Ethical Management of Incidental Findings in Emergency Care Settings

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April 2020

A thesis submitted to McGill University in partial fulfillment of the requirements of the Master of Science degree in Family Medicine with a specialization in Bioethics

Abstract

Incidental findings are findings discovered during medical testing, such as unexpected imaging results from an x-ray, and are unrelated to the primary purpose for which a test was sought. Some incidental findings have implications for patient autonomy and welfare. Incidental findings can involve risks (e.g. physical risks of subsequent invasive tests, anxiety) as well as potential benefits (e.g. when they lead to the discovery of a treatable disorder, preventive care). Incidental findings found in emergency departments are difficult to manage because of the fast-paced and crowded environment, as well as limitations to physician-patient relationships. This thesis explores policy and guideline documents, as well as literature, on the legal, professional, and ethical duties of emergency department healthcare professionals in identifying, disclosing, and managing incidental findings.

In Chapter 1, a background of incidental findings and the importance of exploring it within the emergency department setting is presented, as well as an explanation of the objective and research methods, serve as an overview for the thesis. Chapter 2 consists of a critical interpretive literature review, conducted to explore the current understanding and state of incidental findings in emergency departments, as well as to identify knowledge gaps. Following screening, 98 studies were included, where 78 studies reported empirical data. Most of the 78 studies (87%) presented the frequency of incidental findings in emergency departments, with approximately one-quarter reporting the prevalence of incidental findings to be below 10% and the highest reported being 97%, with an average of 34%. Only 29% explored incidental finding reporting rates in documentation. Most (83%) did not report patient disclosure or follow-up rates, but when reported, notification rates were as low as 0.2%, with an average of 18%. The literature revealed recommendations for effective management, including implementation of automatic feedback or alert mechanisms, clarification of responsibilities within treating teams, protocols and evidence development, and improvements to patient documentation. However, the scope of the literature does not include ethical principles or patient preferences. To identify the ethical and professional obligations of healthcare professionals surrounding incidental finding management, an analysis of policies and guidelines supplemented the literature review.

Following the literature review, Chapter 3 provides a thematic content analysis of codes of ethics, health profession guidelines, research-context guidance, and legislation and

government documents (n=31), as they may be relevant to incidental findings. The emergent themes represent duties and expectations of healthcare professionals for incidental finding management and include: autonomy and informed consent, beneficence and non-maleficence, veracity, justice, standard of care, continuity of care, and guidance development. Few documents contained references that explicitly discuss incidental findings, including encouraging patients to specify preferences on incidental finding disclosure, allocating time to patients appropriately when urgent care is required, and advising to consult experts to identify materiality of findings.

After exploring the literature and policies and guidance on the state of incidental findings and duties of healthcare professionals, Chapter 4 provides an ethical analysis, which identifies the moral challenges distinct to emergency department settings that impede incidental finding management. These challenges include time constraints, determining capacity to consent, and limited physician-patient relationships. Discussions on the transferability of primary care and research-context guidance revealed that emergency settings require context-specific guidance, but can borrow select guidance from other settings. Considerations for autonomy, veracity, and justice, as well as emergency care-specific decision-making models can help inform ethical responsibilities on incidental findings. This work explores the gaps in knowledge, research, and professional policy and guidance on incidental findings in emergency care and can thus help advance ethical discussions and guidance in this setting to elucidate ethical management of incidental findings.

Résumé

Les découvertes fortuites sont des découvertes inattendues, c'est à dire non spécifiquement visées par le test en question, telles que les découvertes médicales accidentelles en radiographie ou en imagerie médicale. Certaines découvertes fortuites ont des implications sur l'autonomie et le bien-être des patients. Ces découvertes peuvent comporter des risques (par exemple, les risques physiques de tests invasifs subséquents suite à la découverte et le risque d'anxiété) ainsi que des avantages potentiels (par exemple, lorsqu'ils permettent de fournir des soins préventifs suite à la découverte d'une maladie traitable). Les découvertes fortuites dans le contexte des services d'urgence sont difficiles à gérer en raison de l'environnement trop rapide et encombré, ainsi que les limites aux relations médecin-patient dans ledit contexte. Cette thèse explore les documents de politique et de lignes directrices, ainsi que la littérature portant sur les obligations juridiques, professionnelles et éthiques des professionnels de la santé des services d'urgence dans le cadre de l'identification, la divulgation et la gestion des découvertes fortuites.

Dans le chapitre 1, le contexte des découvertes fortuites et l'importance de l'explorer relativement aux services d'urgence est présenté, ainsi qu'une explication de l'objectif et des méthodes de recherche, tous servant comme un aperçu de la thèse. Le chapitre 2 consiste en une revue critique interprétative de la littérature, visant à explorer la compréhension actuelle et l'état des lieux des découvertes fortuites dans les services d'urgence et à identifier les lacunes des connaissances dans ce champ. Suite à la sélection des manuscrits, 98 études ont été incluses, dont 78 rapportaient des données empiriques. La majorité des 78 études (87%) présentaient la fréquence des découvertes fortuites dans les services d'urgence avec environ le quart rapportant une prévalence de découvertes fortuites moins de 10 % et la prévalence la plus élevée rapportée était de 97 %, avec une moyenne de 34 %. Seulement 29 % des études sélectionnées ont examiné les taux de déclaration de découvertes fortuites dans la documentation. La plupart (83%) n'ont pas rapporté les taux de divulgation ou les taux de suivi des patients, mais lorsqu'ils ont été rapportés, les taux de notification étaient aussi bas que 0,2 %, avec une moyenne de 18 %. La littérature a révélé des recommandations pour une gestion efficace, incluant l'implantation des retours automatiques ou des mécanismes d'alerte, la clarification des responsabilités au sein des équipes de traitement, l'élaboration des protocoles et des preuves et l'amélioration dans le processus de documentation des patients. Cependant, l'étendue de la littérature n'inclut pas les principes éthiques ou les préférences des patients. Dans le but d'identifier les obligations

éthiques et professionnelles des professionnels de la santé en ce qui a trait à la gestion des découvertes fortuites, une analyse des politiques et des lignes directrices a permis de compléter la revue de la littérature.

Suite à la revue de la littérature, le chapitre 3 fournit une analyse thématique du contenu des codes d'éthique, des lignes directrices relatives tant aux professions de la santé qu'au contexte de la recherche, ainsi que des lois et des documents gouvernementaux (n = 31), qui sont pertinents pour le sujet des découvertes fortuites. Les thèmes émergents représentaient les obligations et les attentes des professionnels de la santé quant à la gestion des découvertes fortuites et incluaient : l'autonomie et le consentement éclairé, la bienfaisance et la non-malfaisance, la véracité, la justice, la norme des soins, la continuité des soins et le développement des directives. Peu de documents contenaient des références qui discutent explicitement des découvertes fortuites, y compris l'encouragement des patients à préciser leurs préférences en ce qui a trait à la divulgation des découvertes fortuites, l'allocation appropriée du temps aux patients lorsque des soins urgents sont requis et le conseil de consulter des experts afin d'identifier la matérialité des découvertes.

Après avoir exploré la littérature, les politiques et les directives relatives aux découvertes fortuites et aux obligations des professionnels de la santé vis-à-vis de ces découvertes, le chapitre 4 fournit une analyse éthique qui identifie les défis moraux spécifiques au contexte des services d'urgence qui entravent la gestion des découvertes fortuites. Ces défis comprennent les contraintes de temps, la détermination de la capacité de consentement et les relations limitées entre les médecins et les patients. Les discussions sur la transférabilité des soins primaires et les directives sur le contexte de la recherche ont révélé que les situations d'urgence exigent des directives spécifiques au contexte, mais peuvent également emprunter des directives spécifiques à d'autres milieux. Les considérations relatives à l'autonomie, à la véracité, à la justice, ainsi que les modèles de prise de décisions spécifiques aux soins d'urgence peuvent aider à éclairer les responsabilités éthiques face aux découvertes fortuites. Ce travail examine les lacunes des connaissances, de recherche, de politique et des directives professionnelles entourant les découvertes fortuites dans le contexte des soins d'urgence et peut ainsi contribuer à faire avancer les discussions éthiques et les orientations dans ce contexte dans le but d'élucider la gestion éthique des découvertes fortuites.

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List of Abbreviations

ACEP: American College of Emergency Physicians

ACR: American College of Radiology

AMA: American Medical Association

ANA: American Nurses Association

CAR: Canadian Association of Radiologists

CIHR: Canadian Institutes of Health Research

CMPA: Canadian Medical Protective Association

CNA: Canadian Nurses Association

CPSO: College of Physicians and Surgeons of Ontario

CT: computed tomography

ED: emergency department

EP: emergency physician

IF: incidental finding

MRI: magnetic resonance imaging

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Acknowledgements

There are several people who helped me during this process who I would like to thank. First, I want to thank the faculty, students, and staff in the McGill Biomedical Ethics Unit for providing a wholesome and invaluable master's experience over these two years. I would also like to thank the Department of Family Medicine for awarding me the Graduate Excellence Award for tuition assistance.

At the beginning, when planning for my thesis, I consulted three individuals who work in emergency medicine, Dr. Allan Mannard, Dr. Andrew McRae, and Dr. Merril Pauls. Thank you for having conversations with me to help me shape my research question and explain to me why this topic is important and worth exploring in this care setting. I appreciated your feedback and your thoughts on this issue. Thank you to Genevieve Gore, without whom I would not have been able to navigate the databases to conduct my literature searches. She taught me useful skills that I will be able to use for future projects. To my committee members, Dr. Eugene Bereza and Dr. Ma'n Zawati, thank you for the time you took to help me cultivate my ideas and for providing feedback on my work during committee meetings.

I am deeply indebted to Dr. Carolyn Ells, my thesis supervisor. I am so glad that I had the opportunity to work with you over these two years. I appreciate your commitment to my success and all the support and encouragement you have given me during this time. Through all our meetings and discussions, you provided me ample feedback and guidance for how to shape my thesis and were always so kind when doing so. Thank you for respecting my opinions and trusting and believing that I could produce good work. Your kindness was and is greatly appreciated.

Thank you to my mother, who shows me unconditional love and who always encourages my growth and independence. I also want to thank my little sister, as well as Monica and Dennis, and all my family and friends for their love and support throughout my life. Without them, I would not know joy or laughter, or have a full appreciation for life. I am so grateful to know and love each of them, and to be loved by them. Thank you for helping me in more ways than I can count and for giving each day a sense of purpose.

Finally, there is one person who has been my rock for my entire life and who would have been so proud of me. She was so happy for me when I told her that I got accepted into this master's program and I wish she could have been here on this journey. To my beautiful

grandmother, who left us the summer before I started this program, I miss you, I love you, and I thank you. Thank you for spending hours with me as a child teaching me reading, writing, language, multiplication, long division, and everything under the stars, before it was even taught in school. You were so patient and ignited in me a love of learning that I will always carry with me. Thank you for walking me to the bus stop in the mornings and picking me up in the afternoons until I was old enough to walk by myself. Thank you for dressing me in the mornings before school until I was able to dress myself and for feeding me after school until I was old enough to feed myself. Thank you for waking me up every morning for school until I went to university. The number of things I am thankful for are endless because you did everything for me and I am forever grateful and blessed. Everything I am is because of you and I am confident that I would not be where I am today without you.

Preface

This thesis was formatted as a manuscript-based thesis, which includes material for two manuscripts, which can be found in the second chapter, “Ethical Management of Incidental Findings in Emergency Care Settings: A Critical Interpretive Literature Review” and the third chapter, “Ethical Codes, Guidelines, and Policies to Direct Incidental Finding Management: A Thematic Content Analysis”. These chapters identify the contributions made by authors. For the purpose of this thesis, other thesis chapters will be referenced in the manuscript chapters.

Chapter 1. An Introduction to Incidental Findings

"He said it doesn't look good
he said it looks bad in fact real bad
he said I counted thirty-two of them on one lung before
I quit counting them
I said I'm glad I wouldn't want to know
about any more being there than that…" *What the Doctor Said* by Raymond Carver

Background

Incidental findings (IFs) are findings discovered during the course of care that are beyond the scope and primary purpose for which a patient sought care (Presidential Commission for the Study of Bioethical Issues, 2013). An example would be a scenario in which a patient is admitted to a hospital because of a motor vehicle accident and consequently has a head computed tomography (CT) scan for blunt trauma, but the scan reveals that the patient has a brain tumour. The literature indicates that IFs are commonly discovered. For example, Katzman et al. (1999) found that of 1000 asymptomatic and healthy volunteers in a research study, 18% of brain magnetic resonance imaging (MRI) scans showed IFs, with a small percentage requiring urgent medical attention. While IFs are common, many are likely benign with minimal clinical significance, but physicians and patients are sometimes unwilling to accept uncertainty and are inclined to evaluate these findings, which causes increased use of diagnostic tools (Berland et al., 2010). Ethical attention on the subject of IFs is necessary because of its growing concern and prevalence, especially with the increased use of imaging. In addition to care settings, IFs are common in other domains, including research and genetic testing. However, this thesis focuses on IFs in emergency care settings, which mostly includes IFs discovered from imaging tests.

This thesis focuses on IFs discovered in the course of care in emergency departments (EDs). To understand why this care context is important, consider that in 2017-2018, there was an estimated 11,482,286 visits to EDs across Canada (excluding Quebec) (Canadian Institute for Health Information [CIHI], 2018). Due to the volume of visits and the increasing rates of these visits, this setting is relevant for discussion and critical to improving healthcare quality for Canadians. The main problems reported from emergency visits were abdominal and pelvic pain, throat and chest pain, acute upper respiratory infections, back pain, and other urinary system

disorders (CIHI, 2018). When visiting the ED, patients undergo diagnostic imaging and also give blood for laboratory testing. In 2008, the expenditure per capita on total diagnostic imaging was $99.06 (CAD), with the most common imaging techniques being MRIs and CT scans (CIHI, 2011). Also, studies of IFs in CT scans have shown additional work-up costs ranging from $13 to 248 (USD) per IF, which only includes imaging and testing costs, but does not include provider time or impact on healthcare facilities and patient productivity (Hanna et al., 2016). Exploring the challenges of IFs in this setting is important because it could help decrease healthcare expenditure and improve overall healthcare quality.

The nature of EDs involves some different healthcare standards and expectations; the long wait-times and urgent scenarios that occur lead to different rules compared to other care settings. The setting is different since patients require immediate care so physicians have less time to gather important information, consult with other professionals, or discuss alternative treatments (American College of Emergency Physicians [ACEP], 2017). Patients in emergency settings are also often unable to participate in decision-making because of illness severity and changes in mental state, which has led to exceptions to informed consent under certain circumstances, such as in the event of emergency surgery (ACEP, 2017). Finally, ED professionals have limited relationships with patients, and patients arrive unscheduled, in crisis, and sometimes without their knowledge and thus, there is limited trust in the physician-patient relationship and physicians do not know the patient's conditions, values, or wishes (ACEP, 2017). This difference seen between typical care settings and EDs makes the ED an interesting and important domain to explore. The moral challenges that distinguish the ED from other settings is discussed in chapter four of this thesis.

Due to the fast-paced and crowded environment of EDs, the management of IFs is difficult and reporting and follow-up of findings is low (Munk et al., 2010; Paluska et al., 2007). One study found that of 392 patients with IFs, 122 had no follow-up and 242 had no medical record of the finding (Devine et al., 2010). A study in Greece reported 522 IFs in 468 trauma hospital patients, with 35% of them receiving diagnostic work-up (Sgourakis et al., 2011). In the Netherlands, 36% of trauma patients had one or more IFs from a CT scan, including 8% of patients who required additional invasive evaluations or treatments and 5% who underwent surgery due to the IF (van Vugt et al., 2012). In Ireland, emergency abdominal CT scans detected IFs in approximately 60% of patients and 37% of them were recommended to have subsequent

diagnostics (Kelly et al., 2015). In a U.S. study, of the 3131 cases (1967 CTs and 1164 ultrasounds), 514 IFs were found (Hanna et al., 2016). A frequency of up to 67% of CTs with IFs were reported in the abdomen-pelvis, which was reported as the number one problem for ED visits (Hanna et al., 2016). In the United States, it was reported that 16% of adults visiting the ED will undergo a CT (Kirschner et al., 2014), and based on the percentage of CTs leading to an IF (16.7%), approximately 3% of ED patients can expect a CT IF (Hanna et al., 2016). The high prevalence of IFs in different ED settings signals us to urgently discuss IFs in this care context.

In addition to studies reporting prevalence of IFs, one research study was conducted to evaluate the adherence to American College of Radiology guidelines on IFs. The U.S. study evaluated whether reporting behaviours of IFs in the ED adhered to recommendations for additional imaging and societal guidelines (Hanna et al., 2016). Of all IFs reported in this study, 67.5% of recommendations to patients were concordant with guidelines, while 32.5% were not (Hanna et al., 2016). Of those that were discordant, 59.9% resulted in recommendations for more aggressive imaging. Research is limited on adherence to IF management guidelines. Given that work-up of IFs varies widely by health professional and region, there is a dearth of standardization and guidance for ED healthcare professionals regarding IF management. Thus, an exploration may help to identify gaps in knowledge and guidance as well as inform healthcare professionals about their care obligations when IFs are discovered.

There are several ethical and practical challenges posed by IFs that require exploration, including the risks associated with false-positives and false-negatives, physical risks from subsequent diagnostic testing, social and behavioural harms, negative psychological responses, unnecessary anxiety for a benign finding, risks to data security, and incurred costs of tests and procedures on patients and the healthcare system (Appelbaum et al., 2014). IFs can also lead to potential benefits, such as discovery of a treatable disorder leading to pain relief or cure, pursuit of follow-up treatment or preventive measures, enhanced life planning, possible positive psychological responses, and social benefits if stigmatizing conditions are prevented (Appelbaum et al., 2014). Some IFs can lead to increased risks without corresponding benefits, such as benign lung nodules, while other findings can lead to more benefits for patients, such as treating a brain aneurysm. The risks and potential benefits from IFs lead to considerable uncertainty regarding how to ethically manage IFs, including when it is morally permissible or impermissible to disclose findings to patients. Such ethical dilemmas are exacerbated in the ED

setting because of the previously mentioned challenges in this setting, including limitations on time and limitations to the physician-patient relationship, making the discussion of IFs in this setting critical.

Table 1.1. Case studies of incidental findings adapted from the literature.

Case 1 ("Grace")	A 37-year-old woman, Grace, presented with abdominal pain, vomiting, and diarrhea, and received a diagnosis of acute gastroenteritis. One month later she returned with worsening abdominal pain, now localized to the right upper and lower quadrants. An ultrasound was performed because of suspected gallbladder disease. The gallbladder was normal, but a "fibroid-appearing" uterus and questionable ovarian mass were noted. These findings prompted the performance of a subsequent ultrasound, which demonstrated a leiomyoma, hydrosalpinx, and dermoid cyst. Grace had one ovary and both fallopian tubes removed, a left cystectomy, and a total abdominal hysterectomy. Postoperatively, she did well (Kendall & Mandavia, 2001).
Case 2 ("Jack")	A 2-year-old child, Jack, in King County, Washington, hit his head in a fall and underwent a head CT scan initially read as normal. However, repeat interpretation of the scan revealed a tumour that was not reported to the family. Fourteen months later, the child was diagnosed with an ependymoma, a tumour, from which he eventually died. The family sued the hospital and radiologist, and settled the case for $5 million (Onwubiko & Mooney, 2018).
Case 3 ("Tina")	Tina, a healthy 33-year-old woman, presented to the ED complaining of intense abdominal pain, nausea, and a bloating sensation. The physician examines her and detects that her pain is predominantly in the right lower quadrant of her abdomen. Although the provider suspects food poisoning based on the patient's last meal consisting of seafood, the physical examination findings are concerning for acute appendicitis. The provider informs Tina that she will need to undergo an abdominal CT to ensure there is no appendicitis. Tina agrees to the examination, but the provider did not mention any risks associated with examination or the potential for IFs. The CT study revealed no appendicitis, but the radiologist notes a one-centimetre "small circumscribed lesion of unknown significance" in her right adrenal gland. The ED provider tells Tina that she has no appendicitis and is safe to go home, but should follow up with her primary care provider for work-up of her IF in the adrenal gland. Tina is relieved about the appendicitis, but is visibly anxious about the IF, which she assumes is malignant. She wishes to ask a provider for more information, but the ED provider has already moved on to another patient. Tina was discharged from the ED (Kole & Fiester, 2013).
Case 4 ("Tom")	A 60-year-old man, Tom, with no vascular risk factors or history of smoking entered the ED reporting numbness and weakness on one side of his body. Tom received a CT angiogram to test for a suspected transient ischemic attack. While analyzing the images, the emergency radiologists noticed a one-centimetre nodule in the left upper lobe of his lung. The patient experienced anxiety and concern for the nodule and followed up with a biopsy of the nodule. During the biopsy, Tom suffered a pneumothorax as well as hypoxia, which led to cardiac arrest. The patient was left with permanent anoxic brain injury. The pathology report later showed that the one-centimetre nodule was benign inflammation (Presidential Commission for the Study of Bioethical Issues, 2013).

