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The Three C's – The Colon, Colonoscopies, and Cancer: A Medical and Legal Overview

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THE THREE C'S – THE COLON, COLONOSCOPIES, AND CANCER: A MEDICAL AND LEGAL OVERVIEW

Samuel D. Hodge[†] and Calina Noah^{††}

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“A colonoscopy is the most effective screening option for early detection. It’s the only screening exam that not only checks for colorectal cancer but can also prevent it.”

---Elizabeth Lindsey, M.D.

For several years, Denise’s physician gently nudged her to obtain a colonoscopy.¹ She hesitated because she was a healthy woman with no family history of colon cancer. Also, the thought of undergoing the procedure was unappealing. However, one day her husband challenged her to have the test, and she reluctantly agreed.² That decision saved her life. Denise’s doctor discovered that she had colon cancer. Since her cancer was in its infancy, surgery was sufficient to remedy the problem.³ Denise noted, “The moral of my story is if I waited until I had symptoms, it would have been too late.”⁴

I. INTRODUCTION

The medical field is constantly evolving and improving. These innovations present multifaceted and challenging medical and legal issues.⁵ These challenging issues are especially applicable in

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1. CTRS. FOR DISEASE CONTROL AND PREVENTION, *Colorectal Cancer Screening Stories*, https://www.cdc.gov/cancer/colorectal/basic_info/stories.htm [<https://perma.cc/GJQ6-NKSB>] (last visited Nov. 17, 2020).
 2. *Id.*
 3. *Id.*
 4. *Id.*
 5. C. Andrew Kistler, *Legal Considerations in Gastroenterology: Key Concerns*, GASTROENTEROLOGY ADVISOR (Dec. 7, 2020), <https://www.gastroenterologyadvisor.com/general-gastroenterology/legal-considerations-in-gastroenterology-key-concerns/> [<https://perma.cc/2QGG-SPDK>].

gastroenterology,⁶ a medical discipline subject to much litigation.⁷ This is not surprising because the techniques to detect abnormalities and malignancies in the gastrointestinal system, such as sigmoidoscopy, colonoscopy, and endoscopy, are employed with regularity. This utilization only increases the risk of malpractice claims because of the danger of an adverse outcome despite the physician's competence and skill.⁸

The public's awareness of colon cancer and the need for proper screening is increasing. As the Honorable Nelson Cantor commented, "A massive epidemic is occurring in this country every day. It is an epidemic of ignorance and failure to utilize noninvasive, inexpensive, commonly used screening devices to detect colorectal cancer ("CRC") early when CRC is most treatable. Such screening and detection would save thousands of lives, billions of dollars and grief and agony of patients and families coping with late-stage CRC."⁹

A proper handling or defense of such a malpractice claim requires an understanding of the large intestine's anatomy and how the procedure is performed. Therefore, this article will present a medical and legal overview of the digestive system focusing on colorectal cancer and colonoscopies, one of the most

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6. As noted by the American College of Gastroenterology, "Gastroenterology is the study of the normal function and diseases of the esophagus, stomach, small intestine, colon and rectum, pancreas, gallbladder, bile ducts and liver. It involves a detailed understanding of the normal action (physiology) of the gastrointestinal organs including the movement of material through the stomach and intestine (motility), the digestion and absorption of nutrients into the body, removal of waste from the system, and the function of the liver as a digestive organ. It includes common and important conditions such as colon polyps and cancer, hepatitis, gastroesophageal reflux (heartburn), peptic ulcer disease, colitis, gallbladder and biliary tract disease, nutritional problems, Irritable Bowel Syndrome (IBS), and pancreatitis. In essence, all normal activity and disease of the digestive organs is part of the study of gastroenterology." AM. COLL. OF GASTROENTEROLOGY, *What is a Gastroenterologist?*, <https://gi.org/patients/gi-health-and-disease/what-is-a-gastroenterologist/> [https://perma.cc/T53W-YKU9] (last visited Dec. 4, 2021) .
 7. Kistler, *supra* note 5.
 8. *Id.*
 9. Nelson Canter, *Legal Implications For Failure To Screen For Colorectal Cancer*, 39 WESTCHESTER BAR J. 9 (2014).

common procedures to diagnose and treat gastrointestinal disorders. This discussion will be followed by an analysis of legislation and case law on the topic of gastroenterology from medical malpractice to informed consent. Individual sections will be devoted to the case law involving the theories of liability, the most significant awards involving colonoscopies, informed consent, medical malpractice, perforation of the colon during a colonoscopy, failure to diagnose and the failure to properly sterilize the medical equipment to name a few.

II. THE DIGESTIVE SYSTEM

Colorectal cancer and the purpose of a colonoscopy may be better understood if one first appreciates the basics of the digestive tract and how it works. This system represents the plumbing of the body with its varied size pipes, bends, and curves. Its job is to accept food, reduce it to nutrients, assimilate those byproducts into the bloodstream, and expel the remaining elements from the body.¹⁰ As noted in *Mid-Western Life Insurance Company of Texas v. Goss*, the system is described as beginning:

. . . with the intake of food, which passes across the lips and into the oral cavity, the mouth, and is propelled down the pharynx by the tongue, the food then goes into the esophagus, and is propelled into the stomach, in which it is mixed with enzymes and acids of digestion. It is then emptied into the small bowel, where digestion is completed, and the contents of the food then empties into the colon, which is propelled into the rectum, and evacuated through the anus. This is the gastro-intestinal system, there are allied associated parts of the gastro-intestinal system, which would include the pancreas and the gall bladder and ducts, which are included in the gastro-intestinal system.

As for a more technical explanation, this system consists of a series of hollow organs formed by a long, twisting tube that extends from the mouth to the anus.¹¹ Also known as the

10. MERCK RSCH. LAB'Y, THE MERCK MANUAL OF MEDICAL INFO. 480 (1997) [hereinafter MERCK MANUAL].

11. NAT'L INST. OF DIABETES, AND DIGESTIVE AND KIDNEY DISEASES, *Your Digestive Sys. & How it Works*, <https://www.niddk.nih.gov/health-information/digestive-diseases/digestive-system->

gastrointestinal or alimentary system, it is made up of the upper gastrointestinal tract, which consists of the oral cavity, esophagus, and stomach, and a lower gastrointestinal region, which is formed by the small and large intestines.¹² A few other organs assist in the digestive process, such as the salivary glands, gallbladder, pancreas, and liver.¹³

This process can be conceptualized by following what happens to a morsel of food when it is consumed. The journey starts with the mouth, the entrance points for the digestive and respiratory systems. The inside of the mouth contains mucus membranes and glands that release saliva to keep the opening moist and begin the digestive process.¹⁴ When the food or bolus is swallowed, deglutition occurs. As the food is guided into the esophagus, a flap in the back of the throat automatically closes off the larynx to thwart the food from traveling down the trachea or “wrong pipe.”¹⁵

The esophagus is a thin-walled, foot-long tube behind the trachea.¹⁶ Anatomically, it links the throat with the stomach.¹⁷ The food is pushed downward towards the stomach by peristalsis, or wavelike contractions of the smooth muscles involving this tube. The bolus reaches the stomach within seconds, passing through the gastroesophageal junction. This connection is an opening that is controlled by the gastroesophageal sphincter which prevents the stomach contents from regurgitating back up into the esophagus.¹⁸ The stomach itself is a bean-shaped pouch

how-it-works [<https://perma.cc/644V-EHLJ>] (last visited Nov. 17, 2021) [hereinafter *Your Digestive Sys.*].

12. SAMUEL D. HODGE, JR. & JACK E. HUBBARD, ANATOMY AND PHYSIOLOGY FOR LEGAL PROFESSIONALS 35–36 (2019).
13. *Id.* at 36. “The liver is an organ about the size of a football. It sits just under your rib cage on the right side of your abdomen. The liver is essential for digesting food and ridding your body of toxic substances.” MAYO CLINIC, *Liver Disease*, <https://www.mayoclinic.org/diseases-conditions/liver-problems/symptoms-causes/syc-20374502> [<https://perma.cc/6YS4-34DE>] (last visited Dec. 4, 2021).
14. MERCK MANUAL, *supra* note 10, at 480.
15. HODGE, JR. & HUBBARD, *supra* note 12, at 37.
16. *Id.*
17. MERCK MANUAL, *supra* note 10, at 480.
18. HODGE, JR. & HUBBARD, *supra* note 12.

that serves as a storage area for the food.¹⁹ It is usually the size of a person's two fists placed next to each other.²⁰ However, the stomach will alter its size based upon the volume of food contained within it. The structure contains flaps or "rugae" that unfold to allow the stomach to expand for the increasing contents.²¹ As the bolus is propelled into the small intestine and the stomach returns to its normal size, the rugae "reappear as deep folds and wrinkles, similar to a shrunken balloon."²²

Once in the stomach, enzymes are released to break down further the remnants of the food, especially the protein segments of that food. Nerve impulses stimulate these secretions to the area.²³ These highly acidic secretions also serve as a barrier against infection by killing most bacteria.²⁴ This cocktail, referred to as gastric juices, is made at the rate of about one and a half quarts a day. These acids break down proteins and other substances.²⁵ This process can take a few hours as the smooth muscles of the stomach contract, churn and mingle the stomach contents. When completed, the food remaining in the stomach acid is now called chime,²⁶ and it is propelled downward into the last segment of the stomach, the pylorus, where it passes through the pyloric valve. This structure stops the reflux of the chyme from backing up into the stomach.²⁷ When the duodenum no longer has space to accommodate the material, it signals the stomach to stop emptying.²⁸

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19. MERCK MANUAL, *supra* note 10.
 20. Tim Taylor, *Digestive System*, INNERBODY RSCH. (Oct. 12, 2020), <https://www.innerbody.com/image/digeov.html> [<https://perma.cc/4X6B-27Z4>].
 21. *What Is The Function of The Rugae In The Stomach?*, STUDY.COM, <https://study.com/academy/answer/what-is-the-function-of-the-rugae-in-the-stomach.html> [<https://perma.cc/69H9-DQR2>] (last visited Dec. 3, 2021).
 22. *Id.*
 23. MERCK MANUAL, *supra* note 10.
 24. *Id.* at 480.
 25. HODGE, JR. & HUBBARD, *supra* note 12, at 37.
 26. *Id.*
 27. *Id.*
 28. MERCK MANUAL, *supra* note 10, at 481.

The small intestine is the first part of the lower gastrointestinal tract where most of the absorption of the nutrients takes place. It is situated just below the stomach and takes up much of the area in the abdominal cavity.²⁹ The small intestine “is coiled like a hose” and the inside area contains a variety of ridges and folds that maximize the digestion of food and absorption of nutrients.³⁰ These elements consist of proteins, fats, carbohydrates, vitamins, minerals, and water.³¹ By the time food exits the small intestine, about 90% of all nutrients have been extracted from the materials that entered it.³²

Ducts from the pancreas and gallbladder enter the duodenum at this point. The gallbladder contains bile made in the liver, a critical element in the breakdown of fats.³³ In turn, the bile moves to the duodenum through an opening; the sphincter of Oddi.³⁴ The pancreas makes various enzymes necessary to break down the fats, proteins, and starches.³⁵ This organ is situated behind the lower part of the stomach, and it also produces insulin to control blood glucose.³⁶

The chyme spends the next several hours traveling along the 22 feet of the small intestine, first through the duodenum, then the jejunum, and finally the ileum.³⁷ The jejunum is the middle part of the small intestine whose chief purpose is to absorb critical nutrients such as “sugars, fatty acids, and amino acids.”³⁸ The ileum is the last and longest part of the small intestine. It has

29. Taylor, *supra* note 20.

30. *Id.*

31. *Your Digestive Sys.*, *supra* note 11.

