktionsbündnis Patientensicherheit – APS*).<sup>161</sup> APS is an interdisciplinary network of representatives from medical insurance, legal, government, and patient organizations with the single focus of improving patient safety.<sup>162</sup> Jonitz praises APS’s work as a “bottom up” approach that offers practical solutions developed using the expertise of practitioners affected at the ground level rather than impractical administrative measures offered by politicians.<sup>163</sup> APS’s work ranges from participation in international patient safety campaigns (like the WHO’s High 5s project, which aimed to reduce five major patient safety issues in five countries over five years), to collaboration on national projects (like the Clean Hands Campaign, designed to reduce treatment-associated infections), to development of regional projects (like Safe in the Hospital, a pilot project designed to improve patient communication in Hessian hospitals), to research designed to better integrate patient safety concepts into medical, pharmaceutical, and psychotherapeutic education.<sup>164</sup>

Later in 2005, ÄZQ organized Germany’s Critical Incident Reporting System (CIRS) with sponsorship from the National Association of Statutory Health Insurance Physicians and the German Medical Association.<sup>165</sup> The CIRS network encompasses systems that allow institutional, regional, and nationwide analysis of error reports as well as discipline-specific systems.<sup>166</sup> CIRS has enabled healthcare institutions in Germany to target organizational

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<sup>159</sup> Günther Jonitz, *Medical Success Leads to Medical Error: How Health Professionals Accept Responsibility for Safety*, Plenary Session at the International Forum on Quality and Safety in Health Care (March 19, 2009) (on file with author and the Bundesärztekammer in Berlin).

<sup>160</sup> Beschlussprotokoll des 108. Deutschen Ärztetages [Resolution of the 108<sup>th</sup> German Medical Assembly] 34-37, May 3-6, 2005 (F.R.G.) (available on file with the Bundesärztekammer in Berlin) (translated from German).

<sup>161</sup> See Aktionsbündnis Patientensicherheit [Coalition for Patient Safety] [APS], *Brief Portrait*, <https://www.aps-ev.de/kurzportrait/> (last visited Jan. 3, 2022); Günther Jonitz & Sonja Barth, *Etablierung von Patientensicherheit – national und international* [*Establishment of Patient Safety – national and international*] 15 *Trauma Berufskrankh*, 154, August 25, 2013 (F.R.G.).

<sup>162</sup> See APS, *supra* note 161; Jonitz & Barth, *supra* note 161.

<sup>163</sup> Jonitz & Barth, *supra* note 161.

<sup>164</sup> See APS, <https://www.aps-ev.de/> (last visited Jan. 3, 2022).

<sup>165</sup> See Jonitz, *supra* note 159 (regarding the establishment of APS); see also Ärztliches Zentrum für Qualität in der Medizin [ÄZQ] [German Medical Center for Quality in Medicine], *CIRSMedical.de*, <http://www.aeqq.de/patientensicherheit/cirs> (last visited Jan. 3, 2022) (regarding the CIRS reporting system and noting that in 2020, the German Medical Association assumed organization of the CIRS network).

<sup>166</sup> ÄZQ, *Netzwerk CIRSMedical.de*, <http://www.aeqq.de/patientensicherheit/cirs/netzwerk-cirsmedical.de> (last visited Jan. 3, 2022).



deficiencies through near-miss error reporting and analysis.<sup>167</sup> APS's project CIRS *forte*, funded by the Innovation Fund of the Federal Joint Committee developed resources to support the implementation of error reporting and learning systems in outpatient settings.<sup>168</sup>

In 2009, APS established the Institute for Patient Safety (*Institut für Patientensicherheit* – IfPS) at Bonn University, which became the first institution in Germany dedicating academic research to patient safety.<sup>169</sup> Although IfPS's initial mission was to evaluate the implementation and effectiveness of APS's recommendations for action, the institute's research and teaching activities have since expanded to encompass patient safety research, innovation, practical recommendations, and training at national and international levels.<sup>170</sup>

On February 26, 2013, Germany's Patients' Rights Act (*Patientenrechtegesetz* – PRG) was enacted to address growing public concern regarding medical errors.<sup>171</sup> The PRG includes measures that attempt to both improve patient safety and strengthen patients' rights.<sup>172</sup> The law requires providers to implement risk and quality management and patient complaint systems.<sup>173</sup> The PRG also mandates internal near-miss error reporting systems and offers financial incentives for participation in cross-facility error reporting systems, both of which enable organizational learning from adverse events.<sup>174</sup> IfPS reported a drastic increase in the number of hospitals with internal CIRS from 2010 to 2015, signaling that the PRG's legislative mandate had a positive impact on the uptake of error reporting and learning systems as an organizational learning mechanism in German hospitals.<sup>175</sup>

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<sup>167</sup> See sources cited *supra* note 165.

<sup>168</sup> APS, *CIRSforte*, <https://www.cirsforte.de/> (last visited Jan. 3, 2022).

<sup>169</sup> Pauli, *supra* note 57, at 33.

<sup>170</sup> See Jonitz & Barth, *supra* note 161; see also Universität Bonn, Institut für Patientensicherheit [IfPS] [Institute for Patient Safety], <https://www.ukbonn.de/ifps/> (last visited Jan. 3, 2022).

<sup>171</sup> Gesetz zur Verbesserung der Rechte von Patientinnen und Patienten [Patients' Rights Act], Feb. 25, 2013, BGBl. I at 277 (F.R.G.).

<sup>172</sup> See BTDrucks 18/10203 (discussing goals of the PRG, which include strengthening patients' rights and improving patient safety), available at <http://dip21.bundestag.de/dip21/btd/18/102/1810203.pdf>.

<sup>173</sup> Sozialgesetzbuch [SGB V] [Social Insurance Code – Statutory Health Insurance] Dec. 20, 1988, Bundesgesetzblatt [BGBl] I, as amended § 135a.

<sup>174</sup> See SGB V § 135a (mandate); see also SGB V § 137 (financial incentives).

<sup>175</sup> Jörg Lauterberg, ABSCHLUSSBERICHT: Befragung zum Einführungsstand von klinischem Risiko-Management (kRM) in deutschen Krankenhäusern [FINAL REPORT: Survey on the implementation status of clinical risk management (kRM) in German hospitals] (IfPS 2012) (F.R.G.), [https://www.aps-ev.de/wp-content/uploads/2016/08/KRM\\_Abschlussbericht\\_final\\_0.pdf](https://www.aps-ev.de/wp-content/uploads/2016/08/KRM_Abschlussbericht_final_0.pdf) (2010 statistics); Fiona McDermott, et al., Deutschlandweite Befragung zum Einführungsstand des klinischen Risikomanagements [Germany-wide survey on the implementation status of clinical risk management] (IfPS 2016) (F.R.G.), <http://www.aps-ev.de/wp-content/uploads/2016/08/ifps-beitrag-3.pdf> (2015 statistics).

### 2.4.3 The Response in the United States

Days after the IOM published *To Err Is Human*, U.S. President Bill Clinton signed the Healthcare Research and Quality Act of 1999 into law.<sup>176</sup> The Act reauthorized the Agency for Healthcare Research and Quality (AHRQ), which received a congressional mandate to:

conduct and support research and build private-public partnerships to: (1) identify the causes of preventable health care errors and patient injury in health care delivery; (2) develop, demonstrate, and evaluate strategies for reducing errors and improving patient safety; and (3) disseminate such effective strategies throughout the health care industry.<sup>177</sup>

Weeks later, AHRQ called for research to identify “systems-related best practices.”<sup>178</sup> That same year, the National Center for Patient Safety was established within the U.S. Department of Veterans Affairs (VA).<sup>179</sup> The VA National Center for Patient Safety seeks to establish patient safety culture in the VA Health System, which is the country’s largest integrated healthcare delivery system.<sup>180</sup> In September 2000, the AHRQ-led Quality Interagency Coordination Task Force (QuIC) began efforts to develop a national strategy for identifying and preventing threats to patient safety in the U.S.<sup>181</sup> This strategy included \$50 million of patient safety project funding, which ultimately led to the development of tools designed to help healthcare organizations create a culture of safety, reduce hospital-acquired infections, eliminate medication errors, and promote error-reporting, among others.<sup>182</sup>

The Joint Commission, a private non-profit regulatory body, also took swift action to improve patient safety following the IOM’s report. Although Joint Commission accreditation is not mandatory, it is required for hospitals that receive federal support through Medicare and

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<sup>176</sup> Patton McGinley, *AHRQ: One Decade after To Err Is Human*, PSQH Analyses (Sept. 8, 2009), <https://www.psqh.com/analysis/september-october-2009-ahrq/>.

<sup>177</sup> Healthcare Research and Quality Act of 1999, 42 U.S.C.A §§ 201 note, 238p note, 254c note, 254c–4, 256e, 295k note, 299, 299a, 299b, 299b–1 to 299b–6, 299c, 299c–1 to 299c–7 (West, Westlaw through Pub. L. No. 106–129).

<sup>178</sup> AHRQ, *Advancing Patient Safety: A Decade of Evidence, Design, and Implementation*, Publication No. 09(10)-0084 (November 2009), available at <https://www.ahrq.gov/sites/default/files/publications/files/advancing-patient-safety.pdf>.

<sup>179</sup> U.S. Department of Veterans Affairs, *VHA National Center for Patient Safety*, <https://www.patientsafety.va.gov/> (last visited Jan. 4, 2022).

<sup>180</sup> Soumya Upadhyay, *Keeping Patients Safe: How Has the Patient Safety Movement Evolved in the U.S.?*, PSQH Analyses (Jun. 23, 2020), <https://www.psqh.com/analysis/keeping-patients-safe-how-has-the-patient-safety-movement-evolved-in-the-u-s/>; see *id.*

<sup>181</sup> McGinley, *supra* note 176.

<sup>182</sup> *Id.*

Medicaid as well as for those who maintain internship and residency programs.<sup>183</sup> In 1999, the Joint Commission amended its mission statement to include patient safety as an explicit goal.<sup>184</sup> In 2002, the Joint Commission began its annual publication of National Patient Safety Goals, which uses information gathered from industry experts to articulate goals and recommendations for improving patient safety in various care and practice settings, including ambulatory, laboratory, home health, hospital, and nursing homes.<sup>185</sup> That same year, in conjunction with the National Quality Forum (NQF), the Joint Commission established the John M. Eisenberg Patient Safety and Quality Awards to recognize individuals and projects that advance healthcare quality and patient safety.<sup>186</sup> In 2004, the Joint Commission launched Shared Visions-New Pathways, an initiative that redesigned the commission's accreditation process to focus on patient safety and organizational performance.<sup>187</sup>

In 2005, Congress passed the Patient Safety and Quality Improvement Act (PSQIA) to improve patient safety and the quality of healthcare.<sup>188</sup> Through the PSQIA, Congress attempted to promote patient safety culture by protecting the confidentiality of certain information gathered by healthcare providers following adverse events.<sup>189</sup> To further this goal, the Act provides a sphere of legal protection for three categories of data defined as Patient Safety Work Product (PSWP).<sup>190</sup> PSWP means:

- any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements--
- (i) which--
- (I) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization; or

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<sup>183</sup> Kerry A. Kearney & Edward L. McCord, *Hospital Management Faces New Liabilities*, 6 (3) Health Law 1, 3 (1992).

<sup>184</sup> The Joint Comm'n, *The Joint Commission: Over a century of quality and safety*, JointCommission.org (2020), available at <https://www.jointcommission.org/-/media/tjc/documents/about-us/tjc-history-timeline-through-2019-pdf.pdf>.

<sup>185</sup> *Id.*; The Joint Comm'n, *National Patient Safety Goals*, <https://www.jointcommission.org/standards/national-patient-safety-goals/> (last visited Jan. 4, 2022).

<sup>186</sup> The Joint Comm'n, *supra* note 185; The Joint Comm'n, *John M. Eisenberg Patient Safety and Quality Awards*, <https://www.jointcommission.org/resources/patient-safety-topics/patient-safety/john-m-eisenberg-patient-safety-and-quality-award/> (last visited Jan. 4, 2022).

<sup>187</sup> See Robert P. Katzfey, *JCAHO's Shared Visions - New Pathways: The New Hospital Survey and Accreditation Process for 2004*, 61(13) Am. J. Health Syst. Pharm. (2004), available at [https://www.medscape.com/viewarticle/482384\\_5](https://www.medscape.com/viewarticle/482384_5).

<sup>188</sup> Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. §299b-21—b-26 (West, Westlaw through Pub. L. No. 109-41).

<sup>189</sup> See S. Rep. No., 108-196, at 6 (2003) ("This legislation recognizes that patient safety can best be improved by fostering efforts to identify and fix errors while ensuring that providers remain accountable for malpractice.").

<sup>190</sup> See *id.* § 299b-22 (West).

(II) are developed by a patient safety organization for the conduct of patient safety activities; and which could result in improved patient safety, health care quality, or health care outcomes; or  
(ii) which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.<sup>191</sup>

Patient Safety Organizations (PSOs) are privately or publicly formed and funded associations that focus on decreasing healthcare risks.<sup>192</sup>

In 2008, the Joint Commission created the Center for Transforming Healthcare to promote a path to “zero harm” in healthcare organizations.<sup>193</sup> The Center uses high reliability science to help organizations improve quality of care by using the systems approach to error prevention.<sup>194</sup>

In 2009, in response to President Barack Obama’s directive to support projects focused on improving patient safety and reducing medical malpractice, the Department of Health and Human Services (DHHS) in conjunction with the AHRQ established the Patient Safety and Medical Liability Initiative (PSMLI).<sup>195</sup> The PSMLI funded seven demonstration projects focused on: “(1) improving communication, (2) preventing harm through the use of ‘best practices,’ and (3) exploring alternative methods of settling claims.”<sup>196</sup> Although a five-year evaluation of the projects’ impacts was limited, the projects generated a plethora of useful resources for improving patient care and patient safety culture.<sup>197</sup>

In 2010, the U.S. Congress passed, and President Obama signed into law the Patient Protection and Affordable Care Act (PPACA).<sup>198</sup> Although the most-championed goal of the PPACA was to improve healthcare access, it also promised to improve healthcare quality.<sup>199</sup> The law’s payment reforms included systems designed to reward or penalize providers based upon

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<sup>191</sup> See *id.* § 299b-21(7).

<sup>192</sup> See 42 U.S.C.A. § 299b-21(4); AHRQ, *Frequently Asked Questions*, <https://www.pso.ahrq.gov/faq> (“What is a PSO?” and “Do PSOs receive federal funding?”).

<sup>193</sup> The Joint Comm’n Center for Transforming Healthcare, *Who We Are*, <https://www.centerfortransforminghealthcare.org/who-we-are/> (last visited Jan. 4, 2022).

<sup>194</sup> *Id.*

<sup>195</sup> Hafemeister & Porter, *supra* note 11, at 743 (2011).

<sup>196</sup> AHRQ, AHRQ Publication No. 16-0038-2-EF, *Longitudinal Evaluation of the Patient Safety and Medical Liability Reform Demonstration Program: Demonstration Grants Final Evaluation Report* (2016).

<sup>197</sup> *Id.*

<sup>198</sup> Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended in scattered sections of the U.S. Code).

<sup>199</sup> David Blumenthal & Melinda Abrams, *The Affordable Care Act at 10 Years — Payment and Delivery System Reforms*, 382 *New Engl. J. Med.* 1057, 1057 (2020).

quality-of-care metrics.<sup>200</sup> The PPACA also created the Center for Medicare and Medicaid Innovation charged with improving the quality of healthcare funded by Medicare and Medicaid.<sup>201</sup> Although data show improvements in healthcare quality following the enactment of the PPACA, David Blumenthal and Melinda Abrams note that quality improvements were trending upward prior to the law's enactment, shedding doubt on whether the PPACA had a direct impact on healthcare quality.<sup>202</sup>

In 2015, the Joint Commission added a "Patient Safety Systems" chapter to its accreditation manual for hospitals.<sup>203</sup> The chapter recognized that patient safety was central to the high-quality healthcare expected of its accredited organizations.<sup>204</sup> It also acknowledged that creating "a fair and just safety culture," in which individual providers are not punished for systemic deficiencies, was central to the ultimate goal of zero harm.<sup>205</sup> The Joint Commission subsequently included the same chapter in accreditation manuals for ambulatory care, critical access, laboratory, nursing care, and behavioural health organizations.<sup>206</sup> In all settings, the chapter's intent is, "to provide organizations [and their leaders] with a proactive approach to designing or redesigning a patient-centered system that aims to improve quality of care and patient safety."<sup>207</sup>

## **2.5 From to Err is Human to a Deeper Examination of the Medical Liability System's Role in Patient Safety**

Preventing errors through a systems approach is not a singular task but rather one that requires the cooperation of all stakeholders in the healthcare system.<sup>208</sup> The IOM identified internal factors (organizational leadership and culture) and external factors (safety-promoting knowledge and tools, professional leadership, legislative and regulatory action, and demand for improvement from purchasers and consumers), which combine to impact patient safety.<sup>209</sup> A detailed discussion of recommended improvements in the internal environment is beyond the scope of this work, as are the external factors regarding national research goals or the roles

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<sup>200</sup> *Id.* at 1057-1059.

<sup>201</sup> *Id.* at 1060.

<sup>202</sup> *Id.* at 1061.

<sup>203</sup> The Joint Comm'n., *Comprehensive Accreditation Manual for Hospitals ch. Patient Safety Systems* (2019), [https://www.jointcommission.org/-/media/tjc/documents/standards/ps-chapters/20190701\\_23\\_camac\\_04a\\_ps.pdf](https://www.jointcommission.org/-/media/tjc/documents/standards/ps-chapters/20190701_23_camac_04a_ps.pdf).

<sup>204</sup> *Id.*

<sup>205</sup> *Id.*

<sup>206</sup> The Joint Comm'n., "Patient Safety Systems" (PS) Chapter, <https://www.jointcommission.org/standards/patient-safety-systems-ps-chapter/> (last visited Jan. 2, 2022).

<sup>207</sup> The Joint Comm'n., *supra* note 203.

<sup>208</sup> *See generally* IOM, *supra* note 2.

<sup>209</sup> *Id.* at 5-15.

of consumers and purchasers.<sup>210</sup> Instead, this work focuses on expanding the view of the legislative and regulatory factors that influence patient safety, specifically by looking at the topic of medical errors within the theoretical and operational workings of the medical liability system.

The ideal role of the external environment in propelling systemic change is to make errors costly enough to induce internal investment in patient safety.<sup>211</sup> The idea is that legislative and regulatory actions can create minimum safety standards that, if violated, would result in sanctions for the healthcare organization.<sup>212</sup> The IOM posited that enforcing these standards across the industry would “level [the] playing field” by requiring all healthcare organizations to make the same minimum investment in patient safety.<sup>213</sup> It broadly defined regulation and legislation to include, “any form of public policy or legal influence, such as licensing or the liability system.”<sup>214</sup> In terms of licensing, accreditation, and professional standards, the IOM recommended the creation of minimum patient safety standards.<sup>215</sup> The IOM stopped short, however, of recognizing the liability system’s role in enforcing these minimum safety standards. Rather, its treatment of the liability system as an external influence was limited to the system’s chilling effect on the disclosure and discussion of errors by providers who feared malpractice litigation.<sup>216</sup> To combat this problem, the IOM recommended federal peer-review protection for patient safety data in error-reporting systems that would shield providers’ disclosure and analysis of non-injury-causing medical errors and enable the development of successful error-prevention strategies.<sup>217</sup> There is, however, a bigger, more central role that the medical liability system has in the larger patient safety agenda, namely, its ability to hold organizations legally responsible for preventing and minimizing errors through the process of CRM.

## 2.6 Conclusion

In a perfect world, healthcare organizations could take on the task of organizational improvement through CRM for purely altruistic reasons with no concern for the liability consequences or the costs of implementing CRM. In reality, as Ofri points out, “bottom line is a powerful motivator,” and healthcare organizations will respond to external influences that levy legal and financial consequences for failure to reasonably manage risks that can cause patient harm.<sup>218</sup> As discussed in this Chapter, modern error prevention research shows that

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<sup>210</sup> However, because all internal and external influencing factors are interrelated, this work will address these recommendations and goals to the extent they interact with the medical liability system.

<sup>211</sup> IOM, *supra* note 2, at 21.

<sup>212</sup> *Id.* at 19

<sup>213</sup> *Id.*

<sup>214</sup> *Id.*

<sup>215</sup> *Id.* at 10, 11.

<sup>216</sup> *Id.* at 43.

<sup>217</sup> *Id.* at 10.

<sup>218</sup> Ofri, *supra* note 11, at 145.

many of those risks stem from deficiencies buried in the belly of the organizational beast. However, as modern error prevention research also shows, there are well researched and widely available CRM tools and resources that enable organizations to identify and eliminate (or at least mitigate) those risks, making the healthcare system safer for patients. The medical liability system can act as a positive external influence by holding healthcare organizations responsible for complying with reasonable CRM standards of care.

### 3. The Medical Liability System

Although there are some structural differences in the American and German medical liability systems, both countries' negligence-based systems seek to not only compensate victims of medical negligence, but also prevent accidents by deterring substandard behavior. To accomplish this goal, broadscale medical liability reform is not necessary; rather, the existing systems can bring the error-preventing capacity of healthcare organizations into focus by recognizing and defining a duty to CRM under the existing medical liability frameworks.

#### 3.1 General Framework

The medical liability system is designed to resolve disputes between individuals and healthcare providers involving injuries caused by the provision of healthcare. Medical liability in both the U.S. and Germany developed within the general framework of private law.<sup>219</sup> At the outset, there are two general distinctions between the American and German medical liability systems that must be discussed. First, the two countries use different systems of law – the U.S. is a Common Law jurisdiction while Germany is a Civil Law jurisdiction. Second, the U.S. usually approaches medical negligence as a tortious cause of action while Germany usually takes a contract-based approach. Despite these differences, the two medical liability systems operate using remarkably similar negligence-based principles.

Turning first to the Common/Civil Law system distinction, a starting point for distinguishing the two systems is the source of law – legal rules in Common Law jurisdictions are generally derived from case law, while legal rules in Civil Law jurisdictions are codified.<sup>220</sup> This source-of-law distinction also impacts the development of law in the two systems. In Civil Law jurisdictions, legal scholars have a significant impact on the codification and, later, the interpretation of legal rules.<sup>221</sup> Basil Markesinis, et al. describe a mutually beneficial relationship between academic writers and German courts through which academics develop and revise legal theories in response to judicial criticism and courts adopt legal theories put forth by academics.<sup>222</sup> In Common Law jurisdictions, lawyers and judges are the main forces propelling changes in the controlling case law.<sup>223</sup>

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<sup>219</sup> Stauch, *supra* note 11, at 6 (discussing Germany); Beth Watson-Dunham, *Medical Malpractice Law and Litigation* 3 (2005) (discussing U.S.). Private law generally governs medical liability in the U.S. and Germany regardless of whether the hospital is a state or private institution. *See* Giesen, *supra* note 23, at 48; Pauli, *supra* note 57, at 112 (“Medical liability is not regulated by specialized legislation. It is an independent area of law which developed in the second half of the 20th century from the principles of contract and tort law and is decisively shaped by the guidelines of the judicial decisions issued in this area (judge’s law).”).

<sup>220</sup> Stauch, *supra* note 11, at 7.

<sup>221</sup> *Id.* at 7-8.

<sup>222</sup> Basil S. Markesinis, et al., *The German Law of Torts: A Comparative Treatise* 8 (5th ed. 2019).

<sup>223</sup> Stauch, *supra* note 11, at 7-8.



Despite these differences, legal scholars have observed that the Civil/Common Law distinction has diminishing practical importance in the development and application of modern law. Mark Stauch notes that, “[u]ltimately, any legal rule – be it contained in a code, statute, or judicial decision – must be subject to further interpretation in the course of its application to settle a given dispute.”<sup>224</sup> Indeed, Jörg Fedtke credits the role of German judges as “oracles of the law” for the one-hundred-plus year stability of the German Civil Code (*Bürgerliches Gesetzbuch* – BGB).<sup>225</sup> He describes German judges as “no less influential with respect to the development of the [private] law than their Anglo-American counterparts.”<sup>226</sup>

However, a more detailed discussion of the general effects of a Civil/Common law distinction can be avoided in this comparative analysis because medical liability law in both jurisdictions was largely developed in the courts. According to Dieter Giesen:

[M]edical malpractice law, then, not only in the Common Law tradition, but also in all the principal Civil Law countries, remains judge-made law. In the case of Civil Law countries, this takes the form of a “vast gloss overlaying a few exiguous Code articles.”<sup>227</sup>

Stauch, facing the same Civil/Common Law distinction in his comparative analysis of medical negligence in England and Germany, found that the differences in the systems of law have limited significance because German medical malpractice law was essentially developed by courts who applied the general laws of contract and tort found in Germany’s Civil Code.<sup>228</sup>

There is, however, one recent development in German medical malpractice law that reminds us of Germany’s strong Civil Law roots. In 2013, Germany passed the PRG, which introduced the “treatment contract” (*Behandlungsvertrag*) into the German Civil Code. The new law regulates the rights and duties of physicians and patients regarding consent, obligations to provide information, treatment documentation requirements, inspection of medical records, and the burden of proof in medical malpractice cases.<sup>229</sup> For the purposes of discussing the effect of the Common/Civil Law distinction in a comparative analysis of medical liability in the U.S. and Germany, it is important to note that the PRG is largely seen by German legal scholars as a codification of the existing case law.<sup>230</sup> This is in keeping with Fedtke’s finding that:

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<sup>224</sup> *Id.* at 7.

<sup>225</sup> Joerg Fedtke, *The Culture of German Tort Law*, 3 JETL 183, 186 (2012).

<sup>226</sup> *Id.* at 209.

<sup>227</sup> Giesen, *supra* note 23, at Preface XI.

<sup>228</sup> Stauch, *supra* note 11, at 8.

<sup>229</sup> Bürgerliches Gesetzbuch [BGB] [Civil Code] Aug. 18, 1896, Reichsgesetzblatt [RGBl] I, as amended § 630a-h.

<sup>230</sup> *See* Hart, *supra* note 68.

Legislative activity is in many cases reduced to mere confirmation of solutions that have already been set out and applied by judges for many years – often in an attempt by the ‘lawmaker’ to keep the BGB up-to-date with developments in the courtroom rather than steer the law in a particular direction.<sup>231</sup>

As a result, while the PRG codified medical malpractice law in Germany to some extent, practically, the adjudication of medical malpractice disputes operates under the same legal principles originally developed in the German case law. Crucially, the principles that control findings of negligence, causation, and damages, discussed in Chapter 4, are comparable to those used by American courts.

The PRG, through its designation of the treatment contract as the liability-controlling instrument, highlights the second jurisdictional distinction in the American and German medical liability systems. Although both the U.S. and Germany recognize concurrent contractual and tortious causes of action for medical malpractice, the U.S. favors the application of tort law, while Germany favors contract law.<sup>232</sup> Like the Common/Civil law distinction, there are several reasons why this tort/contract distinction has limited significance in a comparative analysis of American and German medical negligence law.

The broadest reason is taken from Sanne Taekema’s theory of pragmatist interactionism, which posits that “the legal assessment of cases of tort and contract is largely based on the normative force of interactional expectancies.”<sup>233</sup> According to Taekema, formal rules governing contract and tort law do not operate in isolation but rather within the framework of more flexible standards influenced by the expectations of social interactions.<sup>234</sup> As a result, the rigid tort/contract distinction in medical malpractice claims is mitigated by the application of broader standards informed by the expectations of participants in the healthcare system.

A related but more concrete reason for the limited significance of the contract/tort distinction is the fact that regardless of whether a medical malpractice lawsuit is based on tort or contract law, both jurisdictions rely upon a fault-based model of liability. As a result, the imposition of liability on healthcare providers who breach a legal duty of care, regardless of whether that duty is grounded in contract or tort, will follow similar negligence-based principles. As Giesen explains:

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<sup>231</sup> Fedtke, *supra* note 225, at 205.

<sup>232</sup> Giesen, *supra* note 23, at 10-11 (legal responsibility for medical malpractice can derive from both contractual and tortious obligations in Common and Civil law jurisdictions, with the exception of France), at 9 (Civil law countries take contractual approach while Common law countries take tortious approach).

<sup>233</sup> Sanne Taekema, *Private Law as an Open Legal Order: Understanding Contract and Tort as Interactional Law*, 43(2) *Neth. J. Legal Philosophy* 140, 141 (2014).

<sup>234</sup> *Id.*

[T]here is little difference in practice in the possible consequences of a physician's breach of his contractual duties in the field of medical law or his duty of care in the tort of negligence. Obligations are meant to be fulfilled, promises are meant to be kept. And contractual terms implied by law are usually identical with duties arising in tort from one party's 'undertaking' to act for another, as in the case of professional services."<sup>235</sup>

As a result, negligence law dominates the assessment of medical liability under either tort or contract in both the U.S. and Germany.<sup>236</sup>

In the U.S., the law of negligence holds a person who fails to act reasonably under the circumstances liable for injury that this substandard conduct causes to another.<sup>237</sup> As the nineteenth century saw rapid development in medical science and the emergence of medicine as a profession, the liability system also began to hold medical practitioners accountable for patient injuries under general negligence principles.<sup>238</sup> In 1855, the Supreme Court of Maine articulated the standard by which medical professionals should be held:

The law implies an undertaking on the part of apothecaries and surgeons, that they will use a reasonable degree of care and skill in the treatment of their patients. They are held responsible for injuries resulting from a want of ordinary care and skill.<sup>239</sup>

Although American courts have recognized that implied contractual duties arise from a treatment relationship between a doctor and a patient, they nevertheless view medical malpractice as a tort action for negligence. The Maryland Court of Appeals, responding to an appellant's argument that contract law venue provisions were applicable in a medical malpractice case, found that:

While it may be as appellant argues that a physician impliedly contracts with those who employ him that he possesses and will exercise a reasonable degree of care, skill and learning . . . malpractice is predicated upon the failure to exercise requisite medical skill and, being tortious in nature, general rules of negligence usually apply in determining liability . . . The great majority of courts that have considered the question have

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<sup>235</sup> Giesen, *supra* note 23, at 9.

<sup>236</sup> *See id.* at 8 (civil liability in Civil and Common law countries is largely based on negligence, unless superseded by a no-fault or strict liability scheme).

<sup>237</sup> Watson-Dunham, *supra* note 219, at 3.

<sup>238</sup> *See id.* at 3.

<sup>239</sup> *Simonds v. Henry*, 39 Me. 155, 156–57 (Me. 1855).

concluded that medical malpractice actions sound in tort, and not in contract.<sup>240</sup>

Similarly, negligence also features prominently in the German Civil Code to assess both tort and contract claims. German law defines negligence as, “the failure to observe the socially required level of care.”<sup>241</sup> In tort, BGB §823(1) provides a legal cause of action for those injured by negligent conduct of another. In contract, BGB §§ 276(1) and 280(1) provide a cause of action for negligent performance of a contract. The German Federal Supreme Court (*Bundesgerichtshof* – BGH) has confirmed the unity of contractual and tortious duties of care in the provision of medical treatment:

The Defendant owed the claimant a duty in both contract and tort to provide appropriate medical care. These duties, deriving respectively from the treatment contract and from the positive assumption in tort of the task of treating the claimant, were in effect identical.<sup>242</sup>

A final reason for the diminished importance of the contract/tort distinction is the fact that German medical liability law developed primarily under a tort law regime.<sup>243</sup> This is because, prior to 2002, awards for pain and suffering (*Schmerzensgeld*) were not available in contract and the patient had to rely upon a concurrent tort claim to recover non-economic damages.<sup>244</sup> According to Stauch, “until recently tort law continued to have an important, indeed arguably dominant, role in medical malpractice actions [in Germany].”<sup>245</sup>

In sum, despite their differences, both American and German medical liability systems operate under similar negligence-based principles developed within the larger framework of tort law.

### 3.2 Goals of the Medical Liability System

Since both the U.S. and Germany take a fault-based approach to medical liability, the two negligence-based systems share, in differing measures and with varying success, common goals. These goals include compensation and deterrence.<sup>246</sup> Though several critics of the

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<sup>240</sup> *Benson v. Mays*, 227 A.2d 220, 223 (Ct. App. Md. 1967).

<sup>241</sup> Stauch, *supra* note 11, at 8.

<sup>242</sup> Bundesgerichtshof [BGH] [Federal Court of Justice], Sept. 20, 1988, 1989 NJW 767 (768) (translation from German).

<sup>243</sup> Stauch, *supra* note 11, at 11.

<sup>244</sup> *Id.* at 11 (noting that now BGB § 253 allows the recovery of pain and suffering damages in both contract and tort actions).

<sup>245</sup> *Id.*

<sup>246</sup> David Shuman, *The Psychology of Deterrence in Tort Law*, 42 U. Kan. L. Rev. 115, 118 (1993) (The main goals in American tort law are compensation and deterrence.); Mello & Studdert, *supra* note 3, at 11 (identifying primary functions of U.S. medical malpractice system as compensation, deterrence, and

medical liability system, particularly in the U.S., describe the system as punitive, punishment is generally not a recognized goal of modern tort law outside of rare instances in which punitive damages for particularly egregious conduct are allowed.<sup>247</sup>

### 3.2.1. Compensation

Giesen identifies compensation as the “central purpose” for awarding damages in medical malpractice litigation.<sup>248</sup> There is little question that compensating victims of medical malpractice is a legitimate goal of the American and German medical negligence systems.