The cases in Table 1.1 help to frame the discussion and illustrate events that may result from IF identification, disclosure, and management. Scenarios such as these help to show that the quality of care given to patients would benefit from research on IF management because ethical reflections are not commonly discussed in the ED context. Research on IFs has mostly focused on prevalence and frequencies of IFs in emergency imaging, but studies have yet to reflect on professional and ethical duties or responsibilities in this domain. There is also limited literature concerning whether and how to manage disclosure of risks and potential benefits associated with IFs and informed consent for follow-up with patients. This dearth in literature has left challenges for healthcare professionals and policymakers to determine ethical and best practices for managing findings. The Presidential Commission for the Study of Bioethical Issues ("Bioethics Commission") offered recommendations for managing IFs and one recommendation suggested that increased funding be dedicated toward "the potential costs, benefits, and harms of identifying, disclosing, and managing these findings; and recipient and practitioner preferences about the discovery, disclosure, and management of incidental […] findings" (Bioethics Commission, 2013, p. 7). This thesis reviews the literature with respect to this recommendation to assist in determining ethically best practices for IF discovery, disclosure, and management.

Thesis Objective

This thesis explores the question: What are the legal, professional, and ethical duties of emergency department healthcare professionals for identification, disclosure, and management of incidental findings?

Research Method in Brief

The thesis objective was accomplished in several steps. This thesis begins with a critical interpretive literature review (McDougall, 2015) to explore the climate of ethical management of incidental findings in emergency department settings. The protocol for this critical interpretive literature review was modeled after the preferred reporting items for systematic reviews checklist (Shamseer et al., 2015; Tricco et al., 2018). The search strategy identified literature with terms such as "incidental findings" and "emergency", and derivatives in titles and abstracts, using PubMed, PubMed Central, Scopus, and Web of Science databases, as well as several grey literature sources. The literature was reviewed and relevant information extracted to inform a critical discussion on key ideas and findings.

Following this literature review, the third chapter includes a thematic analysis of codes of ethics, professional policies and guidelines, research-context guidance, and legislation that relate to IFs, categorized by themes that frame the dilemma of IFs. The themes included in this review are: autonomy and informed consent, beneficence and non-maleficence, veracity, justice, standard of care, continuity of care, and guidance development. This chapter is helpful to determine what the duties of healthcare professionals are for the identification, disclosure, and management of IFs, which is a key component of the thesis objective.

Following this, an ethical analysis outlines the characteristics and moral challenges distinct to EDs as they apply to IFs, including time constraints, determining capacity to consent, and limited physician-patient relationships. Further, the analysis draws on the ethical principles of respect for autonomy, veracity, beneficence and non-maleficence, and justice, and relate to relevant themes and findings from the previous literature and document reviews. The discussion also explores the application of primary care setting and research setting guidance to the ED setting and outlines relevant decision-making frameworks that can be used to determine ethical obligations in EDs. This thesis will yield nuanced ethical discussions to develop guidance for healthcare professionals and their professional organizations to manage IFs in emergency care settings responsibly, including when it is obligatory, morally permissible, and impermissible to disclose IFs to patients in ED settings, and how to communicate such information. This review should help to identify what makes the ED setting distinct from other care settings and what ethical challenges are prevalent. The discussion can inform guideline development and assist emergency care workers in understanding their care obligations for managing IFs that arise.

Definitions

As previously discussed, an "incidental finding" is a discovery made in the course of care that is outside the primary purpose sought out by a test or other measure (Bioethics Commission, 2013). One of the earliest references to clinical management plans for IFs was in the context of the discovery of adrenal masses by CT (Glazer et al., 1982). The rise in incidence of IFs follows the timeline for the rise in availability of and improvements to CT and other imaging modalities. The term, "incidentaloma" to describe these silent masses, was also coined in the 1980s in reference to an adrenal mass discovered in asymptomatic patients (Geelhoed & Druy, 1982).

Some IFs are referred to as "material incidental findings", which are IFs reasonably

considered to have significant welfare implications for a research subject (Panel on Research Ethics, 2019). The materiality of IFs is not objectively defined and differs by context and for each patient or subject. However, the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS 2) (Canadian Institutes of Health Research [CIHR], 2018) released conditions of materiality in the context of research, which reports that IFs are material if the finding is accurate and valid, if the finding has potential significance that warrants disclosure to the individual, and if the finding is actionable where steps can be taken to benefit the individual's health or welfare (Panel on Research Ethics, 2019). In the fourth chapter, we return to the idea of materiality and whether these conditions in the context of research can be applied to care settings, in particular emergency care settings.

There are other terms that should be understood when discussing IFs. First, we need to differentiate between IFs and adverse events and medical errors. An "adverse event" is an undesirable and unintended injury or complication that results either expectedly or unexpectedly from a drug or other intervention that can lead to death, disability, or hospital stay (Baker, 2004). IFs are not outcomes that result from the use of a test modality or drug. Also, while IFs do not always need to be reported to institutions or to patients and subjects, adverse events need to be reported to patients, subjects, and institutions. "Medical errors" are actions or omission of actions that could cause minimal harm, but could also lead to negative consequences, such as permanent injury or death (Chamberlain, 2012). "Near misses" happen in clinical settings by healthcare professionals; they include events, situations, or errors that are discovered before impacting patients, and can usually be avoided by following practice standards and are considered mistakes in action or judgment (Grober & Bohnen, 2005; Leonard, 2010). Adverse events are different from medical errors and near misses because medical errors do not always lead to damages to patients and near misses do not lead to harm to patients. However, adverse events, medical errors, and near misses result from a drug or intervention because of health professionals, whereas IFs are present before a patient takes a drug or undergoes an intervention, and are thus not caused by the actions of a healthcare professional or institution.

It is also critical to explain the difference between a secondary finding and an IF. A "secondary finding" is defined as being within the purpose of a test or research objective, but is a secondary or additional finding that is sought by a researcher or practitioner, while an IF is a discovery made that is outside the purpose of a test or research goals. Finally, the literature may

use the terminology, “return of results”, which is usually in reference to provision of results to subjects in research settings (Wolf, 2013). Return of results may include IFs that were discovered, or refer to the general results or outcomes of the research study in which a subject participated.

Different from an IF is a “critical test result” or “critical value”, which are both terms used to identify “abnormal test results that are significantly out of normal range”; these need to be communicated to physicians or patients in the interest of patient safety (College of Physicians and Surgeons of Ontario [CPSO], 2011, p. 2). It can further be defined as having a significant difference from reference values that could lead to critical risk to life, thus requiring urgent intervention (Collège des médecins du Québec & Lacasse, 2012). Also, a “clinically significant test result” is a result requiring follow-up as determined by a physician (CPSO, 2011). IFs can be critical or clinically significant, but not all critical or clinically significant results are incidental because IFs are always outside the purposes and intentions of sought out care. IFs that are critical or clinically significant would be classified as being material IFs according to the definition of materiality in the TCPS 2 (2018).

Other terms are used in the literature to describe IFs, including “unanticipated outcome”, “unexpected result”, “unintended discovery”, “ancillary finding”, “off-target diagnosis”, “unrelated result”, “unsolicited outcome”, and “unsought for finding”. While these terms can be referring to IFs in the way we have defined it, these terms can also be used to refer more generally to unexpected findings and results in any context. We used “incidental findings” to maintain consistency and clarity as well as to reiterate the importance of understanding and defining relevant terminology.

Qualifiers

There are many terms used to describe IFs, including “material incidental findings”. Identifying IFs as being material or not can be assumptive of how a patient would respond to a finding and can be subjective and contingent on each individual. Thus, for the purposes of this thesis, we must recognize that an IF can be considered material for one person, but not material for another person. There are several guidelines that help to define whether findings are material or clinically significant, but these will not be the focus of the thesis and so we will not identify

findings as material. Keeping this in mind, we will err on the side of using "incidental finding" as opposed to "material incidental finding" unless directly quoted.

In this thesis, we also discuss IFs in research settings and often refer to research "subjects". There is some contention on whether we should refer to individuals who partake in research studies as "subjects" or "participants" (Bromley et al., 2015). While some believe there are negative connotations to the term, "subjects", it serves as a reminder that these are vulnerable persons and their rights should not be neglected. For this reason and to maintain consistency, this thesis will refer to these individuals as research or study "subjects".

Finally, in this thesis, we often discuss *physicians,* however all healthcare workers in the ED ("emergency care providers") should be considered in the context of IF management, including radiologists and nurses. We discuss emergency physicians (EPs) more because they are referenced most often in the literature and also are discussed at length in policy and guidance documents. When appropriate, this thesis makes reference to all emergency care providers.

Target Group

This thesis was written for graduate students, emergency care providers, and other healthcare professionals, as well as key stakeholders and policymakers. This thesis was also written to help direct future researchers in the field of incidental findings.

Personal Motivation

This topic is of interest to the author because it relates directly to emergency department ethics, which is a setting that requires critical thinking and fast decision-making. The difference between the standards in emergency care settings compared to other care settings is a reminder of disaster ethics and how certain rules do not always apply. This topic is also of personal interest because these situations are relatable to anyone who has visited the emergency department. Most people will also undergo some sort of diagnostic testing and it is useful to understand the burdens and benefits that may result from these tests but are unrelated to the reasons the tests were performed. Thus, this topic is of interest to anyone who is a patient or a family member to a patient, as well as healthcare professionals themselves.

Chapter 2. Ethical Management of Incidental Findings in Emergency Care Settings: A Critical Interpretive Literature Review

Preface

"Chapter 2: Ethical Management of Incidental Findings in Emergency Care Settings: A Critical Interpretive Literature Review" constitutes a manuscript with plans to publish in a bioethics-related or emergency care-related journal. This manuscript was prepared by following the methodology identified by McDougall (2015) for a critical interpretive literature review, and by consulting the PRISMA-ScR checklist for scoping reviews for protocol preparation. This manuscript follows the general introduction of the thesis and contributes to the thesis objective by providing an extensive review of the literature to explore what is currently known and what are the knowledge gaps surrounding the duties of emergency department healthcare professionals regarding identification, disclosure, and management of incidental findings.

Contribution of Authors

Renata Iskander, B.Sc. (Hons), was the first author on this manuscript. She prepared the protocol, developed the search strategy parameters, conducted the literature search and screening, extracted the data from the literature, summarized and interpreted the results, and prepared the manuscript.

Carolyn Ells, PhD, was the supervising author on this manuscript. She contributed to revising the protocol, reviewed articles that the first author was unsure whether to include, contributed to interpretation of results, and provided guidance and feedback with the manuscript.

Abstract

Incidental findings are findings discovered in the course of healthcare (e.g. blood tests, genetic tests, imaging) that are unrelated to the primary purpose for which a test was sought. Some incidental findings constitute new knowledge that have implications for patient autonomy and welfare. Incidental findings found in emergency departments are difficult to manage, with one study reporting that of 392 patients with incidental findings, 122 had no follow-up and 242 had no electronic record of the finding. A critical interpretive literature review was conducted to explore current practices regarding identification, disclosure, and management of incidental findings in emergency departments, and to identify ethical challenges that require research focus and policy reform. The search strategy included "incidental findings" AND "emergency" and derivatives, retrieving 12,004 studies from databases including PubMed, PubMed Central, Scopus, and Web of Science, as well as handsearching and reference list searching. Following screening, 98 studies were included that fit the eligibility criteria adequately discussing incidental findings in emergency department settings. Data was extracted, analyzed using descriptive statistics, and then critically interpreted to capture key findings. Of 98 included articles, 78 had relevant empirical data. Of the 78, most literature (87%) presented the frequency of incidental findings in emergency departments, with an average frequency of 34%. Most (83%) did not report on patient disclosure rates or follow-up rates. When reported, patient notification rates were as low as 0.2% with an average of 18% over 13 studies. Empirical studies included in the review did not address ethical principles or patient preferences on disclosure. The literature revealed suggestions to manage incidental findings in EDs, including implementation of automatic feedback or alert mechanisms, clarification of responsibilities within treating teams, protocols and evidence development, and improvements to patient documentation. Test results by letter were noted as insufficient because patients are unable to ask questions. Authors suggested further research on optimal follow-up recommendations to alleviate patient and physician distress. The literature on incidental findings in emergency departments focuses too narrowly on frequency, with ad hoc suggestions for practice, research, and policy changes to improve ethical management. Numerous factors, including crucial knowledge gaps, contribute to inadequate management of incidental findings arising in emergency departments. Research and ethics informed policy guidance is needed.

Introduction

Rationale

Incidental findings (IFs) are findings discovered during the course of care that are beyond the scope and primary purpose for which a patient sought care (Bioethics Commission, 2013). IFs are commonly found in emergency department (ED) settings, with approximately 34% to 45% of visits leading to such findings (Munk et al., 2010; Sierink et al., 2014). One study found that of 321 ED patients who underwent a total-body computed tomography (CT) scan, 143 (44.5%) had a sum of 186 IFs (Sierink et al., 2014). Approximately 69% of findings were minor and involved no diagnostic work-up, while 18 patients had IFs involving a severe condition, requiring follow-up.

However, due in part to the fast-paced and crowded environment of EDs, the management of these IFs is difficult and reporting and follow-up of findings is lower than expected (Munk et al., 2010; Paluska et al., 2007). For example, one study found that of 392 patients with IFs, 122 had no follow-up and 242 had no electronic record of the finding (Devine et al., 2010). Currently, there are no literature reviews that explore IFs in the ED setting, which is necessary to understand the knowledge gaps as well as recommendations made for practice and policy. Given the dearth of guidance for ED physicians regarding IF management, an ethical exploration through the literature may help to inform healthcare professionals about their care obligations when IFs are discovered as well as inform future research and policy.

Objectives

This literature review explores the primary question: (1) According to the literature, what is the current state regarding the identification, disclosure, and management of incidental findings in emergency care settings? Other questions that are addressed include: (2) According to the literature, what are the preferences of patients, practitioners, and other stakeholders about identification, disclosure, and management of incidental findings?, and (3) What are the ethical and practical challenges and needs that require research focus and policy reform? This review will also help contribute to the discussion on what makes the emergency department setting different when considering the identification, disclosure, and management of incidental findings.

Methods

Study Design

A critical interpretive literature review (McDougall, 2015) was conducted to identify and analyze guidance concerning ethical management of IFs in ED settings. This type of literature review was chosen because it focuses on capturing and analyzing key ideas relevant to the research questions (Dixon-Woods et al., 2006). The main features of the critical interpretive literature review include answering a research question, capturing relevant key ideas, analyzing the literature as a whole, generating theory, not excluding literature based on rigid criteria, and reporting on the search strategy (Dixon-Woods et al., 2006; McDougall, 2015). The protocol for this critical interpretive literature review was modeled after the extension for scoping reviews of the preferred reporting items for systematic reviews checklist (Shamseer et al., 2015; Tricco et al., 2018).

Eligibility Criteria

This literature review included all different types of studies, including systematic reviews, retrospective reviews, prospective reviews, qualitative reviews, theoretical or conceptual literature, conference proceedings, and dissertations, if they discuss IFs in the context of ED settings or if it may be applied to this setting. Literature was also included if they provided recommendations for research and policy reform on IFs in ED settings. Empirical literature was used to summarize the relevant research in this care setting and to gather research and policy recommendations. Empirical as well as non-empirical literature were used to gather key ideas to help generate theories and inform an ethical analysis. There were no restrictions on publication status, publication year, or language to promote comprehensive results.

Using Covidence software, sources of evidence were first screened by removing duplicates, then by reading the titles and abstracts, and finally, by reading full-text documents. The first author (RI) was the sole reviewer for selecting studies through each phase of the review with some conflicts discussed with CE.

Literature was excluded if unrelated to the primary definition of IFs. Literature that used the term “incidental” to describe research findings or other contexts were not found to be related, such as literature involving incidental appendectomies, which were appendectomies completed in the operating room while another surgery was being performed. Literature was also excluded

if the population was discussing IFs in animals since ethical issues surrounding disclosure and research recommendations would differ. Literature was excluded if the research was conducted in an unspecified care setting or outside the ED setting, with the exception of research conducted in ED settings *and* other settings, such as inpatient settings. Also, literature was excluded if the findings discussed were previously known by the patient, such as a foreign body lodged in their ear. Literature was further excluded if the focus rested on imaging modalities and how to decide on the best imaging test for a presenting case or if it focused on the comparative quality between imaging tests. Results were excluded if the focus of the paper was clinical, with the objective being to discuss cures or treatments, or case reports that focused on managing the primary diagnosis. If IFs were discussed in the context of research subjects, genetics, or while performing autopsies, they were excluded from the final results. Several articles had multiple possible reasons for exclusion, but a primary reason was chosen for the purposes of this literature review.

A simplification that was made is using "incidental findings" as opposed to "material incidental findings" to include more literature results. Some literature was conducted in the outpatient or ambulatory setting, which is not always equivalent to ED settings, but was often unclear in the literature. Literature in these settings were sometimes included if they contributed to the literature review objectives. Also, it should be noted that the literature sometimes referred to IFs as "coincidental findings" or "alternative findings" and sometimes referred to patients with IFs as "asymptomatic" or as having a "differential diagnosis", which were not captured in the search strategy, but searches were conducted to ensure all relevant articles were found. It should be noted that studies set in trauma centres, which are sometimes differentiated from EDs, were also included in the results of this review.

Search Strategy

The basic strategy involved a mix of automated and manual searches to ensure that important articles were not excluded. To avoid publication biases, information sources included the following electronic databases: Scopus, PubMed, PubMed Central, and Web of Science. Grey literature was reviewed through ProQuest Dissertations and Theses Global, WorldCat, Canadian Institute for Health Information, CMA Infobase, Canadian Institutional Repositories, Statistics Canada, and Government of Canada Publications. The following search strategy was used to identify literature in the electronic databases, WorldCat for books and chapters, as well

as ProQuest for dissertations and theses: (incidental findings OR incidentaloma OR unsolicited findings OR unsought for findings OR off-target results) AND (emergency OR ED OR ER OR trauma OR triage). The full search strategy for one database, Scopus, is presented here:

"TITLE-ABS-KEY (incidental* W/3 finding*) OR incidentaloma* OR TITLE-ABS-KEY (unsolicited OR "unsought for" OR off-target OR incidental* OR unanticipated OR unintended OR ancillary OR unexpected OR unrelated PRE/0 finding* OR result* OR discover* OR outcome* OR diagnos*) AND TITLE-ABS-KEY (emergency OR {er} OR {ed} OR triage OR trauma)"

Since the literature on this topic is dispersed across multiple subject areas and because vocabulary surrounding this topic used by authors is heterogeneous, ancillary search procedures were used to find relevant articles. Alternative search procedures included reference list searching, similar articles feature, co-cited article searching, forward citation searching, and handsearching (See Appendix Table 2.1A for further detail on search strategy). In addition to handsearching in journals, this method was also used to find articles that were published following the original search in the consulted databases, which was done by performing a search for most recent articles. The search strategy was evaluated by comparing the search results to a subset of relevant literature previously chosen by the author (RI). The iterative process involved updating the search strategy when new terms were discovered.