32. *Id.*

33. HODGE, JR. & HUBBARD, *supra* note 12, at 37.

34. MERCK MANUAL, *supra* note 10, at 481.

35. HODGE, JR. & HUBBARD, *supra* note 12, at 37.

36. JOHNS HOPKINS MED., *The Digestive Process: What Is the Role of Your Pancreas in Digestion?*, <https://www.hopkinsmedicine.org/health/conditions-and-diseases/the-digestive-process-what-is-the-role-of-your-pancreas-in-digestion> [<https://perma.cc/X6C4-V6MF>] (last visited Sept. 20, 2022).

37. HODGE, JR. & HUBBARD, *supra* note 12, at 38.

38. *Jejunum Overview*, HEALTHLINE, <https://www.healthline.com/human-bodymaps/jejunum#function> [<https://perma.cc/6THF-K3L5>] (last updated Nov. 11, 2021).

many immune tissues which stop bacteria from invading the bloodstream.³⁹ In turn, the ileum connects to the cecum, as the ileocecal valve.⁴⁰

The food continues its journey by rhythmic contractions of the small intestine. This long pathway contains fingerlike projections, the villi, that increase the surface area permitting greater absorption of the nutrients.⁴¹ These elements are then sent to the capillary beds and dispersed to the rest of the body by way of arterial blood flow.⁴²

Undeterred, the remaining materials reach the large intestine that consists of three parts: the cecum, colon, and rectum.⁴³ By this time, all meaningful nutrients have been absorbed, and the intestinal contents are in a fluid state.⁴⁴ The chief function of the large intestine is to absorb water and electrolytes over the five-foot-long tube that propels the remains towards expulsion from the body.⁴⁵ This progression can take between 12 to 36 hours. The colon has an ascending, transverse, and descending component terminating as the sigmoid colon. Many bacteria reside in the large intestine that further the body's assimilation of nutrients and production of essential substances, such as vitamin K.⁴⁶

The sigmoid colon is so named because of its "S" shaped appearance.⁴⁷ The chyme is now called fecal matter and empties into the rectum, the final section of the large intestine. Usually, this area is empty because stools are kept at a higher point in the descending colon. However, as this area becomes full, the feces

39. *Gastrointestinal Tract 4: Anatomy and Role of the Jejunum and Ileum*, NURSING TIMES (Aug. 19, 2019), <https://www.nursingtimes.net/clinical-archive/gastroenterology/gastrointestinal-tract-4-anatomy-role-jejenum-ileum-19-08-2019/> [<https://perma.cc/7CX8-K86U>].

40. HODGE, JR. & HUBBARD, *supra* note 12, at 39.

41. *Id.*

42. *Id.*

43. *Id.*

44. MERCK MANUAL, *supra* note 10, at 483.

45. HODGE, JR. & HUBBARD, *supra* note 12, at 39.

46. MERCK MANUAL, *supra* note 10, at 484.

47. AM. CANCER SOC'Y, *What is Colorectal Cancer?* (June 29, 2020), <https://www.cancer.org/cancer/colon-rectal-cancer/about/what-is-colorectal-cancer.html> [<https://perma.cc/8U79-W9FF>].

pass into the rectum, thereby providing the sensation to empty the bowel.⁴⁸ With defecation, the waste is eliminated through the anus.⁴⁹ This endpoint of the gastrointestinal tract contains circular muscles, the external sphincter ani, that make up the wall of the anus and keep it shut. Secretions produced by nearby glands keep the area moist.⁵⁰

The rectum and the upper aspect of the anal canal are innervated with nerves. As the rectum becomes full, these nerves sense this fact and signal to the brain whether this feeling is caused by gas or a stool.⁵¹ When a person needs to evacuate the rectum, the brain signals the anal sphincter muscles to relax. During this process, the anus opens, and the rectum expels its contents.⁵²

III. THE PROBLEM

A. *What is Colorectal Cancer?*

Tumors are classified as benign or malignant.⁵³ These abnormal growths turn into cancer when some of the cells multiply or grow unchecked.⁵⁴ When these abnormalities occur in the colon or rectum, they are considered colorectal cancer.⁵⁵

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48. MERCK MANUAL, *supra* note 10, at 484.
 49. HODGE, JR. & HUBBARD, *supra* note 12, at 39.
 50. *Picture of the Anus*, WEBMD (June 23, 2021), <https://www.webmd.com/digestive-disorders/picture-of-the-anus> [https://perma.cc/5YS6-ZXK8].
 51. *How the Bowel Works*, BLADDER & BOWEL COMTY., <https://www.bladderandbowel.org/bowel/bowel-resources/how-the-bowel-works/> [https://perma.cc/9JHG-ZFDH] (last visited Dec. 3, 2021).
 52. *Id.*
 53. *Colorectal Cancer: What's Happening Inside My Body?*, FOX CHASE CANCER CTR., <https://www.foxchase.org/clinical-care/conditions/colorectal-cancer/about> [https://perma.cc/LKN5-34R9] (last visited Nov. 17, 2021).
 54. NAT'L CANCER INST., *What Is Cancer?* (May 5, 2021), <https://www.cancer.gov/about-cancer/understanding/what-is-cancer> [https://perma.cc/Z7T9-JFP8].
 55. AM. CANCER SOC'Y, *What is Colorectal Cancer?*, *supra* note 47.

This malignancy usually starts as a growth, or polyp, that forms inside the structure.⁵⁶ At their inception, they are innocuous abnormalities that develop in the inner lining of the large intestines. These polyps are found in about 50% of patients over 50 during a colonoscopy.⁵⁷ Less than 10% of these polyps transform into malignancies. This metamorphosis is slow, and usually develops over a 10-to-20-year period.⁵⁸ While different types of tumors can form in the digestive tract, an adenocarcinoma is the most common type of colorectal cancer. It received its name because of its “saw-tooth appearance under a microscope.”⁵⁹ This abnormality develops in the cells that generate the mucus that lubricates the inside of the colon or rectum.⁶⁰

B. Statistics

Colorectal cancer (CRC) is the second leading cause of death resulting from a malignancy after lung cancer and is the third most frequent cancer among people.⁶¹ The American Cancer Society estimates that 104,270 new colon cancer cases and 45,230 new incidence rate of rectal cancer will be discovered during 2021.⁶² Additionally, more than 53,000 people will have died from

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56. UNDERSTAND CANCER TOGETHER, *What Is Colorectal Cancer?*, <https://www.understandcancertogether.com/understand-cancer/types-of-cancer/colorectal-cancer/> [https://perma.cc/74J9-G2DX] (last visited Nov. 17, 2021).
 57. AM. CANCER SOC'Y, *Colorectal Cancer: Facts and Figures 2020-2022*, at 1, <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/colorectal-cancer-facts-and-figures/colorectal-cancer-facts-and-figures-2020-2022.pdf> [https://perma.cc/VE86-M52G] (last visited Dec. 1, 2021).
 58. *Id.* at 2.
 59. *Id.* at 1.
 60. UNDERSTAND CANCER TOGETHER, *What Is Colorectal Cancer*, *supra* note 56.
 61. Aasma Shaukat et al., *ACG Clinical Guidelines: Colorectal Cancer Screening 2021*, 116 J. AM. COLL. GASTROENTEROLOGY 458, 458–79 (2021).
 62. AM. CANCER SOC'Y, *Key Statistics for Colorectal Cancer*, <https://www.cancer.org/cancer/colon-rectal-cancer/about/key-statistics.html> [https://perma.cc/V8HQ-5RYR] (last visited Sept. 24, 2022). Cancers of the anus are categorized separately from those emanating in the rectum because they typically grow out of different cell types. Therefore, they have different characteristics.

the disorder in 2020.⁶³ Between 2013 and 2017, the incidence rate decreased by around 1% annually, but this development occurred mainly in the older population and it disguised the increased cancer rate among young adults during the past thirty years.⁶⁴ The overall decline in these numbers is thought to be related to deviations in risk influences, early detections of cancer through colonoscopies, screening, and removal of precancerous polyps with colonoscopy and advances in surgical and treatment approaches.⁶⁵

The overall chance of developing colorectal cancer is 1 in 23 for males and 1 in 25 for females. A multitude of additional influences including age and race⁶⁶ can impact a person's odds for developing this form of malignancy.⁶⁷ The incidence and death rates are highest in non-Hispanic blacks, trailed narrowly by Alaska Natives.⁶⁸ These racial and ethnic differences can be attributed to socioeconomic status among races and access to health care.⁶⁹ It is unsurprising that those with the poorest socioeconomic standing have a 40% greater chance of developing colorectal cancer than those who enjoy the highest income levels.⁷⁰ Geographic location also plays a part in the development of this form of malignancy. The highest incidence of CRC is found in parts of the South, Midwest, and Appalachian regions, while the West and Northwest regions have the smallest percentages.⁷¹

A person's lifestyle greatly influences 55% of colorectal cancers. These reasons involve unhealthy diets, not properly

AM. CANCER SOC'Y, *Colorectal Cancer, Facts and Figures 2020-2022*, *supra* note 57.

63. Shaukat et al., *supra* note 61, at 1.
64. AM. CANCER SOC'Y, *Key Statistics for Colorectal Cancer*, *supra* note 62, at 1.
65. Shaukat et al., *supra* note 61, at 3.
66. AM. CANCER SOC'Y, *Colorectal Cancer, Facts and Figures 2020-2022*, *supra* note 57, at 3.
67. AM. CANCER SOC'Y, *Key Statistics for Colorectal Cancer*, *supra* note 62, at 1.
68. *Id.* at 5.
69. *Id.*
70. *Id.*
71. *Id.* at 9.

exercising, drinking alcohol, and cigarette use.⁷² One must also not overlook hereditary and family factors.⁷³ Approximately 30% of colorectal cancer patients have a familial link for the disease, making this a significant risk factor.⁷⁴ Statistically, a person will have an increased risk for this type of malignancy if a parent or sibling develops colon cancer before age 50, several relatives have had CRC, or if there is a familial relationship with cancers in general including endometrial, ovarian, gastric, urinary tract, brain, and pancreatic.⁷⁵

Lynch syndrome has been identified as the most inherited risk element for colorectal cancer.⁷⁶ As noted in *Zhu v. Commissioner, SSA*, “Lynch syndrome, also known as ‘hereditary nonpolyposis colorectal cancer’ is a genetic ‘predisposition to early-onset colorectal cancer.’”⁷⁷ This disorder is a form of inherited cancer linked to those with a genetic predisposition to various cancer types.⁷⁸ Evidence as to whether there is Lynch syndrome in a family consists of various relatives on the same side of a family developing colorectal and/or endometrial cancer.⁷⁹ These relatives have a gene variant that diminishes the cell’s capacity to fix mistakes generated during DNA duplication.⁸⁰

72. *Id.* at 13.

73. *Id.*

74. *Id.*

75. *Risk Factors for Colon Cancer*, MEM’L SLOAN KETTERING CANCER CTR., https://www.mskcc.org/cancer-care/types/colon/prevention-risk?gclid=Cj0KCQiAkNiMBhCxARIsAIDDKNUwdmFm17MYjdbCiPm32EHpMg_zvPrs-hB1WmTSN6sgoSQk3qi8GGIaAnqtEALw_wcB&pn_mapping=pn [<https://perma.cc/P5N4-BYEV>] (last visited Sept. 24, 2022).