While, in theory, the medical liability system is necessary to ensure compensation for patients injured by medical malpractice, in practice, legal experts in both the U.S. and Germany question the efficacy of the system’s compensatory role. In Germany, the strong social healthcare system relegates the medical liability system to a backseat role in providing victim compensation. According to Fedtke, the “elaborate” German social security system would compensate injured victims for most economic damages caused by medical errors (including medical expenses and lost wages) leaving only the “tip of the iceberg” – pain and suffering – to the liability system.<sup>249</sup>

In the U.S., which lacks Germany’s strong social system, a different criticism is launched against the medical liability system’s compensatory function, namely that it fails to compensate most victims of medical errors because those who stand to recover minor damages never file claims.<sup>250</sup> One explanation for these unfiled claims is that American attorneys, who work on a contingency fee basis, are generally unwilling to take cases with an expected award of less than \$250,000.<sup>251</sup> As Joanna Shepherd explains, “[h]igh litigation costs and damage-restricting tort reforms have made it economically infeasible for attorneys to take many medical malpractice

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corrective justice). Similarly, the European Group on Tort Law notes that “damages serve primarily the aim of compensation but also of prevention.” European Group on Tort Law, *Principles of European Tort Law: Text and Commentary* 19 (2005).

<sup>247</sup> See *Tort*, Britannica.com, <https://www.britannica.com/topic/tort> (last visited Jan. 4, 2022) (“Most authors would probably agree that punishment and appeasement are no longer major aims of tort law.”); Legal Information Institute, *Tort*, <https://www.law.cornell.edu/wex/tort> (last visited Oct. 27, 2022) (“In contrast, tort law addresses private wrongs and has a central purpose of compensating the victim rather than punishing the wrongdoer.”).

<sup>248</sup> Giesen, *supra* note 23, at 221. *But see* Thomas Allen Heller, *An Overview of Medical Malpractice Law in the United States Including Legislative and the Health Care Industry’s Responses to Increased Claims*, 10(2) *Med. L. Soc’y* 139, 140 (2017) (the primary purpose of tort law is to prevent accidents and compensation is a corollary goal).

<sup>249</sup> Fedtke, *supra* note 225, at 200-202.

<sup>250</sup> A 1990 Harvard Medical Practice Study found that most patients injured by medical malpractice do not file a claim for damages and are not compensated through the medical liability system. Shuman, *supra* note 246, at 120; *see* Mello & Studdert, *supra* note 3, at 16.

<sup>251</sup> Joanna Shepherd, *Uncovering the Silent Victims of the American Medical Liability System*, 67 *Vanderbilt L. Rev.* 151, 154-55, 187 (2019).

cases.”<sup>252</sup> In Germany, where legal fees are set by the Act on the Remuneration of Lawyers (*Rechtsanwaltsvergütungsgesetz* – RVG) and legal expenses insurance is widely available, injured patients have easier access to the civil justice system boosting the value of the compensatory role of the medical liability system in Germany.<sup>253</sup>

Even when cases are filed in the U.S., there is evidence that victims of medical malpractice are not reliably compensated. A 2006 review of medical malpractice cases in the *New England Journal of Medicine* found that no payment was made to 27% of cases that were determined to contain an error while payment was made in 28% of the cases that were determined to contain no error.<sup>254</sup> And even when victims of medical error are compensated through the tort law system, the high administrative cost of litigation roughly equals the amount of compensatory damages received, calling into question whether the tort system is the most efficient mechanism for compensating victims.<sup>255</sup> Still, some legal scholars, especially legal realists who reject the deterrent capability of tort law, regard the medical liability system’s role as a third-party insurer in compensating patients for medical injuries as the only legitimate goal of the system.<sup>256</sup> Latin however, finds that, “[l]itigation is a very expensive method for accident loss allocation, and the transaction costs of the tort system would not be warranted unless liability achieves some commensurate increase in social utility.”<sup>257</sup> The measure of the medical liability system’s effect on social utility lies in its ability to deter negligent conduct that causes patient injuries.<sup>258</sup>

### 3.2.2 Deterrence

The capacity of a fault-based liability system to deter socially unacceptable behavior is the subject of much interdisciplinary debate. The first question that must be examined is whether deterrence is a recognized goal of the medical liability system. Second is the question of whether deterrence is a feasible goal considering both economic and psychological influences on behavior.

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<sup>252</sup> *Id.* at 155.

<sup>253</sup> See Stauch, *supra* note 11, at 153; *Rechtsanwaltsvergütungsgesetz* [RVG] [Act on the Remuneration of Lawyers] May 5, 2004 *Bürgerlichen Gesetzbuchs* [BGBl] I, as amended.

<sup>254</sup> David M. Studdert et al., *Claims, Errors and Compensation Payments in Medical Malpractice Litigation*, 354(19) *NEJM* 2014 2024, 2028 (2006) (study finding one quarter of litigation outcomes not concordant with the merits). (Figure 1 “Overview of the Relationship among Claims, Injuries, Errors, and Outcomes of Litigation”).

<sup>255</sup> Stephen D. Sugarman, *Torts in Law*, *International Encyclopedia of Behavioral Sciences*, at 12, available at [https://www.law.berkeley.edu/files/Sugarman\\_on\\_Torts\\_International\\_Encyclopedia\\_Social\\_and\\_Behavioral\\_Sciences\\_Reformatted.pdf](https://www.law.berkeley.edu/files/Sugarman_on_Torts_International_Encyclopedia_Social_and_Behavioral_Sciences_Reformatted.pdf).

<sup>256</sup> Richard A. Posner & William M. Landes, *The Positive Economic Theory of Tort Law*, 15 *Ga. L. Rev.* 851, 853 (1980).

<sup>257</sup> Howard Latin, *Problem-Solving Behavior and Theories of Tort Liability*, 73 *Ca. L. Rev.* 677, 733 (1985).

<sup>258</sup> See Heller, *supra* note 248, at 140 (deterrence in tort law is “a form of social control.”).

### 3.2.2.1 Deterrence as a recognized goal

Although there is a stronger case in the literature for recognizing deterrence as an explicit goal of the American liability system, there is evidence that the German system also accepts deterrence as a legitimate goal.

Since the American medical malpractice system exists within the tort law regime and deterrence is an often-recognized, albeit hotly-debated, goal of modern American tort law, there is little question that deterrence is a goal of the American medical liability system.<sup>259</sup> In 1970, Guido Calabresi, described as “one of the principal founders of economic analysis of law,” recognized that tort law had the ability to affect behavior of tortfeasors and victims in a way that could result in the reduction of accidents and the costs of accidents.<sup>260</sup> Forty-one years later, in a vehement defense of deterrence in tort law, Andrew Popper maintains that “[d]eterrence is a real and present virtue of the tort system.”<sup>261</sup> He argues that, “[t]he actual or potential imposition of civil tort liability changes the behavior of others.”<sup>262</sup> Tort law’s ability to deter behavior finds support from prominent American legal minds like Judge Richard Posner as well as from lesser-known judges from all around the country, who discuss the goal of deterrence in their legal decisions.<sup>263</sup> Even George Priest, who criticizes the means that modern tort law uses to achieve deterrence, embraces the goal of accident reduction, which he claims, “command[s] widespread acceptance [because] [a]ll citizens share the goal of reducing the accident rate both, on moral grounds, because no personal injury can ever be fully compensated and, on economic grounds, because reducing accidents conserves valuable and productive resources in human capital.”<sup>264</sup> Of course, as discussed in II.B.2, some scholars launch reasonable attacks on the actual ability of tort law to deter undesirable behavior, but at this point, it is crucial to recognize that those attacks are launched against a generally accepted belief, in practice if not in academia, that deterrence is a legitimate goal of tort law, and hence, a legitimate goal of the American medical liability system.

When considering the goal of deterrence in the German medical liability system, a brief return to the tort/contract distinction is necessary. Of the two private law mechanisms, tort law goals have a broader scope, concerned primarily with prevention of harmful conduct in society generally, while contract law is primarily concerned with compensating an individual for damages incurred because of a broken promise. Giesen explains more thoroughly:

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<sup>259</sup> Mello & Studdert, *supra* note 3, at 17 (“Deterrence is the primary theoretical rationale for the tort liability system”).

<sup>260</sup> Richard Posner, *The Costs of Accidents: A Reassessment*, 64 Md. L. Rev. 12, 13 (2005); *see* Latin, *supra* note 257, at 677.

<sup>261</sup> Andrew F. Popper, *In Defense of Deterrence*, 75(1) Albany L. Rev. 101, 181 (2012).

<sup>262</sup> *Id.*

<sup>263</sup> *See generally id.* (citing U.S. case that recognize deterrence as a goal of tort law); Posner & Landes, *supra* note 256.

<sup>264</sup> George L. Priest, *Modern Tort Law and Its Reform*, 22 Valparaiso U. L. Rev. 1, 8 (1987).

The *law of contract* primarily exists for the purpose of vindicating an individual interest, for instance, in having the promises of others performed. If the promisor fails, or fails properly, to perform his obligation, the law of contract will award the promise damages for breach of contract in order to put him, so far as possible, in as good a position as if the promise had been kept, or to compensate him for the disappointment of his legally protected expectations under the contract. The *law of torts* (or *delict*), on the other hand, aims first of all at the prevention of wrongful harm caused by others and if things go wrong, at compensating injuries or distributing losses thereby suffered.<sup>265</sup>

While it is true that contract law is generally less concerned with prevention as a goal, the merging of contract and tort law principles in the fault-based German medical liability system encompasses the goal of deterrence. According to David Shuman, a fault-based liability system only affords compensation to victims of damage-causing behavior that needs deterring, i.e., negligent behavior.<sup>266</sup> In other words, a fault-based system has no interest in compensation when the behavior causing the injury is not the kind of behavior that society wishes to prevent. From this perspective, while compensation might be a primary goal of medical malpractice liability, in either contract or tort, the compensatory role of any negligence-based system cannot exist without at least a secondary goal of deterring unlawful behavior. Otherwise, a legal system would opt for a no-fault scheme for compensating medical injuries such as the one adopted in New Zealand.<sup>267</sup> Indeed, the German Medical Law Association rejected a no-fault scheme for medical injuries partly because it wished to “preserve a deterrent effect” by subjecting medical conduct to the court system.<sup>268</sup>

Two additional features of Germany’s medical liability system support a goal of deterrence. First, the legislative history for the PRG discusses the goal of improving patient safety by preventing medical errors.<sup>269</sup> Although the Act’s provisions were not adopted exclusively in the Civil Code, this general legislative intent implies that deterrence is a valid goal of the German medical liability system. Second, as already discussed, Germany’s medical liability law primarily developed under tort law principles, which implies that the generally recognized

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<sup>265</sup> Giesen, *supra* note 23, at 9-10.

<sup>266</sup> Shuman, *supra* note 246, at 119.

<sup>267</sup> Giesen, *supra* note 23, at 581.

<sup>268</sup> Stauch, *supra* note 11, at 149.

<sup>269</sup> See BTDrucks 18/10203, available at <http://dip21.bundestag.de/dip21/btd/18/102/1810203.pdf>. (discussing goals of the PRG, which include strengthening patients’ rights and improving patient safety).



goals of tort law, including deterrence, remain relevant in Germany's modern medical liability system, despite its contractual framework.<sup>270</sup>

### 3.2.2.2 Deterrence as a feasible goal

The broad question of whether any fault-based liability regime can deter undesirable behavior has long attracted the interest of not only legal scholars, but also economists and psychologists. This discussion primarily occurs within the context of the American economic theory of tort law but is also found in the economic efficiency model of tort law discussed by German scholars. Additionally, the unique inner workings of the healthcare system influence the extent to which negligence-based medical liability can prevent harm-causing behaviors within healthcare organizations.

Turning first to the general ability of tort law to deter undesirable behavior — and dredging up the first, and likely only, time American law students encounter algebra — I begin with Judge Learned Hand's definition of negligence:  $B < P \times L$ .<sup>271</sup> According to Hand, if the burden of precaution necessary to prevent the accident (B) is less than the probability of the accident (P) times the magnitude of the loss (L), then the relevant standard of care is breached and the defendant is negligent.<sup>272</sup> This formula, named for Judge Hand, has since been adapted by Judge Richard Posner and other proponents of a positive economic theory of tort law to define an economic standard of negligence assigning marginal, rather than absolute, values to the Hand Formula.<sup>273</sup> According to Posner, “[t]his means that it is negligent to use a level of care at which the marginal cost of accident avoidance is less than the marginal benefit from avoidance.”<sup>274</sup>

Tort law's capacity to deter negligent behavior is rooted in this economic approach and, according to Posner, can be traced back to Oliver Wendel Holmes's 1881 writing *The Common Law*.<sup>275</sup> Posner, influenced by Arthur Pigou's concept of social-cost internalization and Ronald Coase's idea that common law could be used to internalize social costs, developed an economic theory of tort law, in which deterrence is not only recognized as an effect of tort law, but a goal.<sup>276</sup> This economic theory of deterrence relies on an expected utility maximization model, which presumes that people will make choices that have the highest chance of maximizing their

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<sup>270</sup> See Heico Kerkmeester & Louis Visscher, *Learned Hand in Europe: a Study in the Comparative Law and Economics of Negligence*, 2003 Ger. Working Papers L. Econ. Paper 6, 10 (2003) (“Goal of tort law should be to influence the behavior of people in such a way that they prevent accidents that should be prevented from a perspective of social welfare.”)

<sup>271</sup> *Carroll Towing Co.*, 159 F.2d at 173.

<sup>272</sup> *Id.*

<sup>273</sup> Posner & Landes, *supra* note 256, at 885.

<sup>274</sup> *Id.*

<sup>275</sup> *Id.* at 852.

<sup>276</sup> *Id.* at 853-856

expected income or wealth.<sup>277</sup> Posner explains that under this model, a rational actor will increase his level of care until an additional increase in care fails to yield a reduction in expected damages greater than the cost of the increased care.<sup>278</sup> It continues that an actor's expectation of damages is directly affected by the potential for tort liability. As a result, liability determinations in tort law should theoretically deter future accidents by inducing the liable actor or similarly situated actors to increase their levels of care in response to the clear risk of tort liability.<sup>279</sup> According to Latin, "virtually all social engineering and 'law and economics' analyses share one central behavioral assumption – that imposition of liability substantially affects how categories of actors respond to the risks they create or confront."<sup>280</sup> Popper finds it "hard to conceive of a healthy economic model where rational actors ignore clear warning signs and thus render themselves vulnerable to sanctions or punishment."<sup>281</sup> While Popper and other advocates of deterrence admit that the tort law system does not have a perfect record of deterring harmful behavior, they maintain that, overall, the system "positively affects the safety and efficiency of goods and services."<sup>282</sup>

Although this economic model of deterrence developed in the Common Law tradition, it has also found acceptance in some Civil Law jurisdictions. According to Heico Kerkmeester and Louis Visscher, "the Law and Economics approach in Europe has received attention especially in Germany."<sup>283</sup> Kötz recognizes deterrence as a goal of German tort law, and he also references the Hand formula to discuss how German courts consider both the cost of preventive measures and expected losses when deciding whether a defendant was negligent, i.e. failed to exercise a socially acceptable level of care.<sup>284</sup> According to Claus Ott and Hans-Bernd Schäfer, the German court system develops efficient standards of care over time, despite the fact that individual courts do not assume the explicit task of setting the applicable standard of care in every case.<sup>285</sup> The process, they argue, develops organically when courts evaluate the social gain of the precaution taken by the tortfeasor and precaution proposed by the victim in individual cases.<sup>286</sup> The courts measure social gain of the precaution by subtracting the cost of prevention from the social gain of the activity "appl[ying] criteria related to economic efficiency like the Learned Hand test" and choose the preventive measure that has the higher social gain to measure negligence in an individual case.<sup>287</sup> As an example, Ott and Schäfer discuss a case in which a builder of an attic was sued after the homeowners discovered dry rot

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<sup>277</sup> *Id.* at 865-66.

<sup>278</sup> *Id.* at 870.

<sup>279</sup> Popper, *supra* note 261, at 183-184.

<sup>280</sup> Latin, *supra* note 257, at 677.

<sup>281</sup> Popper, *supra* note 261, at 184.

<sup>282</sup> *Id.* at 185.

<sup>283</sup> Kerkmeester & Visscher, *supra* note 270, at 9.

<sup>284</sup> *Id.* at 278 (*citing* J. Hein Kötz, *Deliktsrecht* 18-19 (8th ed. 1998)).

<sup>285</sup> *See generally*, Claus Ott and Hans-Bernd Schäfer, *Negligence as Untaken Precaution, Limited Information, and Efficient Standard Formation in the Civil Liability System*, 17 *Int'l Rev. L. Econ.* 15 (1997).

<sup>286</sup> *Id.* at 17.

<sup>287</sup> *Id.* at 19-20.

a year and a half after the attic was completed.<sup>288</sup> While the builder argued that there were no signs of dry rot during the attic construction, the court agreed with the plaintiff that the builder should have noticed and investigated rotten planks, which he could have done at very little cost and which would have revealed the dry rot.<sup>289</sup>

Ott and Schäfer contend that once the court chooses a precaution with a higher social gain, it follows that the negligent tortfeasor will presumably adjust his behavior by subsequently adopting the precaution chosen by the victim or another precaution with at least the same social gain to avoid future liability.<sup>290</sup> As a result, individual cases will continue to shape the standards of care as plaintiffs continue to challenge the sufficiency of precautions taken by defendants and courts continue to apply the social gain balancing test.<sup>291</sup>

Legal realists, like Stephen Sugarman, reject the “magical character” that the positive economic theory ascribes to tort law.<sup>292</sup> They cast doubt on tort law’s ability to simultaneously compensate victims, internalize costs, preempt private retributive justice, prevent accidents, and hold wrongdoers accountable.<sup>293</sup> They dismiss its ability to deter harmful conduct and, instead, credit safe practices to “private morality, market pressures, self-protection instincts, and existing governmental regulation.”<sup>294</sup>

Others, like Priest, accept tort law’s capacity to prevent accidents, but contend that modern American tort law must be “vastly reorganized” to accomplish this goal.<sup>295</sup> Priest claims that tort law has “done a scandalously poor job of controlling the accident rate” partly because courts have accepted that product and service providers are in a better position than consumers to prevent accidents.<sup>296</sup> Priest is especially skeptical of strict liability regimes that hold product and services providers liable in the absence of fault and suggests that liability should only attach to defendants when accidents could have been prevented.<sup>297</sup> When no practical preventive measure existed prior to the accident, Priest claims that “attaching liability will not affect the accident rate.”<sup>298</sup>

Howard Latin too accepts deterrence as a valid goal of tort law but calls for a liability system that targets only “problem-solving actors” to achieve this goal.<sup>299</sup> His approach focuses not on who is most causally connected to the injury, but rather on the actor’s accident prevention

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<sup>288</sup> *Id.* at 24-25.

<sup>289</sup> *Id.*

<sup>290</sup> *Id.* at 20.

<sup>291</sup> *Id.* at 28.

<sup>292</sup> Sugarman, *supra* note 255, at 10-11.

<sup>293</sup> *Id.*

<sup>294</sup> *Id.* at 10.

<sup>295</sup> Priest, *supra* note 264, at 5-6, 10.

<sup>296</sup> *Id.*

<sup>297</sup> *Id.* at 23-24, 31.

<sup>298</sup> *Id.* at 21-22.

<sup>299</sup> Latin, *supra* note 257, at 679.

potential.<sup>300</sup> He criticizes the notion that all actors are “rational utility maximizers” with the information and ability to rationally engage in a cost-benefit analysis. Instead, he argues that:

[T]he assumption that liability rules influence most people’s risk-avoidance behavior in most accident contexts is unproven and appears unwarranted. In many settings, people lack sufficient information and expertise to assess risks properly; they are inattentive to known risks; they do not understand the applicable liability doctrines; and compelling nonlegal incentives shape their behavior.<sup>301</sup>

As a result, Latin proposes classifying actors according to their attention level and only imposing liability on high-attention actors, who have the capacity to prevent accidents.<sup>302</sup>

Shuman argues for a psychological, rather than economic, approach to deterrence in tort law. According to him “economic analysis of tort law proceeds on many behavioral assumptions that are either not validated, or have been disproved by empirical research.”<sup>303</sup> As an example, he posits that organizational decision-makers rarely engage in a cost benefit analysis and rarely prioritize profit maximization when making decisions.<sup>304</sup> Shuman further argues that, according to mainstream behavior theory, certainty of punishment, which the current tort system lacks, is crucial for deterring undesirable conduct.<sup>305</sup> He complains that in a system that doles out sanctions according to the quality of the injury, rather than the conduct, it becomes difficult to predict which conduct will lead to sanctions.<sup>306</sup> Ultimately, Shuman admits that despite the theoretical and practical difficulties of deterrence, tort law plays some role, however cloudy, in shaping the safety behavior of American business.<sup>307</sup> Shuman further acknowledges that “deliberative behavior is more readily deterred by the tort system.”<sup>308</sup>

The medical liability system – as a subsection of the larger tort system – has thus far struggled to effectively deter medical errors. Stauch, in his examination of the medical liability systems in England and Germany, observed that, “while it may suppress the number of claims for compensation, the litigation system does not by itself do enough to promote accident prevention.”<sup>309</sup> Michelle Mello and David Studdert agree that in the U.S., “[t]here is little evidence that the system actually deters negligence in medicine or improves the quality of

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<sup>300</sup> *Id.* at 699.

<sup>301</sup> *Id.* at 692.

<sup>302</sup> *Id.* at 695-696.

<sup>303</sup> Shuman, *supra* note 246, at 138.

<sup>304</sup> *Id.* at 139.

<sup>305</sup> *Id.* at 121-125.

<sup>306</sup> *Id.* at 122-124.

<sup>307</sup> *Id.* at 131.

<sup>308</sup> *Id.* at 163.

<sup>309</sup> Stauch, *supra* note 11, at 154.

care.”<sup>310</sup> One possible reason for the medical liability system’s weak deterrent signal is its continued focus on individual providers’ behavior rather than organizational behavior, including organizational efforts to prevent errors through CRM.

Ofri highlights a significant distinction between individual healthcare providers (i.e., doctors, physician’s assistants, nurses, etc.) and other tortfeasors in the tort system at-large (a driver, a business owner, a mechanic, etc.):

We all want our patients to do well. No clinician with a detectible heartbeat wants her patient to get a hospital-acquired infection, or have surgery on the wrong side of the body, or receive a delayed diagnosis of cancer. Threats of lawsuits are not necessary to instill this priority.<sup>311</sup>

As a result, economic-driven theories of deterrence that may operate in the tort system generally fail at the individual provider level in the medical malpractice system because doctors and nurses generally do not need financial incentives to avoid patient injuries. The primacy of the provider-patient relationship and Hippocratic oath are already at the forefront of the medical profession, and “the vast majority of errors are committed unintentionally by otherwise conscientious doctors and nurses.”<sup>312</sup>

The medical malpractice insurance environment can also affect deterrence in the medical liability system. Mello and Studdert argue that malpractice insurance dulls the deterrent signal from the medical liability system because insurance companies, not healthcare providers, are largely responsible for the costs of medical malpractice litigation.<sup>313</sup> However, they concede that in the U.S., “the incentive-dampening effect of insurance is a less serious problem [for hospitals] than for individual physicians because insurance premiums for hospitals, but not for individual providers, are experience rated.”<sup>314</sup> In Germany, rising medical malpractice claims expenses resulted in increased premiums and the need for higher liability limits, especially for providers practicing in high-risk specialties.<sup>315</sup> In response, some German insurers withdrew

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<sup>310</sup> Mello & Studdert, *supra* note 3, at 18

<sup>311</sup> Ofri, *supra* note 11, at 145.

<sup>312</sup> *Id.* at 144.

<sup>313</sup> Mello & Studdert, *supra* note 3, at 18, 20.

<sup>314</sup> *Id.* at 20.

<sup>315</sup> Dominique Püster, *Entwicklungen der Arzthaftpflichtversicherung* [Developments in Medical liability insurance] 71-97 (2013); Detlef Pohl, *Medical Liability: Arzthaftpflicht: Der Markt schrumpft weiter* [Medical Liability: The market continues to shrink], 110 (1-2) *Dtsch. Arztebl.* (2013), <https://www.aerzteblatt.de/archiv/133901/Arzthaftpflicht-Der-Markt-schrumpft-weiter>; Norddeutscher Rundfunk [NDR], *Haftpflichtschutz belastet Kliniken in Schleswig-Holstein* [Liability coverage burdens clinics in Schleswig-Holstein], *Versicherungsbote* (Aug. 23, 2013), available at <https://www.versicherungsbote.de/id/4781109/Haftpflichtschutz-Kliniken-Schleswig-Holstein-Behandlungsfehler-NDR/>.

from the medical liability market altogether.<sup>316</sup> While German professional regulations require individual providers to carry medical malpractice insurance,<sup>317</sup> the law does not impose the same insurance requirement on hospitals, leaving larger healthcare organizations with the option of being self-insured or obtaining policies with high deductibles.<sup>318</sup> Similarly, many U.S. hospitals have historically exercised the option to be self-insured, though the current trend is for hospitals to maintain insurance with high self-insured retentions.<sup>319</sup> Shuman points out that self-insurance, policies with high self-insured retentions, and uninsured claims undermine the protection that insurance might otherwise offer tortfeasors.<sup>320</sup> As a result, while insurance can decrease deterrence, healthcare organizations that bear some liability costs directly will still respond to the threat of liability.

Shuman also argues that maximization of wealth is not the only motivation to refrain from risky behavior, but rather that behavior is motivated by non-economic factors such as emotion, stress, and time commitment to litigation.<sup>321</sup> Indeed, healthcare providers who commit medical errors are often labeled “second victims” because of the emotional toll they suffer themselves in the aftermath of medical errors.<sup>322</sup> Ofri describes how healthcare providers who commit medical errors experience a “powerful enough dose of grief, shame, and awareness of the error” without a lawsuit. However, those who are sued suffer further from “clinical judicial syndrome” which can lead to depression, anxiety, isolation, and loss of trust in the doctor-patient relationship.<sup>323</sup>

Unfortunately, for individuals, this fear of litigation, leads to what Mello and Studdert label mutant deterrence, more commonly known as defensive medicine, which they describe as “assurance and avoidance behaviors that are induced by apprehension about liability and are of little benefit (compared to their cost), no benefit, or outright harmful.”<sup>324</sup> Although defensive

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<sup>316</sup> See *id.*; see also Karl Otto Bergmann et al. *Krankenhaushaftung: Organisation, Schadensverhütung und Versicherung - Leitfaden für die tägliche Praxis* [Hospital Liability Organization, Loss Prevention and Insurance - Guide for Daily Practice], at 343 (Karl Otto Bergmann & Hans-Friedrich Kienzle eds., Kindle ed. 2015) (ebook).

<sup>317</sup> See Bergmann et al., *supra* note 316, at 338 (citing *Berufsordnung für Ärzte (BOÄ)* § 8).

<sup>318</sup> See *id.* at 340.

<sup>319</sup> See James R Posner, *Trends in Medical Malpractice Insurance, 1970-1985*, 49(2) *Law Contemp. Problems*, 37 at 42-43 (1986); Christopher Cheney, *Hospitals Need to Brace for Upper Trend in Malpractice Claims*, *Healthleaders* (Dec. 2, 2019), <https://www.healthleadersmedia.com/clinical-care/hospitals-need-brace-upward-trend-malpractice-claims>.

<sup>320</sup> Shuman, *supra* note 246, at 130.

<sup>321</sup> *Id.*

<sup>322</sup> See David L. B. Schwappach, *Nach dem Behandlungsfehler: Umgang mit Patienten, Angehörigen und dem involvierten Personal* [After the treatment error: dealing with patients, relatives and the staff involved] 58 *Bundesgesundheitsbl* 80, 82 (2015) (F.R.G.); Janet Barnes, et al., *When Things Go Wrong: Responding to Adverse Events*, 7 (Massachusetts Coalition for the Prevention of Medical Errors 2006), available at [www.macoalition.org](http://www.macoalition.org).

<sup>323</sup> Ofri, *supra* note 11, at 144.

<sup>324</sup> Mello & Studdert, *supra* note 3, at 23.

medicine developed as a concept in the U.S., it is also a recognized, albeit not as prevalent, practice in Germany.<sup>325</sup> One view of defensive medicine is that it is a result of the medical liability system's efforts to deter medical malpractice by targeting primarily individual providers. Given the IOM's report regarding the ineffectiveness of blaming individual healthcare providers as an error prevention strategy, it should come as no surprise that the medical liability system's mutant deterrent signal, which has fallen squarely on individual healthcare providers, has failed to "incentiviz[e] quality improvements."<sup>326</sup>

From an error prevention perspective, the medical liability system's focus on individual providers' actions is also poor identifier of injury-causing events that need to be avoided in the future. First, there is evidence that the system does not reliably identify medical errors, because claims filed in the system are both over- and under- inclusive and thus do not accurately reflect the true nature and rate of medical errors.<sup>327</sup> For example, while American patients who are injured because of negligent care are more likely to file a lawsuit than those who are injured during non-negligent treatment, "most instances of negligence never give rise to a malpractice claim, and many malpractice lawsuits are brought and won by patients even though expert reviewers can identify no evidence of negligent care."<sup>328</sup>

There is a similar disconnect in Germany between medical malpractice claims and the occurrence of medical errors. Studies suggest that a large number of medical errors do not result in claims.<sup>329</sup> Conversely, upon expert review, a large number of malpractice claims are determined to contain no error. In 2020, the medical arbitration boards (*Gutachterkommissionen* and *Schlichtungsstellen*) – pre-litigation review panels composed of medical experts and a judge – found no medical error (or breach of a standard of care) for 4876 (69.1%) of the 7055 claims decided.<sup>330</sup> Similarly, treatment error statistics from Medical Service of the National Association of Health Insurance Funds (*Medizinischer Dienst des Spitzenverbandes Bund der Krankenkassen* – MDS) – a service that provides insureds with free

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<sup>325</sup> Bergmann et al., *supra* note , at 316; Interview by Johannes von Dohnanyi with Prof. Dr. Gerd Gigerenzer, Director, Harding Center for Risk Literacy at the University of Potsdam, Faculty of Health Sciences Brandenburg (Sept. 30, 2015), *available at* <https://www.bertelsmannstiftung.de/de/themen/aktuelle-meldungen/2015/september/bauchentscheidungen>; Roland Brilla et al., *Are neurology residents in the United States being taught defensive medicine?*, 108(4) *Clinical Neurology and Neurosurgery* 374 (2006), *available at* <https://pubmed.ncbi.nlm.nih.gov/16040189/>.

<sup>326</sup> See Mello & Studdert, *supra* note 3, at 23-24.

<sup>327</sup> See Studdert et al., *supra* note 254, at 2031.

<sup>328</sup> Mello & Studdert, *supra* note 3, at 20.

<sup>329</sup> Medizinischer Dienst des Spitzenverbandes Bund der Krankenkassen (MDS), *Behandlungsfehler-Begutachtung der Gemeinschaft der Medizinischen Dienste Jahresstatistik 2020* [MDS Treatment Error Review Annual Statistics 2020], *available at* [https://www.md-th.de/fileadmin/MD-zentraler-Ordner/Downloads/04\\_Behandlungsfehler/2021\\_10\\_12\\_PK\\_BHF\\_Jahresstatistik\\_2020\\_BF.pdf](https://www.md-th.de/fileadmin/MD-zentraler-Ordner/Downloads/04_Behandlungsfehler/2021_10_12_PK_BHF_Jahresstatistik_2020_BF.pdf) (last visited Oct. 29, 2022).

<sup>330</sup> Bundesärztekammer, *supra* note 3; *see also* Hermann Liebermiester, *How to avoid liability litigation in courts – Suggestions from a German example*, 8 *German Med. Science* 3 (2010) (error confirmation rate is consistently around one-third).

expert opinions regarding suspected medical errors – reveals similar results: no error in 9,943 (70.8%) of the 14,042 cases reviewed.<sup>331</sup>

Regardless of the reasons for unreported claims or expert findings of no error in claims reported, this disconnect between malpractice claims and the commission of medical error signals a deeper problem with medical liability system's ability to sufficiently identify, and thus prevent, injury-causing behavior. Compounding the problem in the U.S. is that healthcare providers perceive no rational relationship between medical negligence and the likelihood of being sued.<sup>332</sup>

Second, as discussed in Chapter 2, modern error prevention research teaches that focus on an individual provider's actions, negligent or otherwise, will not reveal the systemic deficiencies that are ultimately responsible for medical errors. As a result, even if individual provider actions are deterred through the medical liability system, it will do little to reduce patient harm caused by the systemic defects, which will continue to induce individuals to commit medical errors.<sup>333</sup> While the healthcare organization itself is responsible for implementing an effective CRM program to make the system safer, as long as individual providers are the primary targets for medical liability, the deterrence signal will be misdirected and manifest as defensive medicine. As a result, deterrence will fail as an error prevention mechanism because the actions targeted by the medical liability system are not the actions most capable of preventing future medical errors. Even worse, the systemic problems that are at the root of medical errors are less likely to get reported by providers who fear individual persecution from the medical liability system. According to Mehlman:

The system is highly punitive; it not only makes wrongdoers pay damages but also makes the process of being found liable for malpractice an extremely negative punishing experience. The experience is so unpleasant that it gives clinicians no incentive to admit their mistakes. The resulting culture of silence makes it very difficult for the system to carry out its deterrence function because it produces little information about why mistakes occur or how they can be prevented in the future.<sup>334</sup>

Mello and Studdert refer to this problem as “cloaking behavior” to describe the reluctance of American healthcare providers to participate in error reporting and learning systems for fear that the reported information will later be used against them in medical malpractice litigation.<sup>335</sup> Although the American medical liability system is generally regarded as more

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<sup>331</sup> MDS, *supra* note 329.

<sup>332</sup> Mello & Studdert, *supra* note 3, at 20.

<sup>333</sup> See IOM, *supra* note 2, at 55-56.

<sup>334</sup> Maxwell J. Mehlman, *Promoting Fairness in the Medical Malpractice System*, in *Medical Malpractice and the U.S. Health Care System* 140 (William M. Sage & Rogan Kersh eds., 2006).