Data Items and Synthesis of Results

After finalizing the included articles, data charting was completed independently (RI) on Microsoft Excel using a data matrix. From each of the 98 articles, extracted data, if available, included: title, author, publication year, country, study type or design, sample size, sample population, test domain (e.g. CT scans), study objectives, frequency of IFs, patient notification rates, percentage of IFs reported in charts or discharge forms, percentage of findings that required follow-up and that received follow-up, relevant key ideas and takeaways, comments on how disclosure and follow-up were managed, interesting quotations, comments on role responsibility, comments on patient or stakeholder preferences regarding disclosure, terminology and definitions surrounding IFs, as well as suggestions for practice, policy, and research.

For empirical data, including the frequencies of IFs and the patient notification rates,

values were extracted and tabulated in the data matrix to calculate averages as well as the number of empirical studies that report these items. If non-empirical results of the literature review were recurrent, the number of studies were summed. For example, if repeated recommendations surrounding IFs were discovered, the count would reflect the number of studies that included each recommendation, such as the number of studies that recommend adopting an automatic feedback system. Qualitative results were summarized by organizing key quotations, themes, and findings into tables, and presenting relevant information.

Results

Following the screening process for the literature review, a total of 98 articles were included (Figure 2.1). Figure 2.1 shows the number of selected sources of evidence, including the number of sources screened, assessed for eligibility, and included in the review, with reasons for article exclusion. The most common reasons that articles were excluded are that many articles had objectives that focused on imaging modalities, including decision-making about which imaging test to order and comparing efficacy of different tests. Another reason was that articles focused on the clinical outcomes and management plan for the primary diagnosis and focused on clinical implications. Some articles had unspecified care settings or care settings that were outside of the ED, so they were excluded. Articles were further excluded if the discussion surrounding IFs was not sufficient or was not a significant aspect of the article where there was not enough information to contribute to the literature review.

Table 2.1 reports general characteristics of included articles (Moher et al., 2009). Of the 98 articles, approximately 15% were published in the last year and more than three-quarters were published in the last ten years. Over 60% of the studies were conducted or written by authors in the United States, while 6.1% were from Canada, slightly more from Europe and Asia, and fewer from Australia, Africa, and South America. The majority of the studies (59.2%) involved retrospective reviews of patient charts and medical records while only one included article involved a literature review of the topic.

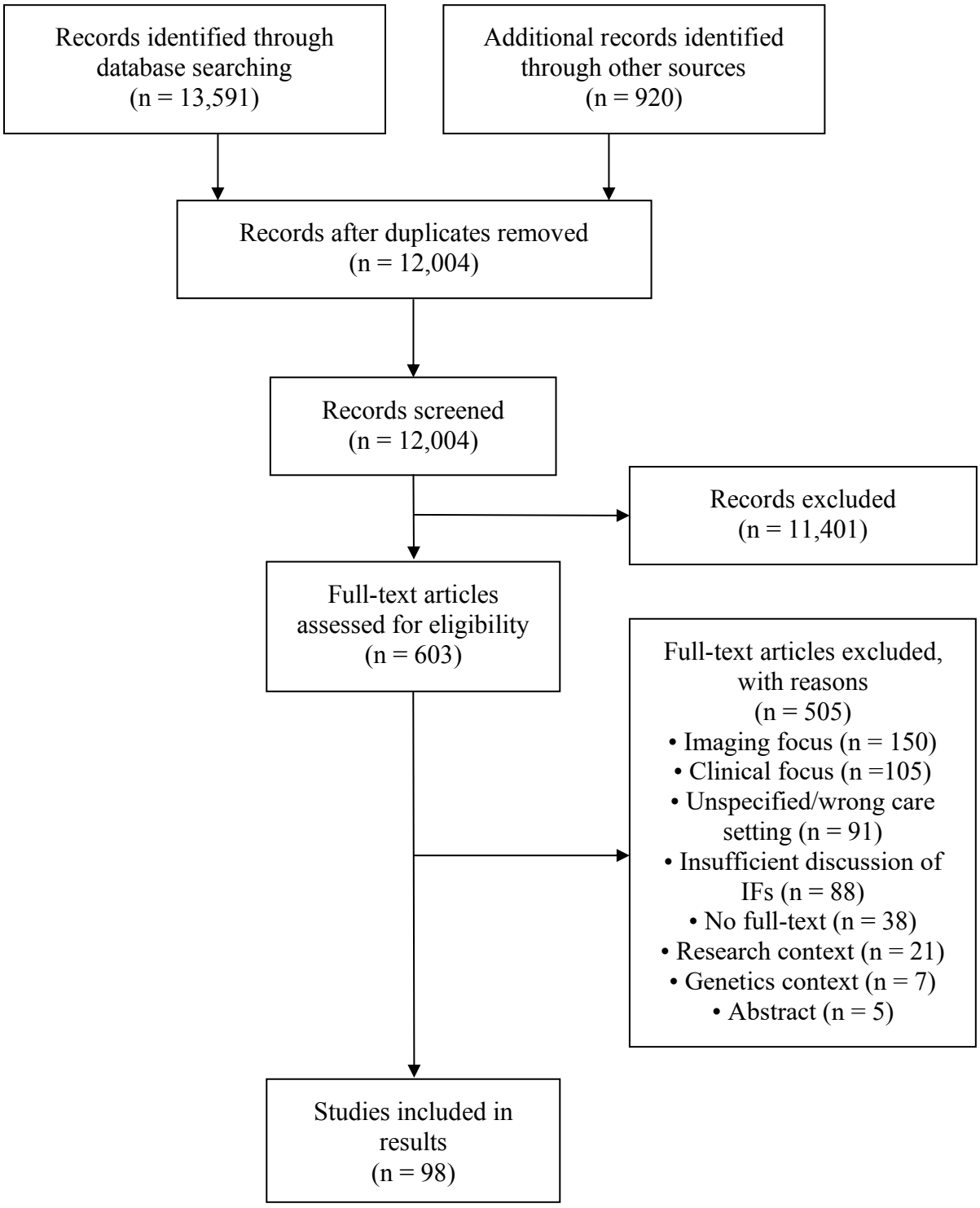

Figure 2.1. PRISMA diagram for source selection.

Table 2.1. General characteristics of included articles (n = 98).

	Articles (n)	Percentage (%)
Publication year		
< 2000	1	1.0
2000 - 2005	5	5.1
2006 - 2011	17	17.3
2012 - 2017	50	51.0
2018	10	10.2
2019 - 2020	15	15.3
Country/Continent		
Africa	1	1.0
Asia	10	11.2
Australia	5	5.1
Canada	6	6.1
Europe	14	14.3
South America	1	1.0
United States	61	62.2
Study Type		
Case-Control	2	2.0
Conceptual*	9	9.2
Cross-sectional	2	2.0
Literature review	1	1.0
Observational	3	3.1
Prospective	13	13.3
Qualitative	3	3.1
Retrospective	58	59.2
Survey	3	3.1
Other**	4	4.1

*includes one paper of guidelines

**includes an app review (Kovacs et al., 2018), a quality improvement report (Emerman, Gallagher, & Diaz, 2012), a questionnaire (Schreiber, Leonard Jr, & Rieniets, 1995), and a before-after study (Yeh et al., 2013)

There were 78 total empirical studies that reported a sample size, with a total sample size of 265,237 across all studies in this literature review (Table 2.2). Most literature included adults in their sample size and only seven studies were measured exclusively in pediatric populations. Sixty-eight of these studies (87%) reported the frequency of IFs in either the sample size of patients or the frequency among all imaging tests reviewed. Frequencies may be overestimated because the numbers only include patients who underwent imaging procedures and does not

incorporate other methods of discovering IFs in the ED. Approximately 22% of studies report the prevalence of IFs to be under 10% with the highest reported prevalence being 97% (Baugh, Weireter, & Collins, 2014). Across the 68 studies reporting IF frequency, the average IF prevalence is 33.7%, which is consistent with other sources.

Of all the included studies, 82% explicitly included a type of imaging test, even if the test type being studied was unspecified. More than two-thirds of the studies mentioning imaging focused their discussion on CTs, whether alone or in combination with other tests. None of the studies focused on IFs arising from other methods, like laboratory testing or genetic testing in the ED setting. Of the 78 studies with relevant empirical data, only 29% explored the rates of reporting of IFs in documentation or discharge summaries. Of these 23 studies, the average reporting rate is 43.7%, which means that more than half of IFs are not documented. This average is an overestimate because it only includes those studies that collected this data and it is likely that if all other empirical studies collected this data, they would find low reporting rates.

Few empirical studies (17%) reported the patient notification or disclosure rates and when reported, rates were as low as 0.2% (Messersmith et al., 2001). Fifty-four percent of the studies reported that less than 10% of IFs were disclosed to patients and the overall average across the thirteen studies was a 18.3% rate of disclosure. These rates are underestimated because most studies did not report whether they informed patients and, in some cases, healthcare professionals may not have documented whether patients were notified, and thus the information is difficult to retrieve from patient charts. Finally, 20 studies (26%) reported the rate of successful follow-up for IFs, which includes either follow-up based on recommendations or follow-up without recommendations. The average follow-up for IFs across these twenty studies was 23%, showing that more than three-quarters of IFs are not followed-up. However, this is an underestimate since it is not confirmed that successful follow-up is always reported. Only one study reported follow-up to be over 50%. This data does not evaluate whether follow-up is necessary because of the uncertainty and subjectivity of IF significance, but does report on follow-up of any IF reported in the literature sources.

Table 2.2. Study characteristics of included articles (n = number of studies included).

	n	%
Sample population* (n = 98)		
Adult	28	28.6
Pediatric	7	7.1
Adult and pediatric	27	27.5
Unspecified	18	18.4
No sample	18	18.4
Sample size (n = 78)**		
0 - 500	27	34.6
501 - 1000	19	24.4
1001 - 1500	9	11.5
1501 - 2000	4	5.1
2001 - 2500	4	5.1
2501 - 3000	1	1.3
> 3000	14	17.9
Total	2645,237	
Overall average (%)	3,400.5	
Frequency of IFs* (%, n = 68)**		
$0 \leq n < 10$	15	22.1
$10 \leq n < 20$	11	16.2
$20 \leq n < 30$	9	13.2
$30 \leq n < 40$	9	13.2
$40 \leq n < 50$	7	10.3
$50 \leq n < 60$	3	4.4
$60 \leq n < 70$	6	8.8
≥ 70	8	11.8
Overall average (%)	33.7	
Test domain** (n = 98)**		
CT	60	61.2
No imaging	18	18.4
Combination	10	10.2
Unspecified	5	5.1
Sonography	3	3.1
MRI	1	1.0
X-ray	1	1.0
Documented IFs (%, n = 23)		
$0 \leq n < 10$	4	17.4
$10 \leq n < 20$	0	0.0
$20 \leq n < 30$	6	26.1
$30 \leq n < 40$	2	8.7
$40 \leq n < 50$	1	4.3
$50 \leq n < 60$	2	8.7

60 ≤ n < 70	3	13.0
≥ 70	5	21.7
Overall average (%)	43.7	
Patient notification and disclosure (%, n = 13)		
0 ≤ n < 1	2	15.4
1 ≤ n < 10	5	38.5
10 ≤ n < 20	1	7.7
20 ≤ n < 30	2	15.4
30 ≤ n < 40	1	7.7
40 ≤ n < 50	1	7.7
≥ 50	1	7.7
Overall average (%)	18.3	
IF follow-up (%, n = 20)		
0 ≤ n < 10	5	25.0
10 ≤ n < 20	5	25.0
20 ≤ n < 30	4	20.0
30 ≤ n < 40	2	10.0
40 ≤ n < 50	3	15.0
50 ≤ n < 60	1	5.0
Overall average (%)	23.4	

*Some of the sample populations included in the adult and pediatric category specify age (e.g. 16+) but were not included in the adult category
**Sample sizes were recorded based on what was reported and either includes the number of patients sampled or the number of imaging tests reviewed depending on the article
***At least two sources explicitly reported the frequency of significant findings, not total number of IFs
****CT includes all types of CT, including pelvic and abdominal, and sonography also includes Focused Assessment with Sonography in Trauma (FAST)

In addition to objectives involving estimating frequency and prevalence of IFs as well as the rate of disclosure or follow-up, other objectives of the included studies were evaluating follow-up interventions and documentation, improving communication, discussing the common and uncommon IFs, exploring management of IFs by mid-level providers, as well as evaluating patient perceptions of communication with healthcare professionals.

All included studies in this review adequately characterized and defined IFs (Table 2.3). Some studies also further classified and defined subtypes of IFs based on level of clinical significance or need for follow-up. The definitions included in this literature in ED settings does not include a description of IFs in a broader context to incorporate genetics, research settings, or IFs found through laboratory testing or through patient discussions, but was only defined in the context of imaging. Many of the definitions described IFs as being an “abnormality”, “unrelated”, not previously known, and found while conducting a test for a different purpose. One study included in their definition that IFs were “not pertinent to the immediate patient care

in the emergency department" (Thompson et al., 2011, p. 1). This definition is interesting to note because it specifically indicates that these findings are not immediately relevant for the ED setting, assuming that they are not urgent, which reveals the significance of prioritizing urgent care over IFs. Few studies refer to the risk or danger that findings can pose for patient health, the actionability of findings, clinical significance, and the need for follow-up. These definitions help determine how authors understood IFs in ED settings.

Several sources made recommendations to improve the management of IFs, in practice, and for further research and policy (Table 2.4). The most common recommendation was to improve reporting and documentation practices in patient medical charts or discharge notes, with 42% of the literature in the review discussing the need for work in this area. Thirty-seven percent of studies discussed the need for enhanced follow-up practices. Over one-third cited the need for improvements to patient communication and discussion and more than one-quarter discussed the need for more communication and collaboration with other healthcare professionals to maintain a closed-loop system.

Twenty-three articles discussed the need for future research to broaden the evidence base to develop guidelines and protocols. Suggestions include research to understand the impact of disclosing IFs by conducting research comparing outcomes between patients who were and were not notified of findings (Devine et al., 2010). Also, Dutta et al. (2013) suggest standardization of reporting formats through consensus guidelines to limit variability for physicians in the ED to identify and respond to follow-up. Zygmont et al. (2016) implemented an educational framework to standardize recommendations in the ED for IFs, which involved compiling guidelines from multiple sources for rapid reference and led to an increase in adherence to guidelines from 63.7% to 80.2%.

Other recommendations included implementation of electronic notification and automatic feedback systems, which was mentioned in 14 articles. Singh et al. (2009) used electronic medical records to transmit important results, but found that automated notification did not eliminate the problem of missed test results and recommended that the design and implementation of computerized notification systems be improved for effective results. Emerman et al. (2012) developed a system to flag and classify IFs, report the information in the patient's electronic medical record, and communicate the appropriate information to the clinician

Table 2.3. Quotations of incidental finding definitions from literature sources.

Source	Definition
Adams, Babyn, & Danilkewich (2016)	"findings that are unrelated to the clinical indication for the imaging examination performed" (p. 541)
Alpers (2001)	"a problem unrelated to the primary reason the patient sought care" (p. 7S)
Andrawes et al. (2017)	"pathologies not related to trauma" (p. 1)
Anjum, Bleeker, & Ohle (2019)	"any previously unknown finding that was identified in the radiologist's final report" (p. 30)
Barboza, Fox, Shaffer, Opalek, & Farooki (2009)	"non-injury-related pathologic conditions" (p. 729)
Barrett et al. (2009)	"unexpected finding not related to trauma seen on SCT that potentially could pose danger to patient's present or future health" (p. 429)
Behbahani et al. (2017)	"incidentally discovered mass or lesion, detected using imaging—performed for an unrelated reason. This includes any unanticipated findings which are detected but which are not directly related to the clinical indication for the specific imaging examination" (incidentaloma) (p. 1046)
Davies, Pichiotino, Black, & Tosteson (2016)	"findings on an imaging test done for other reasons, for which there are no matching symptoms in the patient" (incidentaloma) (p. 650)
Devine et al. (2010)	"pathology unrelated to the trauma that may or may not be clinically significant" (p. 24)
Ganguli et al. (2019)	"actionable results that are unrelated to why one ordered the tests" (p. 2)
Hassan, Che Mohamed, Nazli Kamarulzaman, & Abdul Aziz (2014)	"finding that is discovered unrelated to the clinical indication for the imaging examination performed" (p. 46)
Huynh et al. (2008)	"disease diagnoses unrelated to the injury" (p. 331)
Jambhekar et al. (2016)	"any discovery which was unrelated to the mechanism of injury which required further diagnostic workup or treatment" (p. e204)
James, Francois, Yoeli, Doughlin, & Lee (2017)	"any non-trauma-related abnormality identified on CT imaging" (p. 348)
Kelly et al. (2015)	"any unforeseen pathology that was not previously known or that was not attributable to the presenting symptoms" (p. 1854)
Leung et al. (2019)*	"It's when most of these things come up and looking for one thing and people find the other things, and then you start questioning that because, you know, obviously it's not what I went in there for" (p. 38)

Lumbreras, González-Alvarez, Gómez-Sáez, Lorente, & Hernández-Aguado (2014)	"abnormality which is unrelated to the initial scanning indication" (p. 249)
Messersmith et al. (2001)	"findings that appear unrelated to the original purpose of the scan" (p. 479)
Meyer, Schramm, Bach, Beeskow, & Surov (2017)	"findings that are not related to the scope of the ordered investigation" (p. 1)
Munk, Peitzman, Hostler, & Wolfson (2010)	"findings on CT that are unrelated to the original purpose of the scan" (p. 346)
Rogers et al. (2013)	"any nontraumatic abnormality identified on cranial CT scan" (p. e357)
Ruesseler et al. (2013)	"an abnormal finding not related to trauma seen on MSCT that could potentially pose danger to the patient's present or future health" (p. 849)
Sconfienza et al. (2015)	"an incidentally discovered mass or lesion detected by abdominal CeCT performed for an unrelated reason" (p. 351)
Shuaib, Johnson, Salastekar, Maddu, & Khosa (2014)	"an incidentally discovered mass or lesion, detected on a test or imaging examination unrelated to the reason for the test" (p. 37)
Sierink et al. (2014)	"unrelated to the clinician's reasons for requesting the radiological examination" (p. 840)
Sonis et al. (2017)	"imaging findings not related to the evaluation of PE that generated a recommendation" (p. 656)
Spruce et al. (2020)	"abnormal radiographic findings not related to the indication for the imaging study" (p. 63)
Thompson, Wojcik, Gran, & Ko (2011)	"findings unrelated to the chief complaint and not pertinent to the immediate patient care in the emergency department" (p. 1)

*Patient explaining understanding of definition of IF during interview in second additional file of published article

and patient, which was found to significantly improve the rate of documented communication through text string recognition.

The literature also discussed education for healthcare professionals (8%), delegating management of IFs to mid-level providers and non-physicians (7%), patient education (7%), and clarifying responsibilities (6%). Seven studies also discussed creating a specific role, such as an IF coordinator, to be responsible for managing IFs. Sperry et al. (2010) implemented the role of an IF coordinator, who documented IFs daily from trauma admission, which improved notification, documentation, and follow-up for patients. They found that the IF coordinator resulted in a 2.5-fold increase in IF discovery and significantly improved initiation of patient follow-up and record documentation.