76. AM. CANCER SOC’Y, *Colorectal Cancer, Facts and Figures 2020-2022*, *supra* note 57, at 14.

77. *Zhu v. Commissioner, SSA*, No. 20-3180, 2021 WL 2794533, at *1 (10th Cir. July 6, 2021).

78. *Lynch Syndrome*, CANCER.NET, <https://www.cancer.net/cancer-types/lynch-syndrome> [<https://perma.cc/F8Y4-KC28>] (last visited Nov. 17, 2021).

79. *Id.*

80. AM. CANCER SOC’Y, *Colorectal Cancer, Facts and Figures 2020-2022*, *supra* note 57, at 14.

These reproduction errors cause extra mutations that can eventually result in cancer.⁸¹

Certain medical conditions can also be precursors to the development of CRC. For instance, those who suffer from chronic inflammatory bowel disease have almost twice the chance of developing colorectal cancer as the average person.⁸² Even people with type 2 diabetes have demonstrated an increased risk of producing the malignancy. Interestingly, this risk factor is greater in men than women.⁸³

C. Symptoms of Colorectal Cancer

Colorectal cancer often has no symptoms in its early stages.⁸⁴ As the growth enlarges, it may produce bleeding or blockage of the bowel.⁸⁵ Common symptoms include a continuing alteration in customary bowel movements, diarrhea, constipation, or a change in the size or shape of the stool.⁸⁶ Another symptom of CRC is abdominal pain accompanied by gas or cramps, the sensation that the bowel has not fully evacuated, unexplained weakness, fatigue, or weight loss.⁸⁷ Occasionally, blood loss from the tumor can cause anemia.⁸⁸

D. Stages of Colorectal Cancer

After a physician diagnoses their patient with CRC, the doctor will need to determine how advanced the malignancy is in its progression. This determination is called staging, and it

81. *Id.*

82. *Id.* at 14–15.

83. *Id.* at 15.

84. AM. COLL. GASTROENTEROLOGY, *Q and A About Colorectal Screening*, <https://gi.org/patients/gi-health-and-disease/colon-cancer-fact-sheet/> [<https://perma.cc/B35F-TQFT>] (last visited Nov. 18, 2021).

85. AM. CANCER SOC'Y, *Colorectal Cancer, Facts and Figures 2020-2022*, *supra* note 57, at 2.

86. MAYO CLINIC, *Colon Cancer*, <https://www.mayoclinic.org/diseases-conditions/colon-cancer/symptoms-causes/syc-20353669> [<https://perma.cc/B2JD-KL79>] (last visited Sept. 24, 2022).

87. *Id.*

88. AM. CANCER SOC'Y, *Colorectal Cancer, Facts and Figures 2020-2022*, *supra* note 57, at 3.

measures the amount and progression of cancer in the body.⁸⁹ Staging is also used to explain the chances of survival.⁹⁰ The prognosis for the disease is based upon the depth of the lesion's incursion into the bowel wall and the existence of "both regional lymph node involvement and distant metastasis."⁹¹

The four stages are classified I through IV. Generally, the lower the number, the smaller the risk that the cancer has spread. While most individuals' cases are unique, cancers with similar stages typically have a comparable prognosis and are frequently treated similarly.⁹² The system most employed in detecting CRC is issued by the American Joint Committee on Cancer (AJCC) and is known as "TNM."⁹³ TNM is premised upon three factors: "T" stands for tumor and "how far the cancer has grown into the wall of the colon."⁹⁴ "N" refers to the lymph nodes with a determination if there is lymph node involvement. Finally, "M" references metastasis and whether the cancer has spread to other lymph nodes and organs.⁹⁵ The results are combined to determine the type of cancer for each person. This staging mechanism offers a uniform method to label cancer, so physicians can work in unison to provide the best management.⁹⁶ A related term, "recurrent cancer," refers to a malignancy that has returned after treatment.⁹⁷ The tumor may be discovered in the colon, rectum, or in a different aspect of the body.⁹⁸ Further, metastasis is the word used for when cancer spreads to a body part away from

89. AM. CANCER SOC'Y, *Colorectal Cancer Stages*, <https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/staged.html> [https://perma.cc/5JWP-7H33] (last updated June 29, 2020).

90. *Id.*

91. STEVEN E. PEGALIS, 3 AM. L. MED. MAL. § 16:7. *Colorectal Cancer* (3d ed. 2022).

92. AM. CANCER SOC'Y, *Colorectal Cancer Stages*, *supra* note 89.

93. *Id.*

94. *Id.*

95. *Id.*

96. *Colorectal Cancer: Stages*, CANCER.NET, <https://www.cancer.net/cancer-types/colorectal-cancer/stages>, [https://perma.cc/GFQ4-UGMU] (last visited Sept. 15, 2022).

97. *Id.*

98. *Id.*

where the tumor originated.⁹⁹ Malignant cells can migrate into nearby lymph nodes. They can also travel through blood vessels to distant organs and tissues, including the lungs, brain, or liver, or they can be transmitted into the lining of the abdomen.¹⁰⁰

IV. TESTS FOR COLORECTAL CANCER

It is generally believed that the perfect screening test for cancer “should be noninvasive, have a high sensitivity and specificity, be safe, readily available, convenient, and inexpensive.”¹⁰¹ There are a variety of accepted tests and procedures for the detection of colorectal cancer, and each has its advantages and disadvantages. In certain situations, the ideal screening test is that which is satisfactory to the patient.¹⁰² Nevertheless, a method has emerged to split the assessments tools into two categories: the one-step test and the two-step process.¹⁰³ The American College of Gastroenterology 2021 Guidelines on Colorectal Cancer describes the differences between these two methods.¹⁰⁴ The one-step approach utilizes a colonoscopy to search for abnormalities and polyps throughout the length of the large intestines.¹⁰⁵ The two-step approach employs a stool-based analysis. These assessment tests look for blood or changed DNA in the bowel as the initial step.¹⁰⁶ A positive result is followed up by a colonoscopy.¹⁰⁷

A. Blood Tests

A blood test is unable to determine if a person has colon cancer. However, a physician may examine a patient’s blood for

99. *Id.*

100. *What is Metastasis?*, CANCER.NET (July 2022), <https://www.cancer.net/navigating-cancer-care/cancer-basics/what-metastasis> [<https://perma.cc/F4UU-A25G>].

101. Shaukat et al., *supra* note 61, at 459.

102. *Id.*

103. *Id.* at 459, 461.

104. AM. COLL. GASTROENTEROLOGY, *Q and A About Colorectal Screening*, *supra* note 84.

105. *Id.*

106. *Id.*

107. *Id.*

a chemical occasionally generated by colon cancer. This compound is called a carcinoembryonic antigen, or CEA.¹⁰⁸ One procedure is the Stool DNA test in which a person's stool is scrutinized for any DNA material that an occult colon cancer might discard.¹⁰⁹ The formal name for this test is the guaiac-based fecal occult blood test (gFOBT).¹¹⁰ This procedure utilizes a chemical reaction to discover blood in the stool. Because bleeding from a polyp or cancer may go unnoticed, accurate results mandate yearly testing of three consecutive bowel movements.¹¹¹

The next procedure is the fecal immunochemical test (FIT). This assessment tool looks at antibodies against hemoglobin to discover blood in the stool. It is about two times more accurate than gFOBT in detecting advanced adenomas and cancer. People also prefer this test because it is convenient, fewer specimens must be collected, and there are no dietary limitations.¹¹²

The last test is the multitargeted stool DNA or Cologuard test. This procedure detects blood and genetic mutations in the DNA cells contained within the stool.¹¹³ It has been shown to detect cancer and precancerous growths more frequently than FIT, but has the drawback of producing false positives, which can lead to unneeded colonoscopies.¹¹⁴

108. CLEVELAND CLINIC, *CEA Test (Carcinoembryonic Antigen)*, <https://my.clevelandclinic.org/health/diagnostics/22744-cea-test-carcinoembryonic-antigen> [<https://perma.cc/QFE4-9H5X>] (last visited Sept. 18, 2022).

109. *Prevention and Screening of Colon and Rectal Cancer*, FOX CHASE CANCER CTR., <https://www.foxchase.org/clinical-care/conditions/colorectal-cancer/prevention-screening> [<https://perma.cc/69PU-RR39>] (last visited Sept. 17, 2022).

110. AM. CANCER SOC'Y, *Colorectal Cancer, Facts and Figures 2020-2022*, *supra* note 57, at 21.

111. *Id.*

112. *Id.* at 22.

113. *Id.*

114. *Id.*

B. *Colonoscopies*

A colonoscopy¹¹⁵ is employed to discover abnormalities in the large intestine and rectum.¹¹⁶ It is estimated that more than 15 million colonoscopies are conducted annually in the United States.¹¹⁷ This utilization is attributable to the increasing public awareness of colon cancer and a growing aging population that should undergo periodic screenings.¹¹⁸ A little more than one-half of those between 50 to 75, the most susceptible group, are up-to-date on their colonoscopy testing.¹¹⁹ This caused one scholar to note that when CRC is detected early and properly treated, the five-year survival rate is 90%.¹²⁰ However, because of the low screening rate, less than 40% of colorectal cancer is discovered in its infancy.¹²¹ Colonoscopy also has the longest rescreening gap of

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115. A colonoscopy is a subset of endoscopy and can be both a diagnostic and therapeutic procedure. GEORGE BLUM, MALPRACTICE OR NEGLECT IN CONDUCTING COLONOSCOPY, INCLUDING PRE AND POSTOPERATIVE CARE 34 A.L.R.7TH § 2 (2017). This procedure is different than a sigmoidoscopy, in which the hose is only about two feet long and is only able to visualize the rectum and less than half of the colon. MONIQUE LEAHY, LITIGATION OF MEDICAL MALPRACTICE IN CONDUCTING COLONOSCOPY, 157 AM. JUR. TRIALS 469 § 2 (2022).
116. MAYO CLINIC, *Colonoscopy* (May 18, 2022), <https://www.mayoclinic.org/tests-procedures/colonoscopy/about/pac-20393569> [<https://perma.cc/5DH5-B8TD>].
117. *Let's Get Screened, Part 1: Colon Cancer Screening*, PENN MEDICINE: ABRAMSON CANCER CTR.: FOCUS ON CANCER BLOG (Dec. 17, 2019), <https://www.pennmedicine.org/cancer/about/focus-on-cancer/2019/december/lets-get-screened-colonoscopy> [<https://perma.cc/DZB3-SX6P>]. Some maintain that the procedure is performed too frequently and that a large ratio of the procedures done each year are unnecessary. For instance, one study asserted that this over performance represents more than \$1 million in unneeded health care expenditures. LEAHY, *supra* note 115 § 1.
118. *An Astounding 16.6 Million Colonoscopies are Performed Annually in the United States*, iData Research (Aug 8, 2018), <https://idataresearch.com/an-astounding-19-million-colonoscopy-are-performed-annually-in-the-united-states/> [<https://perma.cc/DAV3-XQMN>].
119. LEAHY, *supra* note 115 § 1.
120. *Id.*
121. *Id.*

all test options. In a normal colon, a ten-year test interval is the average.¹²²

The procedure is not performed on a whim and requires patient preparation. Bowel cleansing is a critical element of the procedure.¹²³ The patient must take a special laxative to cleanse the colorectal area.¹²⁴ This emptying is vital so that the physician can adequately visualize the colon.¹²⁵ Multiple studies have determined that inadequate preparation is more commonly found in those with the following characteristics: those who have experienced prior insufficient bowel preparation; non-English speaking patients; those with Medicaid insurance, or who are single and/or have an inpatient status; patients who take multiple medications, particularly with constipating pills such as opiates; those who are overweight, advanced age, men, and; individuals who have comorbidities including diabetes, stroke, dementia, and Parkinson's disease.¹²⁶ Other factors associated with poor preparation include inadequate observance of preparation instructions, incorrect timing of bowel purgative usage, and longer appointment wait times for the procedure.¹²⁷

The model planning for the test should dependably empty the colon of all fecal matter swiftly “with no gross or histologic alteration of the colonic mucosa.”¹²⁸ The preparation should also be safe, convenient, bearable, and economical. Regrettably, none of the present preparations have all these elements.¹²⁹

During the procedure, the patient is placed on the left side with the knees brought up close to the chest to obtain a better

122. AM. CANCER SOC'Y, *Colorectal Cancer, Facts and Figures 2020-2022*, *supra* note 57, at 19.

123. Amit Rastogi & Sachin Wani, *Colonoscopy*, 85 *GASTROINTESTINAL ENDOSCOPY* 59 (2017).

124. AM. CANCER SOC'Y, *Colorectal Cancer, Facts and Figures 2020-2022*, *supra* note 57, at 19.

125. LEAHY, *supra* note 115 § 9.

126. ASGE Standards of Practice Committee, *Bowel Preparation Before Colonoscopy*, 81 *GASTROINTESTINAL ENDOSCOPY* 781 (2015).