<sup>335</sup> Mello & Studdert, *supra* note 3, at 27-29.



liberal in terms of filings and compensation, Germany's healthcare system is no stranger to the culture of silence, and legal threats are also a recognized barrier to medical error reporting in Germany.<sup>336</sup>

### 3.3 Medical Malpractice Reform

In addition to compensation and deterrence, an overarching goal of the medical liability system, as in any system of law, is fairness.<sup>337</sup> As Heller observes, “[s]ociety will not long respect the legal system if it does not perceive it as fundamentally fair to everyone.”<sup>338</sup> One aspect of fairness in a legal system manifests in the notion that it should “not unduly harm or hinder useful economic activities.”<sup>339</sup> When a system is perceived as fundamentally unfair, calls for reform ensue.

#### 3.3.1 Medical Malpractice Landscape and Proposals for Reform

The medical liability systems in both the U.S. and Germany are not strangers to calls for reform. As early as the 1960s, an increase in medical malpractice claims in Western societies triggered criticism for its perceived role in increasing healthcare cost and decreasing healthcare quality by encouraging the practice of defensive medicine, damaging the physician-patient relationship, and discouraging physicians from entering high-risk specialties.<sup>340</sup> Experts attributed malpractice claims increase to a variety of factors including the increase in litigation generally, rapid advances in medical science and technology, deterioration of the traditional doctor-patient relationship, pro-plaintiff litigation attitudes, urbanization, and increased patient autonomy and awareness.<sup>341</sup>

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<sup>336</sup> Loewenbrück, et al., *supra* note 9, at 313-314; *but See* Duffourc, *supra* note 10 (noting that Germany's conservative discovery and evidentiary rules as well as federal regulations that require error reporting data to remain anonymous help mitigate liability-based fears for German physicians).

<sup>337</sup> *See* Heller, *supra* note 248, at 143 (noting that tort law aims not only to compensate victims and prevent accidents, but to “foster notions of fairness and predictability”).

<sup>338</sup> *Id.* at 140.

<sup>339</sup> *Id.* at 143.

<sup>340</sup> *See* Stauch, *supra* note 11, at 2 (regarding increase in malpractice claims in Western societies); 131-132 (regarding widespread assumption that the practice of defensive medicine occurs in Germany and claims that malpractice litigation undermines trust and confidence in the physician-patient relationship); *see* Studdert, et al., *supra* note 254, at 2025 (proponents of tort reform in the U.S. blame medical malpractice litigation for rising cost of healthcare); Hafemeister & Porter, *supra* note 11, at 739, 744, (discussing the practice of defensive medicine and rising insurance premiums in the U.S.); *see* Heller, *supra* note 248, at 144 (insurers withdrew from high-risk practice areas); Bergmann et al., *supra* note 316, at 341-344.

<sup>341</sup> *See* Stauch, *supra* note 11, at 2 (explaining causes of increased malpractice claims); *see* Patricia Danzon, The Frequency and Severity of Medical Malpractice Claims: New Evidence, 49:2 L. Contemp. Problems, 57, 58 (1986) (identifying factors explaining increase in medical malpractice claims); Bergmann et al., *supra* note 316, at 343 (identifying reasons for sharp rise in medical malpractice claims expenses in Germany).

In the U.S., the frequency and costs of medical malpractice claims increased significantly. Malpractice claims rose from approximately 1.6 claims per 100 physicians in the period from 1956-1963 to 10 claims per 100 physicians by 1985.<sup>342</sup> In terms of costs, one prominent medical malpractice insurer reported a ninety-five percent increase in paid claims costs from 1979-1983.<sup>343</sup> This increase in U.S. malpractice litigation was so drastic that it is credited for causing a medical malpractice crisis so dire that it attracted international attention.<sup>344</sup> In 1980, an English judge warned:

Take heed of what has happened in the United States . . . Experienced practitioners are known to have refused to treat patients for fear of being accused of negligence. Young men are even deterred from entering the profession because of the risks involved. In the interests of all, we must avoid such consequences in England.<sup>345</sup>

The change in the medical malpractice claims landscape was thus deemed a “crisis” and politicians began advocating for reform.

State legislatures in the U.S. responded to the “crisis” by implementing a variety of tort reform measures, including shortened statutes of limitations, damages caps, and pre-litigation screening mechanisms.<sup>346</sup> Nevertheless, the system still faces criticism for its inability to fairly adjudicate claims. In addition to the aforementioned reform measures already adopted by some states, current medical malpractice reform proposals include abolition of legal doctrines of joint and several liability, *res ipsa loquitur*, and the collateral source rule; schedules for non-economic damages; regulation of malpractice insurers; limits on attorney’s fees; health courts; alternative dispute resolution; and adoption of a “no fault” liability system.<sup>347</sup>

Although Germany did not experience a medical malpractice “crisis,” it too saw a sharp increase in medical malpractice lawsuits around the same time as the U.S.<sup>348</sup> In Germany, medical malpractice litigation increased from a handful of medical malpractice claims per year before the 1960s to 6000 claims per year by the end of the 1970s.<sup>349</sup> By 2005, medical

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<sup>342</sup> Reed Olsen, *The Reform of Medical Malpractice Law: Historical Perspectives*, 55(3) Am. J. Econ. and Socio. 257, 260 (1996).

<sup>343</sup> Danzon, *supra* note 341, at 57.

<sup>344</sup> *Id.* at 259-260. (conceding that prior to 1960 the medical malpractice insurance market was stable).

<sup>345</sup> *Whitehouse v. Jordan* (1980) 1 All ER 650 (CA) 658.

<sup>346</sup> *See generally* Heller, *supra* note 248.

<sup>347</sup> Maxwell J. Mehlman, *supra* note 334, at 142-148 (discussing fairness of various medical malpractice reform efforts in the US); *see generally* *Id.*

<sup>348</sup> *See* Stauch, *supra* note 11, at 130 (Germany did not experience “US-style malpractice crises,” but the increase in medical malpractice claims “generated a disproportionate amount of concern.”).

<sup>349</sup> *Id.* at 2.

malpractice claims in Germany were estimated to be 20,000-35,000 per year.<sup>350</sup> Germany also experienced claim cost increases. “In Germany, the average expenses per insurer per claim . . . trebled from 1981-2001; in some sub-areas the rise has been more than six-fold.”<sup>351</sup> Like in the U.S., this increase in medical malpractice filings and costs in Germany spurred calls for reform.

Discussions among academics and practitioners regarding radical reform to medical malpractice law dominated the German Medical Assembly in 1978. Also, in the mid-1970s, at the same time that some U.S. states were implementing medical review panels to screen malpractice claims, the German regional medical boards (*Ärzttekammern*) established medical arbitration bodies to encourage pre-trial resolution of claims.<sup>352</sup> There are still calls for reform in Germany, too. Karl Otto Bergmann, et al. believe that absent reforms, increasing malpractice filings and claims payouts will lead to a “crisis about the insurability of physicians’ services.”<sup>353</sup> On the other hand, patients’ rights advocates in Germany seek reforms that improve patients’ access to court and ability to recover damages and strengthen error disclosure duties in the PRG.<sup>354</sup> One plaintiff’s lawyer in Germany calls for a strict liability system and higher pain and suffering awards.<sup>355</sup> Another plaintiff’s attorney suggests a system in which medical experts chosen by the parties, instead of judges, decide medical malpractice cases.<sup>356</sup>

The ongoing calls for change on both sides demonstrate a deeper dissatisfaction with the medical liability system’s ability to achieve its goals of fairness, accident prevention, and compensation. While it is outside of the scope of this work to comment on the wisdom of each of the various proposals for reforming the medical malpractice systems in the U.S. and Germany, it is notable that both jurisdictions have retained negligence-based systems to govern liability for medical injuries. However, these negligence-based systems often inhibit the healthcare industry’s approach to error prevention, as discussed in Chapter 2. Mello and Studdert note:

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<sup>350</sup> *Id.*

<sup>351</sup> *Id.* at 130.

<sup>352</sup> See Stauch, *supra* note 11, at 146.

<sup>353</sup> Bergmann et al., *supra* note 316, at 34 (translation from German).

<sup>354</sup> See generally Interview with Maria Klein-Schmeink, a German Bundestag Member from the Green Party, in Berlin, Germany (February 2017), available at [www.medriskreport.com](http://www.medriskreport.com) (discussing challenges encountered by victims of medical errors); see also Martin Albrecht, et al., Studie zu den Wirkungen des Patientenrechtegesetzes [Study on the effects of the Patients’ Rights Act] 51-54 (IGES Institut 2016) (F.R.G.), available at [http://www.patientenbeauftragter.de/images/veranstaltungen/2016/patientenrechtegesetz/20161109\\_IGES-Studie\\_Wirkungen\\_Patientenrechtegesetz.pdf](http://www.patientenbeauftragter.de/images/veranstaltungen/2016/patientenrechtegesetz/20161109_IGES-Studie_Wirkungen_Patientenrechtegesetz.pdf) (discussing patients’ rights advocates criticism of the Patients’ Rights Law’s disclosure obligations).

<sup>355</sup> See Alexander T. Schäfer, Plädoyer für einen besseren Schutz der Patienten [Plea for better patient protection], <https://www.schmerzensgeld.info/reform-arzthaftung-schmerzensgeld-300/fachartikeldetail.aspx> (last visited Jan. 4, 2022).

<sup>356</sup> See generally Interview with Jana Hassel, *supra* note 3 (discussing challenges encountered by victims of medical errors).

[T]he tort approach to safety regulation – which is punitive in orientation, individualistic in focus, and adversarial in process – is in serious conflict with the nonpunitive, systems-focused, cooperative approach of the “patient safety movement.”<sup>357</sup>

Thus, finding ways to harmonize the existing medical negligence system with the patient safety movement to accomplish a common goal of medical error prevention is a task that remains. This work argues that recognizing and defining a duty to CRM helps achieve that task.

### 3.3.2 Reforming A Negligence-Based Medical Liability System

Reform efforts within a negligence-based medical liability system are more likely to be successful if they help shift the system’s focus from the actions of individual providers to the actions of healthcare organizations – the same paradigm shift that the IOM ignited in the healthcare industry’s approach to medical error prevention. Christopher Burkle agrees that, “[a]ny future reform should involve system modifications that better correlate with patient safety measures.”<sup>358</sup> A medical liability system that demands that healthcare organizations take actions to prevent medical errors through the process of CRM holds promise for restoring the goals of the tort system generally in reliably compensating patients (by encouraging individual provider error reporting) and preventing medical errors (by deterring negligent risk management conduct of healthcare organizations). As Bergmann, et al. observe, “A modern hospital can no longer do without efficient risk management.”<sup>359</sup>

Although no reform is likely to transform the medical liability system into a perfect deterrent, various deterrence theories support the idea that focusing the liability system on organizational actors can strengthen the system’s deterrence signal. First, there is evidence that healthcare institutions – as opposed to individual providers – may modify behaviors in response to threats of legal or regulatory sanctions.<sup>360</sup> Studies aimed at testing the deterrent effect of medical negligence on healthcare providers suggest that while individual providers are likely not deterred by the risk of medical liability, hospitals might improve care in response to medical malpractice claims.<sup>361</sup> Although the studies supporting this conclusion have been criticized as “limited and . . . vulnerable to methodological criticism,” they provide some support for the idea that organizations are more likely deterred by the threat of liability than individual providers.<sup>362</sup> Crucially, deterrence at the organizational level is more likely to translate to error reduction. Although, as discussed further in Chapters 4 and 5, both the U.S. and Germany

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<sup>357</sup> Mello & Studdert, *supra* note 3, at 29.

<sup>358</sup> Christopher Burkle, *Medical malpractice: can we rescue a decaying system?* 86 *Mayo Clin. Proc.* 326 (2011).

<sup>359</sup> Bergmann et al., *supra* note 316, at 343.

<sup>360</sup> Ofri, *supra* note 11, at 145.

<sup>361</sup> Mello & Studdert, *supra* note 3, at 19.

<sup>362</sup> *Id.*

recognize direct liability for organizational errors, the duties of care in the current law do not encompass a broader duty to CRM. As a result, the liability systems still look primarily to individual providers as the main source of liability for treatment errors, further encouraging defensive medicine and concealing systemic defects. However, as Goldbach notes, expanding organizational liability to include a duty to conduct CRM will “lead to a reduction in liability cases in the long term” because “increased systematics and transparency of treatment procedures should even partially relieve physicians and hospital operators of the fear of increasing liability pressure and thus lead to a decrease in defensive medicine.”<sup>363</sup> Thus, a legal duty to conduct CRM can help align the tort system with the industry’s patient safety goals by connecting a hidden source of medical errors (systemic defects) in the healthcare system to a mechanism for accident prevention (deterrence) in the legal system.

Second, from an expected utility maximization perspective, healthcare organizations will increase systems-based error prevention measures through CRM in response to a clear risk of organizational liability. In addition, focusing liability on healthcare organizations, who are in the best position to identify and correct systemic deficiencies, satisfies Latin’s approach of assigning tort liability “whenever possible to categories of actors who do, in reality, think about accident prevention, loss spreading, and the effects of legal rules, and whose behavior may therefore be significantly influenced by potential liability.”<sup>364</sup> Recognizing a legal duty to conduct CRM would not entirely relieve individual providers of legal consequences for patient harm caused by individual treatment error. It would, however, properly orient “financial and administrative responsibility” for systemic failures to the organization by demanding reasonable CRM from the parties that are able to:

diversify liability risk across a range of specialties and services, insure or self-insure that risk at manageable cost, engage in coordinated injury reduction activities, and enter into efficient contractual arrangements downstream with patients and upstream with health insurers regarding claims for compensation.<sup>365</sup>

Third, under Latin’s taxonomy, healthcare organizations would be classified as high-attention actors susceptible to being deterred by the threat of liability because they “specialize in limited problem elements, are able to adapt their decisions in response to experience derived from many similar choices, and are subject to performance monitoring systems that aim to control pecuniary costs including potential tort damages.”<sup>366</sup> On the other hand, contrary to Latin’s approach, which would apply strict liability to disputes between healthcare organizations and patients, maintaining a negligence-based system would decrease errors without decreasing

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<sup>363</sup> Goldbach, *supra* note 17, at 128-29 (translation from German).

<sup>364</sup> Latin, *supra* note 257, at 681.

<sup>365</sup> Sage, *supra* note 19, at 40-41.

<sup>366</sup> Latin, *supra* note 257, at 693.

participation in the risky activity, here the provision of healthcare.<sup>367</sup> This approach would also satisfy Priest's concern that deterrence is only effective when liability attaches to behavior that can be prevented.<sup>368</sup>

### 3.4 Conclusion

Liability in both systems hinges upon a finding a fault, stemming from substandard behavior, i.e., negligence. Although negligence-based liability systems seek to compensate victims and deter undesirable behavior, focusing liability for harm caused by medical errors on individual providers' actions does not effectively advance these goals, particularly regarding deterrence. Instead, because individual healthcare providers respond to threats of legal liability by practicing defensive medicine, the medical liability system, in its capacity as an external influencing factor on patient safety, inhibits industry systems-based error prevention efforts. On the other hand, focusing liability on organizational actions and deficiencies is more likely to achieve the goal of preventing medical errors. Additionally, because organizational deficiencies are best detected and resolved through the process of CRM, the medical liability system should encompass a cause of action that holds healthcare organizations responsible for patient injuries caused by negligent risk management.

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<sup>367</sup> See Posner & Landes, *supra* note 256, at 876 (“strict liability may result in fewer accidents than negligence - not by inducing the defendant to be more careful but by inducing him in some cases to reduce the level of his activity and with it the expected number of accidents.”).

<sup>368</sup> Priest, *supra* note 264, at 5-6, 10.

#### 4. Establishing Medical Liability

Both American and German medical liability systems recognize three main categories of medical liability: (1) consent or information errors, (2) treatment errors, and (3) organizational errors.<sup>369</sup> Consent and information errors occur when a physician fails to obtain patient consent for medical treatment or properly disclose information regarding the risks of medical treatment.<sup>370</sup> Treatment errors occur when either the provision or failure to provide medical treatment by individual medical providers violate the applicable standard of care.<sup>371</sup> Organizational errors occur when the healthcare organization itself breaches standards governing the medical treatment process.<sup>372</sup>

Liability for consent and information errors is rooted in the protection of autonomy, bodily integrity, and self-determination.<sup>373</sup> As a result, failure to obtain the requisite consent to treat a patient is a legal transgression regardless of whether the treatment itself was “appropriate and carried out skillfully.”<sup>374</sup> Because competency of the medical treatment is not a factor in determining liability for consent or information errors, those errors, strictly speaking, do not

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<sup>369</sup> See Hansis & Hart, *supra* note 145 (regarding Germany); Pauli, *supra* note 57, at 38 (providing a description of error definitions in various fields in Germany); see generally Samuel D. Hodge, Jr. & Maria Zambrano Steinhaus, *The Ever-Changing Landscape of Informed Consent and Whether the Obligation to Explain A Procedure to the Patient May Be Delegated*, 71 Ark. L. Rev. 727, 732 (2019) (discussing the doctrine of informed consent in the US); 61 Am. Jur. 2d *Physicians, Surgeons, Etc.* § 285 (2d ed), Westlaw (database updated Nov. 2021) (discussing cause of action stemming from provision of medical services in the U.S.); S. Allan Adelman & Julie Robertson, *Emerging Trends in Healthcare Liability* (June 19, 2000), [http://archive.healthlawyers.org/google/health\\_law\\_archive/program\\_papers/2000\\_AM/%5B2000\\_AM%5D%20Emerging%20Trends%20in%20Healthcare%20Liability.pdf](http://archive.healthlawyers.org/google/health_law_archive/program_papers/2000_AM/%5B2000_AM%5D%20Emerging%20Trends%20in%20Healthcare%20Liability.pdf) [<http://perma.cc/Q8VG-6FXF>]; 3 Summary Pa. Jur. 2d *Torts* § 37:45 (2d ed.), Westlaw (database updated July 2018) (discussing theories of direct hospital liability).

<sup>370</sup> Edward L. Raab, *The parameters of informed consent*, 102 Trans. Am. Ophthalmol. Soc. 225 (2004), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1280103/> (regarding U.S.); Stauch, *supra* note 11, at 95-96, 100-101 (regarding Germany).

<sup>371</sup> Pauli, *supra* note 57, at 39-40 (regarding Germany); see *Russell v. May*, 400 P.3d 647, 657 (Kan. 2017) (finding that the physician’s duty to the patient obligates him to use a certain standard of care); see also § 24:15. *Duty of physician—In general*, 3 Mod. Tort L. Liab. Litig. § 24:15 (2d ed.) (standard of care applicable to physicians in U.S.).

<sup>372</sup> See 3 Summ. Pa. Jur. 2d *Torts* § 37:45 (2d ed.); see also Yvonne K. Puig, *Liability Overview: New Theories and Challenges* (2001), <https://perma.cc/KPQ8-95XW> (seminar materials *citing* *Welsh v. Bulger*, 698 A.2d 581, 585 (Pa. 1997)) (regarding US); Pauli, *supra* note 57, at 41 (regarding Germany).

<sup>373</sup> Raab, *supra* note 370; Stauch, *supra* note 11, at 95-96, 100-101.

<sup>374</sup> Raab, *supra* note 370; see also *Ehrlich v. Sorokin*, 165 A.3d 812, 818 (N.J. Super. A.D. 2017) (“Informed consent is generally unrelated to the standard of care for performing medical treatment”)’ see S. A. Sommer et al., *Medical Liability and Patient Law in Germany: Main Features with Particular Focus on Treatments in the Field of Interventional Radiology*, 188(4) *RoFo: Fortschritte auf dem Gebiete der Rontgenstrahlen und der Nuklearmedizin* 353, 353 (2016) (“Without an effective consent the treatment is considered illegal whether it was free of treatment error or not.”).

constitute “medical malpractice” but rather “disclosure malpractice.”<sup>375</sup> As such, a discussion of consent errors falls outside of the scope of this work. Instead, the duty to conduct CRM to prevent medical errors occurs primarily at the intersection of treatment errors and organizational errors, both of which will be the focus of this chapter.

#### 4.1 Treatment Errors

A patient might experience two types of harm during the course of medical treatment.<sup>376</sup> First, a patient may experience harm that is caused by the patient’s underlying medical condition. In this case, treatment aimed at curing the patient’s underlying condition may fail, and upon such failure, the natural progression of the patient’s medical condition can harm the patient.<sup>377</sup> Second, a patient might experience a harm that is caused by the medical treatment itself. This type of harm is called an “iatrogenic injury.”<sup>378</sup> Within both categories of harm, negligence is required before liability can be imposed on a healthcare provider for an unintentional medical injury. For example, a healthcare provider might be liable for harm caused by the natural progression of a patient’s medical condition if they negligently failed to diagnose or misdiagnosed the patient’s condition. On the other hand, a healthcare provider will not be liable for patient harm, even harm caused by medical treatment, if the provider rendered treatment with reasonable care. Giesen notes that “neither in contract nor in torts can a conclusion be drawn as to negligence on part of the acting physician from the mere fact that an accident happened or the result was not in accordance with expectation.”<sup>379</sup>

In the U.S., the question is whether, according to the particular facts of the case, the “physician has performed his duties with reasonable care and skill.”<sup>380</sup> The Maine Supreme Court explains:

The law also implies that, in the treatment of all cases which they undertake, they will exercise reasonable and ordinary care and diligence. They are also bound always to use their best skill and judgment in determining the nature of the malady and the best mode of treatment, and in all respects to do their best to secure a perfect restoration of their patients to health and soundness. But physicians and surgeons do not impliedly warrant the recovery of their patients, and are not liable on account of any failure in

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<sup>375</sup> Raab, *supra* note 370 (“Although the legal analyses for malpractice and informed consent are similar, these are distinctly separate causes of action.”); Giesen, *supra* note 23, at 73 (“treatment malpractice and disclosure malpractice are independent of each other.”).

<sup>376</sup> See Stauch, *supra* note 11, at 1.

<sup>377</sup> *Id.*

<sup>378</sup> *Id.*

<sup>379</sup> Giesen, *supra* note 23, at 19.

<sup>380</sup> *Id.*



that respect, unless through some default of their own duty, as already defined.<sup>381</sup>

German law similarly limits liability for medical injuries. Pauli explains that failed medical treatments, natural disease progressions, and unavoidable undesirable events and complications that occur during the course of medical treatment are not indicative of medical errors for which a healthcare provider will be held liable under German law, but rather are risks that the patient assumes when obtaining medical treatment.<sup>382</sup> In a reference decision distributed to medical malpractice litigants by the Saarbrücken Regional Court (*Saarbrücken Landgericht*), the court reminds the parties of the complexities associated with the provision of medical care:

The physician does not owe any treatment success, but only a treatment according to the rules of the medical art. The mere fact that the desired healing success has not occurred or that undesirable complications and risks have materialized cannot be taken to mean that the doctor has acted incorrectly. This is because each person is an individual with his or her own anatomical characteristics. For example, a disease that causes certain symptoms in one person may have completely different symptoms in another. Conversely, certain symptoms can have very different causes. For this reason, even the correct diagnosis is associated with particular difficulties. The mere fact that a doctor does not make the correct diagnosis or does not make it immediately does not necessarily mean that a treatment error has occurred. Moreover, it is not certain in advance whether a particular therapy will be successful for this particular patient. While some patients respond to a certain therapy, the same therapy does not succeed in other patients.<sup>383</sup>

In reality, it can be difficult to determine whether a provider's negligence is responsible for a patient injury since the provision of both reasonable and unreasonable care can combine in various ways to produce damage.<sup>384</sup> However, when a healthcare provider fails to exercise reasonable care, *i.e.*, is negligent, a treatment error occurs, and when that error causes patient harm, then the provider has committed medical malpractice.

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<sup>381</sup> Patten v. Wiggin, 51 Me. 594, 595 (Me. 1862).

<sup>382</sup> Pauli, *supra* note 57, at 40.

<sup>383</sup> 12 Dec 2010 Saarbrücken [judge at the Regional Court of Kaiser], Hinweisbeschluss [Reference Decision] Landgericht Saarbrücken (translation from German).

<sup>384</sup> Hansis & Hart, *supra* note 145.

### 4.1.1 Elements of Malpractice

In the U.S., the medical liability system developed as part of American tort law and is governed primarily by the common law principles of negligence.<sup>385</sup> Tort liability for negligence exists in the U.S. when the following elements are present: (1) a duty of care owed by the defendant to the plaintiff, (2) a breach of that duty, (3) causation, and (4) damage.<sup>386</sup> The German Civil Code provides for a cause of action for medical malpractice under both contract and tort law.<sup>387</sup> Since the German contract for medical treatment is a contract for services, liability will only be imposed when the provider is negligent in the performance of those services.<sup>388</sup> As a result, the elements of malpractice under a contract for negligent performance merge with those under tort for negligent conduct.<sup>389</sup> Tort liability will arise under the German Civil Code when the following exist: (1) a protected right or interest, (2) unlawful interference with that right or interest, (3) causation, and (4) damage.<sup>390</sup>

#### 4.1.1.1 Legal Duties and Obligations

Before liability is imposed on a wrongdoer in either jurisdiction, they must be under a legal duty or obligation to act with a certain level of care. Generally, the relationship between a healthcare provider and their patient requires the provider to act with reasonable care in treating the patient.<sup>391</sup> Giesen depicts the doctor-patient relationship as follows:

Thus, a person who is a medical professional, or who holds himself out as ready to give medical advice or treatment, impliedly undertakes that he is possessed of skill and knowledge for the purpose, and when consulted by a patient will owe him a duty of care, namely in deciding whether to undertake the case, in taking a proper case history, in making careful diagnosis, in properly informing his patient about any proposed treatment or operation and inherent risks of treatment and no treatment, in obtaining a patient's consent to such treatment and in his administration of that treatment or the performance of that

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<sup>385</sup> Watson-Dunham, *supra* note 219, at 3; Mello & Studdert, *supra* note 3, at 11 (“American medical malpractice law revolves around the concept of negligence”).

<sup>386</sup> See *Elam v. Coll. Park Hosp.*, 132 Cal. App. 3d 332, 338 (Cal. Ct. App. 1982); *Jennings v. Badgett*, 230 P.3d 861, 865 (Okla. 2010) (discussing the elements of a medical malpractice claim in the U.S).

<sup>387</sup> Stauch, *supra* note 11, at 8.

<sup>388</sup> *Id.* at 29.

<sup>389</sup> See Giesen, *supra* note 23, at 24 (“contractual duties do not, then, affect the true nature of medical liability, which remains in all countries essentially the legal duty, the breach of which will normally lead that kind the legal liability which exists either in the presence or absence of the contract, and which can properly be described as tortious or delictual liability in all jurisdictions under review.”).

<sup>390</sup> Markesinis, et al., *supra* note 222, at 29.

<sup>391</sup> Giesen, *supra* note 23, at 73-81 (discussing the duty of care generally and in medical malpractice cases in common and civil law jurisdictions).

operation, and, at all stages, in answering questions where he knows or ought to know that the patient intends to rely on his answer.<sup>392</sup>

American courts rely specifically on the doctor-patient relationship to anchor medical liability. In Germany, medical liability can stem from both the medical treatment contract and a more general duty to refrain from interfering with a patient's legally protected interest in life, body, and health.

#### **4.1.1.1.1 The Doctor-Patient Relationship in the United States**

In the U.S., the doctor-patient relationship creates a legal duty owed by the individual healthcare provider to the patient.<sup>393</sup> The Maryland Court of Appeals explains:

We have long recognized, as have most courts, that, except in those unusual circumstances when a doctor acts gratuitously or in an emergency situation, recovery for malpractice “is allowed only where there is a relationship of doctor and patient as a result of a contract, express or implied, that the doctor will treat the patient with proper professional skill and the patient will pay for such treatment, and there has been a breach of professional duty to the patient.”<sup>394</sup>

Although determining whether a doctor-patient relationship exists is a fact-specific inquiry, it is usually established, “when the professional services of a physician are accepted by another person for the purposes of medical or surgical treatment.”<sup>395</sup> In the absence of direct contact between the physician and patient, a doctor-patient relationship can be implied when, “the doctor takes affirmative action to participate in the care and treatment of a patient,” for example, by directing a patient's care over the phone.<sup>396</sup> However, mere consultation with a treating physician, who retains ultimate medical decision-making authority, will usually not establish a doctor-patient relationship between the patient and the consulting physician.<sup>397</sup> Some American courts have also found that physicians can owe a duty to non-patient third parties when the third party's injury stems from the patient's medical care, including cases in

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<sup>392</sup> *Id.* at 81.

<sup>393</sup> *McNulty v. City of New York*, 792 N.E.2d 162, 166 (N.Y. 2003) (“Generally, a doctor only owes a duty of care to his or her patient.”); *Betesh v. U.S.*, 400 F. Supp. 238, 247 (D.D.C. 1974).

<sup>394</sup> *Dingle v. Belin*, 749 A.2d 157, 164 (Md. 2000) (*quoting* *Hoover v. Williamson*, 253, 203 A.2d 861, 862 (Md. 1964)).

<sup>395</sup> Steven E. Pegalis, *American Law of Medical Malpractice* § 2:3, at 3 (3d ed) Westlaw (database updated June 2021); Kelly Gelein, *Are Online Consultations a Prescription for Trouble? The Unchartered Waters of Cybermedicine*, 66 *Brook. L. Rev.* 209, 213 (2000).

<sup>396</sup> *Sterling v. Johns Hopkins Hosp.*, 802 A.2d 440, 455 (Md. Spec. App. 2002).

<sup>397</sup> *See id.*

which third parties contract infections from patients or are injured by a physically or mentally incapacitated patient.<sup>398</sup>

Physicians can be held vicariously liable for the negligence of providers acting under their supervision and control.<sup>399</sup> Although hospitals historically enjoyed immunity from liability for patient injuries in the U.S., in 1957, the New York Court of Appeals in *Bing v. Thunig* found that hospitals could be vicariously liable for the actions of individual healthcare providers employed by the hospital.<sup>400</sup> Following *Bing*, theories pursuant to the doctrines of estoppel and apparent agency emerged and provided additional bases for holding hospitals vicariously liable for patient injuries caused by treatment errors of non-employee physicians.<sup>401</sup>

Because vicarious liability operates independent of joint and several or comparative liability schemes, a physician or hospital that is vicariously liable for injury caused by another's negligence will remain responsible for the entirety of the damages attributable to the negligent provider, "regardless of whether joint and several liability or several liability is the governing rule."<sup>402</sup> However, a physician or hospital held vicariously liable for another's negligence is entitled to seek indemnity from the original tortfeasor to recover the amount it paid to compensate for the tortfeasor's negligence.<sup>403</sup>

#### 4.1.1.1.2 The Treatment Contract in Germany

In Germany, the treatment contract will oblige the provider to provide non-negligent care.<sup>404</sup> This is because German law classifies a contract for medical treatment as a contract for services (*Dienstvertrag*), not a contract for work (*Werkvertrag*) guaranteeing a particular result.<sup>405</sup> In ambulatory settings, the treatment contract in the majority of cases will be concluded between the patient and the individual physician providing the treatment.<sup>406</sup> Inpatient treatment contracts can take several forms. The default rule for patients with statutory health insurance is the total hospital admission contract (*Totaler Krankenhausaufnahmevertrag*), wherein the

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<sup>398</sup> Steven E. Pegalis, American Law of Medical Malpractice § 3:16 (3d ed) Westlaw (database updated June 2021).

<sup>399</sup> American Law Reports, 85 A.L.R.2d 889 (Originally published in 1962) ("A physician or surgeon is liable for the negligence or malpractice of a physician or surgeon acting in the case as his assistant").

<sup>400</sup> See Cassandra P. Priestley, *Hospital Liability for the Negligence of Independent Contractors: A Summary of Trends*, 50 J. Mo. B. 263 (1994) (citing *Bing*, 143 N.E.2d at 8).

<sup>401</sup> See *id.*

<sup>402</sup> Restatement (Third) of Torts: Apportionment Liab. § 13 (Am. Law Inst. 2000).

<sup>403</sup> Restatement (Third) of Torts: Apportionment Liab. § 22 (Am. Law Inst. 2000).

<sup>404</sup> Bergmann et al., *supra* note 316, at 17-25.

<sup>405</sup> Stauch, *supra* note 11, at 29. There are, however, situations in which a contract for medical products or devices will be viewed as a contract for sale and subject the physician to a stricter form of liability when the materials or products used during medical treatment cause harm. (See Giesen, *supra* note 23, at 21-23 for more).

<sup>406</sup> See BGB § 630a.

contract is concluded solely between the hospital and the patient.<sup>407</sup> As a result, the hospital alone has a contractual obligation to provide medical treatment and is held vicariously liable pursuant to BGB §278(1) for individual healthcare providers' treatment errors.<sup>408</sup> Other types of inpatient contracts include the split hospital admission contract (*Gespaltener Arzt-Krankenhaus-Vertrag*) and the hospital admission contract with an additional physician contract (*Totaler Krankenhausaufnahmevertrag mit Arztsatzvertrag*), wherein the patient contracts with both the hospital and the physician.<sup>409</sup> When both the hospital and physician are contractual obligors, they can be held jointly and severally liable, depending on the circumstances of the treatment arrangement, the physician's employment relationship, and the negligence alleged.<sup>410</sup>

In addition to contractual liability, tort liability can arise under German law when a protected interest, including life, body, and health, under BGB § 823 is implicated.<sup>411</sup> As a result, individual healthcare providers can be held liable to a patient under tort principles for the negligent provision of medical care that results in an injury.<sup>412</sup> Under BGB § 831, liability can include vicarious liability for a physician's negligent "selection, instruction, monitoring and equipment provided for his assistants."<sup>413</sup> Similarly, hospitals can be held vicariously liable in tort law for an individual provider's negligence because the individual provider will generally be viewed as an agent of the hospital.<sup>414</sup> Vicarious agents include "anyone who is generally or specifically integrated into the sphere of control and organization of another person and is bound by their instructions."<sup>415</sup> For individual physicians, this includes their employees and subordinate medical providers.<sup>416</sup> For hospitals, this includes physicians providing care under the general time and scope set forth by the hospital despite the hospital operator's inability to control physicians' professional judgment and medical decision making.<sup>417</sup>

In Germany, tort liability for vicarious agents is not strict and can be avoided when the principal establishes either (1) reasonableness in the selection, management, and supervision of the of the agent, or (2) that the damage would have occurred despite proper selection, organization, and supervision.<sup>418</sup> However, the BGH sets standards for presenting exculpatory evidence sufficient to avoid vicarious liability so high that Franz Petry opines that vicarious liability is

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<sup>407</sup> Bergmann et al., *supra* note 316, at 9-10.