Discussion

While the literature on IFs is abundant, much of the literature discusses the domain of IFs in genetics or in research settings. The literature discussing IFs in clinical care, specifically emergency medicine, is not sufficient for developing adequate and comprehensive ethical guidance on identification, disclosure, and management. This interpretive literature review helped to highlight what is currently known and understood about IFs in emergency care settings. Identifying the current state of the topic will help to determine what knowledge, research, and policy gaps are present.

The literature as a whole shows that the majority of focus on IFs in EDs has been discussed mostly in the past fifteen years and is primarily discussed in North American settings. The literature is also focused on IFs in adult populations, which is most likely because IFs are most often found in older adults than in children. The literature also suggests that CT imaging is the most common imaging domain for measuring IF prevalence. Further key ideas gathered through this literature review are that prevalence and frequency of IFs are most often reported and the high prevalence denotes that there is a need to address the problem of IFs. The literature as a whole illustrates the lack of reporting on patient disclosure and documentation of IFs based on the low number of studies that obtained these results, which were only 13 and 23 of the studies, respectively. Similarly, reporting on successful follow-up was not reported often, which demonstrates that it is difficult to monitor follow-up or that successful follow-up is not common. The literature on this topic in this setting is focused most on how common IFs are, but not on

Table 2.4. Recommendations for future practice, research, and policy.

Idea	n	%	Relevant Quotations
Improvements to reporting and documentation of IFs	41	41.8	"Discharge summaries often do not address clinical management or referrals made because of incidental findings. Addressing these components would be an avenue by which to improve quality of care" (Barboza, Fox, Shaffer, Opalek, & Farooki, 2009, p. 728) "Written documentation in the medical record is always mandatory […] We are currently using a checklist on the discharge summary to communicate all CT findings, their clinical significance, and the need for appropriate follow-up to all patients" (Baugh, Weireter, & Collins, 2014, p. 858) "…lack of documentation and referral notes in the patient chart may artificially delay access to appropriate care" (Bell et al., 2019, p. 309) "The lack of documentation of IF on discharge instructions creates an additional potential liability for health systems and providers and may hinder optimal patient care in the setting of clinically significant IF" (Mortani Barbosa & Osuntokun, 2019, p. 6778) "An increase in the quality of documentation decreases the failures in follow-up and prevents future uncertainty" (van Vugt et al., 2012, p. 420)
Improvements to follow-up practices	36	36.7	"Integration of follow-up notifications into electronic medical records will help ensure follow-up imaging at necessary intervals, potentially easing the burden on family physicians as 'quarterbacks' for their patients" (Adams, Babyn, & Danilkewich, 2016, p. 542) "…adrenal incidentalomas follow-up is often overlooked, and that follow-up is influenced by patient, radiologic, and medical provider factors. An adrenal lesion follow-up protocol may improve follow-up rates but requires further analysis" (Maher, Williams, Grodski, Serpell, & Lee, 2018, p. 1360) "From the perspective of the emergency and trauma physician, the goal is to ensure that all patients diagnosed with an incidental finding are referred for appropriate follow-up care where further investigations can be planned" (Munk, Peitzman, Hostler, & Wolfson, 2010, p. 349)

Improvements to patient communication and discussion	34	34.7	"…there could be improvement in conveying findings to the patient […and…] considerable room for improvement within patient– physician communication" (Baugh, Weireter, & Collins, 2014, p. 855,857) "As healthcare moves toward shared decision-making, patients should be informed of any IF which may potentially have some impact on their health or need further action" (Hanna et al., 2016, p. 172) "…there is a need for radiologists to work together with the referring clinicians in communicating the risk of incidental findings to the patient and charting out an appropriate course for further management" (Shuaib, Johnson, Salastekar, Maddu, & Khosa, 2014, p. 39) "…it is within the patient's right to be informed of even seemingly insignificant incidental findings in writing for medical-legal reasons [...and…] it is imperative of emergency Physicians to inform appropriately these incidental findings as to not overly alarm patients beyond getting appropriate followups with their primary providers" (Thompson, Wojcik, Grant, & Ko, 2011, p. 3-4)
Increased communication and collaboration with other healthcare providers	27	27.6	"…clinicians should consult with radiologists directly in problematic or complicated cases, to determine the most optimal management for their patients" (Behbahani et al., 2017, p. 1059) "Our survey highlights the importance of clear communication between radiologists and ED physicians when incidental findings are encountered" (Kutaiba et al., 2019, p. 573) "Radiology departments, working together with the patient's primary care provider and family care practices, could establish closed-loop automated confirmation systems to notify the primary care provider whether a patient has missed the time frame for a recommended follow-up examination" (Mortani Barbosa & Osuntokun, 2019, p. 6778-6779) "Solutions will rely on collaborative efforts between radiologists, trauma and emergency physicians, and primary care physicians" (Munk, Peitzman, Hostler, & Wolfson, 2010, p. 350)

Develop evidence-based guidelines/protocols	23	23.5	"Our findings stress the overall importance of having established follow-up and treatment plans for many trauma patients who are likely to otherwise fall through the cracks because of their ability to cover costs of care" (Bell et al., 2019, p. 310) "Further research is necessary to determine the impact of these incidental findings. This includes outcomes of the patients who were notified and those who were not notified of their CT scan findings" (Devine, Jackson, Lyons, & Mason, 2010, p. 27) "Standardized reporting formats and adoption of consensus practices for incidental findings could reduce variability that makes it challenging for emergency physicians to identify and respond to recommendations for additional imaging" (Dutta et al., 2013, p. 167) "Initiatives could include the development and effective dissemination of point-of-care guidelines and shared decision-making tools, along with other strategies to embrace and communicate uncertainty" (Ganguli et al., 2019, p. 10) "…there remains a relative lack of research and guidance about the management of incidental findings and disparity in clinicians' attitudes may be partly driven by the paucity of data, the lack of clear guidelines with regard to diagnostic and treatment strategies and fear of potential malpractice litigation" (Seah, Murphy, McDonald, & Carrothers, 2016, p. 694)
Implementation of electronic alert or feedback systems	14	14.3	"In the near future, computerized tools should allow physicians to take advantage of electronic medical records through continuous surveillance of radiology reports to provide physicians and patients information on incidental findings" (Dutta, Long, Brown, & Reisner, 2013, p. 163) "An automated system of recognizing incidental findings notations in the radiology reports through an electronic medical records system that generated reports to clinicians and letters to patients improves patient safety" (Emerman, Gallagher, & Diaz, 2012, p. 111) "An ideal situation for most non-emergency situations is where imaging reports are communicated via electronic means to correct referring doctor, with an automatic feedback or alert mechanism if the report is not accessed within a certain time" (European Society of Radiology, 2012, p. 1) "Future studies should address process-of-care issues leading to such communication breakdowns and guide the design and implementation of the next generation of computerized notification systems in ambulatory care" (Singh et al., 2009, p. 1583)

Education for healthcare professionals	8	8.2	"The education of all physicians, nurses, and therapists involved in patient care to the importance of managing incidental findings" (Biegler, McBeth, Tiruta, Ball, & Kirkpatrick, 2012, p. 30) "...education to increase awareness of the importance and the legal ramifications of findings unrelated to the patients' injuries" (Huynh et al., 2008, p. 332)
Creation of role for managing IFs	7	7.1	"We recommend involving the entire team and designating one individual to champion this issue" (Collins et al., 2015, p. 5) "At our center, the ED has employed a full-time health care provider who has the sole task of communicating such results to patients, educating patients who need further evaluation, and assisting with follow-up arrangements when needed. This may be an area of interest for future studies" (Daoud et al., 2017, p. 619) "The [dedicated incidental finding] coordinator documented admissions daily from trauma admission radiology final reads […] resulted in [increased] IF capture […and…] patient notification was verified and follow-up was initiated in 95.8% of cases" (Sperry et al., 2010, p. 618)
Delegating IF management to mid-level providers	7	7.1	"As the most consistent trauma team member, the [trauma nurse practitioner] is ideally placed to receive alerts identified in an EHR system" (Biegler, McBeth, Tiruta, Ball, & Kirkpatrick, 2012, p. 29) "We initiated a care plan in which [midlevel providers] conducted all tertiary surveys and coordinated follow-ups for incidental findings" (Huynh et al., 2008, p. 331) "It has been shown that the addition of NPs to the trauma team increases the quality of documentation, improves the completeness of discharge summaries, and decreases readmissions after discharge, failures to fill prescriptions, and failures to follow up. The successful management and referral of incidental findings may best be addressed and coordinated by these nonphysician providers" (Paluska et al., 2007, p. 161)

Patient education	7	7.1	"This design [observational registry] would also create a reasonable expectation of patient notification and a better chance to educate patients about the meaning of such findings, allowing improved estimates of the patient experience of incidentaloma detection and improved education of the public about the pros and cons of both intervention and observation of incidentalomas" (Davies, Pichiotino, Black, & Tosteson, 2016, p. 655) "We argue that a more robust informed consent process is needed to enable patients to anticipate incidentalomas and to correctly perceive the associated risks" (Kole & Fiester, 2013, p. 1064) "First, a patient information pamphlet is needed to explain the facts about the incidental findings, thus creating realistic expectations and removing unnecessary anxiety. This would be a source of reassurance [from] a reputable source" (Powell, 2014, p. 602)
Clarity of responsibilities	6	6.1	"Clear lines of responsibility and communication should be in place for managing and following up IFs in hospitals and consultant and family practices" (Adams, Babyn, & Danilkewich, 2016, p. 542) "...which actions should be taken and by whom should also be reported on this electronic report" (Sierink et al., 2014, p. 842) "The multidisciplinary trauma team should set out the guidelines indicating who is responsible for the follow-up and how this should be executed" (van Vugt et al., 2012, p. 420)
Creation of referral system	6	6.1	"A good referral system by emergency department physicians and trauma surgeons should be developed for adequate follow-up" (Andrawes et al., 2017, p. 5) "Refer immediately to other surgical or medical subspecialties the patients who have findings that are not within the interest of the surgical team and obtain a confirmation that the patients are seen and given the appropriate consultation or outpatient appointment" (Lanitis et al., 2012, p. 371)
Completing follow-up or assessment before discharge	4	4.1	"Our protocol emphasizes notification of IFs while the patient is hospitalized […] We believe our approach, while logistically somewhat difficult, provides several benefits. First, we eliminate the need to locate a patient after discharge, which may be difficult if a patient does not live locally, is homeless, or was discharged to a rehabilitation facility, nursing home, or a family member's residence. Additionally, addressing findings in the hospital allows for the creation of a plan for further workup, which may be more feasible for patients who are unable or unlikely to follow up after discharge for any reason" (Collins et al., 2015, p. 5)

Classification of findings	2	2.0	"A classification system for these findings practiced nationwide will aid in categorizing the urgency of continued follow-up" (Andrawes et al., 2017, p. 1)
Discussing IFs with patients face-to-face	2	2.0	"The team decided that the ideal communication of incidental findings would be a face-to-face conversation between the ED provider and the patient or family so that they could discuss the finding, along with suggested follow-up. This potentially allowed the patient or family to also ask questions to make sure they understood the finding and recommendations" (Baccei et al., 2018, p. 641)
Trauma follow-up clinic to improve management	1	1.0	"As a result, we perceive a role for a dedicated trauma follow-up clinic that incorporates both primary care and primary prevention in addition to social support for the most high-risk groups" (Biegler, McBeth, Tiruta, Ball, & Kirkpatrick, 2012, p. 30)

their ethical and practical implications or the experiences of patients. The literature also provides several ad hoc recommendations for improving IF management, but do not detail ways in which these suggestions are or could be implemented in practice or initiatives that adopt these recommendations.

Key findings include the recommendations made in the literature, which shows that there is much that can be done to help develop and improve guidelines for emergency care workers. One such suggestion is to improve communication and discussion with patients, which includes ensuring that patients are informed of their IFs. To do this effectively, physicians may discuss IFs with patients face-to-face, which was discussed (Baccei et al., 2018; Wiener et al., 2013). This preference for direct communication echoes the results of a study assessing patient preferences for laboratory test results in ambulatory care (Grimes et al., 2009). This research shows that 64% of patients and 41% of physicians prefer to use a direct phone contacting method to notify and be notified about abnormal results, compared to mail methods for normal results (Grimes et al., 2009). There have been efforts in practice to improve communication systems for IFs, which include the Failsafe method (Jones, 2017), which involves encouraging ED patients to follow up on IFs through notification by phone call and letter, and has received positive responses from patients.

The majority of the literature on IFs in ED settings cite radiologists as having the primary obligation towards the management of these discoveries. Other sources also report referring physicians as having responsibility for the tests that they order and ensuring adequate follow-up. Select sources discuss the role of the family physician or primary care provider, but further discussions and a comparison between the literature in primary care settings and ED settings can further elucidate the role of primary care providers in this context. One source consisting of guidelines (European Society of Radiology, 2012) alludes to institutional responsibility to promote safe practices. It also makes reference to a radiologist's duty to care for patients. Few sources discuss such duties or ethical obligations that healthcare professionals have towards patients. The literature does however include recommendations for increased communication and collaboration between healthcare providers, which could help to mitigate the idea that IF management responsibility only falls on certain healthcare professionals. Consultation should occur between radiologists and clinicians or radiologists and ED physicians when IFs are discovered, which can lead to closed-loop communication systems (Behbahani et al., 2017; Kutaiba et al., 2019; Mortani Barbosa EJ. & Osuntokun O., 2019; Munk et al., 2010).

One way to discuss responsibility of IF management is to clarify these responsibilities by

maintaining communication between healthcare professionals. If care teams establish who is responsible for disclosure, documentation, reporting, and follow-up, there would be a better understanding of duties. These responsibilities do not have to be standardized, but should be discussed within multidisciplinary care teams (van Vugt et al., 2012). As previously mentioned, clarifying responsibilities can be accomplished through collaboration practices between healthcare providers. There should be effective communication tools and practices to facilitate this. One example is to ensure proper reporting of IFs so that all members of the care team are made aware of relevant patient information. While this literature did not detail how to improve reporting, there are several initiatives and systems currently being tested and developed that could serve this purpose. For example, mobile apps can be used for efficiency and ease in reporting of IFs that can be shared with other healthcare professionals on the care team (Kovacs et al., 2018). The literature in this review provides evidence that reporting on whether an IF was disclosed, how it was disclosed, and whether follow-up was sought, is alarmingly low. To navigate this, policy and guideline development should explore current initiatives to combat low reporting and poor communication.

While there is limited discussion on ethical principles surrounding IFs, ethical justifications surrounding disclosure have been alluded to and can be inferred as being within a patient's right to information. Only five of the articles included in this review made reference to preferences of either patients or healthcare providers and thus, further research should aim to discuss preferences surrounding discovery, disclosure, and management of IFs. It was reported that patients may prefer to follow up on IFs prior to discharge to avoid an additional trip to a medical centre or to avoid anxiety over waiting for tests (Alpers, 2001). However, Alpers (2001) also recognized that some patients may prefer that their primary care providers explore the findings in follow-up. Thus, it would be of interest to explore the preferences of patients further in future research, which could be used to update and advise current policy and guidance. Wiener et al. (2013) interviewed patients on perceptions of communicating with providers about pulmonary nodules and one patient noted that they would have preferred to learn about the finding in a face-to-face discussion to avoid anxiety from receiving the news in a letter. The authors suggested that while some patients did not appreciate when physicians minimized the concern surrounding the nodule, other patients expressed relief when physicians seemed unconcerned by the finding (Wiener et al., 2013).

Empirical studies included in the review do not address ethical principles or patient preferences on disclosure. The literature reveals suggestions to manage IFs in EDs, including

implementation of automatic feedback or alert mechanisms, clarification of responsibilities within treating teams, and improvements to reporting and documentation of patient records. Authors suggest further research on optimal follow-up recommendations to alleviate patient and physician distress. Ethical challenges that should be addressed in future research and policy is the standardization of communication of IFs between physician and patient as well as between care providers. The anxiety caused by managing or not managing IFs should be measured, including the impact on healthcare costs, use of physician and patient time, as well as health of individuals undergoing follow-up.

Limitations

This critical interpretive literature review has some limitations that should be discussed. First, it should be noted that there was no quality assessment for the articles included in the review, which is common for critical interpretive literature reviews. Also, the greatest limitation was that the articles for the literature review were screened individually (RI) with additional consultation for some ambiguity in the articles and help with inclusion decisions (CE). Also, there are threats to external validity because the focus on emergency settings makes it difficult to generalize recommendations and findings to other domains where IFs are common, such as genetics. Common limitations of the studies included in the review include the high prevalence of retrospective studies, which are subject to limitations of recall bias. Also, many of the studies were conducted at one hospital or medical centre and thus, the results cannot always be generalized to larger populations. Also, while the definitions of IFs were similar across the studies, the classification of clinical significance of IFs may have led to differences in the results and reported data. The subjectivity of the understanding of clinical significance in the context of IFs introduces the potential for biases.

Conclusion

This review helped to identify what makes the ED setting different when considering disclosure of IFs and what ethical challenges are prevalent that require research and policy focus. This review showed that the literature on IFs in EDs focuses too narrowly on frequency, with ad hoc suggestions for practice, research, and policy changes to improve the ethical management of IFs. The review also revealed that there is little to no literature on the ethical principles and justifications of disclosure in ED settings or on preferences on IF management of patients or healthcare professionals. Numerous factors, including crucial knowledge gaps, contribute to

inadequate management of IFs arising in EDs. Research- and ethics-informed policy guidance is needed to successfully improve work-up, referral, and management of IFs in the high-volume setting of the emergency department.

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Chapter 3. Ethical Codes, Guidelines, and Policies to Direct Incidental Finding Management: A Thematic Content Analysis

Preface

"Chapter 3: Ethical Codes, Guidelines, and Policies to Direct Incidental Finding Management: A Thematic Content Analysis" constitutes a manuscript with plans to publish in a bioethics-related or emergency care-related journal. This manuscript was prepared by following the methods of thematic content analysis as described by Green & Thorogood (2014), and by consulting academic literature on this methodology for protocol and manuscript preparation. This content analysis of ethical codes, guidelines, and policies follows a critical interpretive literature review that explored the current understanding of incidental finding identification, disclosure, and management in the academic literature. This chapter contributes to the thesis objective and expands on the results from the academic literature by identifying and categorizing relevant obligations and duties of emergency department healthcare professionals in ethical codes, guidelines, and policies.

Contribution of Authors

Renata Iskander, B.Sc. (Hons), was the first author on this manuscript. She prepared the protocol, developed the list of relevant documents to include, conducted the document search and screening, extracted the data from the documents, developed a list of themes, conducted the thematic coding of the extracted data, summarized and interpreted the results, and prepared the manuscript.

Carolyn Ells, PhD, was the supervising author on this manuscript. She contributed to revising the list of relevant documents, helped to interpret extracted data from documents, provided input on themes, contributed to interpretation of results, and provided guidance and feedback with the manuscript.