127. *Id.*

128. *Id.*

129. *Id.*

colon angle.¹³⁰ Air, carbon dioxide, or water is used to inflate the colon so that the physician may better visualize the walls of the structure.¹³¹ Several studies report that water-aided colonoscopy provides the most benefit of “less patient discomfort and less need for sedation.”¹³² A small tube about the width of a finger is then inserted into the rectum. This instrument contains a small light and camera on its end that transmits images of the lining of the colon.¹³³ The device is then gently advanced through the length of the bowel.¹³⁴ The scope is flexible so it can conform to the twists and contours of the colon. As the scope is moved forward, small amounts of air are introduced to expand the intestines so that the physician can see more clearly.¹³⁵ The procedure takes about 30 to 60 minutes to complete, during which time the patient is given medication or anesthesia to help rest or sleep during the test.¹³⁶ If an abnormality is visualized, the physician obtains a tissue sample for testing, and irregular polyps are oftentimes extracted. This ability frequently advertises the need for subsequent surgery.¹³⁷

A colonoscopy is a routine procedure, and there are few lasting complications.¹³⁸ However, several specialty societies like the American Society for Gastrointestinal Endoscopy have issued pronouncements on the complications that gastroenterologists and patients should understand pre-procedure due to the chances of litigation.¹³⁹ After all, a colonoscopy does have certain inherent

130. CLEVELAND CLINIC, *Colonoscopy*, <https://my.clevelandclinic.org/health/diagnostics/4949-colonoscopy> [https://perma.cc/RUB7-8XGU] (last updated Oct. 27, 2019).

131. Hyun Gun Kim, *Painless Colonoscopy: Available Techniques and Instruments*, 49 CLINICAL ENDOSCOPY 444 (2016).

132. Rastogi & Wani, *supra* note 123, at 60.

133. LEAHY, *supra* note 115 § 7.

134. *Id.*

135. *Id.*

136. *Id.*

137. *Id.* § 8.

138. Kim, *supra* note 131.

139. C. Andrew Kistler, *Legal Considerations in Gastroenterology: Key Concerns*, GASTROENTEROLOGY ADVISOR (Dec. 7, 2020), <https://www.gastroenterologyadvisor.com/general->

dangers. These risks increase the chance for malpractice claims because of the regularity that these procedures are done and the potential for error, notwithstanding the physicians' skills.¹⁴⁰ These risks include bleeding, infection, a reaction to the anesthesia, severe pain in the abdomen, and perforation of the colon. As one study reported, about 4 to 8 serious complications arise in every 10,000 procedures.¹⁴¹ The research also demonstrated that complications rates increased with age, especially with perforation and bleeding.¹⁴²

Most instances involving bleeding happen in those who have polyps excised. The physician can usually treat this complication during the procedure.¹⁴³ However, there have been reported instances of bleeding up to two weeks after the test, which can be remedied by the physician repeating the colonoscopy.¹⁴⁴ A perforation is commonly acknowledged as one of the most serious complications of a colonoscopy. Although it is an infrequent occurrence, perforation is correlated with a high degree of morbidity and mortality.¹⁴⁵ The consequences of this complication can include surgery, protrusion of a portion of the bowel through the abdominal wall, sepsis, extended hospitalization, and even death.¹⁴⁶ It has been estimated that the perforation rate varies

gastroenterology/legal-considerations-in-gastroenterology-key-concerns/ [<https://perma.cc/8T2H-MTB2>].

140. *Id.*

141. NAT'L INST. OF DIABETES & DIGESTIVE & KIDNEY DISEASE, *Colonoscopy*, <https://www.niddk.nih.gov/health-information/diagnostic-tests/colonoscopy> (last visited November 18, 2021) [<https://perma.cc/V6DV-5SYE>]; Jennifer S. Lin et al., *Screening for Colorectal Cancer: Updated Evidence Report and Systematic Review of the U.S. Preventative Task Force*, 315 J. AM. MED. ASS'N 2576, 2579 (2016).

142. *Id.* at 2584.

143. NAT'L INST. OF DIABETES & DIGESTIVE & KIDNEY DISEASE, *Colonoscopy*, *supra* note 141.

144. *Id.*

145. Varut Lohsiriwat, *Colonoscopic Perforation: Incidence, Risk Factors, Management and Outcome*, 16 WORLD J. GASTROENTEROLOGY 425, 425 (2010).

146. *Id.*

from between 0.005% to 0.85% and this range has not changed meaningfully during the past 15 years.¹⁴⁷

Several mechanisms account for colonoscopy perforations. These include “mechanical trauma, barotrauma, thermal energy, and removal of a tissue lesion.”¹⁴⁸ The largest tears are caused by direct trauma or torque from the scope. The cecum is the most common location of perforation resulting from thermal energy or the removal of a polyp.¹⁴⁹ The prognosis for the injury depends upon the kind of tear. Blunt trauma tends to have more significant tears and a worse outcome. Perforations detected during or immediately after the procedure have much better outcomes than those injuries discovered after delays.¹⁵⁰ An increased risk of early perforation have been found in older patients, women, procedures performed in a hospital setting, therapeutic colonoscopies, and polyp removals. Tears involving the elderly result in a higher incidence of fatalities.¹⁵¹

A joint American Society of Gastrointestinal Endoscopy and American College of Gastroenterology Taskforce on Quality in Endoscopy report advanced certain good practices metrics before, during, and after colonoscopy.¹⁵² These include:

A. Pre-Procedure:

Consideration must be devoted to matters of suitable scheduling, proper patient preparation, focused history and physical examination, assessment of bleeding danger, evaluation for proper sedation, and a team time-out before starting sedation. The team must be mindful of applicable signs and suggested observation breaks premised upon the patient’s risk considerations, such as family history of colorectal cancer, prior polyp formations, genetic colon

147. Su Young Kim, Hyun-Soo Kim & Hong Jun Park, *Adverse Events Related to Colonoscopy: Global Trends and Future Challenges*, 25 WORLD J. GASTROENTEROLOGY 190, 190 (2019).

148. *Id.* at 191.

149. *Id.*

150. *Id.* at 191–92.

151. *Id.* at 192.

152. Linda Lee and John R Saltzman, *Overview of Colonoscopy in Adults*, UPTODATE (2021), <https://www.uptodate.com/contents/overview-of-colonoscopy-in-adults/print> [<https://perma.cc/AS7D-SJ4N>].

cancer syndrome, or inflammatory bowel disease. Finally, the physician must secure the patient's informed consent with a listing of complications linked to colonoscopy procedures.¹⁵³

B. Intra-Procedure:

A skilled examination mandates the ability to see the complete colonic mucosa. Indications of careful visualization metrics include cecal intubation rates, withdrawal times, and adenoma detection rates. A proper procedure also mandates biopsies when confronted with inflammatory bowel disease and extraction of all polyps less than 2 cm.¹⁵⁴

C. Post-Procedure:

It is imperative to properly document in writing and with photographic evidence all findings, and recommendations concerning follow-up care. Biopsies from the procedure must be documented. Pathology results need to be communicated to the patient and referring providers. Lastly, a system must be implemented for tracking complications.¹⁵⁵

Recently, artificial intelligence (AI) has been added to the arsenal of existing assessment and surveillance techniques to uncover abnormalities much earlier in the process when they can be more easily treated.¹⁵⁶ Research demonstrates that even the best clinicians can miss abnormalities during colorectal cancer screenings.¹⁵⁷ On April 9, 2021, the Food and Drug Administration approved the first AI system to help detect

153. *Id.*

154. *Id.*

155. *Id.*

156. *FDA Authorizes Marketing of First Device that Uses Artificial Intelligence to Help Detect Potential Signs of Colon Cancer*, U.S. FOOD & DRUG ADMIN. (Apr. 9, 2021), <https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-first-device-uses-artificial-intelligence-help-detect-potential-signs-colon> [<https://perma.cc/3WUG-XS4L>] [hereinafter FDA, AI, & Colon Cancer].

157. *Id.*

potential signs of colon cancer during colonoscopies.¹⁵⁸ This development has the potential to impact patients' lives and discover polyps at an even earlier stage.¹⁵⁹

It has been shown that physicians can miss abnormalities because of human limitations. A second pair of eyes can improve the ability to detect “hard-to-identify polyps.”¹⁶⁰ AI-assisted colonoscopes have been educated with more than 13 million images of large intestine abnormalities, including many kinds of polyps and “the communal knowledge of gastroenterologists.”¹⁶¹ This intelligence permits physicians to discover more patients with precancerous polyps by more than one-third.¹⁶²

The AI system consists of hardware and software created to highlight aspects of the digestive tract so that the device can detect a problem area.¹⁶³ The software utilizes algorithms to spot areas of interest. Markers are then created which resemble green squares, and these markers are combined with “a low-volume sound” which are then superimposed on the video from the scope's camera.¹⁶⁴ This process alerts the doctor that additional investigation may be required, such as “a closer visual inspection, tissue sampling, testing or removal, or ablation of the lesion.”¹⁶⁵ As a caveat, this new technology is only a compliment to a colonoscopy and is not intended to be an alternative to clinical decision making.¹⁶⁶

158. *Id.*

159. Jessica Levy, *Earlier Detection Is Critical in the Fight Against Colorectal Cancer*, MEDTRONIC (Nov. 12, 2021), <https://www.usatoday.com/story/sponsor-story/medtronic/2021/11/12/earlier-detection-critical-fight-againstcolorectal-cancer/6377989001/> [https://perma.cc/GYX6-FRBL].