<sup>408</sup> *Id.*

<sup>409</sup> *Id.* at 6-7.

<sup>410</sup> *Id.* at 10-17.

<sup>411</sup> Markesinis, et al., *supra* note 222, at 29.

<sup>412</sup> Franz Michael Petry, Medical Liability in Germany, in *Medical Liability in Europe: A Comparison of Selected Jurisdictions* 291 (Bernhard A Koch ed. 2011).

<sup>413</sup> Bergmann et al., *supra* note 316, at 31 (translation from German).

<sup>414</sup> *See* BGB § 831.

<sup>415</sup> Laufs / Katzenmeier / Lipp, *Arztrecht [Medical Law]*, Rn. 19 (8<sup>th</sup> ed. 2021) (F.R.G) (*citing* BGH, Jun. 30, 1966, 1966 NJW 1807 - VII ZR 23/65).

<sup>416</sup> *Id.*

<sup>417</sup> *Id.*

<sup>418</sup> *See* BGB § 831; Markesinis, et al., *supra* note 222, at 125.

akin to strict liability.<sup>419</sup> For example, the Schleswig-Holstein Higher Regional Court applied these standards to summarily reject a hospital's claim that it properly selected and monitored providers in a case involving a birth injury because the providers committed gross errors that delayed the delivery.<sup>420</sup> The Court explained that the hospital, which "presented the actions of their staff as consistently flawless," could not escape vicarious liability because, "[i]f a hospital operator describes objectively incorrect behavior on the part of its staff as correct in the process, it cannot be assumed that it has selected, monitored and instructed the staff correctly."<sup>421</sup>

To further narrow (or eliminate) the Civil Code's exception to strict vicarious liability, German courts also have relied on an employee's right to indemnification by an employer under labor law, a broad interpretation of an entity's liability for "duly appointed representatives" under BGB §§ 31 and 89 (which includes a Chief Physician), the expansion of direct liability for organizational defects under BGB I § 823 (discussed in section II), and contractual liability for persons used to fulfill the organization's obligations under BGB § 278.<sup>422</sup>

When vicarious liability applies, both the hospital and the individual provider would be jointly and severally liable for damages in tort.<sup>423</sup> Finally, tort law also allows recovery by third parties, but limits damages in such cases to those relating to funeral costs and loss of financial support when the original plaintiff is deceased.<sup>424</sup>

#### 4.1.1.2 Breaching the Standard of Care

Once an established legal duty or obligation flows from the healthcare provider to the patient, negligence occurs when the healthcare provider breaches the applicable standard of care. In the U.S., negligence is generally defined as the failure to act reasonably under the circumstances.<sup>425</sup> German law defines negligence (*Fahrlässigkeit*) as the failure to "exercise reasonable care."<sup>426</sup> To interpret this standard, German courts look to "the notional conduct of a careful person engaging in the same sphere of activity as the defendant."<sup>427</sup> It follows that, in both jurisdictions, the duty or obligation that a healthcare provider owes to a patient is a duty to use reasonable care.<sup>428</sup>

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<sup>419</sup> Petry, *supra* note 412.

<sup>420</sup> Oberlandesgericht [OLG] Schleswig [Schleswig Higher Regional Court], Dec. 23, 1998, 1998 BeckRS 13399 (beck-online).

<sup>421</sup> *Id.* (translation from German).

<sup>422</sup> Markesinis, et al., *supra* note 222, at 126-29; Petry, *supra* note 412 (a Chief Physician is a "organ" of the hospital under BGB §§ 30-31).

<sup>423</sup> BGB § 840(1).

<sup>424</sup> BGB §§ 844, 845.

<sup>425</sup> See Watson-Dunham, *supra* note 219, at 4.

<sup>426</sup> BGB § 276(2).

<sup>427</sup> Stauch, *supra* note 11, at 35.

<sup>428</sup> *Id.* at 18; Giesen, *supra* note 23, at 73.

#### 4.1.1.2.1 Breaching the Standard of Care in the United States

In the U.S., the standard of care for medical professionals requires them to “exercise the amount of care, skill, and diligence exercised generally in the community by doctors engaged in the same field.”<sup>429</sup> American courts have made clear that, “the standard of care for physicians is an objective one—physicians must have and employ the same skill and knowledge typically used by physicians in the medical profession, and must keep themselves informed of contemporary developments in the profession.”<sup>430</sup> As a result, an individual physician’s best judgment or good faith is irrelevant when determining whether they breached the applicable standard of care.<sup>431</sup> By the same token, some American jurisdictions hold junior doctors to the same standard of care as more experienced ones.<sup>432</sup>

Although objective, American courts allow for some flexibility in the applicable standard of care. The U.S. Court of Appeals for the First Circuit explained that:

[T]he standard of care for medical doctors is not static or rigid. It is a standard that changes depending on many factors, including a doctor's specialty, the resources available, and the advances of the medical profession at the time of the alleged negligent act.<sup>433</sup>

The Pennsylvania Supreme Court recognized that more than one course of treatment can meet the applicable standard of care and that doctors who choose a course “advocated by a considerable number of his professional brethren in good standing in his community” will not be held liable.<sup>434</sup> American courts also allow variances in the standard of care based upon the availability of equipment and resources in different localities despite the overall trend of moving toward a national standard of care for medical practice.<sup>435</sup> The Mississippi Supreme Court articulated the national standard of care with a “resources-based caveat” as follows:

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<sup>429</sup> Betesh, 400 F. Supp. at 247.

<sup>430</sup> Pringle v. Rapaport, 980 A.2d 159, 170 (Pa. Sup. Ct. 2009).

<sup>431</sup> See Morlino v. Med. Ctr. of Ocean Cty., 706 A.2d 721, 733 (N.J. 1998) (“The physician’s exercise of judgment is to be evaluated not on the basis of the physician’s good faith or honesty, but solely on whether it falls below an objective standard of care.”); Shumaker v. Johnson, 571 So. 2d 991, 994 (Ala. 1990) (noting that a growing number of jurisdictions have abandoned the “good faith” rule in recent years); Hirahara v. Tanaka, 959 P.2d 830, 835 (Haw. 1998) (“The jury must focus on whether the physician breached the standard of care. His or her exercise of “best judgment” is superfluous to this determination.”).

<sup>432</sup> St. Germain v. Pfeifer, 637 N.E.2d 848, 852–53 (Mass. 1994) (citing Centman v. Cobb, 581 N.E.2d 1286, 1289 (Ind. App. 1991) and Jenkins v. Clark, 454 N.E.2d 541 (Ohio App. 3d 1982)); *but see* Jistarri v. Nappi, 549 A.2d 210, 214 (Pa. 1988) (holding an orthopedic resident to a standard of care, “higher than that for general practitioners but less than that for fully trained orthopedic specialists”).

<sup>433</sup> Heinrich v. Sweet, 308 F.3d 48, 63 (1st Cir. 2002).

<sup>434</sup> Duckworth v. Bennett, 181 A. 558, 559 (Pa. 1935).

<sup>435</sup> Steven E. Pegalis, American Law of Medical Malpractice § 3:5 (3d ed) Westlaw (database updated June 2021); *see* Estate of Hagedorn ex rel. Hagedorn v. Peterson, 690 N.W.2d 84 (Iowa 2004) (“the

As a result of its resources-based component, the physician's non-delegable duty of care is this: given the circumstances of each patient, each physician has a duty to use his or her knowledge and therewith treat through maximum reasonable medical recovery, each patient, with such reasonable diligence, skill, competence, and prudence as are practiced by minimally competent physicians in the same specialty or general field of practice throughout the United States, who have available to them the same general facilities, services, equipment and options.<sup>436</sup>

American courts generally require expert testimony to establish both the applicable standard of care and a breach of that standard.<sup>437</sup> The exception to this general rule is when a healthcare provider's "want of skill and lack of care is so apparent so as to be understood by a layman, and requires only common knowledge and experience to understand it."<sup>438</sup> The Alabama Supreme Court articulated various situations that might fall within this exception:

1) where a foreign instrumentality is found in the plaintiff's body following surgery; 2) where the injury complained of is in no way connected to the condition for which the plaintiff sought treatment; 3) where the plaintiff employs a recognized standard or authoritative medical text or treatise to prove what is or is not proper practice; and 4) where the plaintiff is himself or herself a medical expert qualified to evaluate the doctor's allegedly negligent conduct."<sup>439</sup>

As a result, unless an exception applies, a plaintiff must present expert testimony to establish the standard of care applicable to the defendant provider based on what is generally expected by the medical community in the relevant field of expertise and that the defendant's conduct fell below that objective standard.

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facilities, personnel, services, and equipment reasonably available to a physician continue to be circumstances relevant to the appropriateness of the care rendered by the physician to the patient"); *Birchfield v. Texarkana Mem'l Hosp.*, 747 S.W.2d 361, 366 (Tex.1987) ("The purpose of the locality rule is to prevent unrealistic comparisons between the standards of practice in communities where resources and facilities might vastly differ.").

<sup>436</sup> *Hall v. Hilbun*, 466 So. 2d 856, 873 (Miss. 1985), *superceded by statute on other grounds*, Miss.Code Ann. § 85-5-7, as recognized in *Narkeeta Timber Co., Inc. v. Jenkins*, 777 So.2d 39 (Miss. 2000).

<sup>437</sup> *See* American Law Reports, 81 A.L.R.2d 597 (Originally published in 1962) ("The overwhelming weight of authority supports the view that ordinarily expert evidence is essential to support an action for malpractice against a physician or surgeon.").

<sup>438</sup> *Lloyd Noland Found., Inc. v. Harris*, 322 So. 2d 709, 711 (Ala. 1975).

<sup>439</sup> *Holt v. Godsil*, 447 So. 2d 191, 192-93 (Ala. 1984).



#### 4.1.1.2.2 Breaching the Standard of Care in Germany

German law requires physicians to provide medical treatment pursuant to contract that accords with “medical standards . . . generally recognized at the time of treatment.”<sup>440</sup> The standard of care applicable to the treatment contract is the same as the standard of care in tort.<sup>441</sup> The German Federal Court of Justice has found that doctors must demonstrate the standard of care of a respectable and conscientious medical professional of average expertise in the relevant field.<sup>442</sup> While a subjective approach may operate in German law to hold more knowledgeable physicians to a higher standard of care, the threshold level of care that all physicians must provide is objective and not influenced by a doctor’s experience level or personal circumstances.<sup>443</sup> Applying this objective standard of care, the BGH ruled that a junior doctor “owes that same duty of skill and care to the patient as any other doctor.”<sup>444</sup>

German courts reject a singular or fixed standard of care and opt to define the applicable standard of care based upon the circumstances of each case. According to Stauch:

[T]he [medical] ‘standard’ in question will derive from a combination of scientific knowledge, medical experience and professional acceptance. In so doing, it serves to particularise ‘required care’ in relation to a given set of circumstances . . . often a single universally accepted practice does not exist [and] the law will need to leave room for rival schools of thought, with the courts functioning ‘as a form of border control’ (*in einer Art Grenzkontrolle*) in checking if particular method involved undue risks, or was carelessly executed.<sup>445</sup>

The BGH has found that the applicable standard of care can vary based upon the hospital size, specialty, and available staff and equipment.<sup>446</sup> Bergmann and Wever affirm that the case law establishes that the standard of medical care “must take into account the fact that the standard of staffing and equipment in a regional or district hospital is generally lower than in a university hospital.”<sup>447</sup> For example, the BGH found that there was no breach of the standard of care when a plaintiff underwent a laparoscopic tubal sterilization using monopolar high-frequency current despite the fact that the same operation using lower-risk bipolar high-frequency current was available in another hospital.<sup>448</sup> The BGH observed that:

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<sup>440</sup> BGB § 630a.

<sup>441</sup> Bergmann et al., *supra* note 316, at 47.

<sup>442</sup> BGH, Jun. 13, 1960, 1961 NJW 600 (600).

<sup>443</sup> Stauch, *supra* note 11, at 37.

<sup>444</sup> *See id.* at 37 (citing BGH, Sept. 27, 1983, 1984 NJW 655 (657)) (translation from German).

<sup>445</sup> *Id.* at 44.

<sup>446</sup> BGH, Sept. 22, 1987, 1988 NJW 763 (beck-online).

<sup>447</sup> Bergmann et al., *supra* note 316, at 52 (translation from German).

<sup>448</sup> BGH, Sept. 22, 1987, 1988 NJW 763 (beck-online).

[T]he rapid progress in medical technology and the associated acquisition of ever new experience and knowledge mean that there are inevitably differences in quality in the treatment of patients, depending on whether they go to a larger university hospital or a special clinic with particularly well-equipped staff and equipment, or to a general care hospital. Within limits, therefore, the medical standard to be demanded varies depending on the personnel and equipment available. It can be maintained in a medium-sized or smaller hospital, if at least the basic equipment meets modern medical requirements.<sup>449</sup>

As a result, as long as the treatment provided “corresponds to the current state of medicine,” it will not result in a breach of the standard of care.<sup>450</sup>

In Germany, experts must testify regarding the applicable standard of care.<sup>451</sup> However, as Stauch points out, German courts are more critical of expert testimony and will not absolve a defendant physician merely because an expert has testified that the standard of care was met when the courts find that the “socially required care” was not observed.<sup>452</sup> Bergmann, et al. describe the court’s reliance upon medical experts as follows:

In the final instance, it is the courts that have to decide on the required care, on the standard in cases of liability, usually after expert advice. But the standards are also legal, judicial standards of judgment for deciding legal disputes. The standards are ultimately medical guidelines, because the law cannot of itself determine what is possible and necessary on the part of physicians. This is where the relevant expert steps into his or her rights. In the core medical areas of diagnosis, indication and therapy, the courts are dependent on medical expertise and medical experts. Through them, it is the physicians themselves who determine the standard . . . [T]he standard of due care is a necessary, but not an absolutely binding, tool to determine the treatment required.<sup>453</sup>

Consequently, while German Courts rely on the medical knowledge of experts to determine the applicable legal standard, they are still the ultimate arbiters of negligence. In fact, because

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<sup>449</sup> *Id.* at 765 (translation from German).

<sup>450</sup> *See Id.* at 764 (translation from German).

<sup>451</sup> Stauch, *supra* note 11, at 43 (citing BGH Sept. 17, 1985, 1985 VersR 1187; BGH, Mar. 2, 1993, 1993 NJW 2378).

<sup>452</sup> *Id.* at 43-44.

<sup>453</sup> Bergmann et al., *supra* note 316, at 62-63 (translation from German).

of the information asymmetry between plaintiffs and defendant healthcare providers in medical negligence cases, German courts take on a greater investigatory role in an attempt to ensure equality of arms between the parties.<sup>454</sup>

#### 4.1.1.3 Causation

For liability to attach to a healthcare provider who breached a standard of care, that breach must have caused the plaintiff's alleged injury.<sup>455</sup> Because medical malpractice plaintiffs initially seek medical care for a pre-existing medical condition, proving that the provider's breach, rather than the condition itself, caused damages "represents the greatest hurdle for a patient in a medical malpractice lawsuit."<sup>456</sup> In both jurisdictions, the general rule requires medical expert testimony to support a causation finding.<sup>457</sup> Additionally, causation in both American and German law has two parts, both of which must be met: (1) factual causation, or *aequivalenter Kausalzusammenhang*, and (2) legal causation, or *adaquater Kausalzusammenhang* and *schutzzwecklehre*.<sup>458</sup> Giesen describes factual causation as a "preliminary filter eliminating the irrelevant."<sup>459</sup> Damage is not factually caused by negligence unless it would not have occurred without the precedent negligent act or omission.<sup>460</sup> Determining factual causation is fairly straightforward using the common law "but-for" test or the civil law "*condicio sine qua non*" formula.<sup>461</sup> Legal causation, on the other hand, has long been the subject of wrangling amongst legal scholars and judges.<sup>462</sup> This is because legal causation goes beyond the logic underlying factual causation to create a "legal policy filter"

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<sup>454</sup> Petry, *supra* note 412 at 273.

<sup>455</sup> Pearson v. Parsons, 757 P.2d 197, 202 (Idaho 1988) ("In a medical malpractice case, a "plaintiff has the burden of proving not only that a defendant failed to use ordinary care, but also that the defendant's failure to use ordinary care was the proximate cause of damage to the plaintiff.") (citation and internal quotation marks omitted); BeckOGK / Spindler, 1.5.2021, BGB § 823 marginal number 1084-1094.

<sup>456</sup> 12 Dec 2010 Saarbrücken [judge at the Regional Court of Kaiser], Hinweisbeschluss [Reference Decision] Landgericht Saarbrücken (translation from German).

<sup>457</sup> See Ashland Hosp. Corp. v. Lewis, 581 S.W.3d 572, 578 (Ky. 2019) (causation in medical malpractice cases requires expert testimony); Morisch v. United States, 653 F.3d 522, 531 (7th Cir. 2011); Bergmann et al., *supra* note 316, at 300 (noting that main tasks of an expert in German medical malpractice cases is to determine whether there was a treatment error and whether the error caused the resulting damage).

<sup>458</sup> See Stauch, *supra* note 11, at 46 (identifying two-part causation in Germany); see also O'Neal v. St. John Hosp. & Med. Ctr., 791 N.W.2d 853, 858 (Mich. 2010) ("These two prongs are respectively described as "cause-in-fact" and "legal causation."); Marta Infantino & Eleni Zervogianni, *The European Ways to Causation*, in *Causation in European Tort Law* 103-104 (Marta Infantino & Eleni Zervogianni eds., 2017) (noting that both *Adäquanztheorie* and *Schutzzwecklehre* are used to determine legal causation in Germany).

<sup>459</sup> Giesen, *supra* note 23, at 169.

<sup>460</sup> See *id.* at 177.

<sup>461</sup> See *id.* at 177.

<sup>462</sup> See *id.* at 173-74.

that limits liability for negligence as demanded by justice and fairness.<sup>463</sup> The American reasonable foreseeability test and the German adequacy and protective purpose tests generally guide courts' legal causation determinations, which, according to Giesen, both entail "a test on the balance of probabilities . . . to establish that some conduct or event caused or materially contributed to the injury."<sup>464</sup> Thus, both jurisdictions require that the negligent conduct be both a "but-for" cause of the injury and satisfy some criteria by which liability is considered fair under the circumstances.

#### 4.1.1.3.1 Causation in the United States

In the U.S., some courts interpret the term "proximate cause" broadly to encompass both cause-in-fact and legal causation.<sup>465</sup> Other American courts distinguish proximate cause from cause-in-fact.<sup>466</sup> Nevertheless, most courts agree that the causation element of a medical malpractice claim must satisfy two prongs of causation: factual causation and legal causation. To determine whether the factual causation prong is satisfied, courts traditionally apply the "but-for" test to determine whether, "but for" the defendant's actions, the plaintiff's injury would not have occurred."<sup>467</sup> However, some courts also allow factual causation to be determined under a more lenient "substantial factor" test that asks whether the defendant's breach was "a substantial factor in bringing about the injury."<sup>468</sup> The "substantial factor" test is favored when more than one action or omission caused the plaintiff's alleged injury.<sup>469</sup> This is particularly common in medical malpractice cases because a plaintiff's pre-existing medical condition is often cited as

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<sup>463</sup> *Id.* at 175-76.

<sup>464</sup> *Id.* at 183.

<sup>465</sup> See *Craig ex rel. Craig v. Oakwood Hosp.*, 684 N.W.2d 296, 309 (Mich. 2004) ("Proximate cause' is a legal term of art that incorporates both cause in fact and legal (or 'proximate') cause"); *McKellips v. Saint Francis Hosp., Inc.*, 741 P.2d 467, 470 (Okla. 1987) ("Proximate cause consists of two elements: cause in fact and legal causation."); *Marvelli v. Alston*, 100 S.W.3d 460, 469 (Tex. App. 2003) ("To establish proximate cause, the plaintiff must prove: (1) foreseeability, and (2) cause-in-fact."); *Turcios v. DeBruler Co.*, 32 N.E.3d 1117, 1124 (Ill. 2015) ("The term 'proximate cause' embodies two distinct concepts: cause in fact and legal cause.").

<sup>466</sup> See *Kilpatrick v. Bryant*, 868 S.W.2d 594, 598 (Tenn. 1993) ("Causation (or cause in fact) is a very different concept from that of proximate cause."); *Peterson v. Reeves*, 727 S.E.2d 171, 176 (Ga. Ct. App. 2012) ("analysis of the issue of proximate cause . . . [is] distinguished from cause in fact"); *Ploch v. Hamai*, 213 S.W.3d 135, 141 (Mo. Ct. App. 2006) ("To establish causation in a medical malpractice action, the plaintiff must show that the physician's conduct was the cause-in-fact and the proximate cause of the plaintiff's damages.").

<sup>467</sup> *O'Neal*. 791 N.W.2d at 858.

<sup>468</sup> *Bustamante v. Ponte*, 529 S.W.3d 447, 457 (Tex. 2017).

<sup>469</sup> See *Newberry v. Martens*, 127 P.3d 187, 191 (Idaho 2005) (noting that the but-for test is appropriate when there is one possible cause, but the substantial factor test should be used in cases with multiple causes of damage).

a contributing cause of the alleged injury.<sup>470</sup> For example, the Supreme Court of Pennsylvania found that a doctor's failure to diagnose a cancerous breast mass could have been a substantial factor in increasing the plaintiff's health risks despite the defendant's position that the plaintiff was "already suffering from cancer" and the failure to diagnose the tumor had no adverse impact on her existing condition.<sup>471</sup>

The second legal causation prong focuses on the foreseeability of a particular action or omission in causing the injury sustained.<sup>472</sup> The legal causation requirement serves to limit the scope of liability to exclude negligent actions that may have been a cause-in-fact of a plaintiff's injury but are too far removed from the type of injury that the plaintiff ultimately suffered.<sup>473</sup> Foreseeability is judged from the perspective of an ordinary reasonable person under the circumstances.<sup>474</sup> According to a Texas court of appeals, "foreseeability exists if the actor, as a person of ordinary intelligence, should have anticipated the dangers his negligent act creates for others."<sup>475</sup> In Illinois, the foreseeability inquiry is "whether the injury sustained is one that a reasonable person would consider to be a likely consequence of his conduct."<sup>476</sup> In *Morisch v. U.S.*, the Seventh Circuit Court of Appeals agreed with the trial court that there was no proximate cause in a medical malpractice case when the plaintiff's stroke was "not a foreseeable result" of the hospital's failure to immediately relay test results.<sup>477</sup>

American courts are split on the issue of fault apportionment for tortfeasors who simultaneously and independently cause medical injuries. Concurrent (or simultaneous) causes

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<sup>470</sup> See *Scafidi v. Seiler*, 574 A.2d 398, 403 (N.J. 1990) (noting that a majority accept the "substantial factor" test to determine cause-in-fact in medical malpractice cases involving pre-existing medical conditions).

<sup>471</sup> *Jones v. Montefiore Hosp.*, 431 A.2d 920 (Penn. 1981) (finding that the trial court erred in failing to properly instruct the jury on causation based on the substantial factor test).

<sup>472</sup> See *Morisch*, 653 F.3d at 531 ("[T]o prove legal cause, a plaintiff must also show that an injury was foreseeable as the type of harm that a reasonable person would expect to see as a likely result of his or her conduct."); *Easterling v. Kendall*, 367 P.3d 1214, 1226 (Idaho 2016) ("[T]o prove legal cause, a plaintiff must also show that an injury was foreseeable as the type of harm that a reasonable person would expect to see as a likely result of his or her conduct.").

<sup>473</sup> Some U.S. courts view foreseeability as a factor limiting the scope of a legal duty rather than one affecting the causation injury. See *American Law Reports*, 100 A.L.R.2d 942 (Originally published in 1965) (noting that although foreseeability is generally considered to determine liability for negligence, courts are in sharp disagreement regarding whether foreseeability should be considered to determine legal duty versus causation). Some US courts view foreseeability as an element of both duty and causation. See *Macias v. Summit Mgmt., Inc.*, 220 A.3d 363, 376 (Md. Ct. App. 2019); *Westin Operator, LLC v. Groh*, 347 P.3d 606 (Colo. 2015); *Kerns v. Independent School Dist. No. 31 of Ottawa County*, 44 F. Supp. 3d 1110 (N.D. Okla. 2014) (applying Oklahoma law).

<sup>474</sup> *MJS & Assocs., L.L.C. v. Master*, 501 S.W.3d 751, 757 (Tex. App. 2016); *Winchell v. Guy*, 857 N.E.2d 1024, 1030 (Ind. Ct. App. 2006).

<sup>475</sup> *Scurlock v. Pennell*, 177 S.W.3d 222 (Tex. App. Houston 1st Dist. 2005).

<sup>476</sup> *Atchley v. Univ. of Chicago Med. Ctr.*, 64 N.E.3d 781, 794 (Ill. App. 1 Dist., 2016).

<sup>477</sup> *Morisch*, 653 F.3d at 531.

exist when the negligent conduct of two or more separate tortfeasors or two or more actions (or omissions) by one tortfeasor was each independently capable of producing the resulting damage.<sup>478</sup> Some states impose joint and several liability on tortfeasors who “act in concert” to cause harm.<sup>479</sup> Others take a comparative fault approach to hold tortfeasors responsible only for damages corresponding with their percentage of fault.<sup>480</sup>

In the case of successive or intervening causes, which occur subsequent to an actor’s negligent conduct, a prior actor will generally not be relieved of liability if he should have anticipated the negligent intervening act or if the intervening act was a “normal consequence of the situation created” by the prior actor and is not “extraordinarily negligent.”<sup>481</sup> For example, the Ohio Supreme Court found that a doctor’s admitted negligence in failing to promptly treat a patient with preeclampsia upon receiving a nurse’s report of high blood pressure was not enough to sever the nurse’s failure to recognize preeclampsia and/or give the physician a full report of the patient’s condition.<sup>482</sup>

#### 4.1.1.3.2. Causation in Germany

German law also takes a “bifurcated approach” to causation.<sup>483</sup> The first prong of causation considers whether the “conduct played some role in bringing about the Plaintiff’s hurt,” a consideration comparable to cause-in-fact inquiry in American law.<sup>484</sup> The second prong, similar to legal causation in American law, undertakes a normative evaluation of whether conduct that meets the first prong should result in legal liability.<sup>485</sup> However, unlike American law, German law has another, deeper layer that underlies the causation analysis: German law distinguishes between causation that establishes liability (*haftungsbegründende Kausalität*)

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<sup>478</sup> See Giesen, *supra* note 23, at 179.

<sup>479</sup> Woods v. Cole, 693 N.E.2d 333, 337 (Ill. 1998) (“The general principle that tortfeasors who negligently act in concert are held jointly and severally liable for the damages which they cause has been recognized in Illinois for over 100 years.”); see Velez v. Tuma, 821 N.W.2d 432, 437 (Mich. 2012) (“The same comprehensive tort-reform legislation, however, also specifically retained “joint and several liability” in medical malpractice cases.”); Palmer v. Comprehensive Neurologic Services, P.C., 864 N.E.2d 1093 (Ind. Ct. App. 2007) (noting that medical malpractice cases are exempt from Indiana’s comparative fault law).

<sup>480</sup> Volz v. Ledes, 895 S.W.2d 677 (Tenn. 1995) (applies doctrine of comparative fault, rather than joint and several liability, in medical malpractice case); Dumas v. State ex rel. Dep’t of Culture, Recreation & Tourism, 828 So. 2d 530, 537 (La. 2002) (“The comparative fault article, La. C.C. art. 2323, makes no exceptions for liability based on medical malpractice.”); Gardner v. Oregon Health & Scis. Univ., 461 P.3d 222 (Or. 2020) (recognizing the application of comparative fault in a medical malpractice case).

<sup>481</sup> Restatement (Second) of Torts § 447 (Am. Law Inst. 1965).

<sup>482</sup> Berdyck v. Shinde, 613 N.E.2d 1014 (1993).

<sup>483</sup> Markesinis, et al., *supra* note 222, at 60.

<sup>484</sup> *Id.* at 60-61.

<sup>485</sup> *Id.* at 64.

and causation that completes liability (*haftungsausfüllende Kausalität*).<sup>486</sup> Stauch describes the distinction between the two as follows:

The first of these, ‘liability grounding causation’, denotes the link from the defendant’s faulty conduct and *initial* harm to the claimant (in the form of invasion of one of his abstract protected interests). By contrast, the latter, ‘liability-completing causation’, refers to the subsequent link between that invasion and the further, tangible injuries suffered by the claimant (which form the subject of his claim for substantial damages).<sup>487</sup>

Marta Infantino and Eleni Zervogianni describe *haftungsbegründende Kausalität* as a question of causation concerned with the existence of liability and *haftungsausfüllende Kausalität* as a question of causation concerned with the scope or extent of the liability.<sup>488</sup> Although some scholars characterize these two causation questions as a theoretical or philosophical rather than practical distinction, Stauch observes that the distinction can nevertheless be important in medical negligence cases because once the patient establishes liability-grounding causation, liability-completing causation is held to a lower standard of proof.<sup>489</sup>

The BGH confirmed that this evidentiary distinction could have “led to a different, more favorable result for the plaintiff” in a case involving an undiagnosed finger fracture that was discovered one month later when he re-fractured his finger and was diagnosed with Sudeck’s syndrome.<sup>490</sup> Here, the BGH explained that the standard of proof under ZPO § 286 requiring “a degree of certainty useful for practical life” governs the determination of liability that gives rise to the injury (failure to diagnose and properly treat the initial fracture).<sup>491</sup> However, since the standard of proof under ZPO § 287 requiring only a “preponderance of probability” governs liability-filling causation (the second fracture and development of Sudeck’s syndrome), the court remanded the case for a liability-causation redetermination applying the lower standard.<sup>492</sup>

To determine factual causation, German courts use a “‘*condicio sine qua non*’ formula . . . [that] is identical to the ‘but for’ test in common law.”<sup>493</sup> To determine whether a defendant’s conduct is a ‘but for’ cause or *condicio sine qua non* of the plaintiff’s injury, German courts

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<sup>486</sup> Spickhoff / Spickhoff, 3rd edition 2018, BGB § 276 marginal number 17.

<sup>487</sup> Stauch, *supra* note 11, at 50-51.

<sup>488</sup> Infantino & Zervogianni, *supra* note 458, at 104.

<sup>489</sup> Stauch, *supra* note 11, at 51.

<sup>490</sup> BGH, Feb. 12, 2008, VI ZR 221/06 (beck-online) (translation from German).

<sup>491</sup> *Id.* (translation from German).

<sup>492</sup> *Id.* (noting that the OLG applied a standard of proof for liability-filling causation of “probability bordering on certainty,” which is even stricter than what even § 286 ZPO requires). (translation from German).

<sup>493</sup> Stauch, *supra* note 11, at 49.

generally rely on two methods to evaluate causation: (1) “the method of elimination (*Hinwegdenken*)” for negligent actions; and (2) the method of “total substitution” for negligent omissions.<sup>494</sup> Generally, the “the method of elimination (*Hinwegdenken*)” is used to determine whether a defendant’s actions caused an injury, and considers whether the same injury would have resulted if the defendant’s acts are “eliminated in thought.”<sup>495</sup> When a defendant’s omissions allegedly caused an injury, the court will usually apply the “total substitution” method to eliminate the wrongful omission and substitute in the nonnegligent conduct that the defendant should have taken and ask whether the injury would have still occurred.<sup>496</sup> In both cases, an affirmative answer to the question results in no factual causation.<sup>497</sup> Conversely, if eliminating or substituting the defendant’s actions also eliminate the injury, then factual causation exists.<sup>498</sup> As discussed in further section III.B, a common negligent omission in medical malpractice cases – failure to diagnose – will trigger the total substitution method, which could lead to a reversal of the burden of proof on causation.<sup>499</sup>

There are instances when both elimination or substitution methods fail to provide an acceptable solution to causation, for example, in the case of simultaneous independent causes of the same harm.<sup>500</sup> Markesinis, et al. give the example of two motorcycles that simultaneously pass a horse and make it bolt. Assuming that each motorcycle alone would have made the horse bolt, a strict application of the “but-for” test would lead to no liability for either motorcyclist.<sup>501</sup> While Markesinis, et al. advocate for the adoption of the American “substantial factor” test discussed above, they conclude that German courts will consider the conduct of both motorcyclists as a “condition” of the harm at the cause-in-fact stage of the analysis.<sup>502</sup> Thus, tortfeasors who simultaneously and independently cause an injury are jointly and severally liable,<sup>503</sup> unless the resulting harm is divisible and each harm can be clearly attributed to a particular cause.<sup>504</sup> In the case of medical treatment, it is not unusual for several healthcare providers to have concurring duties to a patient to prevent the same harm. For example, the BGH found that both the hospital’s nursing staff and the surgeon had a duty to monitor the placement of an indwelling cannula during a patient’s post-operative care, and thus, both were liable when the cannula became detached, causing a patient injury.<sup>505</sup>

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<sup>494</sup> Markesinis, et al., *supra* note 222, at 61-62.

<sup>495</sup> *Id.* at 61.

<sup>496</sup> *Id.*

<sup>497</sup> *Id.* at 61-62

<sup>498</sup> *Id.*

<sup>499</sup> Petry, *supra* note 412 at 251.

<sup>500</sup> Markesinis, et al., *supra* note 222, at 62.

<sup>501</sup> *Id.* at 62-63.

<sup>502</sup> *Id.*

<sup>503</sup> *Id.* at 50.

<sup>504</sup> BeckOGK / Spindler, 1.5.2021, BGB § 823 marginal number 1021 (noting that if it is possible to clearly delineate the contribution of a cause to a particular portion of the damages, then the physician will only be responsible for the portion of damages they caused).

<sup>505</sup> BGH, Oct. 1, 1984, 1984 NJW 1400 (beck-online).