Abstract

Incidental findings are findings discovered in the course of healthcare (e.g. blood tests, genetic tests, imaging) that are unrelated to the primary purpose for which a test was sought. Understanding the standard of care is important for healthcare professionals to ethically identify, disclose, and manage incidental findings. A thematic content analysis was conducted of codes of ethics, guidance from health professions and other professional bodies, research-context guidance, and legislation that relate to incidental findings or can be relevant for guidance on incidental findings. This analysis was done in order to highlight guiding themes recurrent in these documents to develop the discussion surrounding the duties and obligations of healthcare professionals to identify, disclose, and manage incidental findings in emergency care settings. A total of 31 documents were collected by handsearching the academic and grey literature. The documents were reviewed and important provisions and quotations were extracted from each. Following this, the data was categorized through thematic coding in NVivo 12. The primary themes found were: informed consent and autonomy, veracity and disclosure, beneficence and non-maleficence, justice, standard of care, continuity of care, and guidance development. Eleven of the documents discussed informed consent generally, one legislative document discussed informed consent when time allowed, and four documents discussed informed consent not being required in emergencies. Regarding continuity of care, while not addressed by legislative documents, five other sources discussed the importance of communicating with other healthcare professionals and four sources discussed follow-up of patients, where only one of these four explicitly referred to incidental findings when discussing follow-up. Based on the documents explored here, there is breadth, but a lack of depth, in the guidance on managing incidental findings. While most guidance is not in the context of emergency care settings or explicit to incidental findings, many guidelines can be applicable to developing good practice guidelines and to direct health professionals on duties surrounding identifying, disclosing, and managing incidental findings.

Introduction

Incidental findings (IFs) are findings discovered during the course of care that are beyond the scope and primary purpose for which a patient sought care (Bioethics Commission, 2013). IFs are especially important to explore in the context of emergency department (ED) settings, where patients require urgent care and the interactions between physicians and patients are limited. Healthcare professionals, including ED professionals, must follow the standard of care in clinical practice. The standard of care refers to what a competent physician in the same field would reasonably do under similar circumstances (Moffett & Moore, 2011). Defining the standard of care can help to identify the legal, professional, and ethical duties for identifying, disclosing, and managing IFs in ED settings. There are few to no policies and guidelines that are directly related to IF management in emergency care settings. However, there are many legal and guidance documents that can indirectly assist with medical, professional, and ethical conduct for identifying, disclosing, and managing IFs and for developing a standard of care in practice. The majority of this guidance and legislation related to IFs is focused on research settings and protection of research subjects. Many other policies and guidelines have prioritized the field of genetic testing in research and clinical practice. Current codes, guidance, and legislation may contain relevant guidelines that can be applicable and transferable to emergency care settings. The policies and guidelines described in this report are from the Canadian context, most prominently Ontario and Quebec because they are the largest provinces in Canada. Some policies and guidelines included were also taken from relevant documents in the United States because of their focus on ethical standards in healthcare. Seminal international documents and guidelines were also included if similar guidance was not available in Canada or the United States. This report: (1) summarizes and collates codes of ethics, guidance from health professions and other professional bodies, research-context guidance, and legislation that relate to IFs, and (2) illuminates guiding themes recurrent in these documents that relate to the duties and obligations of healthcare professionals to identify, disclose, and manage IFs in emergency care settings.

Methods

This report used thematic content analysis described by Green & Thorogood (2014). This method allowed for examination of multiple policy and guidance documents, as well as organization based on primary themes. Before thematic coding was completed, RI conducted an academic and grey literature search using handsearching for relevant documents that could provide guidance on IF management, which included: codes of ethics; policies and guidelines

from health professions and other professional bodies, including position statements, policy statements, reports, and relevant online articles; research-context guidance; and legislation. There were no strict exclusion criteria for the review and literature was included as long as it was binding, important to medical practice, or had guidance or recommendations directly or indirectly pertinent to the management of IFs. These literature sources are listed in Table 3.1. Following the search, RI reviewed the documents and extracted important quotations that could be used as guidance in the context of IFs. Following this, a list of themes was developed by looking for regularities in the quotations from the documents to categorize the findings (Green & Thorogood, 2014). Thematic coding of these quotations was an inductive approach because the themes emerged from reviewing the recurring themes in the data in order to derive meaning (Green & Thorogood, 2014). After identifying common themes, two rounds of thematic coding were conducted using NVivo 12 (QSR International) and presented the information based on their primary themes.

Results

The main literature sources used in this review were: codes of ethics, policies and guidelines from health professions and other professional bodies, research-context guidance, and legislation. The documents were interpreted as written and it is possible that these sources do not use the appropriate terminology when discussing IFs.

Codes of ethics help to outline ethical conduct and principles that are critical and relevant to the organization. Codes of ethics are statements that provide members of an organization or professional group with a structural understanding of the ethical norms and duties in their practice, including standards for behaviours and decision-making. Unless explicitly stated, codes of ethics are not legally binding, but set standards and expectations for professional practice and can lead to professional consequences if not followed. Codes of ethics are necessary to understand the underlying values of relevant stakeholders in the discussion surrounding ethical management of IFs in emergency care settings. Discussing these documents will help to develop an understanding of current obligations of healthcare professionals for ethical IF management. While the code of ethics for emergency physicians (EPs) was reviewed, we also discuss codes of ethics for physicians, radiologists, and nurses in Canada and the United States because IF responsibilities are not

Table 3.1. Literature sources used for thematic content analysis (n = 31).

Codes of Ethics	**Policies and Guidelines from Health Professions and Others**	**Research-context Guidance**	**Legislation**
American College of Emergency Physicians (ACEP) – Code of Ethics (2017)	American College of Emergency Physicians (ACEP): Policy Statement – Interpretation of Diagnostic Imaging Tests (2018)	European Medicines Agency – Guideline for good clinical practice E6(R2) (2015)	Act Respecting Health Services and Social Services (Quebec – 2019)*
American College of Radiology (ACR) – Code of Ethics (2019)	Canadian Association for Emergency Physicians: Position Statement – Recommendations for the Use of Point-of-Care Ultrasound (PoCUS) by Emergency Physicians in Canada (Lewis et al., 2019)	Food & Drug Administration: Guidance For Industry Investigator Responsibilities – Protecting The Rights, Safety, And Welfare Of Study Subjects (2009)	The Charter of Human Rights and Freedoms (Quebec –2019)*
American Medical Association (AMA) – Code of Medical Ethics (2001)	Canadian Association of Radiologists (CAR) – CAR Standard for Communication of Diagnostic Imaging Findings (Butler et al., 2010)	Medical Research Council - Framework on the feedback of health-related findings in research (2014)	The Civil Code of Quebec (2019)*
American Nurses Association (ANA) – The Code of Ethics for Nurses with Interpretive Statements (2015)	The Canadian Medical Protective Association (CMPA): Duties and responsibilities - Improving patient handovers (2016)	"Practical approaches to incidental findings in brain imaging research" (Iles et al., 2008)	The Criminal Code of Canada (2019)*
Canadian Medical Association (CMA) – Code of Ethics and Professionalism (2018)	The Canadian Medical Protective Association: Safety of Care (CMPA) – Avoiding pitfalls in the emergency department: Recognizing and managing risks of diagnostic error (2018)	The Royal College of Radiologists – Management of Incidental Findings Detected During Research Imaging (2011)	Health Care Consent Act (Ontario – 2018)*
Canadian Nurses Association (CNA) – Code of Ethics (2017)	The Canadian Medical Protective Association (CMPA): Safety of Care Effectively managing hospital test results — Key to timely diagnosis and patient safety (2012)	Tri-Council Policy Statement – Ethical Conduct for Research Involving Humans (Canadian Institutes of Health Research [CIHR], 2018)	Universal Declaration on Bioethics and Human Rights (2006)**
Ordre des infirmières et infirmiers du Québec – Code of Ethics of Nurses (2002)*	Choosing Wisely Canada – "Unnecessary Care in Canada" (Levinson & O'Toole, 2017)		
The Quebec Code of Ethics of Physicians (2019)*	Collège des Médecins du Québec: "Safety Framework for the Follow-up of Diagnostic and Screening Test Results" (2012)*		
	College of Physicians and Surgeons of Ontario (CPSO): Policy Statement – Disclosure of Harm (2003)		
	College of Physicians and Surgeons of Ontario (CPSO): Policy Statement – Test Results Management (2011)		
	Presidential Commission for the Study of Bioethical Issues: Anticipate and Communicate (2013)		

*legally binding document

**not legally binding, but members states of the United Nations Educational, Scientific and Cultural Organization are encouraged to incorporate provisions into national laws, regulations, or policies

limited to EPs and should be discussed from the perspectives of all emergency healthcare professionals.

To supplement codes of ethics, we included policies and guidelines from health professions and other professional bodies in Canada and the United States because some guidance documents are directly relevant to IF management and should not be neglected. These policies and guidelines are not legally binding but offer an understanding of positions of organizations and professional bodies for different issues that affect their practice. These documents may offer procedural recommendations, guidelines to define practice principles, and other expectations for its members, as well as support to assist healthcare professionals to provide the standard of care. Included here is the Bioethics Commission (2013) document, *Anticipate and Communicate*, which was a government-mandated initiative to advise the President on this ethical issue and identify ethically responsible policies and practices. The chosen documents are important because they relate to EPs, radiologists, emergency care settings, or follow-up care, which are all directly relevant to IF management.

Research-context guidance was included in this review because the realm of research has included extensive guidance for investigators on how to manage IFs. It should be considered whether this guidance can be used or applied to improve management in care settings. Some of these documents are mandated for research to be conducted, such as the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (2018). While there are several documents that overlook research conduct, we chose seminal documents from the United States and Canada, including research involving imaging, which is relevant to emergency care settings where IFs are most commonly found by imaging.

Finally, legislation was used to explore whether there are legally binding responsibilities outlined for healthcare professionals in how they manage IFs. With exception to the *Universal Declaration on Bioethics and Human Rights* (2006), which is nonbinding, all documents in this category are Canadian to serve as an example of what information legislation may present for this context. Among these document sources, relevant themes were consolidated and presented below, starting with informed consent and autonomy.

Informed Consent and Autonomy

Among the major themes found in these documents, the most commonly referenced was informed consent. One-third of the documents discussed informed consent as a requirement. The ACEP *Code of Ethics for Emergency Physicians* (2017) requires EPs to relay sufficient

information for patients to make informed choices about diagnostic and treatment options. The CMA *Code of Ethics and Professionalism* (2018) also discusses empowering patients to make informed decisions by helping them "navigate reasonable therapeutic options to determine the best course of action consistent with their goals of care" (p. 4). All three codes of ethics for nurses also describe respect for patients by acknowledging their right to informed consent by referencing accuracy, completion, comprehensibility, and transparency (ANA, 2015; CNA, 2017; Code of ethics of nurses, 2002). Research-context guidance also discusses informed consent for research subjects (Illes et al., 2008; The Royal College of Radiologists, 2011). The guidelines also offer potential statements to include in informed consent forms to communicate to subjects about IFs, such as explaining that the researchers are not trained to perform diagnoses or that the images used are not optimized to find abnormalities (Illes et al., 2008). They advise investigators to be explicit in their language during the consent process about aspects of IFs including plans for follow-up (Illes et al., 2008). Legislation also acknowledges the autonomous decision-making capacity of patients by discussing the importance of facilitating informed consent. Free and enlightened informed consent is necessary for preventive, diagnostic, and therapeutic interventions and can be obtained by explaining relevant information about the nature, purpose, and possible consequences of such interventions (Civil Code of Quebec, 2019; Code of Ethics of Physicians, 2019; Health Care Consent Act, 2018; Universal Declaration on Bioethics and Human Rights, 2006).

Part of the conditions of informed consent includes comprehension of care, which is emphasized in several codes of ethics. The AMA *Code of Medical Ethics* (2001) states that physicians should adopt policies and procedures where "test results are conveyed sensitively, in a way that is understandable to the patient/surrogate" (Article 2.1.5). Many documents focus on the idea that patients should understand their health information (ANA, 2015; CMA, 2018). The *Code of ethics of nurses* (2002) also specifies that nurses should provide "explanations necessary for the client's comprehension of the care, treatment or other professional services…" (Article 40). Legislation (An Act respecting Health Services and Social Services, 2019; Code of Ethics of Physicians, 2019) discusses the requirement of receiving explanations pertinent to their "understanding of the nature, purpose and possible consequences of the examination, investigation, treatment or research" (Code of Ethics of Physicians, 2019, Article 29). Comprehension of care requires that accurate treatment options be explained to patients to facilitate informed decision-making (ACEP, 2017; AMA, 2001; ANA, 2015; Civil Code of Quebec, 2019; CMA, 2018). The risks and benefits of these treatment options should also be

explained and discussed with patients to respect decision-making, which includes discussing burdens and expected benefits from receiving or forgoing different treatments (AMA, 2001; ANA, 2015; Civil Code of Quebec, 2019; CMA, 2018; Code of Ethics of Physicians, 2019). Following obtaining free and enlightened consent, there are duties to respect the decisions of patients to accept or reject recommendations for treatments and care plans (CMA, 2018).

Informed consent is commonly required for patients and subjects in most care and research settings. However, there are exceptions to this requirement. One notable exception is when the life of a patient is in danger and the urgency of a patient's condition demands an immediate response (ACEP, 2017; Civil Code of Quebec, 2019; Health Care Consent Act, 2018). The AMA *Code of Medical Ethics* (2001) defines a patient's agreement to emergency care as "implicit" (Article 1.1.1), indicating that explicit consent is not required. Part of the reason this exception exists is because in non-emergent situations, consent can be obtained without constraints on time to provide appropriate care. However, consent in emergency situations is not required if "consent cannot be obtained in due time" (Civil Code of Quebec, 2019, Article 13). Part of the challenge in emergency care situations is the constraint on time, which will be further discussed as a moral challenge in the next chapter.

Respect for autonomy and self-determination of patients is a leading ethical justification for informed consent practices. Several documents in this review recognize the importance of the right to self-determination and allowing patients to choose and act autonomously after being informed of health information (ACEP, 2017; ANA, 2015; CNA, 2017; Code of ethics of nurses, 2002). The CMPA (2012) also advises that physicians "engage patients in their own care". Respecting autonomy also requires respecting preferences that patients may have for not receiving certain medical and health information (AMA, 2001; Bioethics Commission, 2013; CNA, 2017). Respecting such preferences to not receive health information may conflict with another duty—the duty to disclose—which relates to another primary theme of this review, veracity.

Veracity and Disclosure

As we have explained, informed consent involves sharing relevant information for patients to understand the nature of their care to facilitate informed decision-making. Sharing this health information is part of the act of disclosing, which can help to promote trust between patients and physicians. Several documents emphasize the need for honesty and truthfulness in order to maintain a relationship of trust (Civil Code of Quebec, 2019; Code of ethics of nurses,

2002). Information should be communicated accurately and truthfully with patients (ACEP, 2017; CMA, 2018), which is relevant to uphold the principle of veracity. As previously mentioned, there should be respect for preferences to not receive health information to honour autonomy and thus, physicians should encourage patients to specify preferences about communication of health information and disclosure should be tailored to patients' needs and expectations (AMA, 2001).

There is a general understanding in several guidance and legislative documents concerning the need to disclose information to patients relating to diagnoses (Civil Code of Quebec, 2019), fatal or grave prognoses (Code of Ethics of Physicians, 2019), harms (CMA, 2018), when medical care is needed (International Conference on Harmonization and Good Clinical Practice, 2015), suspicious findings (Illes et al., 2008), and facts that reasonable persons would want to know (CPSO, 2003). Disclosure of information is similar to providing relevant information to obtain informed consent, which we previously described. Select documents specify that findings and IFs with significant welfare implications, clinical significance, or that may be adverse to a patient's health, should be communicated (ACEP, 2018; AMA, 2001; The Royal College of Radiologists, 2011). In addition to disclosing critical findings, disclosure and acting on findings should be done in a timely fashion (AMA, 2001; CMPA, 2018; Illes et al., 2008), such as during a patient's ED visit to guide treatment decisions (ACEP, 2018). Further recommendations include disclosing information to patients verbally (ACEP, 2018; Illes et al., 2008). While disclosing findings to patients is important, there is also guidance advising that information be disclosed to primary care providers and other healthcare professionals (ACEP, 2018; Lewis et al., 2019). In research settings, the requirement to disclose IFs is more defined than in care settings (ANA, 2015; *Guidance For Industry Investigator Responsibilities – Protecting The Rights, Safety, And Welfare Of Study Subjects*, 2009). The Royal College of Radiologists (2011) even report that the majority of members believe it is unacceptable to tell subjects that they would receive no feedback on imaging and also unacceptable to tell individuals unprepared to learn about IFs that they should not participate in research. There is also moderate agreement that it is unacceptable for a physician or other healthcare professional to identify a potentially harmful finding knowing that the subject will not be informed (The Royal College of Radiologists, 2011).

While there is some agreement over the obligation to disclose medical findings and IFs, there are some exceptions to this obligation. Exceptions include if there is a "just cause" not to inform (Code of Ethics of Physicians, 2019), "impracticability" (CIHR, 2018), and

"impossibility" (CIHR, 2018). The TCPS 2 (2018) defines impracticable as "undue hardship or onerousness that jeopardizes the conduct of research; it does not mean mere convenience" (p. 33). There is also an exception to provide a patient with their health information if it "will result in substantial harm to the patient or others" (CMA, 2018, p. 4). However, the majority of references are in agreement about maintaining veracity and the general obligation to disclose health information, including IFs.

Beneficence and Non-maleficence

Duties surrounding not causing harm, honouring contractual undertakings, and reparation for injury can be found in the Civil Code of Quebec (2019). The Criminal Code of Canada (2019) and Civil Code of Quebec (2019) also discuss general duties of non-maleficence and preventing harm and disregard for safety of other persons. Maximizing benefits and minimizing harm to patients is discussed in the *Universal Declaration on Bioethics and Human Rights* (2006). Non-maleficence is discussed in the context of IFs in the *Unnecessary Care in Canada* document (Levinson & O'Toole, 2017), when it mentions that IFs can cause worry and lead to unnecessary tests. Beneficence is promoting patient well-being and welfare, which is prioritized in several codes of ethics (ACEP, 2017; ANA, 2015; CMA, 2018; CNA, 2017). To ensure patient safety and beneficence, care should be provided in emergent situations, when life is in danger (AMA, 2001; Charter of Human Rights and Freedoms, 2019; Code of ethics of nurses, 2002; Code of Ethics of Physicians, 2019), unless it involves danger to the care provider or a third party (Charter of Human Rights and Freedoms, 2019; Criminal Code of Canada, 2019; Code of ethics of nurses, 2002).

Justice

The principle of justice and fairness requires all patients to have:

> "access to adequate information, guidance, and support in making informed choices about what medical tests to undergo, what kind of information to seek, and what to do with information once received. The principle of justice and fairness also requires affordable access to quality information about [IFs], before and after testing, which when coupled with access to care can be potentially lifesaving or life enhancing" (Bioethics Commission, 2013, p. 9)

Access to care is important to respecting patient autonomy and to upholding the principles of beneficence and non-maleficence. Justice and fairness concern the fair distribution of resources—goods and services. Managing IFs requires a sense of allocating resources because unnecessary tests caused by IFs can increase wait times for other patients (Levinson & O'Toole, 2017). Resource allocation decisions need to be made for patients to promote fair treatment and distribution (CNA, 2017). Emergency physicians should act as "responsible stewards of the health care resources entrusted to them" (ACEP, 2017, p. e7). Physicians should also consider their time as a resource to be allocated, which is noted in the AMA *Code of Medical Ethics* (2001) citing that it is reasonable for physicians to refuse to care for a patient if meeting their need would "seriously compromise the physician's ability to provide the care needed by his or her other patients" (Article 1.1.2). Thus, decisions concerning just and fair resource allocation are critical to providing a basic level of care to all patients.