160. *Id.*

161. *Id.*

162. *Id.*

163. FDA, AI, & Colon Cancer, *supra* note 156.

164. *Id.*

165. *Id.*

166. Levy, *supra* note 159.

V. TREATMENT OF COLON CANCER

Colorectal cancer is one of the few malignancies that is 100% curable if discovered early during its course.¹⁶⁷ The method of treatment is contingent upon how early the cancer is discovered. It may be possible for the physician to excise the polyp during a colonoscopy so that no additional treatment is needed.¹⁶⁸ However, other patients may need operative intervention and/or chemotherapy.¹⁶⁹ This is where the staging of the abnormality comes into play to assist in determining the most effective treatment course. The process is also important in calculating when and how different treatment options are employed.¹⁷⁰

A. *Timing of the Diagnosis*

Early discovery of the cancer significantly influences the patient's prognosis. The American Society of Clinical Oncology estimates that 39% of colon cancer patients have localized lesions that can be removed through surgery following the colonoscopy.¹⁷¹ CRC patients with early-stage disease may also undergo chemotherapy following their surgery.¹⁷² The survival rate for these individuals to live more than five years is 90% if the cancer remains localized.¹⁷³

The treatment options become much more aggressive as the cancer progresses, especially if it has grown into or through the large intestine. For instance, the surgeon may have to perform a partial colectomy wherein the surgeon excises the portion of the intestine that is malignant and a part of the healthy tissue on both sides of the lesion.¹⁷⁴ The physician then attempts to rejoin the healthy tissue through a resection. Surgical advances often

167. HODGE, JR. & HUBBARD, *supra* note 12.

168. *Colon Cancer Treatment*, HOPKINSMEDICINE, <https://www.hopkinsmedicine.org/health/conditions-anddiseases/colon-cancer/colon-cancer-treatment> [<https://perma.cc/U8QP-LNHY>] (last visited Nov. 18, 2021).

169. *Id.*

170. *Id.*

171. *Id.*

172. *Id.*

173. *Id.*

174. MAYO CLINIC, *Colon Cancer*, *supra* note 86.

permit the doctor to perform this operation with a laparoscope.¹⁷⁵ Sometimes it is impossible to reconnect the colon, and in these cases, the surgeon has to make an opening in the abdomen to allow for the elimination of waste into a bag.¹⁷⁶ This remedy may be permanent or temporary.¹⁷⁷ Another step in the process is to remove nearby lymph nodes to test for their possible involvement in the disease process.¹⁷⁸

If the cancer is particularly advanced or if the patient's health is poor, the physician may merely alleviate the obstruction in the intestine. This procedure is not a cure for the malignancy, but it does lessen the symptoms.¹⁷⁹ In situations where the cancer has metastasized to the liver or lung, but the person's health is generally good, the surgeon may remove the cancer and employ chemotherapy to eradicate the malignancy over the long term.¹⁸⁰ In other cases, surgery is not performed. Instead, the lesion is examined to see if it contains certain genetic mutations. This undertaking can assist in determining which chemotherapy medication is best suited for the situation.¹⁸¹ This treatment option attempts to kill the cancer cells, and the chemotherapy drugs can be administered in various ways ranging from injection to the taking of a pill.¹⁸²

In some instances, a colorectal cancer patient will undergo radiation therapy. This mode of treatment involves the employment of "high-energy rays (such as x-rays) or particles to

175. *Id.*

176. *Id.*

177. *Id.*

178. *Id.*

179. *Id.*

180. *Id.*

181. *Chemotherapy for Colon Cancer*, MEM'L SLOAN KETTERING CANCER CTR., https://www.mskcc.org/cancer-care/types/colon/treatment/chemotherapy?pn_mapping=pn_11&gclid=Cj0KCQjA-eeMBhCpARIsAAZfxZBdPkVzCVTmVmRMLUXcLAXK1ornoQwMkJrDesds7O5f3Y_64oY7954aAjI_EALw_wcB [https://perma.cc/M38M-YHMQ] (last visited Sept. 24, 2022).

182. *What is Chemotherapy?*, CANCER.NET: ASCO KNOWLEDGE CONQUERS CANCER (May 2022), <https://www.cancer.net/navigating-cancer-care/how-cancer-treated/chemotherapy/what-chemotherapy> [https://perma.cc/4SBU-5JPQ].

destroy cancer cells.”¹⁸³ This procedure is recommended more frequently in cases of rectal rather than colon cancer. However, chemotherapy and radiation therapy will sometimes be used together because chemotherapy can make radiation therapy more effective. This two-step process is known as chemoradiation.¹⁸⁴

B. Who Benefits from A Late Cancer Diagnosis?

It may seem cynical to ask if anyone benefits from a late diagnosis of colorectal cancer. The truth is that pharmaceutical firms profit from delayed detection.¹⁸⁵ Chemotherapy medications including “fluoropyrimidines irinotecan and oxaliplatin are the standard cytotoxic drugs used in treating metastatic colon cancer.”¹⁸⁶ It is estimated that 11% of all cancer treatment expenses in this country are for colorectal cancer,¹⁸⁷ and the disease has the second-highest cost of any cancer.¹⁸⁸ For instance, the average Medicare expenditure for those with recently diagnosed CRC ranges from \$40,000 to \$80,000.¹⁸⁹

According to the *New England Journal of Medicine*, without chemotherapy, the average survival rate among those with metastatic colorectal cancer is about eight months.¹⁹⁰ Using medication and chemotherapy, the average survival period increases from 12 months to at least 21 months.¹⁹¹ Nevertheless, the treatment regimen continues to be palliative.¹⁹² In addition,

183. AM. CANCER SOC'Y, *Radiation Therapy for Colorectal Cancer* (June 29, 2020), <https://www.cancer.org/cancer/colon-rectal-cancer/treating/radiation-therapy.html> [https://perma.cc/4JTL-37VX].

184. *Id.*

185. Canter, *supra* note 9.

186. *Id.*

187. CTRS. FOR DISEASE CONTROL & PREVENTION, *Cost-Effectiveness of Colorectal Cancer Interventions* (Aug. 18, 2021), <https://www.cdc.gov/chronicdisease/programs-impact/pop/colorectal-cancer.htm> [https://perma.cc/ZSC5-SGWN].

188. *Id.*

189. *Id.*

190. Deborah Schrag, *The Price Tag on Progress – Chemotherapy for Colorectal Cancer*, 351 *NEW ENG. J. MED.* 317, 318-19 (2004).

191. *Id.* at 318.

192. *Id.*

patients experience “sticker shock” when confronted with the cost of chemotherapy drugs. One study revealed that 32,000 people were diagnosed with stage IV colorectal cancer during the year in question, and an additional 24,000 patients developed recurrent metastatic disease.¹⁹³ The medication expense for this total population for an initial eight-week course of treatment was about \$666 million or \$1.2 billion with the addition of monoclonal-antibody therapy. This calculation was only for the drugs and did not include the costs associated with the preparation and administration of the medication.¹⁹⁴

VI. LEGAL REPERCUSSIONS INVOLVING GASTROENTEROLOGISTS

More than half of all physicians in the United States will be confronted with a malpractice claim during their careers.¹⁹⁵ However, gastroenterologists view their specialty as one subject to a higher level of legal risk because they conduct invasive procedures.¹⁹⁶ In this regard, they rank sixth as the most frequent group named in malpractice claims, and the most common procedure named in these claims is the colonoscopy.¹⁹⁷ Each year about 13% of gastroenterologists are presented with claims for

193. Canter, *supra* note 9, at 14.

194. *Id.*

195. Joanne Finnigan, *More Than Half of U.S. Doctors Have Faced Malpractice Lawsuits, Survey Finds*, FIERCE HEALTHCARE (Nov. 15, 2017), <https://www.fiercehealthcare.com/practices/more-than-half-u-s-doctors-malpractice-lawsuit-survey> [https://perma.cc/5H4X-66RU]; Peter Hoffman et al., *Legal Issues for the Gastroenterologist: Part 1*, GI & HEPATOLOGY NEWS (June 1, 2017), <https://www.mdedge-cache.beta.mdedge.com/gihepnews/article/156142/legal-issues-gastroenterologist-part-i> [https://perma.cc/8TBS-6HZY].

196. See Laurie Conklin et al., *Medical Malpractice in Gastroenterology*, 6 CLIN. GASTROENTEROLOGY AND HEPATOLOGY 677 (2008).

197. Jim King, *How to Predict Successful Colonoscopy Malpractice Lawsuits*, MDEdge (Jan. 12, 2021), <https://www.mdedge.com/internalmedicine/article/234524/gastroenterology/how-predict-successful-colonoscopy-malpractice> [https://perma.cc/E3RD-GJSA].

malpractice.¹⁹⁸ The most common assertions focus on mistakes centered around “malignant neoplasms of the colon and rectum, followed by abdominal and pelvic symptoms, regional enteritis, colitis, and malignant neoplasms of the stomach.”¹⁹⁹ Mistakes in identifying colon, stomach, and rectal malignancies occasioned the largest average indemnity payment.²⁰⁰

A. *Complications*

One must remember that colonoscopies generally focus on asymptomatic people to detect colorectal cancer. This makes it important for the physician to assess the significance of the danger and gravity of the risks from screening patients.²⁰¹ This is especially noteworthy in today’s legal environment.²⁰² The *Annals of Internal Medicine* published an article that examined the complication rates stemming from colonoscopies. Statistics were compiled to expose the number of serious complications during the first 30 days after the procedure. These were determined to be: “1) colonic perforation; 2) post-polypectomy syndrome; 3) bleeding requiring overnight hospitalization; 4) diverticulitis requiring overnight hospitalization . . . ; and 5) any other hospitalization within 30 days that was likely to have been caused or exacerbated by the procedure.”²⁰³

B. *Statistics*

The average age for those who suffered serious complications was 63 as opposed to an average age of 62 for those without difficulties.²⁰⁴ The researchers ascertained that the frequency of serious complications was 5.0 per 1,000 tests, with the largest

198. Krishan Patel et al., *Current Trends and Predictors of Case Outcomes for Malpractice in Colonoscopy in the United States*, 56 J. CLINICAL GASTROENTEROLOGY 49, 49 (2020).

199. Hoffman et al., *supra* note 195, at 2.

200. *Id.*

201. Theodore R. Levin et al., *Complications of Colonoscopy in an Integrated Health Care Delivery System*, 145 ANNALS INTERNAL MED. 880, 880 (2006).

202. *See generally* Patel et al., *supra* note 198; Hoffman et al., *supra* note 195.

203. Levin et al., *supra* note 201, at 882.

204. *Id.* at 883.

group suffering bleeding that required hospitalization.²⁰⁵ 0.6 of these patients died from a variety of causes including congestive heart failure, heart attack, sepsis after transfusion for post-polypectomy, and the underlying indication for colonoscopy in the first place.²⁰⁶ The most substantial complication without biopsy was perforation. This occurred in 0.6 complications per 1,000 colonoscopies.²⁰⁷ The first seven days post-procedure proved to be the most troublesome. The most apparent factor for developing a serious problem was whether a biopsy or polypectomy was done. These circumstances elevated the chance for a serious complication by 9.2 times.²⁰⁸

C. Theories of Liability

In a medical malpractice setting, the failure to diagnose colorectal cancer used to be the most common claim brought in lawsuits of this nature, especially when patients displayed indications of the disease.²⁰⁹ However, now the most common claim is the “failure to screen” or the “failure to properly screen.”²¹⁰ Multiple studies and organizational statements note that those individuals who are at increased risk for CRC should be told to undergo a colonoscopy.²¹¹ In many malpractice cases where the plaintiffs were awarded damages for the failure to diagnose CRC properly, greater weight was placed on the failure to screen the patient properly. This preventative measure would have “led to a proper, early diagnosis and therefore early treatment to asymptomatic patients.”²¹²

A Westlaw search of the terms “colonoscopy and malpractice” and “sigmoidoscopy and malpractice” uncovered 437 cases over a twenty-seven year period.²¹³ Irrelevant and identical

205. *Id.*

206. *Id.*

207. *Id.* at 884.