In the case of successive or intervening causes, the first tortfeasor will be relieved of liability for the final harm only in rare instances. Unless the subsequent tortfeasor was grossly negligent<sup>506</sup> or the second negligent act is outside of the scope of risk created by the first negligent act,<sup>507</sup> the first actor will remain jointly and severally liable for the ultimate injury.<sup>508</sup> For example, the BGH held that a family physician's refusal to conduct a home visit for a patient was still a cause-in-fact of an injury caused by delayed treatment even though the plaintiff subsequently consulted with an emergency physician whose negligence may have also caused the delay.<sup>509</sup> In this case, the family physician, who had information about the patient's history and recent complaints and thus should have suspected that the patient had an emergent condition, refused the patient's request for an immediate home visit.<sup>510</sup> After this refusal, an emergency physician responded to the plaintiff's request, diagnosed the condition, and recommended the proper treatment but failed to convey the seriousness of the risk (leg amputation) to the patient.<sup>511</sup> As a result, the patient's delay in seeking the recommended treatment led to a leg amputation.<sup>512</sup> The Court found that the family physician's refusal to conduct a home visit was still a cause of the patient's injury, noting that:

[A] subsequent medical treatment error [by the emergency physician] . . . would not have been so remote from the outset that it could no longer be imputed to the defendant. The summoned emergency physician, who unlike the treating general practitioner lacks knowledge of the patient's medical history and personality, who perhaps also does not have the necessary specialist knowledge, who finally does not enjoy the same trust of the patient as the general practitioner from the outset, can be at a disadvantage compared with the general practitioner when making a diagnosis and advising the patient . . . Even if Dr. P. [the emergency physician] had told the plaintiff with the necessary seriousness and emphasis everything that had to be done from the medical point of view to save the leg, it remains open whether this eliminated all effects of the treatment error to be blamed on the defendant on the further course of the disease. Even then, as long as nothing else is actually established, the possibility remains that the defendant, who would have been obligated to act on his own and who had not given the treatment, would have succeeded differently and better than Dr. P. in

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<sup>506</sup> Stauch, *supra* note 11, at 56.

<sup>507</sup> BGH, Sept. 20, 1988, 1989 NJW 767 (768).

<sup>508</sup> Stauch, *supra* note 11, at 56.

<sup>509</sup> BGH, Jan. 28, 1986, 1986 r + s 176 (beck-online).

<sup>510</sup> *Id.*

<sup>511</sup> *Id.*

<sup>512</sup> *Id.*

convincing the plaintiff that he had to go to a hospital immediately.<sup>513</sup>

In conclusion, an act of medical negligence will likely be deemed sufficient to cause an injury if the injury would not have occurred in the course of treatment rendered in accordance with the applicable standard of care, even if the act or omission was not the sole or even primary cause of the injury.<sup>514</sup>

Legal causation in Germany is determined by applying both the adequacy theory (*adäquater Kausalzusammenhang*) to determine the likelihood of the conduct to cause the injury and a second test to determine whether the injury falls within the protective scope of the relevant law or norm (*schutzzwecklehre*).<sup>515</sup> As in the U.S., the tortfeasor's subjective state of mind does not impact legal causation; German courts use the objective "optimal observer" standard to judge legal causation.<sup>516</sup> The adequacy theory is satisfied when the defendant's negligent conduct was "generally apt" to bring about the type of damage suffered by the plaintiff.<sup>517</sup> Stauch notes that the adequacy theory for legal causation is stricter than the common law reasonable foreseeability test and typically only excludes liability in cases of mere "coincidence."<sup>518</sup> As a result, German courts supplement the adequacy theory with a test that requires the injury to fall within the protective purpose of the law or norm prohibiting the defendant's conduct.<sup>519</sup> Although most injuries caused by medical treatment will fall within the scope of protecting a patient's bodily health and integrity, some will not. For example, the OLG Naumburg found that the unwanted birth of a child resulting from the failure to diagnose a pregnancy at a gynecological visit, during which there was no discussion of a suspected pregnancy or desire to prevent pregnancy, was not within the protective purpose of the treatment.<sup>520</sup> The concept of *schutzzwecklehre* in German causation as applied here is most analogous to what American Courts consider when determining the scope of a defendant's legal duty.<sup>521</sup>

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<sup>513</sup> *Id.* at 177-178. (translation from German).

<sup>514</sup> BeckOGK / Spindler, 1.5.2021, BGB § 823 marginal number 1021-1024.

<sup>515</sup> Stauch, *supra* note 11, at 54-55.

<sup>516</sup> Giesen, *supra* note 23, at 184.

<sup>517</sup> Stauch, *supra* note 11, at 54-55; *see* Giesen, *supra* note 23, at 172-173.

<sup>518</sup> *Id.* at 55.

<sup>519</sup> *Id.*

<sup>520</sup> OLG Naumburg, May 26, 1998, 1999 r+s 67 (beck-online).

<sup>521</sup> *Faucheaux v. Terrebonne Consolidated Government*, 615 So.2d 289, 293-294 (La.1993) ("The scope of the duty inquiry is ultimately a question of policy as to whether the particular risk falls within the scope of the duty. Rules of conduct are designed to protect some persons under some circumstances against some risks. The scope of protection inquiry asks whether the enunciated rule extends to or is intended to protect this plaintiff from this type of harm arising in this manner.").

#### 4.1.1.4 Damages

When, under the principles articulated above, a treatment error causes damages, the medical liability system seeks to compensate the injured party for the damages sustained.<sup>522</sup> In both jurisdictions, damages can be separated into two broad categories: economic (or special) and non-economic (or general).<sup>523</sup> Economic damages are those subject to calculations that can be used to assign a monetary value to the damage sustained.<sup>524</sup> Examples of economic damages include past and future medical expenses, lost wages, and funeral costs. Non-economic damages are those that cannot be easily reduced to a monetary value, including pain and suffering, loss of enjoyment of life, and loss of consortium.<sup>525</sup>

Both American and German medical liability law compensates medical malpractice patients for past and future medical (and related) expenses, past lost wages and future loss of earnings, and past and future physical and mental pain and suffering;<sup>526</sup> however, the jurisdictions diverge regarding the form of recoverable damages, quantum valuation of non-economic damages, and recognition of loss of chance as a recoverable item of damages.<sup>527</sup> First, in Germany, future economic damages are generally paid by quarterly pension while non-economic damages are typically paid in a lump sum.<sup>528</sup> As a general rule in the U.S., all damages awards are paid as a lump sum with future economic damages paid at the present day value.<sup>529</sup> Second, awards for general damages in the U.S. are much higher than those for similar injuries in Germany.<sup>530</sup> However, recent American tort reform efforts have led states to impose damages caps in an attempt to control general damages awards described as “enormously more generous than other legal systems.”<sup>531</sup> Third, damages for a patient’s loss of chance for a better outcome, commonly following a failure to diagnose or misdiagnosis, are recoverable in some U.S. jurisdictions, but not in Germany.<sup>532</sup>

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<sup>522</sup> See Giesen, *supra* note 23, at 221 (“The central purpose of damages for medical malpractice in all jurisdictions under review is to compensate that patient for his loss.”).

<sup>523</sup> *Id.* at 224.

<sup>524</sup> *Id.*

<sup>525</sup> *Id.*

<sup>526</sup> See generally *id.* at 225-239 (discussing various jurisdictions’ approaches to heads of recoverable loss in medical malpractice cases).

<sup>527</sup> See generally *id.* at 228-232 (regarding form of damages and pain and suffering awards); Stauch, *supra* note 11, at 93 (regarding loss of chance in Germany).

<sup>528</sup> Giesen, *supra* note 23 at 228, 241.

<sup>529</sup> *Id.* at 239.

<sup>530</sup> See generally Stephen D. Sugarman, *A Comparative Law Look at Pain and Suffering Awards*, 55 DePaul L. Rev. 399 (2006).

<sup>531</sup> *Id.* at 399-400.

<sup>532</sup> Stauch, *supra* note 11, at 93 (no awards for loss of chance in Germany); see Brian Casaceli, *Losing A Chance to Survive: An Examination of the Loss of Chance Doctrine Within the Context of A Wrongful Death Action*, 9 J. Health & Biomedical L. 521 (2014) (analysis of loss of chance doctrine in the US).

Finally, Germany's strong social insurance system provides an overarching policy reason for differences in damages awards in the U.S. and Germany.<sup>533</sup> Ninety percent of Germans receive health insurance coverage under the country's statutory health insurance system.<sup>534</sup> The system ensures that each member, regardless of income, receives the same medical benefits, including care for prevention and treatment of diseases.<sup>535</sup> In addition to medical care through statutory health insurance, the broader German social insurance system also provides statutory long-term care insurance, statutory accident insurance, statutory pension insurance, and statutory unemployment insurance.<sup>536</sup> Germany's comprehensive social insurance scheme impacts recovery of damages caused by medical malpractice because Germans, unlike Americans, do not need to rely upon medical malpractice lawsuits to pay for their past and future medical care, home care, rehabilitation. It also limits compensation for past or future lost wages. As a result, the German insurance system protects healthcare providers and their insurers from the kind of exorbitant awards for future medical costs, life care plans, and lost wages seen in the U.S.

## 4.2 Organizational Errors

Consistent with a trend in both civil and common law countries of "increasing the accountability of hospitals to their patients," both the U.S. and Germany have been steadily expanding liability for organizational errors that cause medical injuries.<sup>537</sup> In the U.S., while hospital liability was historically determined under strict vicarious liability doctrines,<sup>538</sup> courts now recognize that hospitals can be directly and independently liable for their own organizational errors.<sup>539</sup> In Germany, the BGH is expanding organizational liability for hospitals in two ways.<sup>540</sup> First, as noted in section I.A.1.2., the BGH takes a broad view of hospitals' obligation to sufficiently select, instruct and supervise employees and agents, thereby limiting possible exceptions to vicarious liability vis-à-vis individual provider actions.<sup>541</sup> Second, it recognizes that organizational behavior can directly cause patient harm independent of individual provider actions.<sup>542</sup> According to Giesen, "the *raison d'être* of direct (corporate) hospital liability is to prevent substandard care in the health care system as a whole."<sup>543</sup> Like medical negligence, hospital liability is also judged according to a fault-based

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<sup>533</sup> See Fedtke, *supra* note 225, at 185 ("The German Social Security system is the single most relevant influence on the German legal system.").

<sup>534</sup> Deutscher Ärzte-Verlag, *The Healthcare System in Germany – A Short Introduction* 1 (2012), at 3-8.

<sup>535</sup> *Id.* at 12.

<sup>536</sup> *Id.* at 11.

<sup>537</sup> Giesen, *supra* note 23, at 58.

<sup>538</sup> See Bing, 143 N.E.2d at 8 (finding that a hospital could be vicariously liable for its employees' actions).

<sup>539</sup> *Darling v. Charleston Cmty. Mem'l Hosp.*, 211 N.E.2d 253 (Ill. 1965).

<sup>540</sup> See Giesen, *supra* note 23, at 58-59 (noting the emergence of broader vicarious liability doctrines as well as expanded causes of action for direct liability).

<sup>541</sup> Petry, *supra* note 412.

<sup>542</sup> Markesinis, et al., *supra* note 222, at 126-29

<sup>543</sup> *Id.* at 61.

standard.<sup>544</sup> While the case law discussing organizational errors in both jurisdictions, does not explicitly address negligent CRM, as discussed in Chapter 5, it provides the legal fabric for recognizing and defining a legal cause of action for negligent CRM.

#### 4.2.1 Liability for Organizational Errors in the United States

In the U.S., direct hospital liability emerged as a legal concept in 1965 with the Illinois Supreme Court's opinion in *Darling v. Charleston Community Meml. Hosp.*<sup>545</sup> In *Darling*, the Plaintiff received treatment for a broken leg at the defendant hospital. After his leg was set in a cast, he was admitted for further treatment and observation.<sup>546</sup> During this time, his foot subsequently became swollen, discolored, and numb, and he complained of excruciating leg pain, all of which was either observed by or reported to the hospital staff managing his care.<sup>547</sup> By the time his cast was removed, his leg had suffered necrosis, necessitating a below-the-knee amputation.<sup>548</sup> According to the orthopedic surgeon, the necrosis "resulted from interference with the circulation of blood in the limb caused by swelling or hemorrhaging of the leg against the construction of the cast," which should have been recognized and prevented with proper care management.<sup>549</sup> The *Darling* court recognized that the hospital owed a direct legal duty to the patient to ensure competent and adequate nursing staff, to review the course of treatment, and to require necessary consultation.<sup>550</sup> *Darling* also recognized that healthcare industry, state licensing, and hospital standards and regulations could be used to determine the legal standard of care that hospitals owed to their patients.<sup>551</sup> Now, the Joint Commission's accreditation standards are frequently used to set the applicable standard of care in organizational (or corporate) negligence cases.<sup>552</sup> After *Darling*, other states began to adopt the doctrine of corporate negligence to hold hospitals directly responsible to patients for the negligent provision of healthcare services.<sup>553</sup>

To prove corporate negligence in the U.S., a plaintiff must establish the following: (1) derivation from an accepted standard of care; (2) actual or constructive notice of the defects or procedures that created the harm; and (3) negligent conduct that was a substantial factor in bringing about the plaintiff's harm.<sup>554</sup> In medical negligence cases, legal theories of corporate

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<sup>544</sup> *See id.*

<sup>545</sup> *Darling*, 211 N.E.2d 253.

<sup>546</sup> *Id.*

<sup>547</sup> *Id.*

<sup>548</sup> *Id.*

<sup>549</sup> *Id.* at 329.

<sup>550</sup> *Id.*

<sup>551</sup> *See* Mitchell J. Wiet, *Darling v. Charleston Community Memorial Hospital and Its Legacy*, 14 *Annals Health L.* 399 (2005).

<sup>552</sup> *See* Kearney & McCord, *supra* note 183, at 3.

<sup>553</sup> *See* Priestley, *supra* note 400; *see* Kearney & McCord, *supra* note 183, at 1 (noting in 1992 that 22 states had adopted some form of corporate liability).

<sup>554</sup> *See* 3 *Summ. Pa. Juris.* 2d *Torts* § 37:45 (2d ed.), Westlaw (database updated July 2018); *see also* Puig, *supra* note 372.

negligence against a healthcare organization primarily focus on administrative and managerial actions rather than medical decision-making.<sup>555</sup> In varying degrees, U.S. jurisdictions have held hospitals directly liable for failing to select and retain competent physicians, failing to maintain appropriate facilities and equipment, failing to train and supervise employees, and failing to implement appropriate protocols and procedures.<sup>556</sup>

The majority of corporate negligence cases involve claims of negligent credentialing, which occurs when a hospital fails to exercise due care in granting hospital privileges to a physician who is not qualified to treat patients.<sup>557</sup> The Supreme Court of Texas found that a plaintiff had successfully pled a claim against a hospital for permitting a plastic surgeon to perform several surgeries at the hospital despite its knowledge of complaints that called the surgeon's qualifications in question.<sup>558</sup> In this case, the Court noted that, "[a]lthough neither the Hospital as an entity nor the credentialing board actually performed the surgeries on [the plaintiff], a doctor lacking credentials could not have performed surgery in that hospital."<sup>559</sup>

Related to negligent credentialing, hospitals can also be held responsible for failing to maintain competent staff, which includes failing to train, supervise, and monitor all healthcare providers working in the hospital.<sup>560</sup> A Louisiana court of appeals found that a teaching hospital breached its duty to maintain competent staff when a patient, who suffered a bowel perforation, was never seen by an attending physician and the medical team responsible for her care was inexplicably absent during "her most critical time of need."<sup>561</sup>

Since an individual provider commits the injury-causing act in cases involving negligent credentialing and failure to maintain competent staff, the injured patient will generally have claims for both malpractice against the individual provider and corporate negligence against the hospital. This is because a failure to ensure provider competency "is 'inextricably interwoven' with delivering competent quality medical care to hospital patients."<sup>562</sup> It then

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<sup>555</sup> See *Essig v. Advocate BroMenn Med. Ctr.*, 33 N.E.3d 288, 303 (Ill. App. 4th Dist. 2015) ("Ordinarily, the hospital's institutional duty of care is 'administrative or managerial in character.'").

<sup>556</sup> See generally *Adelman & Robertson*, *supra* note 369; 3 Summary Pa. Juris. 2d *Torts* § 37:45 (2d ed.), Westlaw (database updated July 2018) (discussing theories of direct hospital liability).

<sup>557</sup> Causes of Action Second Series, 32 Causes of Action 2d 1, §6, December 2017 Update (Originally published in 2006).

<sup>558</sup> *Garland Cmty. Hosp. v. Rose*, 156 S.W.3d 541 (Tex. 2004) (finding that the plaintiff's claim against the hospital for negligent credentialing must be properly considered).

<sup>559</sup> *Id.* at 546.

<sup>560</sup> See *Kirby v. State ex rel. Louisiana State U. Bd. of Sup'rs*, 174 So.3d 1, 10 (La. App. 1st Cir. 2014); *Darling*, 200 N.E.2d 149 (upholding hospital liability based upon the inadequacy and incompetency of its medical staff.); *N. Tr. Co. v. Louis A. Weiss Meml. Hosp.*, 493 N.E.2d 6 (Ill. App. 1st Dist. 1986) (finding of hospital liability based upon a failure to have a specially-trained nurse in the nursery at all times).

<sup>561</sup> *Kirby*, 174 So.3d at 9.

<sup>562</sup> *Bell v. Sharp Cabrillo Hosp.*, 212 Cal. App. 3d 1034, 1051, 260 Cal. Rptr. 886, 896 (Ct. App. 1989).

follows that, “[i]f the physician is not negligent, there is no negligent credentialing claim against the hospital.”<sup>563</sup>

The corporate negligence doctrine can also hold a hospital legally responsible for patient injuries in the absence of an individual provider’s negligence based upon duties to maintain appropriate facilities and equipment and to implement appropriate protocols, policies, and procedures.<sup>564</sup> The duty to maintain appropriate facilities and equipment does not require hospitals to employ the best available medical technology, but they must have the facilities and equipment necessary to safely provide the medical treatment offered to their patients.<sup>565</sup> For example, the Georgia Court of Appeals dismissed a claim of hospital negligence when the hospital treated a patient with an incubator that was not the newest model when there was no evidence that the incubator was defective or not reasonably suited for its intended purpose.<sup>566</sup> On the other hand, a hospital was negligent in failing to maintain proper equipment when a crash cart used in the patient’s care did not have a functioning EKG machine or the right size endotracheal tubes.<sup>567</sup>

Additionally, some U.S. jurisdictions require hospitals to adopt policies and procedures designed to ensure patient safety, including duties to provide both quality medical care and sanitary facilities.<sup>568</sup> Hospitals have been held liable under the doctrine of corporate negligence for negligent policies and procedures governing the administration of oxygen to premature infants,<sup>569</sup> allowing an anesthesia provider with its own negligent policies and procedures to treat hospital patients,<sup>570</sup> and failing to assist physicians in obtaining a specialist consultation in accordance with hospital bylaws.<sup>571</sup> While some states exclude liability for failure to implement policies and procedures that control the actions of independent physicians,<sup>572</sup> others recognize that hospitals have a duty to ensure patient safety by using their administrative

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<sup>563</sup> *Hiroms v. Scheffey*, 76 S.W.3d 486, 489 (Tex. App. 2002).

<sup>564</sup> *See Adelman & Robertson, supra* note 369 (liability imposed on hospital management company); *but see In re Otero County Hosp. Assn., Inc.*, 527 B.R. 719 (Bankr. D.N.M. 2015), on reconsideration in part, 11-11-13686 JL, 2018 WL 882394 (Bankr. D.N.M. Jan. 29, 2018) (corporate negligence doctrine does not extend to hospital management companies). *See also Kearney & McCord, supra* note 183 at 4 (identifying duties imposed by the corporate negligence doctrine).

<sup>565</sup> *See Adelman & Robertson, supra* note 369; *Lauro v. Travelers ins. Co.*, 261 So.2d 261 (La. App. 4th Cir. 1972) (finding that a hospital’s duty is measured by the degree, care, and skill generally exercised by hospitals in the same community).

<sup>566</sup> *Emory v. Porter*, 103 Ga. App. 752 (Ga. App. 1961).

<sup>567</sup> *Kirby*, 174 So.3d at 9.

<sup>568</sup> *See Kearney & McCord, supra* note 183 at 4 (duty to formulate policies to ensure safety of medical care); *Sibley v. Bd. of Sup’rs of Louisiana State U.*, 477 So. 2d 1094, 1099 (La. 1985) (duty to have procedures to ensure safety of building and grounds).

<sup>569</sup> *Air Shields, Inc. v. Spears*, 590 S.W.2d 574 (Tex. Civ. App.--Waco 1979).

<sup>570</sup> *Denton Regl. Med. Ctr. v. LaCroix*, 947 S.W.2d 941 (Tex. App.--Fort Worth 1997).

<sup>571</sup> *Johnson v. St. Bernard Hosp.*, 399 N.E.2d 198 (Ill. App. 1st Dist. 1979).

<sup>572</sup> *Gafner v. Down E. Community Hosp.*, 735 A.2d 969, 979–80 (Me. 1999) (quoting *Hottentot v. Mid-Maine Med. Ctr.*, 549 A.2d 365, 370 (Me. 1988) (Hornby, J., concurring)).

expertise to create, implement, and enforce adequate policies and procedures on a broader scale.<sup>573</sup> For example, the Kentucky Court of Appeals held that a hospital could be directly liable for allowing an uncertified nurse anesthetist to administer anesthesia without supervision in violation of the hospital's own anesthesiology policies.<sup>574</sup> The court, in rejecting the hospital's argument that it was not responsible for supervising non-employee anesthesiologists practicing in the hospital, noted that:

[T]he legal duty in the case at bar, which appellant claims the hospital owed him and which he claims is breached, is not the duty to supervise or review the medical treatment given him, but the duty to enforce its policies which, if followed, would have precluded his receiving any anesthetic treatment in the first place solely from an unqualified, uncertified, inexperienced nurse with temporary, limited staff privileges.<sup>575</sup>

Thus, while there are limitations on a hospital's ability to control individual providers' medical decision making, the line between what qualifies as control over the individual provider and control over a patient's medical care more broadly is not always easy to discern.

#### **4.2.2 Liability for Organizational Errors in Germany**

Hospitals in Germany can also be held directly liable for organizational negligence.<sup>576</sup> This liability stems from the hospital's "non-delegable duty to organize and ensure what can be called a safe hospital system."<sup>577</sup> German courts have acknowledged that the activities of the physicians and the hospital are inextricably tied, such that the hospital should be responsible for patient injuries that occur on its premises.<sup>578</sup> The BGH takes a broad view of direct hospital liability:

It [the hospital operator] operates the hospital and makes its staff and facilities available to those citizens who need clinical treatment as patients. As a result, it becomes the guarantor for the protection of patients from avoidable harm in the use of its hospital and in the treatment and care it provides. It is thus obligated not only in contract, but also in tort, to do everything

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<sup>573</sup> Williams v. St. Claire Med. Ctr., 657 S.W.2d 590, 594 (Ky. App. 1983); Johnson, 399 N.E.2d 198.

<sup>574</sup> *Id.* at 592.

<sup>575</sup> *Id.* at 594.

<sup>576</sup> See Goldbach, *supra* note 17, at 26 (discussing statutory bases for direct organizational liability in Germany).

<sup>577</sup> See Giesen, *supra* note 23, at 60.

<sup>578</sup> See *id.* at 57.



reasonable within its power to avert possible dangers to patients.<sup>579</sup>

Thus, organizational liability in Germany arises when (1) a hospital is obliged under principles of both contract and tort to protect its patient from harm, (2) it fails “to make all reasonable efforts required to provide the best possible medical care to the patient and to protect the patient from inadequate and erroneous treatment measures;” and (3) damage is caused by such failure.<sup>580</sup> To avoid liability, hospitals in Germany must maintain “proper hospital communication and organization.”<sup>581</sup> This includes the maintenance and enforcement of organizational standards that ensure adequate personnel, facilities, and equipment.<sup>582</sup>

Regarding the adequate provision of hospital personnel, the BGH demands that hospitals exercise due diligence in the selection, training, and supervision of hospital employees.<sup>583</sup> For example, when a patient suffered syringe paralysis after a nursing assistant, rather than a nurse, administered intramuscular injections, the BGH found the hospital was subject to liability for failing to properly select, instruct and supervise its staff concerning the administration of such injections.<sup>584</sup> In support of this finding, the Court noted that (1) the relevant professional guidelines governing the scope of practice for nursing assistants does not generally authorize them to perform such injections due to the risk of serious injury, and (2) even if an exceptionally qualified and trained nursing assistant could perform these injections, the defendant hospital granted blanketed authorization to all nursing assistants to give these injections.<sup>585</sup>

Outside of its own employees, the hospital must also provide for the safe organization of treatment by physicians providing care on its premises. This includes ensuring that patients are treated by qualified physicians.<sup>586</sup> Unless there is an emergency situation for which no other organizational provision can be made, the hospital must ensure that treatment is carried out by sufficiently trained and experienced providers.<sup>587</sup> For example, the Frankfurt Higher Regional Court rejected a hospital’s assertion that the patient’s physician was exclusively responsible for providing medical treatment upon hospital admission for labor.<sup>588</sup> In this case, because the patient was not properly examined upon admission, fetal macrosomia went undetected and the risk of complications from shoulder dystocia, which the plaintiff ultimately suffered during

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<sup>579</sup> BGH, Jun. 18, 1985, 1985 NJW 2189 (juris) (translation from German).

<sup>580</sup> *Id.*

<sup>581</sup> Giesen, *supra* note 23, at 63.

<sup>582</sup> *Id.* at 64.

<sup>583</sup> BGH, May 8, 1979, VI ZR 58/78 (juris).

<sup>584</sup> *Id.*

<sup>585</sup> *Id.*

<sup>586</sup> BGH, Sept. 27, 1983, 88 BGHZ 248 (juris); *see* OLG Frankfurt, Dec. 11, 2002, 13 U 199/98 (juris) (“Hospitals have organizational duty to ensure that patients have access to specialist obstetrics care upon admission either at that hospital or via transfer to another hospital”).

<sup>587</sup> BGH, Sept. 27, 1983, 88 BGHZ 248 (juris).

<sup>588</sup> OLG Frankfurt, Dec. 11, 2002, 13 U 199/98 (juris).

birth, was not properly identified and managed.<sup>589</sup> The court found that the hospital was negligent in failing to ensure that the patient had access to specialist obstetrics care upon admission either at the defendant's hospital or via transfer to another hospital.<sup>590</sup>

Shortages in staffing cannot be used to excuse a hospital from providing patients with necessary medical care.<sup>591</sup> When the hospital cannot sufficiently staff a department, it cannot simply "close its eyes" to the problems and rely on physicians to protect the patient from harm associated with understaffing; instead, it must take other actions to ensure proper staff ratios and provide protocols regarding how to handle unexpected staff shortages to protect patients.<sup>592</sup> For example, when a plaintiff suffered brain injury after a complication from anesthesia monitored by a junior anesthesiologist, the BGH noted that the hospital's failure to properly organize the anesthesia service could not be excused by the shortage of anesthesiologists available to fill open positions.<sup>593</sup>

However, similar to the situation in the U.S., German courts will exclude hospital liability when the medical error in question concerns medical decision making rather than the organization of the treatment process.<sup>594</sup> For example, in a case in which the plaintiff suffered damages following a caesarean section, the Court found that the relevant inquiry for plaintiff's claims of organizational negligence was not the selection of a cesarean section versus alternative vaginal delivery, but rather implementation of organizational measures in connection with the performance of the cesarean section.<sup>595</sup>

Hospitals in Germany must maintain proper facilities and equipment, which includes ensuring functioning equipment<sup>596</sup> and hygienic facilities.<sup>597</sup> For example, when a patient suffered a brain injury caused by a faulty anesthesia machine, which was likely damaged while stored in a crowded hospital corridor, the BGH noted an objective violation of the hospital's obligation to provide functioning equipment.<sup>598</sup> The Court further noted that while it might be impossible to prevent all damage to equipment in operation, the hospital still has an obligation to reduce the risk of patient injury by "eliminating all recognizable sources of danger as far as possible . . . [or] by increased controls."<sup>599</sup> With regard to organizational errors related to hygiene, the most common source of injury results from hospital-acquired infections. In these cases, the BGH instructs:

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<sup>589</sup> *Id.*

<sup>590</sup> *Id.*

<sup>591</sup> *Id.*

<sup>592</sup> BGH, Jun. 18, 1985, 1985 NJW 2189 (juris) (translation from German).

<sup>593</sup> *Id.*

<sup>594</sup> BGH, Jan. 12, 2021, VI ZR 60/20 (juris).

<sup>595</sup> *Id.*

<sup>596</sup> BGH, Oct. 11, 1977, VI ZR 110/75 (juris).

<sup>597</sup> BGH, Aug. 16, 2016, VI ZR 634/15 (juris).

<sup>598</sup> BGH, Oct. 11, 1977, VI ZR 110/75 (juris).

<sup>599</sup> *Id.* (translation from German).

If it is certain that the infection must have originated in a hygienically controllable area, the hospital operator or the physician is liable for the consequences of the infection both in contract and in tort, unless he is able to exonerate himself to the effect that he is not at fault for the non-observance of the hygiene requirements, i.e. he proves that all organizational and technical precautions against avoidable germ transmission originating from the personnel of the hospital or the physician's practice were taken.<sup>600</sup>

For example, in a case involving a patient's development of sepsis after receiving an infusion with contaminated fluid, the BGH found organizational liability when the hospital could not prove that it took all reasonable measures to prevent contamination of the fluid while it was prepared and stored in the hospital.<sup>601</sup> On the other hand, when it is possible that the source of infection stems from an area outside of the hospital's control, the burden of proof is not reversed, and the plaintiff must prove that the hospital violated applicable hygiene standards.<sup>602</sup> In a case involving infection from bacteria found in all humans and which could have been carried by the plaintiff himself or visitors, the plaintiff was not entitled to a burden of proof reversal.<sup>603</sup> Nevertheless, the court found that the plaintiff proved a hygiene violation by showing that he was placed in the same room as another patient with an infected open knee wound.<sup>604</sup>

Finally, hospitals in Germany must maintain treatment records and know of their whereabouts at all times.<sup>605</sup> When a hospital was unable to produce x-ray images because it sent them to the hospital where the patient was subsequently transferred, the BGH found that the hospital violated this obligation.<sup>606</sup> Hospitals must also ensure the accuracy of medical records, and a hospital can be liable for a transcription error that causes harm to a patient.<sup>607</sup> For example, when a patient's record incorrectly noted that a muscle biopsy was "not indicated," the BGH found that this erroneous notation could be considered an organizational error if the physician's failure to order the biopsy, which led to a delayed diagnosis, was based on the transcription error.<sup>608</sup>

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<sup>600</sup> BGH, Mar. 3, 2007, 2007 r+s 519 (520) (beck-online) (translation from German).

<sup>601</sup> BGH, Nov. 3, 1981, 1982 NJW 699 (beck-online). *See* BGH, May 9, 1978, 1978 NJW 1683 (beck-online) (contamination of alcohol used to disinfect skin was organizational error).

<sup>602</sup> BGH, Aug. 16, 2016, VI ZR 634/15 (juris).

<sup>603</sup> *Id.*

<sup>604</sup> *Id.*

<sup>605</sup> BGH, Nov. 21, 1995, VI ZR 341/94 (juris).

<sup>606</sup> *Id.*

<sup>607</sup> BGH, Nov. 7, 2017, VI ZR 173/17 (juris).

<sup>608</sup> *Id.* (translation from German).

## 4.3 Proving Liability

The U.S. and Germany both require the plaintiff to bear the burden of proving liability, provide avenues for the plaintiff to obtain evidence needed to meet this burden, and employ burden-shifting mechanisms to either lessen or eliminate the plaintiff's burden of proof in certain circumstances. However, the jurisdictions have rules that diverge in each of these areas of proof as discussed below.

### 4.3.1 Proof Rules

The default position in both the U.S.<sup>609</sup> and Germany<sup>610</sup> is that the plaintiff bears the burden of proving medical malpractice. As a general rule, both jurisdictions require expert testimony to prove both a breach of the applicable standard of care and that the breach caused the alleged damages.<sup>611</sup> The jurisdictions diverge, however, on the standard of proof required to meet the plaintiff's burden.

#### 4.3.1.1 The Preponderance of Evidence Standard in the United States

In the U.S., the plaintiff must prove both breach of the applicable standard of care and causation by a preponderance of the evidence.<sup>612</sup> Black's Law Dictionary defines "preponderance of the evidence" as follows:

The greater weight of the evidence, not necessarily established by the greater number of witnesses testifying to a fact but by evidence that has the most convincing force; superior evidentiary weight that, though not sufficient to free the mind wholly from all reasonable doubt, is still sufficient to incline a fair and impartial mind to one side of the issue rather than the other. This is the burden of proof in most civil trials, in which the jury is instructed to find for the party that, on the whole, has the stronger evidence, however slight the edge may be.<sup>613</sup>

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<sup>609</sup> 61 Am. Jur. 2d *Physicians, Surgeons, Etc.* § 309 (2d ed), Westlaw (database updated Nov. 2021).

<sup>610</sup> Stauch, *supra* note 11, at 62-63.

<sup>611</sup> See Bergmann et al., *supra* note 316, at 300 (regarding Germany); Steven E. Pegalis, American Law of Medical Malpractice § 8:1 (3d ed) Westlaw (database updated June 2021) (regarding U.S.).

<sup>612</sup> See La. Stat. Ann. § 9:2794 (West); *Evans v. DeKalb Cty. Hosp. Auth.*, 267 S.E.2d 319 (Ga. Ct. App. 1980); *Todd v. United States*, 570 F. Supp. 670, 677 (D.S.C. 1983); *Klug v. Ramirez*, 830 S.W.2d 801, 804 (Tex. App. 1992).

<sup>613</sup> *Preponderance of the Evidence*, Black's Law Dictionary (11th ed. 2019).