Standard of Care

In applying principles such as respect for autonomy, veracity, beneficence, non-maleficence, and justice, physicians can work towards providing the standard of care for patients. Part of the standard of care is ensuring that care provision is useful and appropriate, which includes ordering appropriate and necessary tests. The AMA *Code of Medical Ethics* (2001) discusses the patient's right to "timely, responsive attention to his or her needs" (Article 1.1.3), which should be adhered to for acting on and reviewing significant findings in a timely manner. Documents provide recommendations for ensuring adherence to the standard of care, including gathering an appropriate medical history and conducting and documenting an appropriate physical exam to manage the risk of diagnostic errors (CMPA, 2018), including delayed diagnosis of IFs. Also, codes of ethics clarify that physicians should use the most appropriate methods to make diagnoses (Code of Ethics of Physicians, 2019), recognize that inappropriate use of treatments and resources can lead to ineffective care (CMA, 2018), and physicians can decline providing care to patients when patients request scientifically invalid care (AMA, 2001). The Bioethics Commission (2013) believes that practitioners should adopt "diagnostic elegance" and "therapeutic parsimony" by "ordering and conducting only tests and interventions necessary for addressing health concerns related to their patient" (p. 12). Before communicating test results with medically suspicious abnormalities to patients, Illes et al. (2008) advise that expert review of scans be performed, which also helps to ensure appropriate care is provided.

While diagnosing accurately and ordering appropriate tests help to provide patients with a standard of care, there are steps to take following confirmation of an IF, which includes reporting and documenting these findings in patient records, and to healthcare professionals and patients. These findings should be documented in a physician's report (ACEP, 2018; Lewis et al., 2019), include direct communication of such findings from the radiologist to the referring physicians before the formal written report (Butler et al., 2010), or be followed up with written communication following informed consent in research settings (Illes et al., 2008). These actions are part of ensuring continuity of care.

Continuity of Care

Documenting and reporting on results of IFs help to begin the process of ensuring continuity of care. Part of continuity of care for patients is that physicians help to coordinate care with other healthcare professionals and that physicians will not discontinue treatment without arranging for alternative care or referring the patient (AMA, 2001). Physicians accept responsibility for their patients and should continue to provide care until no longer required or wanted, or until they can secure another physician to assume responsibility for the patient (CMA, 2018). Physicians should identify back-up healthcare professionals for results before ordering tests (Collège des médecins du Québec & Lacasse, 2012). Securing follow-up care for patients for test results is part of continuity of care. Ordering healthcare professionals are responsible for following up on test results because they have "an ethical obligation to provide follow-up care as dictated by the patient's condition" (Collège des médecins du Québec & Lacasse, 2012, p. 8) unless they ensure another professional can be responsible (Code of Ethics of Physicians, 2019). In managing test results, practitioners should ensure that a system is in place for physicians to follow up on test results appropriately, where follow-up is defined as "clinically appropriate action taken following receipt of a patient's test results" (CPSO, 2011, p. 2). The AMA *Code of Medical Ethics* (2001) advises physicians to provide reasonable assistance in securing follow-up care for IFs if requested. Thus, follow-up is an essential part of providing patients with appropriate care and can be facilitated by transferring care and referring patients to other healthcare professionals. A patient handover is described as "the transfer of responsibility and accountability for some or all aspects of care for a patient or group of patients, temporarily or permanently" (CMPA, 2016). Transfer of care should be facilitated for patients when appropriate (AMA, 2001) and for research subjects to seek appropriate care following an IF (*Guidance For*

Industry Investigator Responsibilities – Protecting The Rights, Safety, And Welfare Of Study Subjects, 2009).

In order for physicians to transfer care to other healthcare professionals for patients to have continuity of care, there needs to be communication between healthcare professionals. Healthcare professionals should be in communication about test results, especially radiologists to ordering providers (ACEP, 2018; Butler et al., 2010). Communication and collaboration is key to ensuring patient care plans are facilitated and that there is continuity of care (AMA, 2001) and might include a structured communication approach (CMPA, 2018). The CMPA (2012) advises physicians to be aware that "good communication between hospital departments and between providers is essential to an effective system for managing diagnostic test results". Communication is essential to allowing for continuity of care, patient follow-up, and transfer of care, which all contribute to ensuring that the standard of care is met.

Communicating with healthcare professionals is important because it involves consulting with other healthcare professionals on test results and how to manage IFs. It is advised that physicians seek consultations from other health professionals when appropriate (ACR, 2019), which includes consulting "knowledgeable sources" (ACEP, 2018, Article 46). For researchers, it is advised to consult with medical professionals to interpret images or to assist in communicating sensitive medical information when an IF is discovered (CIHR, 2018; Illes et al., 2008; The Royal College of Radiologists, 2011). Finally, the AMA *Code of Medical Ethics* (2001) discusses consultation "for help in assessing the relative benefits and harms associated with delaying disclosure" (Article 2.1.3) by discussing this with healthcare professionals, but also the patient's family or ethics committee if necessary. Consultations are helpful when making diagnoses and interpreting imaging, determining whether findings are clinically significant, and assessing benefits and burdens.

Guidance Development

As we have explored in the previous chapter, there are several recommendations to develop further policies and guidelines on how to manage IFs. The documents in this review make similar recommendations on how to improve current guidance. The Bioethics Commission (2013) calls for professional and public health organizations to produce evidence-based standards for screening programs to measure the likelihood that IFs will arise from different diagnostic modalities and should provide guidance for clinicians on IF management. It also recommends that federal agencies "study the comparative benefits to patients and the cost

effectiveness of using bundled tests or a battery of tests versus conducting sequential, discrete diagnostic tests" (Bioethics Commission, 2013, p. 11). The CMPA (2012) recommends that physicians be aware of hospital procedures and protocols to manage test results, which requires these hospitals to outline such procedures. To uphold the standard of care, physicians should recommend evidence-informed treatment options, which should be clearly outlined (CMA, 2018). In research, it is expected that researchers follow good practice guidelines in the study country (Medical Research Council, 2014).

As previously mentioned, the Bioethics Commission (2013) recommends anticipating the possibility of IFs. This is a common recommendation among research-context guidance, which advise that investigators anticipate the possibility of IFs during experimental design (Illes et al., 2008) as well as their potential severity, clinical significance, and whether the finding is actionable with strategies for prevention, treatment, and management (Medical Research Council, 2014). In addition to recommending imaging research centres to assess the frequency and type of IFs that are likely to arise, the Royal College of Radiologists (2011) recommends that IFs be viewed as a medical issue because it leads to a transition from research subject to patient, which involves a different set of standards and responsibilities.

Communication protocols between healthcare providers and between healthcare providers and patients should be established to facilitate better care upon IF discovery. Organizations should provide support for managing patient communication, including communication of IFs that were not available when the patient was in the ED (ACEP, 2018). These results should be communicated in a method that is appropriate based on the significance of the finding and closed-loop communication is encouraged (ACEP, 2018). To ensure patients are informed of test results, physicians should advocate for policies about when the patient can expect to learn about test results, how results will be conveyed, and what to do if they do not receive results in the expected timeframe (AMA, 2001). Thus, practitioners should be transparent about their plan for disclosure and communication of IFs, including the scope of findings that will be communicated and the steps to be taken following discovery (Bioethics Commission, 2013). In the research context, guidance includes establishing a pathway for IF management that is transparent in the consent process by explaining how IFs will be handled and follow-up responsibilities (Illes et al., 2008) as well as considering how and when feedback will be given to research subjects (Medical Research Council, 2014).

While communication and disclosure plans are part of management, there are other aspects of handling IFs that require plans and procedures to be developed. Organizations should

develop operating procedures to clarify communication of test results, as well as quality assurance, follow-up, and IF communication (ACEP, 2018). Practitioners should inform patients about their management plan for IFs, which requires developing these plans (Bioethics Commission, 2013). Management plans for IFs should be systematic with an audit process to assess reliability of follow-up of diagnostic and screening test results (Collège des médecins du Québec & Lacasse, 2012). In the research context, there is also a call to develop management plans, including considering how IFs will be identified, whether they need to be verified, and who will be involved in feedback of findings (Medical Research Council, 2014). The TCPS 2 (2018) also recommends that investigators develop a management plan or process to follow when IFs are discovered, which is required for genetics research. Illes et al. (2008) further establish that "no action is taken beyond articulating a plan for handling IFs in the informed consent process" (p. 9) so that investigators are encouraged to develop plans of action upon IF discovery.

Overall, while guidance, communication, and management plans ought to be developed, there should also be a push towards education on IFs, which is discussed by the Bioethics Commission (2013). They recommend informing stakeholders, including practitioners and potential recipients, about the ethical, practical, and legal implications of IFs.

Table 3.2. Number of source documents that reference each of the themes and sub-themes.

Themes	Codes of Ethics (n=8)	Guidance from Health Professions and Others (n=11)	Research-context Guidance (n=6)	Legislation (n=6)	Total (n=31)
Autonomy and informed consent					
Autonomy and self-determination	4	1	0	0	5
Comprehension of care	5	0	0	1	6
Explain risks and benefits	4	0	0	1	5
Informed consent	6	0	2[b]	3	11[b]
Informed consent if time allows	0	0	0	1	1
Informed consent not required in emergencies	2	0	0	2	4
Provide accurate treatment options	4	0	0	1	5
Respect competent decision to accept or reject treatment	1	0	0	0	1
Respect preferences for not receiving health information	2	1[a]	0	0	3[a]

Beneficence and non-maleficence					
Act on and review significant findings in timely fashion	1	1	0	0	2
Beneficence	0	0	0	1	1
Duty	0	0	0	2	2
Non-maleficence	1	1[a]	0	3	5[a]
Patient well-being and welfare	4	0	0	0	4
Provide care unless dangerous	1	0	0	2	3
Provide care when emergent	3	0	0	1	4
Continuity of care					
Communicate with other healthcare professionals	1	4[a]	0	0	5[a]
Continuity of care	2	1	0	0	3
Follow-up with patients	2[a]	2	0	0	4[a]
Obtain consultation to identify materiality	0	0	2[b]	0	2[b]
Obtain consultation when appropriate	3	0	1[a]	0	4[a]
Refer for transfer of care	1	1	1[a]	0	3[a]
Guidance development					
Anticipate possibility of IFs	0	1[a]	3[c]	0	4[d]
Communication plan	1	2[b]	2[b]	0	5[d]
Guidance development and evidence-based practices	1	2[a]	1	0	4[a]
Management plan	0	3[b]	3[c]	0	6[e]
Prepare educational materials	0	1[a]	0	0	1[a]
Justice					
Allocation of time to patients	1	0	0	0	1
Justice	0	1[a]	0	0	1[a]
Resource allocation	1	1[a]	0	0	2[a]
Steward of resources	1	0	0	0	1
Standard of care					
Document and report IFs	0	3[b]	1[a]	0	4[c]
Ensure accurate diagnosis	1	0	1[a]	0	2[a]
Ensure care is useful and accurate	3	1	0	0	4
Order appropriate and necessary tests	1	1	0	0	2
Veracity and disclosure					
Communicate truthfully	2	0	0	0	2
Disclose	2	1	2[b]	1	6[b]
Disclose important findings	1[a]	1	1[a]	0	3[b]
Disclose in timely fashion	1	2	1[a]	0	4[a]

Disclose to patients and healthcare professionals	0	2[a]	0	0	2[a]
Disclose unless there is harm	1	0	0	0	1
Disclose verbally	0	1	1[a]	0	2[a]
Encourage preference specification for disclosure	1	0	0	0	1
Exceptions to disclosure	1	0	1[a]	0	2[a]
Non-disclosure is unacceptable	0	0	1[a]	0	1[a]
Promote trust and fidelity	1	0	0	1	2
Tailor to patient needs for disclosure	1	0	0	0	1

[a]IFs are explicitly referenced in one of these documents; [b]IFs are explicitly referenced in two of these documents; [c]IFs are explicitly referenced in three of these documents; [d]IFs are explicitly referenced in four of these documents; [e]IFs are explicitly referenced in five of these documents; no superscript indicates that none of the documents explicitly mention IFs, but general guidance could be relevant

Discussion

There were several themes found in the policy and guidance literature that are summarized in Table 3.2 (See Appendix Table 3.1A and Table 3.2A for detailed references of each theme). The most prominent theme found in the policy and guideline sources concerned informed consent and autonomy. Informed consent at the time of testing is important for IF management because it helps patients be aware of the possibility that IFs are likely to arise, which findings will be disclosed, and how they will be disclosed. Without informed consent playing a vital part in IF management, patients will not have sufficient comprehension and information about the nature of their diagnostic tests—including the risks and benefits—and will be unprepared for incidental information. Part of informed consent is providing patients with accurate treatment options and ensuring comprehension of care. Since we are discussing the emergency care context, it is important to highlight the distinctions in this setting, which include the obligation for informed consent if time allows and informed consent exceptions in emergency scenarios. Informed consent from patients respects patient autonomy and capacity for decision-making, it is part of respecting a patient's decision to accept or reject treatment options if they are sufficiently provided, and it promotes respecting patient preferences, including preferences for not receiving certain health information.

There is limited discussion surrounding informed consent and autonomy in this context and setting, which is evidenced by the literature review in the previous chapter as well as the review above. However, in our critical interpretive literature review, a third of the literature recommended improvements to patient communication and discussion, which often included ensuring that patients remain informed about IFs, contributing to our discussion of this theme.

This information can be used to extend the current policies and guidelines on informed consent and patient communication by introducing guidance on what elements of informed consent are important for ethical management of IFs. Also, six of the papers recommended patient education, which also made explicit references to informed consent practices, including helping patients anticipate IFs and correctly understand their risks (Kole & Fiester, 2013). Most references to informed consent and autonomy in this document review were only present in codes of ethics documents, and few references about informed consent were explicitly mentioned in the context of IFs, including one reference of respecting preferences for not receiving information on IFs (Bioethics Commission, 2013). Among legislative documents, the Civil Code of Quebec (2019) made the most references to this theme, compared to other documents. Autonomy is central to respecting the rights of patients and is thus necessary to highlight and consider for improvements to policy and guidance surrounding IF management.

Another overarching theme found among the guidance documents is that of veracity and disclosure. Veracity is the principle of truth telling and disclosure is the action and application of this principle or responsibility. Disclosure of IFs relates to the idea of wanting patients to have all relevant information about their care, which then connects to our previous theme of informed consent. Disclosure involves several questions and concerns surrounding when to disclose IFs, which IFs should be disclosed, and who should disclose this information, which all serve the veracity principle. Veracity includes communicating information truthfully, promoting trusting relationships between patients and professionals, disclosing clinically significant findings versus any finding, disclosing information in a timely fashion, and even exceptions to disclosure (e.g. disclose unless harm may result). Similar to the previous theme, recommendations from the literature review to improve patient communication and discussion are also relevant here. One-third of the literature made reference to these recommendations, including informing patients of IFs in the act of disclosure. Despite the low reporting in the literature about how often patients are notified of findings, there were few recommendations to implement disclosure policies and guidelines. Currently, there is more policy and guidance on veracity and disclosure in codes of ethics and research-context guidance compared to health profession guidelines and legislation, with the exception of the ACEP Policy Statement (2018) on interpreting diagnostic imaging tests. This highlights the need for further guidelines on the theme of veracity and disclosure in the context of IFs. There were few references to explicitly disclosing IFs outside of research-context guidance documents, which is important to note because healthcare professionals do not have formal guidelines on disclosing this information to patients.

In this review, we highlighted relevant references to the principles of beneficence, non-maleficence, and justice within these documents. While the principles of beneficence and non-maleficence are not explicit in guidance, they are relevant for this discussion because beneficence promotes patient welfare. These principles are more common in codes of ethics documents when discussing not doing harm to patients and providing care when emergent or unless dangerous. There were few references in the guidance that relate to the justice principle despite its importance in this context. Allocation of resources, including imaging tests in the ED, helps to make sure that all patients receive a basic level of care. Allocation of time dedicated to patients is also relevant to respecting justice, but is only discussed in the AMA *Code of Medical Ethics* (2001). The ACEP (2017) discuss EPs as stewards of healthcare resources in their code of ethics, which is worth considering for IFs. The lack of discussion of these principles in the policy and guidance documents reveals gaps that could contribute to healthcare professionals not understanding their obligations and responsibilities surrounding IF management.

Upholding the standard of care in practice was also found as a commonality within the policy and guidance documents. Ensuring that care is useful and accurate, that diagnoses are accurate, and tests ordered are appropriate and necessary, were reflected in these documents. Guidance on details of documenting and reporting IFs was also observed to maintain the standard of care. Continuity of care was referenced at length in these documents, most commonly in codes of ethics and research-context guidance. Continuity of care is necessary when managing IFs because healthcare professionals need to ensure that patients are followed and transferred to other care services to receive care for important findings. Continuity of care with respect to IFs are discussed in research-context guidance, as well as by the CAR (2011) and the AMA *Code of Medical Ethics* (2001). Continuity of care involves securing follow-up for patients with IFs and transferring care, communicating with other healthcare professionals regarding patient care, and obtaining consultation when necessary. For improved practice, such recommendations should be consolidated and incorporated into health profession guidelines.

Finally, several of the policy and guidance documents recommended further guidance development relating to IFs, which echoes the results from the critical interpretive literature review. These were discussed most by the Bioethics Commission (2013), the ACEP Policy Statement (2018), and research-context guidance. Some of the guidelines advise anticipating the possibility of IFs, preparing communication and management plans, preparing educational materials, and overall guidelines that discuss developing context-specific guidance and evidence-based practices. Codes of ethics documents did not typically address this theme, but instead

addressed ethical principles and standard of care responsibilities. Guidance from health professions and legislative documents also did not address this and both types of documents had the fewest references overall to help healthcare professionals manage IFs.

The critical interpretive literature review we previously conducted provided several recommendations for future policy. Based on this document review, several of these recommendations are not addressed in these guidance and policy documents, including the implementation of electronic alert or feedback systems to improve disclosure and communication practices, education initiatives for healthcare professionals on IFs, delegation of IF management to mid-level providers or creating a specific role for IF management, clarity of responsibilities for healthcare providers, ensuring appropriate classification of the significance of IFs, and the possibility of a trauma follow-up clinic. However, the documents in this review made recommendations involving improvements to: reporting and documentation of IFs, follow-up and referral practices, patient communication and discussion verbally and through informed consent, patient education, communication and collaboration with other healthcare providers, and evidence-based guidelines and protocols.

Conclusion

Based on the documents explored in this review, there is breadth, but a lack of depth, in the guidance involving improvements to the management of IFs that relate to themes of informed consent and autonomy, veracity and disclosure, beneficence and non-maleficence, justice, standard of care, continuity of care, and further guidance development. While not all guidance is in the context of emergency care settings or explicit to IFs, many of the guidelines can be applicable and transferable to develop good practice guidelines and to direct healthcare professionals on their duties and responsibilities for identifying, disclosing, and managing IFs. This review can be used to help policymakers and health professions develop more extensive guidance by assessing gaps in current guidance. The review can be used to enhance current guidance and draw attention to how different guidelines and policies might be interpreted in the context of IFs. Improving current guidance by including relevant themes explored here can be helpful for healthcare professionals to navigate the ethical uncertainties of identifying, disclosing, and managing IFs. Further discussion involving guidance development for emergency healthcare professionals should include an exploration on whether broad and general guidelines are more appropriate than specific policies. When applying guidance from other contexts, including research, it is essential to discuss what rules can or cannot be transferred from research

subjects to patients as well as what duties can or cannot be applied from investigators to physicians. While several of the recommendations explored in the second chapter were addressed by the policy and guidance documents, there were also several gaps that should be addressed and implemented into further guidance, including implementing feedback systems, delegating IF management to mid-level providers, and clarifying roles and responsibilities of healthcare providers.

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Chapter 4. The Ethical Landscape of Incidental Findings in Emergency Care Settings

Introduction

As evidenced by our literature review and review of policy and guidance documents, there is little to no discourse surrounding the ethical concerns or obligations of IFs in ED settings. Currently, literature is focused on a quantitative understanding of the scope of this issue, including the number of IFs discovered, the rate of reporting in medical records, the frequency of patient disclosure, and the level of follow-up. All of these values, except for the number of IFs discovered, are alarmingly low. This dearth in the literature urges us towards an ethical exploration of IFs to show why these low values are problematic. If there were no ethical, legal, or managerial concerns surrounding IFs, the limited or lack of reporting, disclosure, and follow-up would not be worthy of discussion.