208. *Id.*

209. Canter, *supra* note 9, at 12.

210. *Id.*

211. *Id.*

212. *Id.*

213. Patel et al., *supra* note 198, at 49, 50 (referencing the period spanning from 1980 to 2017).

decisions were then discarded, producing 305 opinions for review.²¹⁴ An analysis of those cases demonstrated that the average patient was almost 55 years old, with a little more than half being female.²¹⁵ The greatest number of lawsuits were from New York, California, Pennsylvania, Massachusetts, and New Jersey.²¹⁶ Defense verdicts were returned in almost 52% of the trials, and the median award was \$995,000. The majority of claims asserted multiple theories of liability, but the most frequent allegations involved “delay in treatment (65.9%), delay in diagnosis (65.6%), procedural error/negligence (44.3%), and failure to refer/order tests.”²¹⁷ Perforation of the colon was the most repeated assertion, making up 67% of all claims.²¹⁸ Lack of informed consent was the most common theory advanced by those who experienced perforation of the large intestines, and the verdicts tended to favor the defendants. This result is not surprising since a perforation is a well-known complication of a colonoscopy.²¹⁹ On the flip side, medication mistakes foretold a verdict in favor of the patient and focused mainly on difficulties with sedation or anesthesia.²²⁰

A study involving a “Verdict Search” database revealed that the most significant awards or settlements involved the failure to conduct the colonoscopy according to screening guidelines.²²¹ Compensation in these matters ranged from \$135,000 to \$7.1 million.²²² A Westlaw search, however, reveals that the largest reported payment was rendered in *Merlo v. Bassi* in the amount of \$49.8 million.²²³ This matter involved a patient who was

214. *Id.* at 50.

215. *Id.*

216. *Id.*

217. *Id.*

218. *Id.*

219. *Id.* at 53.

220. *Id.*

221. Kistler, *supra* note 5.

222. *Id.*

223. *Merlo, By and Through His Conservator and Guardian Ad Litem, Merlo v. Bassi*, CRNA; American; Ambulance; Portillo; Freer; Schneider, JVR No. 2112010004, 2021 WL 5767818 (Cal. Super. Ct. Oct. 5, 2021).

undergoing an upper endoscopy and colonoscopy when complications arose.²²⁴ The nurse anesthetist immediately administered oxygen and intubated the patient, and an ambulance took the patient to a hospital.²²⁵ During the transport, the paramedics extubated and reintubated the patient to “readjust the endotracheal tube.”²²⁶ Various errors were later found in the ambulance medical records.²²⁷ In the emergency room, blood was discovered in the patient’s mouth and the emergency physician reintubated the patient.²²⁸ Unfortunately, the individual suffered anoxia, a loss of oxygen to the brain,²²⁹ which left him to a “permanent vegetative state, and brain damage.”²³⁰

The patient’s spouse alleged that the injuries were caused by the negligence of the nurse anesthetist, paramedics, and employees of the ambulance company.²³¹ The defendants denied these allegations.²³² Nevertheless, the jury found the ambulance company and its paramedics liable for “his medical expenses, lost future earnings[,] and the loss of consortium” by his pregnant wife.²³³

D. Credentials

A colonoscopy is a challenging technique that mandates much instruction, practice, and knowledge for optimal results. Proper performance requires a combination of medical perceptiveness, sophisticated manipulative abilities, a functional understanding

224. *Id.*

225. *Id.*

226. *Id.*

227. *Id.*

228. *Id.*

229. Tim Jewell, *What Causes Anoxia and What Can You Do About It?*, HEALTHLINE (Oct. 17, 2017), <https://www.healthline.com/health/anoxia> [https://perma.cc/ZYT9-HUDA].

230. *Merlo*, 2021 WL 5767818.

231. *Id.*

232. *Id.*

233. Nicole Bleier, *Calif. Jury Awards Nearly \$50M In Ambulance Ride Injury Suit*, LAW360 (Oct. 6, 2021), <https://www.law360.com> (enter the title of the article into the search bar on the homepage, then click “search”).

of gastrointestinal structures, and the use of safe operational tools.²³⁴ A properly trained specialist should be able to identify all clinically significant “colorectal pathology, obtain representative tissue samples, completely resect most colorectal polyps, prevent and manage complications, and integrate findings into effective patient management.”²³⁵

These procedures are performed by gastroenterologists, colorectal surgeons, general surgeons, family doctors,²³⁶ nurses, and physician assistants. Several studies have found a strong correlation between the complication frequency of colonoscopy performance and the interventionist’s experience.²³⁷ For example, studies suggest that the specialty of the physician performing the procedure is a good indicator of the colonoscopy’s quality. Those who have negative colonoscopies done by practitioners other than gastroenterologists have a higher rate of interval colorectal cancer development and a later surge in mortality.²³⁸ According to the American College of Gastroenterology, gastroenterologists conduct more of these procedures than any other specialty and those outside of this specialty who perform the test have a five times greater likelihood in missing colorectal cancer during colonoscopy.²³⁹ This makes an investigation into the background of the medical technician a key aspect of any malpractice claim.

234. John Bond & James Frakes, *Who Should Perform Colonoscopy? How Much Training Is Needed?*, 49 GASTROINTESTINAL ENDOSCOPY 657 (1999).

235. *Id.*

236. It is the position of the American Academy of Family Physicians that these procedures are within the scope of family practice. Dennis Worthington, *Colonoscopy: Procedural Skills*, AM. FAMILY PHYSICIAN (Sept. 1, 2000), <https://www.aafp.org/afp/2000/0901/p1177.html> [<https://perma.cc/24AW-WFH2>] (supporting the position of the American Academy of Family Physicians that these procedures are within the scope of family practice).

237. Bond & Frakes, *supra* note 234, at 657.

238. CLEVELAND CLINIC, *Does Endoscopist Specialty Affect Colonoscopy Quality Outcomes?*, <https://consultqd.clevelandclinic.org/does-endoscopist-specialty-affect-colonoscopy-quality-outcomes/> [<https://perma.cc/6WQD-U4EP>] (last visited Dec. 4, 2021).

239. AM. COLL. GASTROENTEROLOGY, *Your Doctor Has Ordered A Colonoscopy: What Questions Should You Ask*, <https://gi.org/patients/gi-health-and-disease/your-doctor-has-ordered-a>

E. Informed Consent

Informed consent is an essential component of the shared decision-making process and necessitates a patient being told of the benefits, risks, and options to a medical procedure.²⁴⁰ This knowledge aids a patient to choose whether to go forward with the recommended treatment plan.²⁴¹ The concept has its foundation in the idea of patient autonomy as a basic human right. It is the individual's decision to fully understand what may be done to their body and to weigh the dangers and advantages before agreeing to a procedure.²⁴² Conversely, a doctor's function is to serve as a facilitator in the patient's decision-making process by offering details about the proposed treatment and answering questions.²⁴³

According to the American Society for Gastrointestinal Endoscopy (ASGE), informed consent should include a discussion of: (1) the patient's medical diagnosis and test results; (2) the nature of the procedure; (3) the reason for the procedure; (4) the benefits of the procedure; (5) the risks and complications of the procedure (i.e. "the relative incidence and severity, that would be material to the patient's decision-making process"); (6) any alternative treatments; and (7) any potential risks if the procedure is declined.²⁴⁴ The sedation plan should also be discussed as part of the informed consent process.²⁴⁵

All jurisdictions have some form of informed consent laws.²⁴⁶ The exact language of the individual statutes has varied over the years and differs from state to state. However, the basic premise

colonoscopy-what-questions-should-you-ask/ [https://perma.cc/XY6E-L99F] (last visited Dec. 4, 2021).

240. Samuel D. Hodge, Jr. & Maria Zambrano, *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 (2019).

241. *Id.* at 728.

242. *Id.*

243. *Id.*

244. Philip Schoenfeld, *Quality in Colorectal Cancer Screening with Colonoscopy*, 30 GASTROINTEST. ENDOSC. CLIN. N. AM. 541, 543 (2020).

245. *Id.*

246. Hodge, Jr. & Zambrano, *supra* note 240, at 732.

is that of patient knowledge.²⁴⁷ Exceptions do exist for emergencies and legally decided mental incompetency or physical incapacity.²⁴⁸ The kind and degree of information that must be revealed is based upon two core values owed by the physician: the obligation “to do good,” and respect for the person’s autonomy.²⁴⁹ For example, in *Flores v. Alva*, the plaintiff was admitted to the hospital for swelling in the legs.²⁵⁰ A CT scan of the abdomen was done, and the defendant recommended a colonoscopy be performed.²⁵¹ When the physician discussed the procedure with the patient before the colonoscopy was performed, the patient told the defendant that he did not want a colonoscopy.²⁵² Also, the plaintiff’s informed consent was never secured for the procedure nor were the risks, advantages, or alternatives explained.²⁵³ Nevertheless, the defendant proceeded with the test and accidentally perforated the patient’s colon, causing the patient’s abdomen to become contaminated with fecal matter. These complications caused septic shock requiring emergency surgery and hospitalization for more than 30 days.²⁵⁴

The physician disagreed that he failed to discuss the risks but admitted he failed to talk about any alternative treatment options to performing the colonoscopy on the patient.²⁵⁵ The defendant’s expert witness maintained that there were no available

247. *Id.*

248. *Id.* at 733.

249. *Id.*

250. *\$1 Million Verdicts in Suit Alleging Failure to Obtain Informed Consent for Colonoscopy*, GWC INJ. LAWS.: MED. MALPRACTICE BLOG (July 21, 2017), <https://www.gwclaw.com/blog/colonoscopy-injury-award-informed-consent/> [<https://perma.cc/6H2Q-XGZY>].

251. *Id.*

252. *Id.*

253. *Id.*

254. *Id.*

255. Robert Kreisman, *\$1.012 Million Cook County Jury Verdict for Patient’s Bowel Puncture in Medical Malpractice Case*, KREISMAN L. OFF.: CHI. MED. MALPRACTICE ATT’Y BLOG (Sept. 14, 2017), <https://www.robertkreisman.com/medical-malpractice-lawyer/1-012-million-cook-county-jury-verdict-patient-bowel-puncture-medical-malpractice-case/> [<https://perma.cc/Y246-RNVV>].

alternatives to the plaintiff's medical condition.²⁵⁶ The jury found for the plaintiff and returned a verdict for \$1,011,950.²⁵⁷

In *Maybrier v. La. Med. Mut. Ins. Co.*, the plaintiff consented to a hemorrhoidectomy.²⁵⁸ While performing this procedure, the physician chose to perform an additional procedure, a colonoscopy, to which the plaintiff had not consented.²⁵⁹ The informed consent form that the plaintiff signed had the word "colonoscopy" handwritten on it. However, whether this was added before or after the procedure was undetermined.²⁶⁰ Regardless, the form did not list any of the known, material risks of a colonoscopy.²⁶¹ The trial court held that a physician "may not act beyond his patient's authorization," except in life-threatening situations.²⁶² In this case, there was not an immediate threat to the patient's life so he should have been allowed to pick a physician for the colonoscopy which he thought "possessed greater specialized skills."²⁶³ The court also concluded that the risk of a perforated colon was "substantial enough that a reasonable patient" would have attached significance in deciding whether to undergo the procedure.²⁶⁴ As a result, summary judgment in favor of the physician was reversed, and the case was remanded.²⁶⁵

The opposite result was held in *Eddis v. United States*, where the plaintiff underwent a colonoscopy and suffered a perforation.²⁶⁶ The plaintiff then brought suit alleging that his

256. *\$1 Million Verdicts in Suit Alleging Failure to Obtain Informed Consent for Colonoscopy*, *supra* note 250.

257. *Id.*

258. *Maybrier v. La. Med. Mut. Ins. Co.*, 12 So. 3d 1115, 1117 (La. Ct. App. 2009).

259. *Id.*

260. *Id.*

261. *Id.* at 1119.