U.S. courts have further explained that proof of a fact by a preponderance of the evidence requires it to be proven more probably true than not true or its existence more likely than not.<sup>614</sup> One adjustment to the preponderance of evidence standard in medical malpractice cases is the requirement by some jurisdictions that expert testimony establishing breach of the applicable standard of care and causation be given “to a reasonable degree of medical certainty;” however there are inconsistent judicial interpretations of this standard.<sup>615</sup> In Pennsylvania, expert opinions in medical malpractice cases do not meet the requisite standard if they are expressed in terms of possibility, likelihood, or even high probability.<sup>616</sup> On the other hand, Virginia courts equate the “reasonable degree of medical certainty” standard with the “preponderance of evidence” standard.<sup>617</sup> Similarly, other jurisdictions use the “reasonable degree of medical probability” standard for expert testimony and interpret it as having the same effect as the “preponderance of evidence” standard, which is to exclude mere speculation or possibility.<sup>618</sup>

#### 4.3.1.2 The Full Judicial Conviction Standard in Germany

In Germany the standard of proof is governed by the Civil Code of Procedure, which requires the court, “to decide, at its discretion and conviction, and taking account of the entire content of the hearings and the results obtained by evidence being taken, if any, whether an allegation as to fact is to be deemed true or untrue.”<sup>619</sup> Stauch expresses this standard as requiring the court to be, “overwhelmingly convinced of the facts,” which he notes is higher than the common law “more likely than not” standard.<sup>620</sup> The BGH has explained the standard of proof as requiring “[f]ull judicial conviction in the form of a degree of certainty that silences doubts for practical purposes, even if it does not eliminate them entirely.”<sup>621</sup> However, the BGH has

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<sup>614</sup> James v. McHenry, 828 So. 2d 94, 95 (La. App. 2 Cir. 2002); Cook v. Michael, 330 P.2d 1026, 1032 (Or. 1958); Matter of Briscoe Enterprises, Ltd., II, 994 F.2d 1160, 1164 (5th Cir. 1993); Nauheim v. City of Topeka, 432 P.3d 647, 653 (Kan. 2019); Herman & MacLean v. Huddleston, 459 U.S. 375, 390 (1983); Volz, 895 S.W.2d at 679.

<sup>615</sup> Morisch, 653 F.3d at 531; Griffin v. Univ. of Pittsburgh Med. Ctr.-Braddock Hosp., 950 A.2d 996, 1000 (Pa. 2008)

<sup>616</sup> See Griffin, *id.* at 1000 (noting that reasonable degree of medical certainty standard is not met by an expert opinion rendered in “more likely than not” terms).

<sup>617</sup> Hoffman v. Carter, 215, 648 S.E.2d 318, 326 (Va. Ct. App. 2007).

<sup>618</sup> Ashland Hosp. Corp., 581 S.W.3d at 577–78 (expert testimony cannot be “contingent, speculative, or merely possible”); Morsicato v. Sav-On Drug Stores, Inc., 111 P.3d 1112, 1116 (Nev. 2005) (expert’s speculative testimony failed to meet standard); Am. Radiology Servs., LLC v. Reiss, 236 A.3d 518, 532 (Md. Ct. App. 2020) (expert’s opinion must be based upon “more than speculation or conjecture”).

<sup>619</sup> Zivilprozessordnung [ZPO] [civil procedure statute] Sep. 12, 1950, Bundesgesetzblatt [BGBl] I, as amended § 286.

<sup>620</sup> Stauch, *supra* note 11, at 65-67. Stauch notes that the higher standard of proof is related to the inquisitorial nature of civil law jurisdictions, wherein the court seeks to uncover the truth rather than just judging the stronger case as presented by advocates.

<sup>621</sup> *Id.* at 65 (citing BGH, Feb. 17, 1970, 53 BGHZ 245 (256)).

also noted that requiring a standard of “probability bordering on certainty” is stricter than what the Code requires.<sup>622</sup>

German courts aim to sculpt proof rules to create an “equality of arms” between the litigants.<sup>623</sup> The German Federal Court observes the competing interests that medical malpractice cases invoke:

On the one hand, there is the patient’s need for proof, who must in principle prove that the doctor made a mistake as the basis for a claim, but who has only limited insight into the doctor’s actions, and often no insight at all, for example due to anesthesia. On the other hand, the physician is confronted with the difficulty that incidents, which as a rule indicate medical malpractice, can in many areas, as a result of the unpredictability of the living organism, exceptionally also occur as a result of fate; that the latter was the case, he could only prove with sufficient certainty if he secured every detail of his actions as evidence by documentation and the presence of witnesses.<sup>624</sup>

To balance the competing interests of patients and providers at the proof level, the burden of producing evidence in German medical malpractice cases is slightly modified by shifting the initial burden of production to the defendant provider. German law requires the defendant provider to first produce information, usually in the form of medical records, regarding the patient’s course of medical treatment.<sup>625</sup> As a result, the plaintiff’s burden of producing evidence is relaxed to accommodate for their information deficiency and lack of expert medical knowledge.<sup>626</sup>

#### **4.3.2 Modification of Proof Rules**

Both jurisdictions allow for some modification of the default burden of proof rules. U.S. courts are more willing to ease the burden of proof for a plaintiff by observing legal inferences or presumptions of negligence in medical malpractice cases in certain circumstances while German courts will relieve the plaintiff of their burden of proof by shifting the burden to the defendant in certain categories of cases.

##### **4.3.2.1 *Res Ipsa* in the United States**

In the U.S., the common law doctrine of *res ipsa loquitur* is the legal mechanism by which courts can ease the plaintiff’s burden of proof. Meaning “the thing speaks for itself,” *res ipsa*

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<sup>622</sup> BGH, Feb. 12, 2008, VI ZR 221/06 (beck-online) (translation from German).

<sup>623</sup> See Bergmann et al., *supra* note 316, at 300 (regarding Germany) (translation from German).

<sup>624</sup> BGH, Mar. 14, 1978, VI ZR 213/76 (juris) (translation from German).

<sup>625</sup> *Id.*

<sup>626</sup> See Bergmann et al., *supra* note 316, at 300 (regarding Germany).

*loquitur* creates an inference of negligence in tort cases when (1) the injury does not ordinarily occur in the absence of negligence, (2) the agency or instrumentality of the injury is in the exclusive control of the defendant, (3) the plaintiff was not contributorily negligent, and (4) the defendant is in a superior position to explain the accident.<sup>627</sup>

Once a plaintiff invokes the doctrine of *res ipsa loquitur*, a rebuttable inference or presumption of negligence arises, and a burden of production shifts to the defendant to produce evidence that they are not negligent.<sup>628</sup> If the defendant can rebut this presumption, plaintiff must prove that the defendant was negligent and that such negligence caused the plaintiff's injury.<sup>629</sup> Medical malpractice cases that are generally suited for application of the *res ipsa loquitur* doctrine include cases in which a surgeon operates on the wrong body part or injury to a body part not involved in the surgery<sup>630</sup> and cases in which foreign objects are found in a patient's body after surgery.<sup>631</sup>

All states, with the exception of Alabama, Alaska, Georgia, and South Carolina, allow plaintiffs to invoke the doctrine of *res ipsa loquitur* to ease their burden of proving negligence in medical malpractice cases.<sup>632</sup> Nevada, in addition to recognizing the doctrine of *res ipsa loquitur* generally, has also codified rebuttable presumptions in medical malpractice cases involving a foreign body left in a patient following surgery, an explosion or fire during the course of treatment, an unintended burn during the course of treatment, injury to a body part not directly involved in the treatment, or a surgical procedure performed on the wrong patient, organ, or

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<sup>627</sup> Karyn K. Ablin, *Res Ipsa Loquitur and Expert Opinion Evidence in Medical Malpractice Cases: Strange Bedfellows*, 82(2) Va. L. Rev. 325 (1996).

<sup>628</sup> See *Chapman v. Harner*, 339 P.3d 519, 525-526 (Colo. 2014) (discussing "the effect of *res ipsa loquitur* as a rebuttable presumption").

<sup>629</sup> See *Id.*

<sup>630</sup> *Long v. Hacker*, 520 N.W.2d 195 (Neb. 1994) (wrong vertebra); *Manax v. Ballew*, 797 S.W.2d 71 (Tex. App. 1990) (wrong part of back); *Wick v. Henderson*, 485 N.W.2d 645 (Iowa 1992) (operation for gallbladder, injury to left arm); *Dalley v. Utah Valley Regional Medical Center*, 791 P.2d 193 (Utah 1990) (Caesarean, burn on calf); *Beaudoin v. Watertown Memorial Hosp.*, 145 N.W.2d 166 (Wis. 1966) (vaginal polyp removed, burns on buttocks); *Simmons v. Neuman*, 50 A.D.3d 666 (N.Y. App. Div. 2d Dept. 2008) (Patient who allegedly suffered burns to her right thigh during surgery on her right shoulder sued her physician for medical malpractice.); *Ceresa v. Karakousis*, 210 A.D.2d 884 (N.Y. App. Div. 4th Dep't 1994) (unusual compression fracture to arm and shoulder during surgery to remove tumor from lower spine); *Kerber v. Sarles*, 151 A.D.2d 1031 (N.Y. App. Div. 4th Dept. 1989) (absence of front teeth which had been knocked out during foot surgery).

<sup>631</sup> *Tiller v. Von Pohle*, 230 P.2d 213 (Ariz. 1951) (large cloth sack lodged in plaintiff's bowel after abdominal operation, inference that it was a result of the operation would be permitted); *Kambat v. St. Francis Hosp.*, 678 N.E.2d 456 (N.Y. App. Div. 2d Dept. 1997) (18 x 18-inch towel or laparotomy pack); *Gravitt v. Newman*, 114 A.D.2d 1000 (N.Y. App. Div. 2d Dept. 1985) (tip of an internal vein stripper left in the patient's leg during surgery for varicose veins); *Critelli v. Long Island Jewish-Hillside Medical Center*, 115 A.D.2d 632 (N.Y. App. Div. 2d Dept. 1985) (laparotomy pad left in abdomen).

<sup>632</sup> See *Sides v. St. Anthony's Medical Center*, 258 S.W.3d 811, 816-18 (Mo. 2008).

body part.<sup>633</sup> While the doctrine generally only gives rise to a rebuttable presumption of negligence, in Louisiana, the burden of proof shifts entirely to the defendant in medical malpractice cases where the court finds that the doctrine of *res ipsa loquitur* is applicable.<sup>634</sup>

The states diverge on the issue of whether plaintiffs can present expert testimony in medical malpractice cases that invoke the doctrine of *res ipsa loquitur*. Most states, in accordance with Comment D to Restatement (Second) of Torts,<sup>635</sup> allow expert testimony in medical malpractice cases to assist laypeople on the jury to determine whether the plaintiff's medical injury is the kind that necessitates an inference of negligence.<sup>636</sup> Eight states, however, refuse to allow expert evidence in medical malpractice cases that invoke the *res ipsa loquitur* doctrine reasoning that the doctrine can only be applied in cases that allow lay jurors with common knowledge to infer negligence without any specialist knowledge or explanation.<sup>637</sup>

#### 4.3.2.2 Burden Shifting in Germany

Like the doctrine of *res ipsa loquitur*, Germany's *Anscheinsbeweis* or *Prima Facie Beweis* doctrines can reduce a plaintiff's burden of proving negligence when their injury does not occur "in the typical course of events" absent negligence.<sup>638</sup> However, for plaintiffs in medical malpractice cases, the PRG codified a more advantageous burden shifting mechanism for certain categories of cases.<sup>639</sup>

The plaintiff's burden of proving negligence will shift to the defendant in two scenarios. First, the burden will shift when manifestation of a "fully masterable" risk – a risk that was fully in the control of the defendant – caused the plaintiff's injury.<sup>640</sup> "Fully masterable" risks include patient positioning, hygiene deficiency, and equipment insufficiency.<sup>641</sup> Second, the burden will shift when the treating party fails to document a medically necessary measure.<sup>642</sup> If a required medical measure is not documented, the court will presume that it was not carried out, and the burden of proof will shift to the defendant if it is "sufficiently likely" that the missing measure would have revealed something relevant for the patient's medical treatment.<sup>643</sup> However, if the missing measure was omitted from the patient's treatment as a result of a

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<sup>633</sup> N.R.S. 41A.100. Required evidence; exceptions; rebuttable presumption of negligence (2015).

<sup>634</sup> La. Stat. Ann. § 9:2794 (West).

<sup>635</sup> Restatement (Second) of Torts § 328D comment m (Am. Law Inst. 1965).

<sup>636</sup> Sides, 258 S.W.3d, at 816.

<sup>637</sup> *Id.* at 818.

<sup>638</sup> Stauch, *supra* note 11.

<sup>639</sup> *See* Goldbach, *supra* note 17, at 95 (noting that the PRG codified burden of proof rules previously developed by the case law).

<sup>640</sup> BGB § 630h(1).

<sup>641</sup> Bergmann et al., *supra* note 316, at 55.

<sup>642</sup> BGB § 630h(3); *see* Sommer et al., *supra* note 374, at 355.

<sup>643</sup> *See* Sommer et al., *supra* note 374, at 355.



treating physician's diagnostic error, the burden of proof will not shift to the defendant who failed to carry out the medically necessary measure.<sup>644</sup>

The plaintiff's burden of proving causation will shift to the defendant in two scenarios. First, in the case of "beginners' errors" – when a provider is not qualified to carry out the treatment – the court will presume that the lack of qualifications caused the injury.<sup>645</sup> Second, the burden of proof on causation shifts to the defendant when the plaintiff's injuries are caused by "gross errors."<sup>646</sup> Gross errors are the primary reason for burden shifting in German medical malpractice cases.<sup>647</sup> According to the BGH, gross errors include those that occur, "when a physician has definitely violated established medical treatment rules or latest medical knowledge and committed an error that no longer seems to be understandable from an objective point of view because it simply must not occur."<sup>648</sup> Additionally, organizational errors can also be considered gross errors, for example, when the organization of the admission process for new-born babies is "severely" flawed and leads to an "incomprehensible" and "unacceptable" delay in treatment.<sup>649</sup>

In the case of an erroneous failure to make a diagnostic finding, the burden of proof will shift with regard to causation if it is sufficiently probable that the diagnostic finding, had it been made, would have warranted a further response which, if not taken, would have constituted a gross error.<sup>650</sup> For example, the Koblenz Higher Regional Court found that the failure to investigate a patient's post-operative complaints was not itself a gross error, but it was highly probable that had the investigation occurred, a perforated ulcer, which ultimately caused the plaintiff's death, would have been discovered. Further, because failure to respond to the discovery of a perforated ulcer would have constituted a gross error, the plaintiff was entitled to a reversal of the burden of proof on causation.<sup>651</sup>

### 4.3.3 Proof of Malpractice

Both jurisdictions provide legal avenues for obtaining evidence of medical negligence. In the U.S., the adversarial process of pre-trial discovery dominates the evidence-seeking stage of litigation. Pre-trial discovery is a mechanism through which parties in litigation can obtain information and documents pertaining to the disputed matter. Generally, discovery in American civil litigation, which typically allows "discovery regarding any nonprivileged matter that is

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<sup>644</sup> Bergmann et al., *supra* note 316, at 56.

<sup>645</sup> BGB § 630h(4); *see* Sommer et al., *supra* note 374, at 355.

<sup>646</sup> BGB § 630h(5).

<sup>647</sup> Bergmann et al., *supra* note 316, at 55.

<sup>648</sup> Albrecht Wienke, Errors and pitfalls: Briefing and accusation of medical malpractice – the second victim, 12 GMS Current Topics in Otorhinolaryngology – Head and Neck Surgery 1, 7 (2013).

<sup>649</sup> OLG Bremen, Jan. 13 2006, 2011 BeckRS 16440 (beck-online) (translation from German).

<sup>650</sup> OLG Koblenz, Jan. 10, 2008, 2008 NJW-RR 1055 (beck-online).

<sup>651</sup> *Id.*

relevant to any party's claim or defense and proportional to the needs of the case,"<sup>652</sup> is more liberal and broader in scope than its German counterpart. The U.S. Court of Appeals for the Fifth Circuit has observed that "many foreign countries, particularly civil law countries, do not subscribe to our [American] open-ended views regarding pretrial discovery, and in some cases may even be offended by our pretrial procedures."<sup>653</sup> This is particularly true in Germany, where the concept of *nemo tenetur se ipsum accusare*, meaning "no man has to accuse himself" provides an important limitation on discovery in all legal proceedings. G. Arthur Martin observes:

In the German law of procedure – not only civil and criminal, but also administrative, labour, social, etc. – the rule "*nemo tenetur se ipsum accusare*" has been generally accepted for well over one century. It is based upon the ethical concept that the procedural interest in the exploration of the truth must stand back behind the higher valued interest of the individual to be protected from any coercion to self-incrimination.<sup>654</sup>

In medical malpractice litigation, pre-trial discovery is primarily centered around documents relating to the plaintiff's medical treatment. While both jurisdictions provide plaintiffs with access to their medical treatment records, they also limit the types of documents that litigants can obtain in medical malpractice cases.

#### **4.3.3.1 Obtaining Proof in the United States**

In the U.S., the Health Insurance Portability and Accountability Act of 1996 (HIPAA) provides patients with a right to request medical treatment records.<sup>655</sup> This includes medical treatment, billing, and insurance records as well as any records used "to make decisions about individuals."<sup>656</sup> However, patients are not entitled to "[i]nformation compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding."<sup>657</sup> Attorneys in medical malpractice litigation may obtain a plaintiff's medical records via a HIPAA-compliant authorization to release records to a third-party.<sup>658</sup>

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<sup>652</sup> Fed. R. Civ. P. 26.

<sup>653</sup> *In re Anschuetz & Co., GmbH*, 838 F.2d 1362, 1364 (5th Cir. 1988).

<sup>654</sup> G. Arthur Martin, *The Privilege against Self-Incrimination under Foreign Law*, 51 J. Crim. L. Criminology & Police Sci. 161, 172 (1960-1961).

<sup>655</sup> Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended in scattered sections of 18, 26, 29, and 42 U.S.C.); HHS's privacy regulations, which implement section 264(c) of HIPAA, are codified at 45 C.F.R. §§ 164.500-164.534. See 45 C.F.R. §§ 164.508; 45, 164.524, 164.526.

<sup>656</sup> 45 C.F.R. § 164.501.

<sup>657</sup> 45 C.F.R. § 164.524(a)(1)(ii).

<sup>658</sup> 45 C.F.R. § 164.506.

Additionally, the parties can obtain medical records from one another pursuant to procedural rules that allow litigants to request documents and electronic information in pre-trial discovery by “describ[ing] with reasonable particularity each item or category of items to be inspected.”<sup>659</sup> Although U.S. courts are split regarding whether plaintiffs are required to sign HIPAA authorizations allowing third-party access to medical records as part of pre-trial discovery,<sup>660</sup> HIPAA itself allows healthcare providers to provide medical records pursuant to a court order, subpoena, or discovery request “in the course of any judicial or administrative proceeding.”<sup>661</sup>

There are two main privileges that protect documents from discovery in medical malpractice litigation in the U.S. First, the peer review privilege, which is codified in nearly every state,<sup>662</sup> excludes information developed by hospital peer review committees from pre-trial discovery.<sup>663</sup> Peer review committees are designed to evaluate both the competency of physicians and the quality of medical treatment provided in the hospitals to discover and correct deficiencies and improve the overall quality of care.<sup>664</sup> The Seventh Circuit Court of Appeals articulated the policy interests behind extending confidentiality to the peer review process:

Candid and conscientious evaluation of clinical practices is a *sine qua non* of adequate hospital care. To subject these discussions and deliberations to the discovery process, without a showing of exceptional necessity, would result in terminating such deliberations. Constructive professional criticism cannot occur in an atmosphere of apprehension that one doctor's suggestion will be used as a denunciation of a colleague's conduct in a malpractice suit.<sup>665</sup>

Although the peer review privilege generally protects the peer review process, including investigation, deliberations, and decisions, from use in litigation, peer review information

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<sup>659</sup> See Fed. R. Civ. P. 34(b)(1)(A). Although most medical malpractice cases are litigated in state courts, most states have adopted or closely model their civil procedure rules after the federal rules. See U.S. Legal, *State Rules of Civil Procedure*, <https://civilprocedure.uslegal.com/rules-of-civil-procedure/state-rules-of-civil-procedure/> (last visited Jan. 5, 2022).

<sup>660</sup> See *Wymore v. Nail*, No. 5:14-CV-3493 2016 WL 1452437, at 3 (W.D. La. Apr. 13, 2016) (“Rule 34, along with rule 37, empowers federal courts to compel parties to sign written authorizations consenting to the production of various documents”); cf. *Chase v. Nova Se. Univ., Inc.* No. 11-61290-CIV, 2012 WL 1936082, at 1 (S.D. Fla. May 29, 2012) (finding that the court does “not possess the authority to routinely require a plaintiff to execute a release for medical records”).

<sup>661</sup> 45 C.F.R. § 164.512(e)(1).

<sup>662</sup> Kenneth R. Kohlberg, *The Medical Peer Review Privilege: A Linchpin for Patient Safety Measures*, 86 Mass. L. Rev. 157, 157 (2002).

<sup>663</sup> See *id.*

<sup>664</sup> See Katherine T. Stukes, *The Medical Peer Review Privilege After Virmani*, 80 N.C. L. Rev. 1860, 1862-63 (2002).

<sup>665</sup> *Mem’l Hosp. for McHenry Cty. v. Shadur*, 664 F.2d 1058, 1062 (7th Cir. 1981).

available from other sources is usually exempt from the privilege's protection.<sup>666</sup> Additionally, U.S. courts have found several additional exceptions to the peer review privilege by limiting the privilege's scope depending on how closely connected the information was to the formal peer review committee process.<sup>667</sup>

The second discovery privilege that arises in U.S. medical malpractice litigation is found in the PSQIA. The PSQIA promotes the development and use of PSOs to analyze medical error reports from healthcare organizations and recommend preventive measures.<sup>668</sup> To encourage providers to work with PSOs to improve the quality of healthcare, the PSQIA provides a level of confidentiality for data and records, "assembled or developed by a provider for reporting to a PSO" from discovery in litigation.<sup>669</sup> This category of data and information, referred to as PSWP, is protected from pre-trial discovery.<sup>670</sup> However, similar to the peer review privilege, PSWP does not "include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system."<sup>671</sup>

#### 4.3.3.2 Obtaining Proof in Germany

Germany also provides two avenues for medical malpractice plaintiffs to obtain their medical records. First, patients in Germany have a legal right to inspect their medical records.<sup>672</sup> Medical records subject to inspection include, "all data arising in connection with the patient's medical treatment," including incidents that occur, "within the scope of the treatment."<sup>673</sup> Patients in Germany can request their medical records directly or seek assistance from their health insurance companies, who are obligated to assist their members in the case of a suspected medical error.<sup>674</sup>

Second, medical malpractice plaintiffs can request medical records pursuant to their broader right to obtain documents during litigation. The German rules of civil procedure allow parties to request documents by describing the document, the facts the document intends to prove, the contents of the document, the circumstances under which the opposing party allegedly has possession of the document, and the legal ground supporting the opposing party's obligation to produce the document.<sup>675</sup>

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<sup>666</sup> See American Law Reports, 69 A.L.R.5th 559 (Originally published in 1999).

<sup>667</sup> See *id.*

<sup>668</sup> 42 U.S.C.A. §299b-21 – b-26 (2005); see also S. Rep. No., 108-196, at 3 (discussing the intent of the Act).

<sup>669</sup> See 42 U.S.C.A. § 299b-22; 42 U.S.C.A. § 299b-21(7).

<sup>670</sup> 42 U.S.C.A. § 299b-21(7).

<sup>671</sup> 42 C.F.R. § 3.20 (2009).

<sup>672</sup> BGB § 630g.

<sup>673</sup> Jasmin Thüß, Rechtsfragen des Critical Incident Reportings in der Medizin [Legal issues of critical incident reporting in medicine] 116 (Christian Katzenmeier ed., 2012) (F.R.G) (translation from German).

<sup>674</sup> See SGB V § 66.

<sup>675</sup> ZPO § 424.

Both avenues of obtaining medical records for German medical malpractice plaintiffs are limited to exclude certain information related to a healthcare organization's efforts to improve patient care generally. As discussed above, the basic concept of freedom from self-incrimination in German law could preclude discovery of information and documents relating to a medical error but outside of an individual's treatment records, including error reports and discussion of a patient's injury for the purposes of improving the quality of care.<sup>676</sup> German scholars observe that patients generally do not have a right to access records relating to organizational failures, though potentially relevant to a medical malpractice claim, because the information sought is not necessary for the plaintiff's medical treatment.<sup>677</sup>

#### 4.4 Conclusion

Establishing liability for a medical injury under both American and German law hinges primarily on an individual provider's negligence via breaching a standard of medical care while treating a patient. While the concept of organizational and corporate negligence is well established in both American and German jurisprudence, it has never focused on the healthcare organization's duty to prevent systemic errors through the process of CRM.<sup>678</sup> Better defining and strengthening a cause of action for negligent risk management as a viable avenue for recovering damages caused by medical errors will help focus the medical liability system on organizations rather than individual providers without the need for a complete overhaul of the system. As Sage observes:

The key is to embed malpractice reform within, and thereby leverage, existing regulatory and self-regulatory mechanisms that advance health care quality rather than merely creating another stand-alone, reactive institution such as a "medical court."<sup>679</sup>

Correcting organizational or systemic deficiencies through the process of CRM is critical to medical error prevention because, in most cases, these deficiencies either induce or fail to prevent individual acts of medical negligence. As a result, nearly every medical malpractice case against an individual provider should include a concurrent cause of action for negligent

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<sup>676</sup> See Landgericht Bonn [LG Bonn] [Bonn Trial Court] Sep. 2, 2009, 5 S 19/09 MedR 573 (finding that a report concerning a patient's fall in the hospital hallway was not discoverable).

<sup>677</sup> See Thüß, *supra* note 673, at 116-120; Pauli, *supra* note 57, at 279-281.

<sup>678</sup> At least twenty-two states in the US have adopted some form of organizational liability, under which the hospital can be found directly negligent; however, in the United States, there is no consensus on whether a tort action can be based upon a hospital's duty to generally ensure the quality of healthcare through the adoption of rules and policies. See Kearney & McCord, *supra* note 183. Likewise, Germany has recognized several theories of organizational failure by healthcare organizations, but there is no express recognition of a duty to risk management in the case law. See Goldbach, *supra* note 17, at 49-51.

<sup>679</sup> Sage, *supra* note 19, at 43.

CRM against the healthcare organization. Including risk management failures in the primary medical liability discussion will allow for the much-needed legal evaluation of risk management activities and corresponding liability for organizations whose actions fall below accepted standard of care for CRM.

## 5. Liability for Negligent Clinical Risk Management

A legal cause of action for negligent CRM<sup>680</sup> under the existing medical liability systems in both the U.S. and Germany requires finding that the hospital owes the patient a legal duty or obligation to prevent or minimize medical errors through the process of risk management. In Germany, legal scholars have written extensively regarding whether German medical liability law supports imposing liability for negligent CRM, with the majority finding such support.<sup>681</sup> In the United States, there is no known academic discussion of the subject. Additionally, there are no medical liability cases in either jurisdiction that explicitly oblige healthcare organizations to conduct CRM.<sup>682</sup> As such, the question of whether medical liability law in both jurisdictions supports finding an affirmative duty or obligation to conduct CRM must be examined in the context of the existing organizational liability law and tort law more broadly. German academics find support for an obligation to CRM in organizational liability law by relying on the existing laws and regulations that require healthcare risk management. Additionally, they rely on tort law more broadly to support an obligation to CRM by looking to the existing legal obligations of manufacturers to prevent injury under product liability law. As a result, the German academic literature finding that CRM is a logical extension of existing German tort law generally, and organizational negligence law specifically, serves to guide a similar finding in the U.S.

Once the existing law supports a duty or obligation to conduct CRM, then a framework for determining the applicable standards of care must be identified. Again, because German legal scholarship has already tackled the question of whether organizational liability encompasses CRM, it also provides guidance for structuring the applicable standards of care based upon internationally recognized concepts for conducting CRM in healthcare organizations.

Finally, liability for negligent CRM requires an evidentiary framework that balances the confidentiality needed for the CRM process to successfully function in healthcare organizations with the transparency required for injured patients to recover damages caused by negligent CRM. Courts can strike this balance through a combination of evidentiary and burden-shifting rules. Regarding evidentiary rules, courts can rely on recommendations from the IOM and other patient safety organizations to provide confidentiality for certain CRM information and documents. Regarding the burden of proof rules, German legal scholars have identified a functional burden-shifting paradigm that can guide courts in determining liability for negligent CRM in both jurisdictions.

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<sup>680</sup> Clinical risk management focused on improving patient safety is to be distinguished from risk management focused on liability consequences that can stem from a broad range of operational risks. See Goldbach, *supra* note 17, at 5-7 (explaining the difference between “liability-based” risk management and “medical” risk management).

<sup>681</sup> See Goldbach, *supra* note 17, at 46-49 (“although there is no uniform picture of the RM obligation in the literature, the number of affirmative voices is successively increasing.”).

<sup>682</sup> See *supra* note 22 and accompanying text.

## 5.1 Legal Bases for Requiring Clinical Risk Management in Medical Liability Law

To recognize liability for negligent CRM in both American and German tort law, healthcare organizations must be legally obliged to conduct CRM. Ultimately, finding a duty or obligation to conduct CRM can be supported in both jurisdictions as an extension of organizational liability by (1) looking through the larger lens of negligence-based medical liability and, (2) considering liability in other legal spheres that stems from a violation of duties and obligations established to prevent harm. Here, in both jurisdictions, existing laws and regulations requiring healthcare risk management as well as existing product liability law provide strong support for extending the existing framework for organizational liability in medical negligence law to include liability for negligent CRM.

### 5.1.1 Liability for Negligent Clinical Risk Management under Existing Organizational Negligence Law

As a starting point, liability for negligent CRM must be distinguished from the existing organizational liability already recognized by courts in both jurisdictions. As discussed in Chapter 4, both jurisdictions already recognize that healthcare organizations can face organizational liability for patient injuries. Thus far, the case law in both jurisdictions confirms that healthcare organizations are responsible for negligence in the following areas: organization and competency of personnel; organization of the medication administration process; provision of safe equipment and facilities; communication and medical record keeping; and the provision and qualification of specialists. Some German scholars opine that despite the lack of an explicit reference to “risk management” in the case law, CRM is already required by the case law on organizational liability.<sup>683</sup> Indeed, the BGH has articulated a broad scope for organizational liability by obliging hospitals “to make all reasonable efforts . . . to provide the best possible medical care to the patient and to protect the patient from inadequate and erroneous treatment measures.”<sup>684</sup>

Goldbach, however, makes a convincing argument that organizational liability thus far recognized by German courts is not broad enough to encompass negligent CRM. Because American courts have not yet articulated a broad duty to organize the medical treatment process as expressed by the BGH, Goldbach’s distinction is important for finding liability for negligent CRM in the U.S. using a comparative lens.

To distinguish the two, Goldbach categorizes existing organizational liability as based on “specific obligation[s] to monitor treatment” and CRM as an “abstract obligation to monitor

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<sup>683</sup> Pauli, *supra* note 57, at 194; Dieter Hart, *Patientensicherheit, Fehlermanagement, Arzthaftungsrecht – zugleich ein Beitrag zur rechtlichen Bedeutung von Empfehlungen* [Patient safety, error management, medical malpractice law - also a contribution to the legal significance of recommendations], 30 MedR 1-15 (2012) (F.R.G.).

<sup>684</sup> BGH, Jun. 18, 1985, 1985 NJW 2189 (juris) (translation from German).



treatment.”<sup>685</sup> According to Goldbach’s view, specific treatment monitoring is concerned with the prevention of individual incidents and, thus, focuses solely on the last component of the risk management cycle – risk control.<sup>686</sup> In the current organizational negligence jurisprudence, and this is true in both jurisdictions, courts focus on specific treatment monitoring through the absence or faulty implementation of a specific organizational guideline, practice, or procedure that could have prevented the individual plaintiff’s injury. Examples of specific treatment monitoring include use of a faulty piece of equipment, inadequate staffing procedures, negligent hiring of a provider, and failure to implement a specific hygienic precaution. In contrast, the CRM process begins further upstream in the organizational workflow and encompasses risk identification, risk analysis, risk assessment, and risk control, a process that Goldbach labels “abstract treatment monitoring.”<sup>687</sup> Examples of abstract treatment monitoring include implementation of an error reporting system and investigation of near-miss incidents. Goldbach rejects the idea that German courts have already imposed an obligation to CRM: “The case law has not yet stipulated in any decision that the hospital operator must actively inform itself about uncertainties and is obliged to systematically analyze and eliminate the causes of critical and undesirable events.”<sup>688</sup> Similarly, U.S. courts, have thus far, also limited treatment of organizational negligence in medical malpractice cases to duties involving specific therapy monitoring.

Nevertheless, the ongoing development and expansion of organizational duties in the case law provides support for incorporating liability for negligent CRM, especially considering the legal basis for requiring CRM under general tort law principals in both jurisdictions.

### **5.1.2 Liability for Negligent Clinical Risk Management under General Tort Law**

While case law explicitly recognizing liability for negligent CRM is lacking in both countries, general tort laws combined with regulations establishing risk management obligations provide support for recognizing a theory of liability for negligent CRM under the existing medical liability framework.

#### **5.1.2.1 Legal Basis for an Obligation to Conduct Clinical Risk Management in German Medical Liability Law**

German social law, especially following the PRG, requires hospitals to implement quality management,<sup>689</sup> which, according to Goldbach, encompasses risk management.<sup>690</sup> To

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<sup>685</sup> Goldbach, *supra* note 17, at 52-53(translation from German).

<sup>686</sup> *See id.*

<sup>687</sup> *See id.* at 53-54(translation from German).

<sup>688</sup> *See id.* at 54(translation from German).