While this discussion is largely focused on the ED setting, it should be noted that many problems may be comparable in other domains and settings. To begin, we should identify the challenges and conflicts that render the identification, disclosure, and management of IFs a matter for ethics. When considering identification, a main challenge is determining which findings are material or clinically significant, which have been outlined in clinical guidance documents (Hoang et al., 2015; Kirkpatrick et al., 2019; Patel et al., 2013). Also, identification requires emergency healthcare professionals to consider whether and which tests should be conducted and who should be identifying materiality of findings. Under disclosure, many questions can be asked, including: *Should the EP disclose the finding to the patient? How should the finding be disclosed? When should the finding be disclosed?* Finally, ethical management requires us to consider the emergency healthcare professional's responsibilities, whether and when they should consult other healthcare professionals, when and to whom should patients with IFs be referred, how to document such findings, and also determining appropriate follow-up protocols.

In addition to these overarching challenges, there are several ethical conflicts that present when considering IFs in ED settings. The first conflict that is prevalent for EPs concerns the dual responsibility of ensuring efficient use of health resources while also providing quality care to patients. This conflict exists because while ED healthcare professionals must prioritize patient welfare when proffering care through beneficence, they must also maintain the principle of

justice and sufficiency of healthcare resources for all patients. For example, an EP who orders a slew of diagnostic tests for and spends hours focused on one patient may be providing quality care to one patient, but foregoing both provision of required care to other patients and the equitable sharing of resources. Similarly, when an ED healthcare professional discovers an IF, they may be conflicted over the extent to which their duties require them to both oversee the management of this finding—even if not an immediate priority—and continue to care for other emergency patients with more urgent concerns. Thus, there is a conflict of duties and obligations. Emergency healthcare professionals may also experience uncertainty about whether the patient would want to be informed of a discovered IF, especially when there are no apparent urgent health consequences. This can be viewed as a conflict between respect for autonomy and beneficence. Similarly, a conflict between respect for autonomy and non-maleficence is also present when considering that some patients may experience needless harm or anxiety from learning of a discovery, but the healthcare professional may want to maintain the right to self-determination and respect for persons by sharing their personal health information. Overall, there are several conflicting values and principles that are present, which are necessary to identify in order to determine ethical practice. Finally, it is also important to name the stakeholders, or who the conflicting ethical principles concern. Ethical dilemmas involving IFs concern the patient, the patient's family, the responsible physician, and the care institution. The differences in moral viewpoints in the dilemma could be within the same individual faced with deciding whether they prefer disclosure or how to pursue follow-up, as well as between physician and institution, physician and patient, patient and family members, and between stakeholders and existing social, legal, or institutional norms.

Understanding the ethical dilemmas involving identification, disclosure, and management of IFs, as well as acknowledging the ethical conflicts and stakeholders is critical to situating our ethical discussion. In this chapter, we: (1) outline the characteristics and moral challenges distinct to EDs as they apply to IFs; (2) explore relevant ethical principles that are critical to managing IFs in this care setting, including autonomy, beneficence, veracity, and justice; (3) consider whether primary care guidelines on IF management can be applied to this care context; (4) consider whether research-context guidance on IFs are transferable to ED settings; (5) outline relevant decision-making frameworks in ED settings; and (6) reintroduce and discuss the previously defined case studies. This chapter helps to elucidate relevant ethical challenges and principles that can be applied to fill the knowledge gaps in the literature and policies and guidance about whether, when, and how IFs should be identified, disclosed, and managed. As a

starting point, we must establish the moral challenges and characteristics of EDs to be able to guide healthcare professionals in this setting on ethical IF management.

Characteristics of the Emergency Department

To contextualize the problem of IFs in EDs further, we must outline the relevant characteristics in EDs that make IFs morally challenging. The *Code of Ethics for Emergency Physicians* (2017) discusses the principles of ethics for EPs, including the moral challenges and virtues of emergency medicine. This statement will help determine what makes the ED a unique setting that requires moral attention to ethically manage IFs. The first three moral challenges discussed in the Code of Ethics (*The Code of Ethics for Emergency Physicians*, 2017) are the most relevant for the purpose of this thesis: time constraints, determining capacity to consent, and limited relationships with patients.

Time Constraints

The ED setting cares for patients with acute illnesses or injuries that require immediate care, sometimes under time constraints. The *Code of Ethics for Emergency Physicians* (2017) explains that "in these emergent situations, emergency physicians have little time to gather additional data, consult with others, or deliberate about alternative treatments. Instead, there is a presumption for quick action guided by predetermined treatment protocols" (p. e8). In this statement, EPs are expected to act in a timely manner to provide adequate care for patients. Thus, in ED settings, it is difficult to comprehensively consider the implications of IFs when treating patients. There is limited time to explain the risks and benefits of IFs and disclosure to patients, or to consult with other experts on the clinical significance of an IF. Oftentimes, quick decisions need to be made with little deliberation about the consequences or outcomes of decisions. When time is constrained, general patient welfare, namely physical health and wellbeing, is prioritized and is acted upon first before considering patient autonomy and care preferences. EPs must show vigilance in practice because emergency medicine requires immediate assistance for an array of patients and EPs must remain "alert and be prepared to meet unpredictable and uncontrollable demands" (*The Code of Ethics for Emergency Physicians*, 2017, p. e9). The Code (2017) specifies that action be guided by predetermined treatment protocols, which are not presently developed for management of IFs in EDs. The literature review did not reveal significant guidance that helps to explicitly navigate the challenge of time constraints, but many of the

recommendations can be justified as helpful to manage time constraints, such as clarifying responsibilities or delegating IF management to mid-level providers. Relevant to time constraints, four documents discussed disclosing information in a timely fashion, two of the documents discussed acting on and reviewing significant findings in a timely manner, and only the AMA *Code of Medical Ethics* (2001) discussed allocation of time to patients, which shows that current policy and guidance does not sufficiently recognize and address this challenge in ED settings. Among all policy and guidance documents reviewed, only the Civil Code of Quebec (2019) mentioned that informed consent is only required if time allows. Thus, another salient feature of providing care in ED settings is the effect of time constraints on determination of patients' capacity to consent.

Determining Capacity to Consent

Patients in the ED are often "unable to participate in decisions regarding their health care because of acute changes in their mental state" (*The Code of Ethics for Emergency Physicians*, 2017, p. e8). In the ED, EPs cannot always obtain informed consent for the many exams, tests, and treatments associated with a patient's care. The diversity of patients who present to the ED make it challenging for healthcare professionals to assess capacity to consent. The differences between patients that present to the ED make it difficult for EPs to gauge how to manage IFs that arise, whether they should be disclosing such discoveries to patients directly, and whether to trust that the patient will seek follow-up care. In other care settings, the level of care comprehension is less variable between patients, and physicians can better determine whether there is informed consent, especially given that they are not constrained by time in the same way as EPs. The literature review revealed that more than one-third of the literature suggested improving patient communication and discussion, citing the patient's right to be informed; however informed consent is not discussed in most of these sources. One of the main themes in the document review was autonomy and informed consent, showing that almost one-third of the documents discuss informed consent, with four documents specifying that informed consent is not required in emergency situations, which consists of situations where care is required to avoid death or severe injury to patients. A main reason why determining capacity to consent is difficult in the ED relates to the third feature of emergency medicine—the limited physician-patient relationship.

Limited Physician-patient Relationship

There is an asymmetry of information, with the physician having more knowledge, skills, and experience than the patient. This power imbalance requires that patients trust that the physician will provide ethical care. To avoid promoting a climate of distrust and to cultivate optimal interactions between physicians and patients, physicians should minimize the asymmetry of information by providing all the relevant information patients need to make voluntary choices about healthcare decisions, which is further complicated by the previously described moral challenge of determining capacity to consent. Trust is compromised in the ED because the relationship between the physician and patient is sometimes limited in EDs. EPs usually have had no prior relationship with ED patients. ED patients arrive "unscheduled, in crisis, and sometimes against their will" (*The Code of Ethics for Emergency Physicians*, 2017, p. e8). The Code (2017) specifies that EPs "cannot rely on earned trust or on prior knowledge of the patient's condition, values, or wishes regarding medical treatment. The patient's willingness to seek emergency care and to trust the physician is based on institutional and professional assurances rather than on an established personal relationship" (p. e8). Unlike other healthcare professionals, like primary care providers, EPs do not usually have an extensive relationship with patients. Due to the constraints in time, EPs are limited in their ability to develop a relationship or to receive comprehensive information about a patient, including their values and wishes involving IF disclosure and follow-up care preferences. This third distinguishing feature of the ED makes it ever more challenging for EPs to navigate through the discovery of an IF, which is not sufficiently addressed or acknowledged in the literature or guidance documents. Unlike primary care providers, the duties and obligations of EPs to patients is short-lived and may involve a different set of responsibilities. These three moral challenges and distinguishing features manifest themselves in ethical principles in emergency care that include respect for autonomy, veracity, beneficence and non-maleficence, and justice, which EPs should model in their professional practice.

Principles of Ethics for IFs in Emergency Care

Respect for Autonomy

Respect for autonomy involves respect for persons and their self-determination. Beauchamp and Childress (2013) define personal autonomy as "self-rule that is free from both controlling interference by others and from certain limitations such as an inadequate

understanding that prevents meaningful choice" (p. 101).[1] It involves freedom of choice and the ability to exercise rational decision-making capacities. To respect individuals as autonomous agents requires recognizing their rights to make choices and to take actions based on their personal values and beliefs (Beauchamp & Childress, 2019). The purpose of the informed consent process is to promote autonomy as well as protect patient welfare (Beauchamp & Childress, 2019; Berg et al., 2001). Consent forms should provide patients with adequate information to make informed and autonomous decisions in healthcare. We will further discuss the role of informed consent when discussing the application of research-context guidance to this context. The principle of respect for autonomy should manifest in all care settings, including ED settings and in the management of IFs. In the policy and guidance document review, one of the most prominent themes pertained to autonomy and informed consent, which was focused most in codes of ethics documents. Respect for autonomy requires healthcare professionals to provide accurate treatment options, respect a patient's competent decision to accept or reject certain treatments including follow-up for IFs, and respect a patient's preferences for not receiving certain health information, including IFs. While the focus on autonomy and self-determination rests in codes of ethics, it is important for guidance for ED settings to incorporate the right to autonomy. To maintain respect for autonomy and to encourage informed decision-making, patients should receive objective and comprehensive information relevant for their care and health needs, including an understanding of risks and benefits, which is the premise of the next principle, veracity.

Veracity

Respecting patient autonomy also relates to the obligations of veracity and truth telling because it entails explaining accurate information to patients to acknowledge them as autonomous agents with the right to self-determination. One of the main challenges of determining ethical management of IFs surrounds the issue of disclosure (Bioethics Commission, 2013). Disclosure refers to the provision of relevant information to patients by physicians and comprehension of said information (Beauchamp & Childress, 2019; Etchells et al., 1996). There is considerable discussion surrounding when it is ethically permissible to withhold information from patients (Bioethics Commission, 2013), even outside the context of IFs (Beauchamp &

[1] While the most recent version of *Principles of Biomedical Ethics* by Beauchamp & Childress (2019) was used throughout the thesis, this definition from a previous edition (2013) is relevant and important to understand autonomy.

Childress, 2019). Decisions surrounding information disclosure are related to the principle of veracity. Veracity is the "timely, accurate, objective, and comprehensive transmission of information" (Beauchamp & Childress, 2019, p. 328). Justifications for veracity obligations include respect owed to others by promoting patient autonomy and right to self-determination, the ability to make healthcare decisions, and ensuring that patients receive all relevant health information (Beauchamp & Childress, 2019). It also promotes a relationship of trust between the physician and patient because it encourages open and honest communication as well as transparency (Beauchamp & Childress, 2019).

To navigate through these obligations, there are standards of disclosure, including the "reasonable patient standard", which requires disclosing information needed to make an informed decision. If a patient would act differently without knowing this information, the patient is not informed and the reasonable patient standard is not met in order for nondisclosure to be permissible. The "professional standard" refers to the obligation to share information that the community of healthcare professionals understands as relevant and required (Dranseika et al., 2017). The "subjective standard" or "individual standard" requires that healthcare professionals understand what is relevant to the particular patient by honouring their informational needs and preferences (Dranseika et al., 2017). Preferences surrounding what patients want to know about their personal health information as well as how they want it to be communicated and by whom, are not always known by healthcare professionals, especially in ED settings. There is some research that discusses preferences of return of results, but not in the ED setting. For example, among women diagnosed with breast cancer, when asked about genome sequencing, most were interested in learning about actionable information and some were not interested or ambivalent towards information considered not actionable (Kaphingst et al., 2016). Thus, we should expect preferences concerning disclosure of IFs to differ among patients, making the subjective standard ideal for developing IF disclosure and management plans.

Truth telling is not always ethically obligatory when veracity conflicts with other obligations (Beauchamp & Childress, 2019). Healthcare professionals may rationalize nondisclosure if disclosure can lead to patient harm or anxiety, or because it will cause information overload that will not benefit the patient. Disclosure of IFs can result in harms or undesirable effects for patients when the accuracy of the finding is uncertain, there is no clinical significance, or when the finding is not clinically actionable or curable. Disclosure of a prognosis of death can violate obligations towards beneficence and non-maleficence by causing anxiety, destroying hope, countering a therapeutic outcome, or leading a patient to commit suicide

(Beauchamp & Childress, 2019). However, it can also lead to important benefits for individuals who wish to know this information for life planning purposes, and respect beneficence when there are actions that can be taken to reduce pain and suffering, such as palliative care. Thus, it is important to identify potential risks and benefits of disclosure for each findings, as well as understand patient preferences in order to determine responsibilities surrounding disclosure, especially disclosure of IFs because they are usually unanticipatable. Patients are most likely to benefit from disclosure of IFs that are 1) validated by accurate testing measures, 2) have urgent clinical significance, and 3) are actionable.

Overall, there has been a shift in attitude towards disclosure, which reflects the obligations of veracity. In 1961, 88% of surveyed physicians sought to avoid disclosing a cancer diagnosis, but by 1979, 98% cited a disclosure policy for cancer patients (Beauchamp & Childress, 2019). This change was a result of increases in availability of treatment options, improved rates of cancer survival, fear of malpractice suits, changes in societal attitudes towards cancer, and heightened attention to patient rights (Beauchamp & Childress, 2019). While this example is in the context of cancer diagnoses, we can see how disclosure of any health information, including IFs, are ethically complex because of patient differences and uncertainty of consequences.

In our previous document review of policy and guidance, veracity and disclosure was a prominent theme, with discussions surrounding disclosure of important findings, disclosing in a timely fashion, disclosing to both patients and healthcare professionals, disclosing verbally, disclosing unless there is harm, communicating truthfully, encouraging preference specification for disclosure, not disclosing information being unacceptable, promoting trust and fidelity, and tailoring to patients' needs for disclosure. Potential risks and benefits of disclosing IFs were identified and outlined in Table 4.1. Some of these potential risks and benefits were also found upon reflection from other sources, including the Bioethics Commission (2013) and Appelbaum et al. (2014). Identifying the potential risks and benefits is important for anticipating potential harms of IFs and leads us to consider the principles of beneficence and non-maleficence.

Beneficence and Non-maleficence

In addition to informing patients of the risks and potential benefits of IF disclosure, healthcare professionals should also work to minimize those risks and maximize the potential for benefits. In healthcare, beneficence implies a duty of care with the goal of benefitting patients and

Table 4.1. Risks and potential benefits of IF disclosure.

Risks	Potential Benefits
• Risk of false-positive result • Risk of false-negative result • Findings may have errors or are wrongly interpreted • Physical risks if individual seeks further invasive diagnostic or follow-up treatments • Possible negative psychological responses (e.g. from learning of different paternity) • Possible confusion from ambiguity of results • Possibility that future interpretations of findings may be different as knowledge advances • Behavioural harm leading to potentially risky or irrational decisions or changes in lifestyle • Social harm of stigma/discrimination (e.g. genetic discrimination affecting insurance or changes in relationships from stigmatizing diseases) • Costs from potential need for further testing, counseling, or follow-up, and the unavailability of funds to pay for it or needing to take time off work for follow-up leading to wage loss	• A treatable disorder might be discovered leading to cure, slowing of disease progression, or pain relief • Preventive measures may be available to decrease chances for some disorders • Reproductive techniques (e.g. PGD) may allow carriers of disease to have children with minimal risks • Pharmacogenetic status identification can increase likelihood of medication efficacy and reduce adverse reactions • Learning of propensity for developing particular conditions can enhance life planning • Knowledge of carrier status for a disease mutation can relieve anxiety for some people • Possible positive psychological responses (e.g. relief from depression or improved quality of life) • Social benefits of preventing stigmatizing condition that could interfere with insurance, employment, or relationship status

non-maleficence involves preventing or minimizing harm or injury (Beauchamp & Childress, 2019). The application of these principles is accomplished through a risk-benefit assessment, such as the one outlined in Table 4.1. Risks should be minimized and reasonable in relation to anticipated benefits for IF identification, disclosure, and management. There are varying understandings of what constitutes a "risk" or "benefit" in care. IFs are commonly viewed as indirect benefits and it is argued that the potential benefits patients may derive from IFs should not be weighed in the risk-benefit analysis, however this is argued in the context of research studies (Parker, 2008). Similarly, if IFs are not a direct benefit because they are not within the primary purpose of the test, they should not be a consideration in the risk-benefit assessment when ordering diagnostic tests. In other words, when an EP orders an imaging test, they should not consider the possibility of discovering IFs as a benefit to motivate ordering the diagnostic test. There should also be an additional risk-benefit assessment for returning (i.e. disclosing) IFs to patients. A distinction should be made between the risks and benefits involved with the care procedures, like diagnostic testing, and the risks and benefits involved with disclosure and subsequent follow-up of IFs that materialize from those care procedures. In EDs, EPs show

beneficence by acting for the benefit of their patients by responding to acute illnesses and injuries to prevent and minimize pain and suffering, loss of function, and death (ACEP, 2017). Through our document review, we note that while there is little explicit mention of these principles, documents do discuss the duties and standard of care of healthcare professionals; they also discuss acting on and reviewing significant findings in a timely fashion, respecting patient well-being, providing care unless dangerous, and providing care when emergent. The *Universal Declaration on Bioethics and Human Rights* (2006) specifies that direct and indirect benefits for patients should be maximized and harms minimized, and other sources discuss non-maleficence by minimizing harms to patients. It is difficult for EPs to balance beneficence and non-maleficence with the challenges of time constraints, determining capacity to consent, and the limited physician-patient relationship. Not only should risks and potential benefits be anticipated for patients, but also for how to fairly manage IFs, which can be explored through the principle of justice.

Justice

Due to the nature and moral challenges of the ED environment, EPs must exhibit a commitment to the principle of justice. Justice involves the fair distribution and allocation of goods and services (Beauchamp & Childress, 2019) and "helps emergency physicians shepherd resources, make appropriate triage decisions, and employ therapeutic parsimony, refusing marginally beneficial care to some while guaranteeing a basic level of care for all others" (*The Code of Ethics for Emergency Physicians*, 2017, p. e9). In considering some of the distinguishing features of EDs, there are characteristics or traits that are important to being a virtuous EP, including being *fair* and *just*. To reduce the constraints of time in EDs and to manage emergencies, triaging is used to allocate scarce resources. The pattern of triage in ED settings involves first treating the sickest and then patients are treated on a first-come, first-served basis (Iserson & Moskop, 2007). Concerning IFs, triaging strategies could follow in ED settings to triage different patients with urgent, moderate, or nonurgent IFs to maintain the principle of justice and fair allocation of services provided by emergency care providers. Could a case be made that emergency care providers have a responsibility to act in some way (e.g. assess, contact patient, transfer care) when IFs are discovered to be urgent? What about IFs that are moderate? Nonurgent? An argument has been made that nonurgent IFs should not be reported in order to focus on important aspects of patient care (Pandharipande et al., 2016). It is reasonable and

justifiable for EPs to transfer responsibility of managing IFs to other healthcare professionals once the primary purpose for which a patient entered the ED is managed.