262. *Id.* at 1122.

263. *Id.* at 1122–23.

264. *Id.* at 1123.

265. *Id.*

266. *Eddis v. United States*, No. 02-3604, 2003 Dist. LEXIS 4214, *3 (E.D. Pa. Mar. 19, 2003).

physician did not inform him of the risk of perforation.²⁶⁷ However, the federal district court found that the physician “credibly testified” that it was his unchanging practice to communicate the risks of the procedure before permitting the patient to sign the consent form.²⁶⁸ The court also noted that the plaintiff had personal knowledge of the procedure since he had undergone three prior colonoscopies, and his brother and sister had both died of colon cancer.²⁶⁹ Further, the court concluded that the risk of perforation would not have been a substantial factor in the plaintiff’s decision to undergo the colonoscopy due to his family history and the claimant’s own experience with pre-cancerous polyps” which confirmed a genetic propensity.²⁷⁰ Thus, judgment was entered in favor of the defendant physician.²⁷¹

F. Medical Malpractice

Although the colonoscopy is considered a relatively safe procedure, 1.6% of colonoscopies lead to complications.²⁷² This translates to an afflicted 224,000 patients every year or 613 patients every day in the U.S.²⁷³ Several common errors can lead a patient to file a lawsuit. One error that can lead to a medical malpractice lawsuit is the failure to recommend a colonoscopy, and this failure may prevent a patient from receiving “timely and correct treatment.”²⁷⁴ Another error is the failure to inform patients of the procedure’s risks such as rectal bleeding, post polypectomy electrocoagulation syndrome, or a perforated

267. *Id.* at *4.

268. *Id.*

269. *Id.* at *8–9.

270. *Id.* at *9–10.

271. *Id.* at *11.

272. *Medical Malpractice Post Colonoscopy: Oregon Medical Malpractice Attorney Explains*, KUHLMAN LAW, LLC (Jan. 5, 2022), <https://stoppingmedicalmistakes.com/medical-malpractice-post-colonoscopy-oregon-medical-malpractice-attorney-explains/> [https://perma.cc/LZ6J-ZXD3].

273. *Id.*

274. *Colonoscopy Errors*, BUNDZA & RODRIGUEZ, P.A. (Jan. 8, 2019), <https://www.daytonallawyers.com/colonoscopy-errors/> [https://perma.cc/6WXJ-TWNC].

intestine.²⁷⁵ During the procedure, improper sedation can lead to a “plunging blood pressure or other complications.”²⁷⁶ In addition, there could be a failure to diagnose cancerous growths, failure to remove polyps, puncturing the colon with the camera, not correctly monitoring vital signs, and the lack of proper sterilization of medical equipment leading to infection.²⁷⁷

1. Perforation

A perforation of the large intestine is a known risk of a colonoscopy. Thus, in the absence of clear evidence of excessive force, it is difficult for a plaintiff to prevail on this injury alone.²⁷⁸ For instance, in *Hillyer v. Midwest Gastrointestinal Assocs., P.C.*, the plaintiff alleged a deviation from the standard of care.²⁷⁹ She asserted that her physician used excessive force during her colonoscopy which caused the instrument to perforate her colon.²⁸⁰ The case ended up resting on the credibility of the two opposing experts.²⁸¹ The plaintiff’s expert testified that a large perforation like the one sustained by the plaintiff, which was 6 to 7 centimeters, could have occurred “only due to excessive force.”²⁸² However, the defendant’s expert maintained that colon perforation is a “known and accepted complication . . . occur[ing] even when the best medical care is provided.”²⁸³ The defendant also testified that during the procedure he “did not encounter resistance” and “did not use excessive force to advance the

275. Minesh Khatri, *Colonoscopy Risk*, WEBMD (Mar. 1, 2020), <https://www.webmd.com/colorectal-cancer/colonoscopy-risks> [<https://perma.cc/MG22-VL9C>].

276. *Colonoscopy Errors*, *supra* note 274.

277. *Colonoscopy Malpractice Lawsuit: When a Routine Procedure Goes Wrong*, HAMPTON & KING, <https://www.hamptonking.com/blog/colonoscopy-lawsuits-when-a-routine-procedure-goes-wrong/> [<https://perma.cc/ZM64-RFCW>] (last visited Jan. 5, 2022).

278. *Hillyer v. Midwest Gastrointestinal Assocs., P.C.*, 96, 883 N.W.2d 404 (Neb. App. 2016).

279. *Id.* at 77.

280. *Id.* at 77.

281. *Id.* at 79.

282. *Id.* at 78–9.

283. *Id.* at 79.

colonoscopy.”²⁸⁴ The jury returned a verdict in favor of the defendants.²⁸⁵

Alternatively, in *McCade v. Wills Eye Hospital*, a patient complained of “severe pain” the day following his colonoscopy.²⁸⁶ His physician instructed him to go to the emergency room. A CT scan showed no free air, which meant no perforation. The patient was treated with antibiotics and continued to be monitored. After a few days, a second CT scan showed a perforation warranting emergency surgery. The physician contended that perforation is a “known complication” of a colonoscopy, and this was indicated on the informed consent form. However, the patient alleged that his colon was overinflated to “a level beyond the standard of care.” Over two feet of his colon had to be removed due to the perforations. The jury ultimately agreed with the patient and awarded him a \$2 million verdict against the physicians who cared for him.

2. Failure to Diagnose

In *Webster v. CDI Indiana*, a patient was diagnosed with Stage 1 rectal cancer after undergoing a colonoscopy.²⁸⁷ The tumor was removed during the initial procedure and more extensively in a subsequent colonoscopy.²⁸⁸ She was declared cancer-free at this point.²⁸⁹ However, five years later, the plaintiff experienced constipation and found blood in her stool.²⁹⁰ Her gastroenterologist ordered a CT scan.²⁹¹ The radiologist who read the CT scan failed to identify a tumor in the plaintiff’s rectum.²⁹² Because of this error, a curable rectal cancer spread to her lungs

284. *Id.* at 80.

285. *Id.*

286. *McCade v. Wills Eye Hosp.*, No. 090601763, LEXIS 211396, *2 (Phila. Ct. Com. Pl. Oct. 31, 2011).

287. *Webster v. CDI Indiana*, No. 1:16-2677, LEXIS 86, *1 (S.D. Ind. July 2018).

288. *Id.*

289. *Id.*

290. *Id.*

291. *Id.*

292. *Id.*

becoming a terminal condition.²⁹³ The plaintiff had to prove “apparent agency and a standard of care violation.”²⁹⁴ The patient successfully proved both of these elements because of the misreading of the CT scan and the failure to diagnose rectal cancer.²⁹⁵ The jury awarded the plaintiff \$15,000,000.²⁹⁶

In *Upton v. Littenberg*, medical negligence and wrongful death claims were brought for a six-month delay in the diagnosis of a patient’s Stage III colon cancer.²⁹⁷ In May 2010, the plaintiff’s physician performed a colonoscopy, removed a polyp, and took several biopsies.²⁹⁸ The patient’s colon cancer was diagnosed five months later after he underwent a colectomy and appendectomy.²⁹⁹ The patient’s estate alleged that the physician violated the standard of care by failing to diagnose the cancer in May.³⁰⁰ The estate argued that if the patient’s cancer had been initially diagnosed during the earlier colonoscopy, he would have had a 55% chance of survival and a 79% probability of five-year survival after treatment.³⁰¹ The physician denied violating the standard of care and contended that the chance of survival would not have improved if the cancer was discovered in May instead of November.³⁰² The jury returned a verdict in favor of the physician finding that he was not negligent in his care and treatment.³⁰³

3. Failure To Properly Sterilize Medical Equipment

A study discovered that about 15% percent of flexible endoscopes employed to view the gastrointestinal system at five hospitals contained containments from patients who had previously undergone procedures. This contamination was present

293. *Id.*

294. *Id.*

295. *See id.*

296. *Id.*

297. *Upton, on Behalf of Upton, Estate of v. Littenberg, M.D.*, JVR No. 2002100050, 2019 WL 7897744 (Cal. Sup. 2019).

298. *Id.*

299. *Id.*

300. *Id.*

301. *Id.*

302. *Id.*

303. *Id.*

even after the instruments had been cleaned.³⁰⁴ Therefore, it is unsurprising that cases have arisen in which dirty instruments form the basis of a claim. In *Kolangi v. Rosman*, a patient alleged that her physician “failed to properly clean, rinse and sterilize” the colonoscope before her procedure.³⁰⁵ She asserted that her injuries included acute colitis, gastroparesis, aggravated irritable bowel syndrome (IBS), daily vomiting and abdominal bloating.³⁰⁶ However, her physician denied these claims and maintained that the patient’s complaints were caused by her “long-standing IBS condition” and that abdominal discomfort was an expected side effect of the procedure.³⁰⁷ He added that the patient was experiencing nausea and vomiting before the colonoscopy took place which meant she had gastroparesis prior to the procedure.³⁰⁸ Finally, he denied that the patient experienced colitis or chemically induced colitis.³⁰⁹ With this testimony, the jury returned a verdict in favor of the physician.³¹⁰

In *Gonzalez v. Arya*, the patient alleged that her hepatitis C was caused by her physicians’ use of unsterilized equipment.³¹¹ The patient’s illness spurred an investigation of one of the physicians’ practices by the New York City Department of Health and Mental Hygiene.³¹² The investigation revealed the use of “ungloved hands,” “expired disinfectant,” “unsterile syringes,” and that used colonoscopes were kept next to sterile instruments.³¹³ The plaintiff argued that these findings demonstrated that the physician’s practice routinely engaged in

304. Dan Mangan, *Dirty Endoscopes Raising Alarms for Colonoscopies*, CNBC (June 8, 2013, 1:18 PM), <https://www.cnbc.com/id/10079833> [<https://perma.cc/N7GK-MCVY>].

305. *Kolangi v. Rosman*, M.D., JVR No. 1909160018, 2019 WL 4439921 (N.Y. Sup. 2019).

306. *Id.*

307. *Id.*

308. *Id.*

309. *Id.*

310. *Id.*

311. *Gonzalez v. Arya*, No. 20709/10, 2016 Jury Verdicts LEXIS 6261 (N.Y. Civ. Ct., Jan. 29, 2016).

312. *Id.*

313. *Id.*

“unsterile techniques.”³¹⁴ Further, the plaintiff’s infectious-diseases expert concluded that her hepatitis was contracted during her colonoscopy, which was performed directly after her physician had treated a patient with hepatitis.³¹⁵ The physician’s expert countered that the patient contracted hepatitis before her colonoscopy was performed and that her procedure “did not involve an unsterile act.”³¹⁶ The jury found that the physicians were liable for the patient’s hepatitis and awarded her \$5.1 million in damages.³¹⁷

4. Improper Sedation

In *Pritt v. Munster Same Day Surgery*, a 68-year-old man was experiencing pain and rectal bleeding.³¹⁸ His medical providers sent him to a clinic for a colonoscopy and esophagogastroduodenoscopy (EGD).³¹⁹ Before the procedures, the patient was injected with Visatril, a sedative for anxiety, and Robinul which decreases the level of stomach acid.³²⁰ After the injections, the patient alleged that he felt a burning sensation in his leg and foot which turned into intense pain.³²¹ The nurses did not alert the doctor to this discomfort.³²² Three months later, testing showed that the patient had an injured sciatic nerve.³²³ He was later diagnosed with RSD and complained of constant pain.³²⁴

The nurses who administered the injections denied having breached the standard of care.³²⁵ They also denied that the plaintiff had RSD and added that he had several pre-existing

314. *Id.*

315. *Id.*

316. *Id.*

317. *Id.*

318. *Pritt v. Munster Same Day Surgery*, No. 45D05-0908-CT-124, 2012 IN Jury Verdicts Rptr. LEXIS 57 (Ind. Oct. 20, 2011).