<sup>689</sup> Though German law uses the terms “Quality Management” and “Quality Assurance,” it does not define these terms, leading German legal scholars to find that they are synonymous. *See* Goldbach, *supra* note 17, at 13-14, 18-19.

<sup>690</sup> Goldbach, *supra* note 17, at 16-17.

determine that hospitals are similarly obliged to implement risk management under Germany's general negligence law, which requires the exercise of reasonable care, and are consequently subject to liability for failure to exercise such care under § 823(1) BGB, German scholars find support from the establishment of obligations comparable to risk management in German product liability law. Additionally, German law, under § 823(2) BGB, imposes liability for a violation of protective law<sup>691</sup> which, considering statutes and regulations mandating the implementation of healthcare quality assurance and risk management, further support finding that organizations can be liable for negligent CRM under German medical negligence law.

The passage of the PRG in 2013 enhanced existing social law obligations for hospitals to perform quality management and introduced the term "risk management" into the law.<sup>692</sup> Prior to the Act, § 135a II SGB V already required hospitals to implement intra-facility quality management systems, which, per GB-A regulations, included systems that prevented errors and enhanced patient safety.<sup>693</sup> The PRG amended § 135 SGB V to require additional and more specific quality management measures, including participation in "cross-institutional quality assurance," and introduction and further development of intra-facility quality management, including a patient complaint system.<sup>694</sup> Additionally, the PRG included legal protection for "[r]eports and data from [i]nternal and cross-facility risk management and error reporting systems" required by the law.<sup>695</sup> Finally, the PRG delegated the task of determining, "the basic requirements for an institution's internal quality management . . . [including] essential measures to improve patient safety and in particular lay[] down minimum standards for risk management and error reporting systems."<sup>696</sup> The GB-A, though the PRG's legislative delegation, published guidelines to set forth, "basic requirements for a successful introduction and implementation of quality management."<sup>697</sup> The current guidelines specifically identify risk management as a method and instrument of quality management.<sup>698</sup> Goldbach notes that the error-prevention and patient safety goals of the GB-A's pre-PRG regulations combined with the fact that the International Organization for Standardization's published standards for quality management systems includes the basic CRM process (risk identification, analysis, and improvement) confirm that even the pre-PRG obligation to conduct quality management included an obligation to conduct CRM.<sup>699</sup> However, if there was any doubt about whether the social law required CRM, it dissipated with the passage of the PRG, which specifically identifies risk management as part of quality management.<sup>700</sup>

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<sup>691</sup> BGB § 823(2).

<sup>692</sup> Goldbach, *supra* note 17, at 17-19(translation from German).

<sup>693</sup> *Id.* at 14-17.

<sup>694</sup> SGB V § 135a(2).

<sup>695</sup> SGB V § 135a(3).

<sup>696</sup> SGB V § 136a(3); *see* SGB V § 137 (authorizing G-BA enforcement).

<sup>697</sup> G-BA, Qualitätsmanagement-Richtlinie [Quality Management Guidelines], <https://www.g-ba.de/richtlinien/87/> (last visited Jan. 5, 2022) (translation from German).

<sup>698</sup> *Id.* at 8.

<sup>699</sup> Goldbach, *supra* note 17, at 16-17.

<sup>700</sup> *See id.* at 18 (The PRG "should make it clear once and for all that RMS are a mandatory component of the obligation to perform internal QM.").

Relying on the healthcare organization's obligation to implement CRM as established in the social law, German scholars determined that the existing case law in the areas of organizational negligence and product liability also support tort liability for failure to exercise reasonable care in implementing CRM.<sup>701</sup> Like organizational liability for healthcare providers, product liability for manufacturers in German law imposes direct corporate tort liability for injuries caused by unreasonable conduct.<sup>702</sup> Product liability law requires that manufacturers organize the manufacturing process, which, according to Goldbach, corresponds with a requirement that hospitals organize the treatment process already established as specific treatment monitoring in the case law.<sup>703</sup>

Additionally, German product liability case law more-broadly requires manufacturers to monitor the post-market safety of products. This includes "actively and systematically monitor[ing] and evaluat[ing] the risk and to take appropriate action, not only in the case of new products but also in the case of products that have already been introduced, and also irrespective of any damage that has already occurred."<sup>704</sup> Goldbach draws a parallel between the jurisprudentially established obligation to abstract product monitoring in product liability law to the yet-to-be recognized obligation to abstract treatment monitoring in hospital organizational liability law to conclude that viewing liability in the context of a uniform legal system requires finding a legal obligation to conduct CRM in the medical negligence law.<sup>705</sup> Pauli agrees and lays out the similarities between the two:

The producer's liability as well as the organizational liability of the hospital operator are aimed at safety for the benefit of consumers and patients. The producer's liability and the organizational liability of the hospital operator intervene if the breach of a duty of conduct incumbent on the producer or hospital operator has caused an infringement of the consumer's or patient's rights. In both areas, the risks originate from a sphere that the consumer or the patient cannot understand or influence. Both the producer and the hospital operator are obliged to organize their company in such a way that identifiable risks are excluded. For this purpose, the goods manufacturer is obliged, among other things, to take suitable measures to identify and exclude risks. Taking into account the above, there are no reasons why the obligation to identify and prevent or minimize risks should not apply analogously to the hospital operator, as it

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<sup>701</sup> See *id.* at 75; Pauli, *supra* note 57, at 233.

<sup>702</sup> Goldbach, *supra* note 17, at 66.

<sup>703</sup> *Id.* at 67.

<sup>704</sup> *Id.* at 69(translation from German).

<sup>705</sup> *Id.* at 75.

undoubtedly aims to increase patient safety and protect the legal interests of life, body and health.<sup>706</sup>

Once an obligation to abstract treatment monitoring, and thus CRM, is justified through comparison to the abstract product monitoring obligations recognized in product liability, the obligations to CRM set forth in social law form a legal basis for tort liability under BGB § 823(1), because “solutions to problems under social law cannot be irrelevant to liability law.”<sup>707</sup>

A separate basis for liability for negligent CRM in the German Civil Code is provided by BGB § 823(2), which imposes liability for the violation of a statute, “intended to protect another person.”<sup>708</sup> Following the PRG, passed with the express purpose of improving patients’ rights *and safety*, it is difficult to dispute that the legal obligation to quality management articulated in the social law are intended to protect patients.<sup>709</sup> Goldbach rejects the argument that sanctions for a violation of legally required quality management, which, as discussed above, includes CRM, are limited to those imposed by the G-BA pursuant to §137 I 2 SGB V for two reasons.<sup>710</sup> First, the sanctions do not provide a remedy for individual damages caused by failure to comply with the existing quality assurance regulations, leaving a need for individual patient protection in the general liability law.<sup>711</sup> Second, there is no indication that the legislature sought to restrict remedies for individual damages caused by violation of the quality management regulations.<sup>712</sup> As a result, liability for negligent CRM can also accrue under protective law according to § 823(2), though such a claim is ultimately judged under the same standard of reasonable care as a cause of action for general negligence under § 823(1).<sup>713</sup>

### **5.1.2.2 Legal Basis for a Duty to Conduct Clinical Risk Management in American Medical Liability Law**

The legal discussion surrounding the existence of liability for negligent CRM in German tort law through a combination of organizational and product liability law leads to a similar analysis and conclusion that there is a duty to conduct CRM in American tort law for the same reasons. Additionally, while the U.S. does not separate general negligence and protective law theories of tort liability, protective statutes do play an important role in determining liability under American tort law in that, “the violation of a statute or ordinance prescribing a duty for the protection and safety of persons or property is generally treated as evidence of negligence.”<sup>714</sup> As such, the legal basis for finding a duty to conduct CRM in American tort law is predicated

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<sup>706</sup> Pauli, *supra* note 57, at 233(translation from German).

<sup>707</sup> Goldbach, *supra* note 17, at 78(translation from German).

<sup>708</sup> BGB § 823(2).

<sup>709</sup> Goldbach, *supra* note 17, at 111.

<sup>710</sup> *Id.* at 112-115.

<sup>711</sup> *Id.* at 115.

<sup>712</sup> *Id.* at 113.

<sup>713</sup> *Id.* at 116.

<sup>714</sup> 65 C.J.S. Negligence § 135.

on the following: (1) the existence of laws and regulations that impose risk management obligations for the protection of patients, and (2) liability for negligent CRM as a logical extension of organizational liability by relying on tort liability for a breach of similar duties already recognized in product liability law.

While healthcare quality assurance laws and regulations are not as centralized in the U.S. as they are in Germany, there are some federal laws and regulations that address healthcare quality. First, the Centers for Medicare and Medicaid (CMS), the agency authorized to establish standards for Medicaid and Medicare providers, requires participating hospitals to establish a quality management program, designed to, “improve health outcomes and identify and reduce medical errors” and “measure, analyze, and track quality indicators.”<sup>715</sup> Second, the Affordable Care Act seeks to improve healthcare quality through value-based healthcare purchasing programs that consider quality of care, mandatory physician reporting of quality measures, and publication of quality reports.<sup>716</sup> Third, the Patient Safety and Quality Improvement Act offers legal protection for data and records, “assembled or developed by a provider for reporting to a PSO.”<sup>717</sup> In terms of national uniformity, the Joint Commission, a private accreditation organization for the healthcare industry,<sup>718</sup> includes an entire chapter dedicated to patient safety in its accreditation manual.<sup>719</sup> The chapter, “Patient Safety Systems,” is intended, “to provide health care organizations with a proactive approach to designing or redesigning a patient-centered system that aims to improve quality of care and patient safety, an approach that aligns with the Joint Commission’s mission and its standards.”<sup>720</sup> Finally, because the individual states primarily govern healthcare quality, general negligence, and medical liability, consideration of state statutes and regulations concerning duties to healthcare risk management is essential to establishing a legal duty to conduct CRM in tort law.

Ten U.S. jurisdictions have statutes that directly address healthcare risk management. Maryland, Massachusetts, and Alaska require implementation of hospital risk management systems as condition of licensure.<sup>721</sup> In Maryland, risk management encompasses “an internal staff committee structure to conduct ongoing review and evaluation of risk management activities, a formal written program for addressing patient complaints, a documented facility-

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<sup>715</sup> 42 C.F.R. § 482.21 (2019).

<sup>716</sup> Lora A. Reineck & Jeremy M Kahn, *Quality measurement in the Affordable Care Act: a reaffirmed commitment to value in health care*, 187(10) Am. J. Respir. Crit. Care Med. 1038 (2013), available at [https://www.atsjournals.org/doi/10.1164/rccm.201302-0404ED?url\\_ver=Z39.88-2003&rfr\\_id=ori%3Arid%3Aacrossref.org&rfr\\_dat=cr\\_pub++0pubmed&](https://www.atsjournals.org/doi/10.1164/rccm.201302-0404ED?url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Aacrossref.org&rfr_dat=cr_pub++0pubmed&).

<sup>717</sup> 42 U.S.C. § 299b-22 (2005).

<sup>718</sup> Although Joint Commission accreditation is not mandatory, most internships and residency programs as well as federal support through Medicaid and Medicare require accreditation. See Kearney & McCord, *supra* note 183.

<sup>719</sup> The Joint Comm’n, *supra* note 203.

<sup>720</sup> *Id.*

<sup>721</sup> Md. Code Ann., Health-Gen. § 19-319 (West); Mass. Gen. Laws Ann. ch. 111, § 203 (West); Alaska Stat. Ann. § 18.20.075 (West).

wide risk reporting system, and ongoing risk management education programs for all staff.”<sup>722</sup> Massachusetts mandates participation in the State Board of Registration in Medicine’s risk management and quality assurance programs with an exception for hospitals who “participate in pre-existing risk management programs.”<sup>723</sup> Alaska’s statute requires adoption of a risk management program that “investigate[s] the frequency and causes of incidents in hospitals that cause injury to patients; develop[s] and implement[s] measures to minimize risk of injury to patients; [and] analyze[s] patient grievances relating to patient care.”<sup>724</sup>

Florida, Kansas, North Carolina, and Rhode Island impose statutory requirements for healthcare organizations to conduct risk management. Notably, Florida directly imposes a legal duty to manage healthcare risks, the breach of which can lead to liability.<sup>725</sup> Florida’s statutes generally require identification and analysis of adverse events and development of measures to prevent the same.<sup>726</sup> Under Florida law, preventive measures should include:

- (a) educating and training nonphysician personnel, (b) prohibiting staff members from attending to a patient in the recovery room unless authorized (except in emergencies or while under electronic/live surveillance), (c) prohibiting an unlicensed person from assisting or participating in any surgical procedures unless authorized or under immediate supervision of a licensed physician, (d) developing and implementing evaluation of procedures to accurately identify patients, planned procedures, and the correct site of the planned procedures.<sup>727</sup>

Kansas focuses its risk management statutes on the management of “reportable incidents,” which are defined as “an act by a health care provider that: (1) [i]s or may be below the applicable standard of care and has a reasonable probability of causing injury to a patient; or (2) may be grounds for disciplinary action by the appropriate licensing agency.”<sup>728</sup> Kansas law requires “medical care facilit[ies]” to maintain an “internal risk management program” consisting of reporting, investigation, and analysis of “reportable incidents” and the development of “measures to minimize reportable incidents.”<sup>729</sup> North Carolina requires hospitals “to develop a risk management program to identify, evaluate, and manage risks of injury to patients through loss reduction, prevention techniques, and quality assurance activities.”<sup>730</sup> Rhode Island requires hospitals and their insurance carriers to jointly establish a

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<sup>722</sup> Md. Code Ann., Health-Gen. § 19-319 (West).

<sup>723</sup> Mass. Gen. Laws Ann. ch. 111, § 203 (West).

<sup>724</sup> Alaska Stat. Ann. § 18.20.075 (West).

<sup>725</sup> Fla. Stat. Ann. § 766.110 (West).

<sup>726</sup> Fla. Stat. Ann. § 395.0197 (West).

<sup>727</sup> *Id.*

<sup>728</sup> Kan. Stat. Ann. § 65-4921 (West).

<sup>729</sup> Kan. Stat. Ann. § 65-4922 (West).

<sup>730</sup> N.C. Gen. Stat. Ann. § 131E-96 (West).

risk management program that includes an internal complaint system, collection of data relating to quality of care data and costs, medical assessment of quality of care, and education for hospital staff.<sup>731</sup>

California and Michigan delegate risk management duties to hospital administrators. In California, hospitals must appoint a Director of Risk Management to “implement processes, tools, and systems to identify, assess, measure, and monitor risks.”<sup>732</sup> Michigan law tasks hospital owners, operators, and governing bodies with organizing medical staff to review the quality and necessity of care provided for the purpose of reducing morbidity and mortality.<sup>733</sup>

New York encourages risk management in hospitals by providing grants to hospitals that integrate medical and risk management functions “to establish quality improvement activities which will enhance all institutional processes, including clinical, managerial and support functions; support integration of management information systems to improve health care delivery; and develop an educational program on continuous quality improvement to inform staff of the institution's mission and plan for quality.”<sup>734</sup>

Finally, although not specifically designated as a risk management process, most states have medical error reporting systems.<sup>735</sup> Of these, West Virginia, Georgia, and Oregon have adopted voluntary adverse event reporting systems,<sup>736</sup> which, according to the IOM and WHO, are valuable tools for identifying latent failures and enabling systemic learning,<sup>737</sup> key components of CRM. Although duties and obligations for healthcare organizations to implement risk management systems are spread out between federal, state, and industry law, regulations, and guidelines, together they provide strong support for finding that healthcare organizations have legal duty to conduct CRM, noting that at least one state already explicitly acknowledges a legal duty to conduct risk management.

Additionally, as in Germany, existing duties in product liability law further support expanding current theories of organizational liability in medical negligence law to include liability for negligent CRM. Although, an abstract duty to monitor products for safety is not the general rule (as in Germany), similar abstract duties exist in the form of pre-market testing for all manufacturers and post-market monitoring for drug and medical device manufacturers. Regarding pre-market testing, manufacturers must perform reasonable testing to discover risks as well as undertake responsive “risk-avoidance measures.”<sup>738</sup> Additionally, drug and medical

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<sup>731</sup> R.I. Gen. Laws Ann. § 23-17-24 (West).

<sup>732</sup> Cal. Health & Safety Code § 50912.5 (West).

<sup>733</sup> Mich. Comp. Laws Ann. § 333.21513 (West).

<sup>734</sup> N.Y. Pub. Health Law § 2807-i (McKinney).

<sup>735</sup> Duffoure, *supra* note 10, at 592.

<sup>736</sup> *Id.*

<sup>737</sup> IOM, *supra* note 2, at 89-90 (recommending voluntary reporting systems to improve patient safety); WAPS, *supra* note 114 (recommending error reporting systems to improve safety).

<sup>738</sup> Restatement (Third) of Torts: Prod. Liab. § 2 comment m (Am. Law Inst. 1998).

device manufacturers have post-market duties to monitor product safety.<sup>739</sup> Federal district courts in New York describe a drug manufacturer’s continuous duty to monitor as two-fold, requiring “the manufacturer to keep abreast of the current state of knowledge of its products as gained through research, adverse reaction reports, scientific literature, and other available methods, and to take reasonably necessary steps to bring that knowledge to the attention of the medical profession.”<sup>740</sup>

Additionally, a violation of the Federal Drug Administration’s continuing reporting requirements, which require medical device manufacturers to both monitor and report adverse health consequences, can form the basis of a product liability claim under either state or federal tort law.<sup>741</sup> Similarly, a federal district court in Pennsylvania explicitly recognized a legally cognizable claim against a drug company for negligent risk management under state law based on an allegation that, “Bayer is liable for breaching a “duty to have in place a reasonable risk management procedure” that ensured that non-conforming products (a female birth control device which did not work as intended) could be tracked appropriately, and that adverse reports were considered in its risk analysis.”<sup>742</sup>

In sum, as in Germany, the existing legal obligations to conduct risk management activities as well as the imposition of liability for the breach of similar risk management obligations under product liability law support expanding organizational negligence in medical liability law to encompass a legal duty to CRM.

## 5.2 Legal Standards of Care for Clinical Risk Management

Once a healthcare organization is legally obliged to conduct CRM and thus can be liable for negligent CRM in tort law, the question remains: what are the standards of care that govern this obligation? The healthcare industry is seeing an explosion of internal and external regulations and policies governing CRM, all of which create new potential standards of care for healthcare organizations.<sup>743</sup> Although legal, regulatory, and institutional standards should

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<sup>739</sup> 157 Am. Jur. Trials 91 *Litigation of Continuing or Post-Sale Duty to Warn, Retrofit, or Recall in Products Liability Actions* §5 Westlaw (database updated Dec. 2021).

<sup>740</sup> *Id.* (citing *Rosen v. St. Jude Med., Inc.*, 41 F. Supp. 3d 170, 184 (N.D.N.Y. 2014)); *Baker v. St. Agnes Hosp.*, 70 A.D.2d 400 (N.Y. App. Div. 2d Dept. 1979).

<sup>741</sup> *McConologue v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 93, 108 (D. Conn. 2014) (citing *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 776 (5th Cir. 2011); *Gale v. Steinberg*, 989 F.Supp.2d 243 (S.D.N.Y. 2013); *Simmons v. Boston Scientific Corp.*, CV 12–7962 PA FFMX, 2013 WL 1207421 (C.D.Cal. 2013)).

<sup>742</sup> *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 820 (E.D. Pa. 2016) (ultimately finding that the plaintiff failed to prove causation and therefore could not sustain a claim for negligent risk management).

<sup>743</sup> Mitchell J. Weit, *Darling v. Charleston Community Memorial Hospital and Its Legacy*, 14 Annals Health L. 399, 401 (2005) (noting that in the United States, courts have been able to rely upon a “virtually limitless evidentiary base” of regulations for finding direct negligence against the hospital); see Goldbach, *supra* note 17 (noting that the law “does not distinguish between . . . a standard of



reflect the industry's best practices and provide flexibility, holding healthcare organizations to such vast and vague standards of care in court may jeopardize the very safety culture that new risk management standards are meant to create. According to Shuman, “[b]ecause of the importance of certainty in deterrence theory, tort law should articulate a clear, understandable standard of behavior that is communicated to decision makers who can then modify their behavior to avoid the tort sanctions that would otherwise accrue.”<sup>744</sup> Goldbach agrees that “it is incumbent on the judiciary to review the behavioural requirements established in fact for their normative suitability and, if necessary, to concretize them through judicial law.”<sup>745</sup>

Generally, healthcare industry standards for preventing injuries through CRM will be similar in the U.S. and Germany because they are derived from internationally accepted concepts in medical and error prevention science.<sup>746</sup> German legal scholars, drawing from these concepts, have suggested that the jurisprudential development of legal standards of care for CRM be organized in accordance with the core CRM process.<sup>747</sup> Pursuant to this process, CRM occurs in four phases: (1) risk identification, (2) risk analysis, (3) risk assessment, and (4) risk control.<sup>748</sup> All stages of CRM require the hospital to employ adequate personnel and resources to carry out the iterative CRM process.<sup>749</sup> This includes retention of risk management specialists, who ensure the proper functioning and continued development of the CRM process, as well as provision of physical and technical components needed for the CRM process to function.<sup>750</sup>

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treatment and an organizational standard,” and to date, there is no “uniform criteria” to guide the judicial development of organizational standards of care).

<sup>744</sup> Shuman, *supra* note 246, at 123.

<sup>745</sup> Goldbach, *supra* note 17, at 63(translation from German).

<sup>746</sup> *See id.* at 60-62 (acknowledging acceptance of RM as an essential component of healthcare by all stakeholders in the German healthcare industry). *See* NEJM Catalyst, *What Is Risk Management in Healthcare?*, [catalyst.nejm.org](https://catalyst.nejm.org) (Apr. 25, 2018), <https://catalyst.nejm.org/doi/full/10.1056/CAT.18.0197> (acceptance of proactive risk management in the US healthcare industry).

<sup>747</sup> *See generally* Pauli, *supra* note 57; Goldbach, *supra* note 17; Hart, *supra* note 68.

<sup>748</sup> Pauli, *supra* note 57, at 241. *See also* APS, Requirements on Clinical Risk Management Systems in Hospitals (Feb. 2017), *available at* <https://www.aps-ev.de/hempfehlungen/requirements-on-clinical-risk-management-systems-in-hospitals/>; *see* International Organization for Standardization [ISO], *ISO 31000:2018: Risk Management*, ISBN 978-92-67-10784-4 (2018) (the risk management process includes identifying, analyzing, evaluating, and where required, treating risks).

<sup>749</sup> *See* APS, *supra* note 748; NEJM Catalyst, *supra* note 746 (describing the various components required for risk management in healthcare).

<sup>750</sup> Pauli, *supra* note 57, at 242-44 (comparing risk management to a medical specialty, which requires continuous training to remain up-to-date with current medical standards). *See* NEJM Catalyst, *supra* note 746 (describing the various components required for risk management in healthcare).

### 5.2.1 Risk Identification

Identifying the existence of risks that can lead to patient injuries is the first step in the CRM process. According to Pauli, the hospital must organize the treatment process to incorporate methods of collecting information that can identify potential risks to patient safety.<sup>751</sup> Goldbach agrees that healthcare organizations are legally required to “do everything reasonable to ensure that the greatest possible information is obtained about possible risks of damage.”<sup>752</sup> Sources of risk information can include internal sources like patient complaint systems, error reporting systems, and claims information, as well as external sources that discuss near-misses, errors, claims, and medical liability judgments occurring outside of the hospital.<sup>753</sup> Although the size and scope of tools used to collect information about organizational risks may vary with the healthcare organization, the obligation to conduct CRM should require hospitals take an active role in collecting risk-identifying information. In addition to collecting risk information, the standard of care for risk identification includes a “continuous duty to ensure up-to-date sources of information and effectiveness of current information sources.”<sup>754</sup>

In Germany, Goldbach opines that the implementation of internal patient complaint and error-reporting systems already required by federal regulations, as well as participation in and monitoring alerts from external reporting systems are required to satisfy a legal duty to risk management.<sup>755</sup> Goldbach notes that although more than 95% of German hospitals have patient complaint systems, risk management requires incorporation of patient complaint systems into the risk identification phase of CRM.<sup>756</sup> Regarding internal error-reporting, implementation of Germany’s anonymous CIRS system, “represent[s] the standard of good organization in the hospital.”<sup>757</sup> Regarding participation in external error-reporting, Goldbach opines that some level of participation in freely accessible external supra-regional reporting systems, like Krankenhaus-CIRS-Netz-D, should be required under the legal standard of care.<sup>758</sup> This includes “systematic observation and analysis of at least the most significant cases.”<sup>759</sup>

In the U.S., the lack of centralized regulations concerning complaint and error reporting systems highlights the need for a uniform legal standard of care for risk identification under a duty to conduct CRM. As in Germany, U.S. healthcare organizations should, at a minimum, implement and integrate internal patient complaint and error reporting systems into the CRM process as well as monitor risk information from external sources. To accomplish the error

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<sup>751</sup> Pauli, *supra* note 57, at 242.

<sup>752</sup> Goldbach, *supra* note 17, at 82-91(translation from German).

<sup>753</sup> Pauli, *supra* note 57, at 242. *See* NEJM Catalyst, *supra* note 746 (describing the need to identify risks using data, institutional and industry knowledge and engaging all actors in the healthcare system).

<sup>754</sup> Pauli, *supra* note 57, at 243.

<sup>755</sup> Goldbach, *supra* note 17, at 82-91.

<sup>756</sup> *Id.* at 83.

<sup>757</sup> *Id.* at 88(translation from German).

<sup>758</sup> *Id.* at 91.

<sup>759</sup> *Id.* (translation from German).

prevention goals of CRM, internal error reporting systems, like Germany’s CIRS, should focus on near-misses and be voluntary, anonymous, and sanction-free.<sup>760</sup> Examples of external risk information sources in the U.S include reports and recommendations from the AHRQ’s Patient Safety Network Web Morbidity and Mortality (WebM&M) program<sup>761</sup> and risk reduction information gleaned from The Joint Commission’s Sentinel Event Policy.<sup>762</sup>

### 5.2.2 Risk Analysis

At the risk analysis stage, risk management specialists analyze information from risk identification sources to determine the causes and effects of and relationships between identified risks.<sup>763</sup> Implementing systems designed to identify patient safety risks is pointless if the risk information collected from those systems does not become a catalyst for minimizing or preventing potential harm. As Goldbach points out, “the hospital operator is also obligated to respond to the risk information obtained by doing everything reasonable to eliminate avoidable hazards.”<sup>764</sup> This includes the provision of adequate personnel, technology, equipment, and procedures for carrying out risk analysis.<sup>765</sup> To properly conduct CRM at the risk analysis stage, healthcare organizations can meet the standard of care for analyzing risks using one or more accepted methods for risk analysis in healthcare including, but not limited to: root cause analysis (RCA); failure modes effect analysis (FMEA); fault tree analysis (FTA); Blunt End/Sharp End Evaluation; and Ishikawa diagramming.<sup>766</sup> Regardless of the chosen method, the hospital should maintain clear policies and procedures for carrying out risk analysis using its chosen methods as well as records showing that risk analysis is a continuous functioning process as evidence of compliance with the standard of care for CRM.

### 5.2.3 Risk Assessment

Once risks are identified and analysed, they must be assessed to determine the likelihood and degree of severity of potential harm posed by each risk.<sup>767</sup> Proper assessment of risks allows the healthcare organization to prioritize risks so that they can be managed accordingly in the

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<sup>760</sup> See Duffourc, *supra* note 10 (explaining why the US should adopt Germany’s internal error reporting systems); see also IOM, *supra* note 2, at 89-90 (recommending voluntary reporting systems to improve patient safety); WAPS, *supra* note 114 (recommending error reporting systems to improve safety).

<sup>761</sup> AHRQ, *Patient Safety Network: Submit a Case to WebM&M*, <http://psnet.ahrq.gov/webmm/submit-case> (last visited Jan. 5, 2022).

<sup>762</sup> The Joint Comm’n., *Sentinel Event Policy and Procedures*, [https://www.jointcommission.org/sentinel\\_event\\_policy\\_and\\_procedures/](https://www.jointcommission.org/sentinel_event_policy_and_procedures/) (last visited Jan. 2, 2022).

<sup>763</sup> Pauli, *supra* note 57, at 247; APS, *supra* note 748.

<sup>764</sup> Goldbach, *supra* note 17, at 91 (translation from German).

<sup>765</sup> Pauli, *supra* note 57, at 247.

<sup>766</sup> See Pauli, *supra* note 57, at 247-48 (identifying RCA, Ishikawa diagram, FTA as acceptable methods of risk analysis); NEJM Catalyst, *supra* note 746 (identifying Blunt End/Sharp End Evaluation, RCA, and MFEA as acceptable methods of risk analysis).

<sup>767</sup> Pauli, *supra* note 57, at 248; APS, *supra* note 748.

risk control phase of the CRM process.<sup>768</sup> As with risk analysis, healthcare organizations are free to choose a method of risk assessment, which can include one or more of the following: risk matrix or map method; Fuzzy Analytic Hierarchy Process; Sequential Updating Approach; and Pareto Analysis.<sup>769</sup> Again, as with risk analysis, regardless of the risk assessment method chosen, healthcare organizations must implement and maintain a functioning risk assessment strategy to comply with the standard of care for CRM.

#### 5.2.4 Risk Control

Risk control involves the development of measures that eliminate or minimize identified, analyzed, and assessed risks.<sup>770</sup> In this phase of risk management, healthcare organizations are “obligated to respond to the risk information obtained by doing everything reasonable to eliminate avoidable hazards.”<sup>771</sup> Depending on the type and severity of the risk, risk control can manifest in a variety of ways including risk avoidance by eliminating the risk-producing activity, risk reduction through preventive measures, risk reduction through transferring the risk, and /or risk acceptance with or without additional supervision.<sup>772</sup> According to Pauli, the standard of care as it relates to the risk control process allows healthcare organizations to consider the financial and time expenditures involved with risk control measures that equally maximize patient safety to determine which measure to employ.<sup>773</sup>

The specific risk control measures required vary widely and can include, but are not limited to: changes to the physical treatment environment (i.e. lighting, placement of equipment); staffing protocols (i.e. scheduling, training, supervision); guidelines (i.e. checklists, instructions); changes in equipment and apparatus (i.e. medical device repairs, provision of surgical instruments); and improved communication (continuity of care guidelines, protocols for patient communication).<sup>774</sup> As discussed above in Section I.A., although the process of deriving risk control measures through a more comprehensive CRM process is not explicitly recognized as an organizational duty, the failure to implement specific risk control measures can already constitute organizational liability under the existing case law. As such, jurisprudential precedents already exist in both jurisdictions to guide a determination of whether implementation of or failure to implement a specific risk control measure falls below the standard of care.

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<sup>768</sup> Giacomo Pascarella et al., *Risk Analysis in Healthcare Organizations: Methodological Framework and Critical Variables*, 14 Risk management and healthcare policy, 2897 (2021), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8275831/>.

<sup>769</sup> Pauli, *supra* note 57, at 248; Pascarella et al., *id.*

<sup>770</sup> Pauli, *supra* note 57, at 248.

<sup>771</sup> Goldbach, *supra* note 17, at 91(translation from German).

<sup>772</sup> APS, *supra* note 748.

<sup>773</sup> Pauli, *supra* note 57, at 249.

<sup>774</sup> See Hart, *supra* note 683.

Risk control does not end however upon selection and implementation of a specific risk control measure. Instead, once risk control measures are identified and implemented, they must be properly communicated to necessary personnel and their effectiveness monitored and evaluated.<sup>775</sup> According to Pauli, “[r]isk communication means providing the right information and evaluations to the right recipients at the right time and in the right way.”<sup>776</sup> Proper communication ensures that predicted damage from identified risks is prevented or minimized within a reasonable time.<sup>777</sup> To meet the standard of proper risk communication, healthcare organizations must identify the proper means and modes of communication, which, depending on the nature of the risk, can range from communication via email, to alerts on an intranet, to discussion at employee meetings, to publication in a staff newsletter.<sup>778</sup> Once properly implemented and communicated, specific risk control measures must be monitored and evaluated to determine compliance, effectiveness, and sustainability.<sup>779</sup> Risk monitoring and evaluation can lead to further duties to re-analyze and re-assess identified risks and to reconsider risk control measures.<sup>780</sup> Like all other stages of the risk management process, proper documentation of actions taken during the risk control phase is crucial to showing compliance with the standard of care. As Pauli points out, “[i]n the event of liability, proper documentation can make it easier for the hospital operator to prove that it has done what was necessary and reasonable to avoid the risk.”<sup>781</sup>

### 5.3 Legal Rules Governing Proof of Negligent Clinical Risk Management

In addition to identifying a framework for developing legal standards of care, a cause of action for negligent CRM also requires the development of proof rules that balance the plaintiff’s ability to recover damages caused by negligent CRM with the defendant’s ability to implement and maintain a patient safety culture that enables successful CRM.

Safety culture is central to the success of a CRM system. The APS describes safety culture in the CRM process as “the manner in which safety is organised in the context of patient care and thus reflects the attitudes, convictions, perceptions, values and conduct of management and other staff with respect to the safety of patients, staff and the organisation itself.”<sup>782</sup> The Joint Commission similarly defines safety culture as, “the product of individual and group beliefs, values, attitudes, perceptions, competencies, and patterns of behavior that determine the

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<sup>775</sup>Pauli, *supra* note 57, at 249-250. Risk evaluation, risk monitoring, and risk communication are sometimes listed as separate phases of clinical risk management. *See* APS, *supra* note 748 (listing risk evaluation as a separate phase of clinical risk management).

<sup>776</sup> Pauli, *supra* note 57, at 249 (translation from German).

<sup>777</sup> *Id.*

<sup>778</sup> *Id.* at 250.

<sup>779</sup> *Id.*

<sup>780</sup> *Id.*

<sup>781</sup> *Id.* (translation from German).