319. *Id.*

320. *Id.*

321. *Id.*

322. *Id.*

323. *Id.*

324. *Id.*

325. *Id.*

comorbidities, which included issues with his leg.³²⁶ The nurses argued that there was no causal connection between the injections and the patient's alleged injury and that his pain was managed by medication.³²⁷ Lastly, they argued that the patient "failed to mitigate his damages."³²⁸ The jury returned a verdict in favor of the defendants.³²⁹

5. Failure To Diagnose Cancerous Growths

In *Debrow v. Harless*, the spouse of the decedent filed a suit for the failure of the defendant to timely diagnose the patient's rectal cancer.³³⁰ The facts show that the decedent first visited the physician because of a leg injury.³³¹ It was claimed that at no time during his visits to the doctor was he ever informed to undergo a colonoscopy despite being more than 50 years old.³³² On the other hand, the defendant claimed that he spoke to the patient several times about having a colonoscopy, but he refused.³³³ Some years later, the patient died from colon cancer.³³⁴

The plaintiff asserted that the failure to advise the patient about the necessity for a colonoscopy was the proximate cause or a substantial factor in causing his death.³³⁵ The defendant's motion for a directed verdict was granted, and an appeal was taken of that decision.³³⁶ The plaintiff claimed that a dispute existed as to whether the defendant ever advised the decedent to undergo a colonoscopy. However, the evidence demonstrated that the patient's wife did not always accompany the patient to the doctor's visits.³³⁷ The plaintiff's expert also admitted that if the

326. *Id.*

327. *Id.*

328. *Id.*

329. *Id.*

330. *Debrow v. Harless*, 183 So.2d 904 (Miss. Ct. App. 2015).

331. *Id.* at 906.

332. *Id.*

333. *Id.*

334. *Id.*

335. *Id.*

336. *Id.*

337. *Id.* at 907.

physician had informed the patient to undergo a colonoscopy, he would have satisfied the standard of care. Nevertheless, the expert adamantly maintained that such notification and refusal should have been documented in the medical records.³³⁸ Because no evidence existed to contradict the defendant's testimony that the patient was told about the need for a colonoscopy, the plaintiff failed to establish a prima facie case of malpractice. Therefore, the trial court's grant of a directed verdict in favor of the physician was proper.³³⁹

In *Thomas v. Rodriguez*, a patient was experiencing "rectal bleeding, change in bowel habits[,] and stomach pain."³⁴⁰ A gastroenterologist performed a colonoscopy and found two polyps and internal hemorrhoids but no indication of cancer.³⁴¹ The patient visited his physician regularly over the next year and a half where he complained of "rectal bleeding, abdominal pain[,] and pain radiating into his back."³⁴² Despite these consistent complaints, his physician did not take any further action.³⁴³ The patient returned after six months and was in "stage 4 metabolic adenocarcinoma, which had spread."³⁴⁴ The patient argued that the physician should have re-scoped his patient within twelve months when his symptoms became increasingly severe.³⁴⁵ If the patient had been diagnosed with stage 1 cancer, he could have engaged in the appropriate treatment and experienced remission.³⁴⁶

6. Failure To Remove Polyps

In *Semeraro v. Connolly*, the spouse of the decedent filed a suit for the failure of the physician to completely remove a

338. *Id.*

339. *Id.*

340. Hope Thomas, as personal representative of the Estate of Ronald Thomas v. Miguel Rodriguez M.D. and Feller, Kafka, Grijian M.D. PA d/b/a Miami Gastroenterology Association, No. 04-23523, 2007 Fla. Jury Verdicts LEXIS 41936 (11th Cir. Mar. 31, 2007).

341. *Id.*

342. *Id.*

343. *Id.*

344. *Id.*

345. *Id.*

346. *Id.*

polyp.³⁴⁷ The facts show that the patient underwent a colonoscopy during which her physician found a polyp on her colon.³⁴⁸ This growth was removed, and the physician scheduled a follow-up appointment to make sure that the entire growth had been extracted.³⁴⁹ However, at the follow-up appointment, the physician was unable to verify whether the polyp was completely removed due to poor preparation of the patient's colon area.³⁵⁰ No subsequent appointments were scheduled, and the physician did not treat the patient at any later time.³⁵¹ Six years later, the patient underwent another colonoscopy which indicated the presence of a "large polyp growth and tumor" on her colon.³⁵² Although the tumor was surgically removed, the patient died two years later.³⁵³

The plaintiff argued that his spouse's tumor resulted from the physician's failure to thoroughly remove the polyp growth during the first colonoscopy.³⁵⁴ Further, the plaintiff contended that if his spouse had been notified of the physician's deteriorating condition due to Alzheimer's disease, she would have picked a different physician to perform the procedure, or if she had been notified after the procedure, she would have opted to be reexamined. This would have provided her with the opportunity for early intervention.³⁵⁵

The court explained that the informed consent doctrine does not permit recovery for "failure to reveal information pertaining to the personal characteristics of the physician."³⁵⁶ Instead, the doctrine's purpose is to ensure that a patient is sufficiently informed about the procedure.³⁵⁷ Therefore, the court found that

347. *Semeraro v. Connolly*, No. 92-4636, 1992 U.S. Dist. WL 392621, at *1 (E.D. Pa. 1992).

348. *Id.*

349. *Id.*

350. *Id.*

351. *Id.*

352. *Id.*

353. *Id.*

354. *Id.* at *2–3.

355. *Id.* at *3.

356. *Id.*

357. *Id.*

the failure to notify the patient of the physician's cognitive decline was insufficient to maintain a cause of action for battery due to a lack of informed consent.³⁵⁸

In *Hustig v. Domalakes, M.D.*, a patient underwent a routine colon screening in July 1991 at a clinic which revealed a polyp.³⁵⁹ His physician decided to monitor it instead of removing it.³⁶⁰ Over the next ten years, the patient's colon was monitored with "ultrasound and a proctoscope."³⁶¹ In 2000, the patient began to experience fatigue, lethargy, altered bowel habits, and rectal bleeding.³⁶² Physicians at the same clinic found a tumor in his rectum, and he was diagnosed with cancer.³⁶³ Shortly after, he passed away.³⁶⁴ The decedent's spouse alleged that the physician violated the standard of care by failing to remove the polyp when it was first discovered.³⁶⁵ However, the physician denied these allegations and argued that he properly treated his patient by consistently screening him.³⁶⁶ The jury agreed that the physician had breached the standard of care and awarded the patient's estate \$4 million.³⁶⁷ Due to Nebraska state law, this award was capped at \$1.25 million.³⁶⁸

E. Reimbursement for Colonoscopies

The cost to a patient for a colonoscopy can vary between \$1,250 to \$4,800.³⁶⁹ The national average for the

358. *Id.*

359. Phyllis Hustig, individually and administratrix for the Estate of Paul Hustig, v. Michael Domalakes, M.D., and Physicians Clinic, LEXIS 39764 (Neb. Douglas Cnty. Oct. 10, 2007).

360. *Id.*

361. *Id.*

362. *Id.*

363. *Id.*

364. *Id.*

365. *Id.*

366. *Id.*

367. *Id.*

368. *Id.*

369. Alyssa Corso, *How Much Does a Colonoscopy Cost in 2021?*, MIRA (Dec. 1, 2021), <https://www.talktomira.com/post/how-much-a-colonoscopy-costs> [<https://perma.cc/AST9-BWD7>].

procedure is \$2,750,³⁷⁰ but this expense can be influenced by a number of factors such as where the procedure is performed.³⁷¹ Procedures undertaken on an outpatient basis are much less expensive than those done at inpatient facilities.³⁷² For instance, the average cost for an outpatient colonoscopy is \$2,550 while the procedure runs an average of \$4,350 in a hospital.³⁷³ In fact, one hospital in a survey charged \$27,679 for the procedure.³⁷⁴

The cost is also dependent upon the location where the procedure is performed, with large metropolitan cities charging more for the procedure than more remote locations.³⁷⁵ Los Angeles is the most expensive city to have the procedure performed with an average cost as high as \$4,600, while Atlanta's highest average expense is \$3,000.³⁷⁶

The reimbursable cost for the procedure also varies among insurance carriers. This disparity is mainly due to how much the insurance plan covers for the colonoscopy.³⁷⁷ However, a patient who does not have insurance can expect to pay the complete charges for the procedure.³⁷⁸ The Affordable Care Act³⁷⁹ has also influenced the cost of the procedure. The Act provides that private insurers and Medicare cover the costs of colorectal cancer screening tests.³⁸⁰ The statute mandates that individuals

370. Christina Vanvuren, *How Much Does A Colonoscopy Cost?*, NEW CHOICE HEALTH, <https://www.newchoicehealth.com/colonoscopy/cost> [<https://perma.cc/7RXD-32JC>] (last visited Mar. 8, 2022).

371. Corso, *supra* note 369.

372. *Id.*

373. Vanvuren, *supra* note 370.

374. Katie Adams, *Colonoscopy Costs Reveal Significant Price Variances Across Hospitals*, HOSPITAL CFO REPORT (Aug. 12, 2021), <https://www.beckershospitalreview.com/finance/colonoscopy-costs-reveal-significant-price-variances-across-hospitals.html> [<https://perma.cc/K6E6-PNP2>].

375. Corso, *supra* note 369.

376. Vanvuren, *supra* note 370.

377. *Id.*

378. *Id.*

379. Affordable Care Act (ACA) 42 U.S.C. ch. 157 (2010).

380. Taayoo Murray, *Colonoscopy Costs Aren't Always Accepted by Insurance—Here's How to Get Yours Covered*, HEALTH (Dec. 9,

should not be charged out-of-pocket costs such as copays or deductibles.³⁸¹ However, what constitutes “guaranteed coverage” is a slippery slope, and carriers often find loopholes “of how they define ‘screening’ tests to avoid paying for the procedure.”³⁸²

VII. CONCLUSION

Colorectal cancer is the second most common cause of cancer deaths in the United States, and colonoscopies are an essential screening tool to catch the disease in its infancy. When colorectal cancer is treated early, the survival rate is as high as 90%. In addition, a colonoscopy is the only screening test that can detect and prevent cancer by removing the pre-cancerous lesions. Thus, scheduling regular colonoscopies starting at age 45 (or earlier for higher-risk individuals) is the most effective way to reduce the incidence of CRC. An individual may also benefit from an earlier screening if a family history of CRC or if their race makes them more susceptible to such complications, among other risk factors.

Colonoscopies are a helpful medical tool, and they are becoming more commonplace. Nevertheless, there has been an increase in colonoscopy-related medical malpractice suits, ranking sixth among all malpractice claims. These suits address various issues such as colon perforation, improper sedation, informed consent, and failure to diagnose, among other things. If an aggrieved party can prove that a physician or hospital breached the standard of care in the test, they may be awarded damages. However, multiple cases exit where the suit is dismissed by the judge or end with a defense verdict. This result can occur when there is not enough evidence of harm or there is a lack of causal connection between the defendant’s actions and the plaintiff’s injuries.

A proper handling or defense of such a malpractice claim requires an understanding of the large intestine’s anatomy and how the procedure is performed. Accordingly, this article has attempted to address those issues.

2021), <https://www.health.com/money/colonoscopy-costs>
[<https://perma.cc/3KCA-XL76>].

381. *Id.*

382. *Id.*