<sup>782</sup> APS, *supra* note 748.

organization's commitment to quality and patient safety."<sup>783</sup> The successful development of safety culture in healthcare organizations requires a delicate balance of confidentiality and accountability.<sup>784</sup> On one hand, healthcare providers should be "afforded a certain level of confidentiality necessary to promote open discussion of medical errors."<sup>785</sup> On the other hand, patients should be able to hold healthcare providers accountable for damages caused by negligent CRM.<sup>786</sup> To support the development and maintenance of safety culture, a legal cause of action against healthcare organizations for negligent CRM should aim to strike a balance between providing confidentiality for some CRM activities through evidentiary protections while also giving patients a viable path to recovering damages caused by negligent CRM through burden-shifting mechanisms.

### 5.3.1 Evidentiary Protections

Evidentiary protections that maintain confidentiality of voluntary error reporting systems used in the risk identification phase of CRM are necessary to safeguard safety culture. The Joint Commission describes non-punitive error reporting and learning as "absolutely crucial" to safety culture. Germany too has embraced sanction-free error reporting as an indispensable element of a "trustworthy learning and safety culture."<sup>787</sup> The WHO also agrees that implementation of non-punitive error reporting and learning systems are necessary to detect, and ultimately prevent, systemic errors.<sup>788</sup> To ensure that participation in voluntary error reporting systems are non-punitive and sanction-free, error reports made within these systems should not lead to liability for individual healthcare providers who either report or are implicated in reports. As such, voluntary error reports made during the risk identification phase should neither be discoverable nor admissible as evidence in claims against healthcare organizations for negligent CRM.<sup>789</sup>

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<sup>783</sup> The Joint Comm'n., *The essential role of leadership in developing a safety culture*, 57 *Sentinel Event Alert* 1 (2017, revised June 18, 2021), *available at* [https://www.jointcommission.org/assets/1/18/SEA\\_57\\_Safety\\_Culture\\_Leadership\\_0317.pdf](https://www.jointcommission.org/assets/1/18/SEA_57_Safety_Culture_Leadership_0317.pdf)

<sup>784</sup> Duffourc, *supra* note 10.

<sup>785</sup> *Id.*

<sup>786</sup> *Id.*

<sup>787</sup> See Sonja Barth, *Aus Fehlern lernen –Schwachstellen im System rechtzeitig erkennen [Learn from errors - Identifying weaknesses in the system at an early stage]* I *Berliner Ärzte*, 14 (2009) (F.R.G.); Jonitz & Barth, *supra* note 161(translation from German).

<sup>788</sup> WAPS, *supra* note 120.

<sup>789</sup> See IOM, *supra* note 2, at 102; Robert L. Phillips et al., *The AAFP Patient Safety Reporting System: Development and Legal Issues Pertinent to Medical Error Tracking and Analysis*, in *Advances in Patient Safety: From Research to Implementation (Volume 3: Implementation Issues)* 121 (Henriksen K, Battles JB, Marks ES, et al., eds. 2005), *available at* <https://www.ncbi.nlm.nih.gov/books/NBK20535/> ("Leaders of the patient safety movement agree that voluntary reporting systems can measurably improve safety if reporting is protected against discovery and provides reporters with useful information from expert analysis.").

Both jurisdictions have made some efforts toward providing legal protection for voluntary error reports, but neither has offered a comprehensive privilege sufficient to ensure the requisite sanction freedom. Pursuant to the PRG in Germany, data from voluntary error reporting systems cannot be used against the reporter in legal proceedings.<sup>790</sup> While this legal protection is primarily aimed at protecting whistleblowers and not individual healthcare providers more broadly, data from Germany's CIRS system has thus far not been used against healthcare providers in medical malpractice litigation, leaving the question of admissibility of CIRS data in civil litigation unanswered in the case law.<sup>791</sup> Regardless of how German courts resolve the question of admissibility, anonymization of CIRS data and Germany's conservative discovery rules are likely to prevent voluntary error reports from being used as evidence against healthcare providers.<sup>792</sup> In the U.S., peer-review and PSWP discovery privileges, as discussed in Chapter 4, provide some protection for data in voluntary error reporting systems, but the case law applying these privileges to voluntary medical error reports is inconsistent.<sup>793</sup> Additionally, liberal discovery practices in the U.S. threaten the confidentiality of voluntary error reports, and therefore, also threaten the establishment of safety culture required for successful CRM.<sup>794</sup> To date, both jurisdictions are still lacking clear and comprehensive evidentiary protections for voluntary error reports used for risk identification in the CRM process. As such, liability for negligent CRM should also incorporate legal rules excluding data relating to individual voluntary error reports from discovery and evidence in negligent CRM claims.

To ensure access to evidence regarding the reasonableness of an organization's CRM activities in civil litigation, there must be limits to the confidentiality provided by evidentiary protections for the sake of transparency and accountability. To accomplish this goal, documents that relate to the existence of an error-reporting system, including guidelines and protocols for implementation and maintenance of the system, statistics regarding the number and types of reported errors, and documents that show a final organizational response to reported errors through the risk control process should be discoverable. While voluntary error reports

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<sup>790</sup> SGB V §135a(3) (providing that data from error reporting systems cannot be used against the reporter in legal proceedings, except under exceptional circumstances when needed to prosecute a criminal offense of maximum five years imprisonment).

<sup>791</sup> See BTDrucks 18/10203, at 4-5, available at <http://dip21.bundestag.de/dip21/btd/18/102/1810203.pdf> (discussing legal protections for whistleblowers). Cf. Pauli, *supra* note 57, at 279-281 (opining that a patient has no right of access to the documentation or data from clinical risk management and hospital-internal CIRS systems); but cf. Thüß, *supra* note 673, at 154 (arguing that the circumstances under which CIRS reports can be used in civil litigation are unclear).

<sup>792</sup> Duffourc, *supra* note 10 ("Germany's conservative discovery and evidentiary rules make it unlikely that a litigant could obtain CIRS data").

<sup>793</sup> See Cynthia J. Dollar, *Promoting Better Healthcare: Policy Arguments for Concurrent Quality Assurance and Attorney-Client Hospital Incident Report Privileges*, 3 Health Matrix 259 (1993).

<sup>794</sup> See Duffourc, *supra* note 10 ("broad discovery practices in medical malpractice litigation threaten the anonymity and confidentiality requisite for the successful operation of error reporting and learning systems.").

identifying and discussing individual events as well as the analysis and assessment of those individual events should be protected from discovery, general information about compliance with CRM standards is required to hold organizations accountable for negligent CRM, or as Pauli points out, exonerate organizations who meet the CRM standards of care.<sup>795</sup>

Still, information and documents regarding the general operation and maintenance of CRM should only be admissible to prove claims of organizational negligence, including negligent CRM, against the healthcare organization but not admissible to prove claims of medical negligence against individual healthcare providers. As Goldbach points out, “the organizational measures required by the RM do not interfere with individual medical treatment, but rather set an external framework with general requirements without affecting medical treatment decisions.”<sup>796</sup> For a legal duty to conduct CRM to incentivize organizational improvements, courts who recognize a liability for negligent CRM must resist the common urge to associate medical damages with “bad doctors” and “bad nurses” and remain focused on evidence relating to the organization’s CRM activities. Carefully developed evidentiary rules can help maintain this organizational focus.

### 5.3.2 Burden-Shifting

Proving organizational negligence based on a failure to conduct CRM is difficult for several reasons. First, because patients’ primary contact with the healthcare system is an individual provider, they generally “equate[] medical errors with a personal failure on the part of the physician” leaving them unaware of possible negligent organizational behaviour.<sup>797</sup> Second, even if they suspect an organizational error, patients neither have insight into the inner workings of the healthcare organization nor are they expected to be experts on the process of CRM.<sup>798</sup> Third, the evidentiary protections recommended in Section III.A impose limitations on a patient’s ability to obtain information and documents about the organization’s CRM process. As a result, for a claim of negligent CRM to function in practice, there must be an appropriate modification of the burden of proof rules.<sup>799</sup> Once again, German legal scholars have already discussed modifying the burden of proof in claims for negligent CRM, and this discussion can serve to inform jurisprudential rules in both jurisdictions. The German discussion of the burden of proof for claims of negligent CRM is grounded in the burden shifting mechanisms found in the PRG, which are discussed in detail in Chapter 4. Of course, American courts can impose similar burden-shifting rules or legal presumptions for claims of negligent CRM that make a cause of action for negligent CRM practically viable from a proof standpoint.

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<sup>795</sup> See Pauli, *supra* note 57, at 265-66.

<sup>796</sup> Goldbach, *supra* note 17, at 128 (translation from German).

<sup>797</sup> *Id.* at 129(translation from German).

<sup>798</sup> *Id.* at 94-96.

<sup>799</sup> See *id.* at 93-94 (noting that if plaintiffs cannot prove negligent risk management recognizing a duty to negligent risk management has no “practical relevance”).



### **5.3.2.1 The Burden of Proving a Breach of the Standard of Care for Clinical Risk Management**

In Germany, Goldbach opines that because the entire process of CRM is controlled by the healthcare organization, plaintiffs who claim negligent CRM are initially relieved from proving a breach of the standard of care under the law shifting the burden of proof for negligence in cases involving “fully controllable” risks.<sup>800</sup> However, in order to take advantage of the burden-shifting mechanism, a plaintiff should “first demonstrate that the risk actually originates from this fully controllable area” by providing some “evidence that suggests that a breach of the RM obligation is probable.”<sup>801</sup> According to Goldbach, the defendant can then rebut the presumption of negligence by showing that either (1) the injury that the plaintiff sustained could not have been prevented through risk management, or (2) reasonable risk management measures to prevent the injury were in place.<sup>802</sup>

In the U.S., shifting the burden of proving a breach of the standard of care in negligent CRM actions could similarly manifest as follows. First, the plaintiff would be required to make a prima facie case of negligence by putting forth some evidence that (1) they sustained an injury that (2) was within the scope of risks that could be controlled by proper CRM. Upon making a prima facie case, a rebuttable legal presumption of negligence would arise. Second, the defendant could rebut this presumption of negligence by producing evidence that the kind of risk that materialized to cause the plaintiff’s injury is outside of the scope of risks prevented by compliance with CRM and/or that it reasonably complied with CRM standards of care to prevent the risk that allegedly led to the plaintiff’s injury. In other words, there is no liability for risks that could not have been reasonably prevented through a functioning CRM system.

### **5.3.2.2 The Burden of Proving that a Breach of the Standard of Care for Clinical Risk Management Caused the Plaintiff’s Injury**

In Germany, the PRG codified the previous case law that shifted the burden of proof on causation for “gross errors.”<sup>803</sup> According to Goldbach, this burden-shifting mechanism would apply to causes of action for negligent CRM if, judged under the facts of the case, the degree of deviation from the organizational standard was objectively “so serious as to justify the application of the reversal of the burden of proof.”<sup>804</sup> For example, she opines that insufficient implementation of a CRM process might not be considered a gross error, while an absolute failure to analyze, assess, and control risks that were previously identified in the CRM process would be considered a gross error, thereby reversing the burden of proof on causation.<sup>805</sup> She provides a caveat that “the risk whose non-observance makes the breach of duty appear gross

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<sup>800</sup> *Id.* at 96; BGB § 630h(1).

<sup>801</sup> Goldbach, *supra* note 17, at 97(translation from German).

<sup>802</sup> *Id.* at 97-98.

<sup>803</sup> BGB § 630h(5).

<sup>804</sup> Goldbach, *supra* note 17, at 99(translation from German).

<sup>805</sup> *Id.* at 99-100.

would also have to have materialized” making the damage foreseeable.<sup>806</sup> Such would be the case in a situation in which several near-miss errors concerning the administration of medication that did not lead to patient damage were reported to the healthcare organization in the risk identification phase, and because the hospital did nothing to subsequently analyze, assess, and control the risk, the plaintiff suffered damages from a same or similar medication administration error.

The concept of gross negligence is recognized in American tort law as “an act or omission involving subjective awareness of an extreme degree of risk, indicating conscious indifference to the rights, safety, or welfare of others.”<sup>807</sup> While there are legal consequences for tortfeasors who commit gross negligence,<sup>808</sup> they do not include reversing the burden of proof on causation for tort law causes of action. However, Germany’s approach to shifting the burden of proof on causation will likely prove essential to the development of a cause of action for negligent CRM in American medical negligence law. As such, American courts can, and should, develop a comparable burden-shifting framework either through (1) a complete shifting of the burden of proof on the element of causation in the case of gross negligence, thereby requiring the defendant to prove by a preponderance of the evidence that the plaintiff’s injury was not caused by the grossly negligent practice at issue, or (2) the application of a legal presumption, which can be rebutted using a relaxed standard of proof, whereby the defendant must produce some evidence (less than a preponderance) refuting causation to shift ultimate burden of proving causation back to the plaintiff.

## 5.4 Conclusion

Liability for negligent CRM is supported in both jurisdictions by the existing general tort law, including existing case law recognizing direct organizational liability for medical injuries and existing legal duties and obligations to risk management found in other legal and regulatory spheres. A duty or obligation to conduct CRM is further supported by existing legal duties and obligations imposed on products’ manufacturers to identify and control risks in product liability law in both jurisdictions. To achieve the dual goals of compensating plaintiffs for damages caused by negligent CRM and deterring future error-causing organizational behaviour, the framework for an emerging cause of action for negligent CRM must include: (1) predictable CRM standards of care that follow the generally accepted CRM process, and (2) legal proof rules that simultaneously provide the requisite level of confidentiality for successful CRM while also enabling patients to succeed on valid claims of negligent CRM.

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<sup>806</sup> *Id.* at 100.

<sup>807</sup> Am. Law Torts § 10:15, Westlaw (database updated Dec. 2021).

<sup>808</sup> *See Myers v. Lashley*, 44 P.3d 553 (Okla. 2002), *as amended*, (Mar. 20, 2002) (contributory negligence is not a defense against gross negligence); New York Medical Malpractice § 1:426, Westlaw (database updated Nov. 2021) (gross negligence in a malpractice action may support a claim for punitive damages in New York); *Cooper v. Rodriguez*, 118 A.3d 829 (Md. Ct. App. 2015) (finding that corrections officer was grossly negligent and, thus, was not entitled to immunity).

## 6. Conclusion

Modern medicine, which seeks to provide patients with scientifically reliable and therapeutically beneficial treatment, did not begin to develop until the late nineteenth century. As medical practice gained success and acceptance as a central societal institution, hospitals also transformed from houses for the sick and dying to institutions for teaching, research, and healing. Modern hospitals have considerable influence over how and where patients receive medical treatment. They also control the organization of the treatment process within the hospital and can directly affect the rate of medical errors through the process of CRM.

CRM is the branch of risk management that seeks to improve the quality and safety of patient care. It can reduce the risk of harm caused by medical errors by identifying, evaluating, and correcting deficiencies in the organizational processes that impact nearly every aspect of patient care in the hospital. Effective CRM turns a healthcare institution into a self-learning system that constantly improves the medical treatment process. A successful CRM strategy requires interdisciplinary collaboration that incorporates organizational science, medicine, and law. Central to this strategy is the creation of an organizational safety culture.

The idea that medical errors were primarily caused and could be better prevented by focusing on organizational culture rather than individual providers' actions was popularized by the IOM's 1999 report, *To Err Is Human: Building a Safer Health System*. In this report, the IOM relied on the organization and error research of sociologist, Charles Perrow, and psychologist, James Reason to explain that medical errors primarily occur in modern healthcare, a high-risk system, because of systemic, rather than individual provider, failures. It pointed to the prevailing "blame and shame" culture of healthcare, which focuses on punishing individual healthcare providers, as a barrier to systemic improvement and effective medical error reduction strategies. To reduce medical errors, the IOM recommended that healthcare organizations develop a safety culture to enable the identification and elimination of organizational defects.

The IOM's report attracted the attention of healthcare systems worldwide, which responded with efforts to decrease medical errors through organizational improvement. The WHO has since encouraged its members to collaborate to advance national and international patient safety efforts. Drawing from the IOM's report, the WHO focuses these efforts on systemic improvement and discourages individual blame. The WHO identified voluntary, anonymous, and sanction-free error reporting systems as a critical tool for organizational learning. The OECD also acknowledged the global cost of medical errors and urged healthcare systems to focus on prevention by creating a patient safety culture designed to expose and remedy systemic defects. In Europe, the European Union prioritized patient safety and initiated several international and national efforts to decrease medical errors, including recommendations designed to empower and inform patients, improve training and work conditions for healthcare workers, implement effective CRM strategies, facilitate error-reporting and learning, and

encourage international collaboration through research to develop systems-based patient safety strategies.

In Germany, patient safety was being tackled both as part of the EU's patient safety strategy and nationally. In 2001, the Federal Health Monitoring Report quantified the problem of medical errors in Germany and focused its preventive call to action on curing organizational deficits. Progress toward establishing patient safety culture in Germany to prevent medical errors continued in 2002 as the ÄZQ's newly established Patient Safety Expert Group sought to develop a common strategy for error reporting and analysis. In 2003, the German Advisory Council for Concerted Action in Healthcare's biannual report discussed the systemic causes of medical errors and encouraged systems-based solutions, including the use of error reporting and analysis. 2005 was a landmark year for patient safety in Germany. That year, the APS was founded to encourage an interdisciplinary "bottom up" practical approach to solving the problem of medical errors in Germany. Through the APS's efforts, German healthcare organizations began participating in international and national patient safety campaigns to reduce healthcare-related patient injuries. The year 2005 also saw the birth of Germany's CIRIS, a national anonymous error reporting and learning system designed to identify and correct organizational deficiencies. In 2009, APS established the IfPS, which conducts academic research surrounding the issue of patient safety and provides recommendations and training aimed at preventing medical errors. In 2013, Germany's PRG sought to both improve patient safety and strengthen patients' rights. The PRG mandated the implementation of risk and quality management as well as patient complaint and error-reporting systems in healthcare organizations, prompting a drastic increase in the uptake of error reporting as a preventive strategy in Germany's hospitals.

In the United States, Congress passed the Healthcare Research and Quality Act of 1999, which tasked a new agency, the AHRQ, with identifying and remedying causes of medical errors. The AHRQ funded projects designed to improve patient safety culture, reduce medical errors, and resolve medical malpractice claims out-of-court. In 2005, Congress passed the PSQIA to improve patient safety and the quality of healthcare. The PSQIA encouraged the development and use of PSOs that analyze organizational performance to improve patient safety. In the private sphere, shortly after the IOM's 1999 report, the Joint Commission, which accredits hospitals, also began to focus its regulatory efforts on patient safety and organizational performance. By 2008, the Joint Commission advocated for a "zero harm" strategy by using a systems approach to medical error prevention based on high reliability science. In 2015, Congress passed the PPACA, which prioritized quality of care in its new funding and payment systems. In 2015, the Joint Commission began including patient safety chapters in its accreditation manuals for hospitals and other healthcare organizations. These chapters are designed to provide organizations with a strategy for reaching the ultimate goal of "zero harm" through systems improvement, and particularly the implementation of "a fair and just safety culture."

While the IOM's report identified external factors, including the legal system, as affecting patient safety within healthcare organizations, it underestimated the ability of the medical

liability system to hinder the industry's patient safety efforts. While the legal system should encourage organizational investment in preventing medical errors through a systems approach by making errors "costly," a crucial question is: by whom is this cost being absorbed? Because both the American and German medical liability systems target primarily the actions of individual healthcare providers rather than organizations, there is a disconnect between the entities responsible for and capable of preventing medical errors through systems design (healthcare organizations) and the persons held legally responsible for medical errors (individual providers). For the medical liability system to support, rather than hinder, healthcare industry efforts to prevent medical errors through organizational improvement, it must provide a real threat of legal liability for healthcare organizations who fail to comply with modern CRM standards.

The U.S. and Germany both have negligence-based medical liability systems, despite operating within separate Common Law and Civil Law systems, respectively. Medical negligence law in both jurisdictions is primarily judge-made law, though Germany's PRG codified some of the existing medical malpractice case law. A second distinction for medical liability in the two jurisdictions is the primacy of tort law in the U.S. versus contract law in Germany. Nevertheless, both jurisdictions apply similar legal standards for deciding medical malpractice cases. This can be attributed broadly to pragmatist interactionism or more concretely to the fact that the principles of negligence govern both tortious and contractual causes of action for medical malpractice in both countries.

Negligence-based systems impose liability on actors who exhibit sub-standard conduct. As a result, the medical liability system in the U.S. and Germany seeks to both provide compensation for injuries caused by substandard conduct and deter actors from engaging in substandard conduct. In Germany, the compensatory role of the medical liability system for victims of medical errors takes a backseat to the compensation provided by Germany's strong social security system. In the United States, the compensatory role of the medical liability system is criticized for being unreliable, ineffective, and inefficient.

Regarding the medical liability system's role in deterring undesirable, or substandard, conduct, both jurisdictions recognize deterrence as a legitimate goal of the system. In the U.S., tort law generally seeks to deter negligent conduct and reduce accidents, and as a subsection of tort law, medical negligence law also seeks to prevent medical errors by deterring healthcare providers from falling below acceptable standards of care. In Germany, the merging of contract with tort law to evaluate medical liability using the negligence standard implicitly encompasses a goal of deterrence. Additionally, both the German Medical Law Association and German legislators have explicitly recognized deterrence and error prevention, respectively, as driving forces behind Germany's medical liability system.

Whether fault-based liability effectively deters substandard conduct and prevents accidents has long been the subject of interdisciplinary debate. The economic theory of American tort law and the economic efficiency model in German tort law support a conclusion that imposing liability for negligent conduct that causes injuries will deter others from engaging in that same

conduct going forward. According to the economic theory of tort law, rational actors will avoid liability-inducing behavior for their own economic benefit. German tort law operates under a similar theory, which poses that courts organically create standards of care by weighing the social gain of an activity against the cost of preventive measures and that actors will correspondingly adjust their behaviors to comply with the evolving standards of care.

Legal realists believe that factors external to the tort system are responsible for non-negligent behavior and accident prevention. Other legal scholars posit that while the tort system is capable of deterrence, its current organization frustrates the system's ability to change conduct. Priest blames this failing partly on the system's reliance on strict liability, which holds actors legally responsible for harm regardless of their ability to prevent it. Latin posits that the tort system fails to target "problem-solving actors" who have the greatest ability to prevent accidents. Shuman's psychological approach to tort law dictates that behavior will not change in response to the current tort system because not all actors are rational decision makers, and that even if they were, the requisite certainty of punishment for substandard behavior through the tort system is lacking.

The current medical liability systems in the U.S. and Germany, while recognizing deterrence as a goal, have had little success in preventing medical errors. The relationships between individual healthcare providers and their patients distinguish medical malpractice defendants from tortfeasors generally making potential economic motivations for behavior less impactful. Since individual healthcare providers generally prioritize their patients' well-being regardless of the potential for liability, the emotional and professional consequence of being named defendants in a medical malpractice lawsuit leads not to better, safer behavior, but rather the practice of defensive medicine. Defensive medicine, at best, has no impact on patient safety, and, at worst, increases the rate of medical errors. Because defensive medicine is behavioral change in response to tort liability, Mello and Studdert label it "mutant deterrence."

The medical liability system also fails to reliably identify medical malpractice, making it a poor source of information for why medical errors occur and how they can be prevented in the future. As a result, the medical liability system is often viewed by individual healthcare providers as arbitrary, and therefore, lacking the requisite certainty needed to trigger a deterrent effect. However, even if individual acts of negligence were successfully deterred by the medical liability system, the effect on the medical error rate would likely be negligible because targeting preventive efforts toward active errors by individuals that occur at the end of the process chain will not cure the organizational deficiencies that induced the injury-causing error in the first place. Even worse, the unrecognized organizational deficiencies will likely continue to induce similar injuries in the future. Finally, in addition to practicing defensive medicine, the medical liability system also makes providers reluctant to report and discuss the systemic causes of medical errors for fear of legal repercussions for themselves.

The medical liability system must also be perceived as fair, an attribute that considers the impact on what society views as valuable economic activity. Thus far, both the U.S. and Germany have rejected the proposed adoption of no-fault medical liability, opting instead to

retain a negligence-based system. Reform efforts in both countries address issues like out-of-court dispute resolution, screening panels, and damages caps to curb reported rising malpractice insurance premiums, deterioration of the doctor-patient relationship, and reluctance of doctors to practice in high-risk specialties. These reforms attempted to address the perception, whether accurate or not, that the medical liability system was unfair.

To achieve effective medical liability reform within a negligence-based system, efforts should attempt to trigger a paradigm shift that aligns the medical liability system with the organization-focused systems approach to medical errors used in the healthcare industry. Shifting liability from individual providers to healthcare organizations holds more promise for achieving the medical liability system's goal of deterrence while simultaneously removing barriers to error prevention efforts in the healthcare industry. If the medical liability system focused more on organizational actors, who are most responsible for and capable of preventing medical errors and whose behavior is most likely to be deterred by the cost of incurring liability, the medical liability system could play a crucial role in preventing future medical errors.

Both jurisdictions evaluate civil liability for medical and organizational errors under a negligence-based regime, which seeks to deter unreasonable conduct and compensate injured patients. Medical negligence occurs when the violation of an established legal duty or obligation causes a patient injury. In the U.S., that legal duty or obligation to the patient arises in conjunction with the doctor-patient relationship. In Germany, providers are obliged specifically under the treatment contract and broadly under German tort law to provide non-negligent treatment to patients. As a result, U.S. courts will primarily look to duties owed in tort, while German courts focus primarily on the relationships established by the treatment contract. Nevertheless, both jurisdictions examine the behavior of individual providers to determine whether treatment malpractice occurred, and both jurisdictions recognize theories of vicarious liability for physicians and healthcare organizations that oversee or employ negligent providers. Additionally, both jurisdictions recognize that healthcare organizations can commit organizational errors by directly and independently causing patient harm.

Reasonable conduct in the context of medical treatment by an individual provider incorporates standards established by the medical profession. Both jurisdictions apply objective standards of care guided by the state of medical science at the time of the alleged malpractice but that are still flexible enough to consider the circumstances of each individual case. As a result, while both jurisdictions hold physicians to an objective competence-based standard of care set by the current state of medical science generally (i.e., the proper dose of medication), they will adjust the standard of care based upon the resources available to that physician (i.e., access to particular piece of imaging equipment). Establishing a breach of the applicable standard of care generally requires the opinion of an expert witness in both jurisdictions. However, while American courts might dispense with the requirement of expert testimony to establish the standard of care, German courts will require expert testimony, but may disregard the expert's opinion regarding the applicable legal standard of care.

To determine whether a breach in the standard of care sufficiently caused a medical injury, both jurisdictions consider whether the breach was the but-for cause of the injury. Additionally, both jurisdictions require that the breach and resulting injury be sufficiently connected to render the imposition of liability as fair and just. In the U.S., the injury must be a reasonably foreseeable consequence of the breach, while Germany requires that the breach be “generally apt” to bring about the patient’s injury and that the injury be within the protective purpose of the law governing the negligent conduct. Additionally, neither jurisdiction requires that negligent conduct be the sole cause of an injury, and a tortfeasor will generally not be relieved of liability in the case of concurrent or successive causes.

When a breach in the standard of care causes a patient injury, compensable damages include both economic damages, including calculable damages such as medical expenses and lost wages, as well as non-economic damages, including pain and suffering and loss of enjoyment of life. The jurisdictions diverge on several aspects of damages for medical injuries. Substantively, loss of a chance of a better outcome is a recoverable damage in the U.S., but not in Germany. On quantum, German general damages awards are eclipsed by the large pain and suffering awards handed down by American juries, though medical malpractice caps limit general damages in some U.S. jurisdictions. On form, American courts generally pay lump sum amounts for future economic damages while Germany opts for quarterly pensions. On a policy level, Germany’s strong social insurance system provides a level of protection for basic human needs including, healthcare and housing, which decreases reliance on damages awarded through the legal system as social insurance, as seen in the U.S.

The same negligence framework governs liability for organizational errors; however, since the organization does not technically practice medicine, organizational errors are consumed under different norms for legal duties and obligations and standards of care. Both jurisdictions agree that modern hospitals have independent responsibilities to the patient to organize medical treatment rendered in the hospital. In the United States, an organization can be directly liable for failure to select and retain competent physicians, maintain appropriate facilities and equipment, train and supervise employees, and implement appropriate protocols and procedures. Likewise, German law has recognized several organizational duties including duties to organize and monitor personnel schedules, supervise and guide employees, establish organizational structure for the reception of patients, as well as organizational errors related to consent, documentation, hygiene, and safety of sedated patients. The standard of care applicable to healthcare organizations in the U.S. is primarily derived from a combination of state and regulatory licensing and accreditation standards as well as the organization’s own standards and regulations. In Germany, the organizational standard of care requires reasonable efforts to ensure quality medical care and elimination of errors according to accepted standards in medicine. Despite an expanding legal framework for organizational negligence in both jurisdictions, the law in this area has never focused on the healthcare organization’s responsibility to prevent medical errors with CRM.

In both jurisdictions, the default proof rules require plaintiffs to establish the elements necessary to prove their claims. One distinction in the proof rules is the standard of proof by



which causation is determined, with the U.S. employing a “reasonable degree of medical certainty” standard, and Germany a stricter “full judicial conviction” standard. There are some circumstances in which the plaintiff’s burden of proving that the defendant breached the standard of care is lessened or eliminated. In the U.S., the doctrine of *res ipsa loquitur* provides the plaintiff with a presumption of negligence that must be rebutted by the defendant. In Germany, the concept of “fully masterable risks” serves to shift the burden of proving negligence (or lack thereof) to the defendant. German law will also shift the burden of proving causation in cases of beginner’s or gross errors.

The primary source of proof in medical malpractice cases is the plaintiff’s medical treatment records. Both jurisdictions provide patients with a legal right to obtain their own medical records by requesting them directly from the defendant provider. Germany additionally provides patients who suspect a medical error with a legal right to assistance from their health insurer, which can include assistance obtaining medical records. Both jurisdictions also allow parties to request records from one another in the course of litigation, though Germany’s pre-trial discovery rules are more conservative than those in the U.S. and impose more restrictions on access to documents. Germany’s conservative discovery practices are primarily driven by its recognition of a freedom from self-incrimination in both criminal and civil contexts. Finally, both jurisdictions make some effort to provide confidentiality to documents and information used to improve the quality of care by exempting them from discovery; however, more reliable protection of an organization’s efforts to improve patient safety is crucial to establishing a legal duty for organizations to manage healthcare risks.

For liability for negligent CRM to arise in both medical liability systems, healthcare providers must first have a legal duty or obligation to patients to conduct CRM. German legal scholars opine that a legal obligation to conduct CRM, though not explicitly recognized by the case law, can be found as an extension of the existing organizational obligations imposed on healthcare organizations. This extension they argue is supported by the general negligence law, the existing organizational case law, and the existing obligations of products manufacturers to prevent risks in product liability law. In the U.S., there is a comparable basis for finding a duty to conduct CRM because (1) medical liability in both jurisdictions operate using similar negligence-based principles, (2) case law in both jurisdictions similarly recognize existing legal obligations for healthcare organizations, and (3) product liability law in both jurisdictions impose similar risk management obligations on manufacturers. As a result, both countries’ existing medical liability systems support finding that healthcare organizations are legally obliged to conduct CRM.

Once healthcare organizations are responsible for conducting CRM in medical liability law, there must be standards of care by which this responsibility is judged. For the imposition of liability for negligent CRM to be an effective deterrent, standards of care should be both reasonable and predictable. Again, German legal scholars have already considered a framework for organizing standards of care for CRM. This framework is based upon an existing CRM process that is internationally recognized in the healthcare industry, and which can be organized into four risk management phases: risk identification; risk analysis; risk assessment;

and risk control. Risk identification requires healthcare organizations to implement systems designed to discover systemic deficiencies. Voluntary error-reporting and learning systems are a crucial part of the risk identification process. Risk analysis is used to determine the causes and effects of risks identified to better understand why risks manifest and how they can be prevented or minimized. Risk assessment determines the probability and severity of each risk so that risks can be prioritized for the risk control process. Risk control requires healthcare organizations to develop, implement, and monitor risk prevention measures. There are various methods for conducting each phase of the CRM process that meet the standard of care, the selection of which can depend upon the size and resources of the healthcare organization and/or the character of the specific risks identified.

Finally, a legal cause of action for CRM must balance confidentiality needed to establish a safety culture in healthcare organizations, which is crucial to the success of CRM, with transparency of the CRM process needed to ensure that healthcare organizations can be held accountable for negligent practices. To ensure confidentiality that enables safety culture critical to a functioning CRM system, courts should offer discovery and evidentiary protections for documents and information developed within CRM system that relate to individual incidents and identify individual providers. To ensure that patients have a viable cause of action when organizations engage in negligent CRM practices, courts should follow a burden-shifting paradigm that: (1) gives rise to a presumption of negligence when the plaintiff's injury arises out of a CRM activity fully within the organization's control; and (2) shifts the burden of proof (or applies a legal presumption) on the issue of causation in the event of grossly negligent CRM activities. Some variation of these proof rules is critical to the successful development of a duty to conduct CRM.

In sum, liability for negligent CRM is a crucial aspect of medical error prevention because it can deter unsafe organizational behavior, improve patient safety culture by abating individual providers' fears of being shamed, blamed, and sanctioned in the legal liability system, and curb the practice of defensive medicine by making liability a more reliable identifier of organizational injury-causing behavior. However, courts adjudicating causes of action for negligent CRM must use evidentiary and proof rules as tools to strike the delicate balance between confidentiality required to maintain a safety culture in healthcare organizations and transparency required to hold healthcare organizations accountable for negligent CRM. While the medical liability system cannot, and is not expected to, be *the* driving force for medical error prevention, it should reinforce the accepted norms governing error prevention in modern healthcare, and at least, not hinder industry prevention efforts. A well-crafted cause of action for negligent CRM will help better align the medical liability system in both the U.S. and Germany with the healthcare industry's systems-based approach to organizational errors, which recognizes that "[e]rrors can be prevented by designing systems that make it hard for people to do the wrong thing and easy for people to do the right thing."<sup>809</sup>

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<sup>809</sup> IOM, *supra* note 2, at ix.

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