Emergency care providers must provide a basic level of care to all patients, and in doing so, they may need to refer patients with less than urgent care, including those with IFs, to other healthcare professionals in order to attend to the multitude of patients in the ED, which can be accomplished without significant adverse outcomes (Derlet et al., 1995). Emergency care providers must treat patients with the same regard and should not offer extra care to one patient over another or provide care that is not urgent or immediate when other patients are in need of emergency care. Thus, it would be prudent for EPs to refer and transfer responsibility of care for IFs to other physicians and specialties to uphold just practices and maintain the goals of the ED, which is to provide healthcare for emergent situations. While acting justly means treating patients regardless of race, creed, gender, or other properties, it also requires EPs "to act as responsible stewards of the health care resources entrusted to them" (*The Code of Ethics for Emergency Physicians*, 2017, p. e10). EPs must allocate resources, including diagnostic technologies, in a way that maximizes benefits and minimizes harms for patients. In this context, management of IFs in the ED can lead to decreased resources for the health needs of other patients with urgent health needs, and can increase costs for the healthcare system involved with confirming the IF, obtaining appropriate interpretation of the finding, returning the finding responsibly, as well as providing referral and follow-up. Such factors are important to consider for ethical practice but are not likely to be prioritized over beneficence towards individual patients.

If we consider the duty of an emergency care provider, it is to provide care and embrace patient welfare. If emergency care providers take on the responsibilities involved with managing IFs, care quality may deteriorate. Therefore, if the motive of EPs to forego responsibilities of IFs is driven by the mere duty to do what is right, referring or transferring care of nonurgent IFs is justified and upholds the principle of justice. However, if it is exclusively for maximizing utility, improving population health, or decreasing the cost of healthcare caused by subsequent testing of IFs, the moral merit of these actions may not be justified. However, it can be argued that treating only emergent and urgent medical situations in the ED does treat all people with respect and as ends in themselves because it is right and just to first treat those who need care most imminently. The principle of justice is imperative in the practice of emergency medicine and helps to release EPs from duties that would transfer their priorities to less than urgent patient care, but also

maintains that patient welfare is a priority and EPs should ensure that patients receive proper care when risks to their welfare are discovered.

Comparing Emergency Medicine to Primary Care

Unlike emergency medicine, one of the main principles of primary care involves the central role of the physician-patient relationship, which allows physicians to earn the trust of their patients and gain knowledge about each patient's specific values and preferences. Thus, it is the primary care provider who is able to determine a patient's capacity to understand information about their diagnosis or condition with fewer constraints on time and lower levels of medical urgency. These physicians can help a patient determine the best next steps for managing their care and receiving follow-up for an IF. As previously discussed in the literature review, several sources believe primary care providers should be primarily responsible for IF management, which is logical when considering the fundamental role of the physician-patient relationship in primary care. It was found that the longer the relationship between the physician and patient, the better the primary care provider was at understanding how much information patients wanted or needed and the more likely patients value the physician's input on clinical decision-making (Zafar et al., 2016).

One question that could be asked to advance guidance in emergency care settings is: to what extent can duties and obligations of primary care providers be applied to emergency care providers? This is a complex question because it requires us to define and distinguish between the obligations and duties of both primary care providers and emergency care providers. In some cases, especially in rural areas, EPs also practice as primary care providers and thus, they have dual responsibilities, which can further complicate identifying their duties and obligations. One way to navigate this is for these clinicians to abide by the principles of whichever setting they are practicing at the time of the IF discovery. For example, if an EP—who is also a primary care provider—is working in the ED when an IF is discovered, the EP must prioritize emergency medicine principles and care for patients in need of urgent care, but can manage non-urgent IFs when they are not wearing their EP hat. However, the implications of this navigation of dual responsibilities should be further elucidated.

In one study discussing the factors that influence primary care providers on follow-up of IFs, it was found that many primary care providers were not comfortable following up with IFs that were unfamiliar to them or IFs discovered outside their scope of practice (Zafar et al., 2016). Similar to EPs, primary care providers should seek consultation when they are unsure of the

clinical significance of an IF or the appropriate follow-up care procedures. Research has also shown that primary care providers are more likely to trust recommendations and reports by radiologists they knew personally (Zafar et al., 2016) and that primary care providers lack the resources and information to counsel patients on IFs (Golden et al., 2015), which could indicate that there is a gap in guidance for this care context. This helps to justify a need for more collaboration between primary care physicians, specialists, and EPs to improve IF management and reduce factors that complicate IF management.

Key ideas found in our previous literature review suggests that a referral system be developed to help manage IFs. If a patient has a finding that is not in the interest of the ED's care goals, they should be referred to another medical specialty for proper treatment (Lanitis et al., 2012). One-quarter of the literature suggested increasing communication and collaboration with other healthcare providers. Increased communication can lead to a closed-loop system to allow patients to receive the appropriate follow-up care following an IF. Communication protocols should exist between EDs and primary care settings to ensure that patients appearing in EDs have an identified primary care provider for follow-up care, or a mechanism in place to recommend a primary care provider for patients without one. More multidisciplinary involvement should occur between emergency medicine and primary care to appropriately manage IFs and to delegate responsibilities in a way that embraces patient welfare, which echoes recommendations learned from our literature review. Unlike emergency medicine, primary care promotes physician-patient relationships as being central to the primary care setting because of the heightened continuity of care provided to patients and building of trusting care relationships. Thus, while many guidelines are broadly applicable to all healthcare professionals, it is difficult to translate guidance on IF management from emergency medicine to primary care because there is a different set of expectations in the physician-patient relationship. It is important to discuss because primary care providers are often implicated in the circle of care when IFs are discovered and play a critical role in their ethical management.

Comparing Emergency Medicine to Research Settings

While this discussion is in the clinical context with patients being the target population, IFs are also commonly found during testing in research subjects. In research studies involving imaging, up to 84% of investigators have reported the existence of IFs (Illes et al., 2004). There is significance to discussing IFs in both contexts to underline the critical similarities and

differences in each domain. For example, in research settings, little is known about the research subjects, including medical history, and there is oftentimes less of a relationship between an investigator and subject compared to a physician and patient, especially in primary care. Thus, it is more difficult to understand the preferences of a research subject concerning the disclosure and management of IFs as well as their personal values, which is similar to ED settings where relationships between physicians and patients are limited and understanding of preferences is also minimal because of the short-term interactions. In research settings, the information about subjects may be anonymous or deidentified, creating a larger barrier of contact and communication between the investigator and subject. Also, in ED settings, there are fewer informed consent discussions involving IFs with patients compared to research subjects because it is not codified in policies and guidelines. However, in research settings, IFs that are anticipated must be disclosed to subjects in a stringent informed consent process (CIHR, 2018). The TCPS 2 (2018) also recommends for all research that an IF management plan be developed, and is a requirement for genetics research. Emergency care settings can adopt these recommendations for healthcare teams to develop a management plan not unlike research settings.

Discussing and distinguishing between both contexts is relevant because this thesis focuses on emergency care settings, which has elements of both care and research in the context of IFs. As we have discussed, emergency medicine often involves a limited relationship between the EP and the patient, which is similar to research settings. EPs have short-term contact with patients similarly to investigators with research subjects, unlike primary care providers and other healthcare professionals in other care settings. However, emergency settings are dissimilar to research settings in that IFs are not explicitly discussed with patients in consent forms, prior to interventions or ordering of tests. Guidance in research contexts was considered because several guidance documents and policies exist in the research context and by examining the applicability and ethical justifications of this guidance, we can contribute to new knowledge in clinical care practice and reinforce important distinctions between research and clinical settings.

There is some guidance in the realm of research ethics to help investigators ethically manage IFs as well as whether there is a duty to disclose. However, it is important to consider whether such guidance and responsibilities can be applied to emergency medicine. Thus, in order to manage IFs in care settings, we should consider the application of guidance from research settings. We should also consider whether we ought to have similar ethical obligations towards patients as we do towards research subjects for IF management. While the mission of the researcher is to generate knowledge and the mission of the physician is to promote the well-

being of patients, the obligations of both researcher and physician can overlap. Despite the close relationship between research and care and the similar trajectory of a patient and subject both beginning at a baseline state, receiving an intervention, and resulting in an outcome, research and care have diverted as two separate activities (Sacristán, 2015), making it difficult to apply rules from one context to the other. In short, we contend that the lines between research and care should not be blurred and effective and appropriate guidance for IFs should remain context-specific. However, there are several general recommendations applied to researchers that can also apply to EPs, but there should be more distinct guidelines for each domain.

The Bioethics Commission (2013) discusses overarching recommendations for ethical management as well as recommendations for clinical and research settings. By comparing the recommendations in clinical and research contexts, it can help to determine how transferable these recommendations are. Based on these, we argue that the guidance on IFs in research contexts cannot be directly applicable to clinical contexts. One reason being is that guidelines in research settings focus primarily on the informed consent process. While some clinical contexts may involve a more comprehensive informed consent process, informed consent processes are not extensive in EDs, which we can attribute to our description of the three moral challenges in the ED. The Bioethics Commission (2013) suggests that researchers convey the scope of IFs, including whether they will be disclosed, how they will be disclosed, and how subjects can opt out of receiving IF information during the informed consent process. It also recommends that researchers develop action plans to be reviewed by institutional review boards, including a process for evaluating and managing unanticipated findings (Bioethics Commission, 2013). These recommendations cannot be directly applied to emergency care settings, most notably since the jurisdiction of institutional review boards does not extend beyond oversight of research involving humans, informed consent standards differ between research and care settings, and informed consent practices in EDs are even more limited than in other care settings. The Bioethics Commission (2013) recommends that all contexts improve informed consent processes, which would be revolutionary in ED settings. Emergency medicine professional bodies, medical advisory bodies, or institutional policy mechanisms may be enabled to review and approve ED IF management plans.

Faden and Beauchamp (1986) critically discuss informed consent as a theory in legal and medical contexts. The Nuremberg Code (1947) emphasizes the importance of informed consent within their principles. To respect autonomy, one must respect informed consent and in order to have informed consent, there needs to be adequate information, comprehension, and

voluntariness (Belmont Report, 1979). Informed consent serves the purpose of ensuring voluntary participation in clinical or research activities. The difference between clinical care and research concerning informed consent is that clinical care should always directly benefit the patient, so patients accept potential risks involved in care (Cahana & Hurst, 2008). However, in research, subjects accept the risks ideally for the benefit of future patients and they do not typically confer direct benefits and so, risks cannot be imposed on them and thus informed consent is even more critical in research (Cahana & Hurst, 2008). Therefore, recommendations involving informed consent to ethically manage IFs would and should be treated differently for emergency care settings compared to research settings and are not directly transferable. Although it would be ideal for clinical care settings to adopt more stringent informed consent processes, the level of risk compared to potential benefit involved in both domains make the matter of informed consent context-specific.

Slovic (2005) claims that risk is socially constructed, based on lived experiences, and contingent on "psychological, social, cultural, and political factors" (p. 689). Risk is measured based on magnitude or severity of harm (CIHR, 2018). Harm is defined as anything that has a negative effect on welfare, and "the nature of the harm may be social, behavioural, psychological, physical or economic" (CIHR, 2018, p. 21). Slovic (2005) reports that the public relies on subjective perceptions of risk, while experts characterize risk based on objective assessments. The differences in attitudes towards and perceptions of risks, as well as benefits, indicates that patients, similarly to research subjects, should have a degree of input in the amount of risk compared to benefit, they are willing to incur, with regard to IF disclosure and management. Neither physicians nor researchers can infer an individual's perception of risks or benefits because they are not aware of all the factors that influence the individual. Therefore, the onus should be on physicians in the context of care to identify and disclose the risks in relation to the potential benefits that may result from IFs, just as they would for regular care procedures. Valid informed consent is fundamental to ethical conduct in research and federal regulations in the United States require that investigators provide subjects information about benefits and "any reasonably foreseeable risks or discomforts" (45 CFR 46.116(b)(2)). Disclosing risks and potential benefits helps promote autonomy through informed consent. In this dilemma, the risks and potential benefits of IF disclosure must be explained prospectively to patients before expressing preference on disclosure or agreeing to care interventions.

To further discuss the application of research-related guidance on IFs to clinical care, we can discuss the TCPS 2, which governs research conduct in Canada. The TCPS 2 (2018)

recognizes the obligation to disclose IFs, unless it is impracticable or impossible for the researcher to do so. While impracticability has been defined in the context of research, it has not been defined for clinical care contexts, including emergency settings. In EDs, there is a large patient population being served, patients may die in the ED or after care is provided, and there are patient populations, like homeless individuals, who are difficult to track. However, the exceptions to disclosure and management of IFs have not been similarly applied in EDs. The TCPS 2 considers IFs as "material" if they are validated, have clinical significance, and are actionable (Panel on Research Ethics, 2019). In emergency care settings, these three criteria are not sufficient. Compared to other settings, the ED prioritizes caring for patients with urgent medical needs. Thus, in addition to the three criteria of materiality, the ED should require that the IF has imminent health implications on the patient where which if not addressed, will lead to irreparable harm or injury for the patient. If the IF is not considered "emergent", then its management can be delegated or delayed. Thus, materiality in the ED is more stringent because it is a low-resource setting and because the main purpose of the ED is to provide care for medical emergencies. Thus, the guidance for research settings, while applicable in a general sense, is not sufficient to accommodate for all the complexities and moral challenges of the ED.

While beyond the scope of this discussion, it is essential to define the differences between care and research to further understand the applicability of research guidance to emergency care guidance for IF management. While care promotes the well-being of patients, the purpose of research is for producing generalizable knowledge (Sacristán, 2015). It is equally important to determine the differences between the main actors in both settings—patients and research subjects. In their report on IFs in imaging research, The Royal College of Radiologists (2011) recommend that IFs be viewed as a medical issue because it involves a transition from research subject to patient when an IF is discovered. Some may believe that if IFs are a medical issue, policies and guidelines surrounding their management should be equivalent for both care and research settings. However, based on our discussion, we determined that the different contexts require different guidelines. Although it is possible for research subjects to become patients, IF guidance should not be universally applicable to both subjects and patients, but obligations and guidance should be assessed when a research subject becomes a patient. This sentiment is worth exploring to know how to appropriately translate research-context guidance on IFs to EDs and other care settings.

Emergency Medicine Ethical Decision-Making Frameworks

After determining the unique nature of EDs and how IF management in both primary care and research contexts are not sufficient to guide emergency care providers through the ethical turmoil involved in IFs, it is imperative that we identify frameworks to guide decision-making specific to emergency care settings. In addition, these models and frameworks are important considering that there is often no time to consult ethics committees because of the chaos and overcrowding in the ED as well as the scarcity of resources and healthcare professionals. While there are several decision-making models focused on resource allocation, the most common in emergency care involves the idea of triage. Triage methods are used when there is a scarcity of resources that need to be allocated and where a healthcare provider assesses each patient's medical needs to assign a treatment priority (Iserson & Moskop, 2007). ED triage systems are designed to first treat most urgent cases, followed by less urgent cases on a first-come, first-served basis (Iserson & Moskop, 2007). Those who are less ill or injured must wait longer than those who need imminent medical assistance and some triage systems are designed to identify patients with minor concerns and refer them for treatment outside the ED (Iserson & Moskop, 2007). Triage systems can be adopted to manage IFs in the ED by establishing a classification system of IFs and accurately identifying each IF as clinically urgent, significant, or insignificant. While only two included sources recognized the importance of classification of findings (Andrawes et al., 2017; Spruce et al., 2020), it is reasonable to adapt triage practices and strategies to manage IFs justly. Thus, triage systems that are already used in ED settings can be applied to ethical dilemmas involving IFs to respect the principle of justice.

Iserson (2015) developed a modified version of his 1995 approach to ethical problems in emergency medicine, the *Rapid Approach to Emergency Ethical Problems* (p. 14).[2] The first question asks: "Is this a type of ethical problem for which you have already worked out a rule or is it at least similar enough so that the rule could reasonably be extended to cover it?" (Iserson, 2015, p. 14). If yes, one ought to follow the rule. If not, Iserson (2015) asks: "Is there an option which will buy you time for deliberation without excessive risk to the patient?" (p. 14) If yes, he advises to take that option. If the answer is no, it requires the actor to apply the following three tests: the Impartiality Test, the Universalizability Test, and the Interpersonal Justifiability Test (Iserson, 2015). These tests are akin to asking the questions, "What would you want if you were the patient?", "Would your decision work in every other instance?", and "Could you justify your

[2] The *Rapid Approach to Emergency Ethical Problems* model (Iserson, 2015) is widely cited in the literature, but it is difficult to determine how much it is endorsed or used in practice.

actions to others?", respectively (Edwards & Robey, 2010, p. 456). In taking this approach to managing IFs, it recognizes that emergency care providers have to make rapid decisions. It would be difficult to find a rule for emergency care providers to refer to for each specific incidental discovery, but if they have experienced a similar case previously of a similar IF, they may have already worked out a rule to make a decision. If not, it would be ideal if there was enough time for deliberation to manage the IF, which is sometimes possible unless it requires immediate medical attention. However, it would still be important for the emergency care provider to work through the three tests Iserson (2015) proposes. Similar to triage, this model accommodates for the first moral challenge of EDs—time constraints—and recognizes that care should be prioritized when urgent, which reiterates the fourth condition of urgency for determining materiality of IFs. If time constraints are not a concern after discovering an IF, there can be a more engaged method for decision-making that involves the patient on a higher level.

The method and procedure of managing IFs does not rest on the healthcare professional alone, but also on the patient through shared decision-making. Probst et al. (2017) developed a decision-making framework for ED settings that should be used when there is clinical equipoise, which refers to scenarios of uncertainty where there are two or more clinically reasonable options, when the patient has decision-making capability, and when time is not limited. The questions to ask in this model are: "Is there more than one reasonable option?", "Is the patient willing and able to participate in decision?", and "Is there enough time to engage patient in discussion?" (Probst et al., 2017, p. 689). While shared decision-making is ideal, it is difficult in the context of IFs when the ethical dilemma involves asking whether to disclose this information to the patient. Thus, the EP has to engage in some physician-directed decision-making to determine first whether the finding is material, then whether to disclose, and then they can involve the patient. Patients should then be consulted on their values, preferences, and expectations of care, including whether they would want to learn about the findings, which can assist EPs in decision-making. This model also discusses the factor of time, which is critical in emergency medicine. The answers to these questions may be subjective and contingent on the EP, including whether time is limited, and thus, the EP decides whether to engage the patient about their IF. If the EP decides to disclose the information to the patient after determining clinical significance, they can engage the patient in shared decision-making about follow-up care, treatment options, and referrals, which respects the principles of respect for autonomy, veracity, and beneficence. With the shared decision-making model, it can be difficult to accommodate the moral challenges of the ED, but it is a step towards rectifying the limits of the

physician-patient relationship and helps the EP better determine a patient's capacity to consent. This model is focused on the physician managing the IFs, however we have observed that there are suggestions for delegating IF management to other healthcare providers.

R.O.L.E. is a model for emergency nurses that can also be applied to EPs and other healthcare professionals. This model may be especially helpful if management of IFs is delegated to mid-level providers. The acronym represents: Risks of medical treatment, Opinion of patient, Life quality, and External factors (Kokiko & Watts, 1995). For risks of medical treatment, decision-makers should consider the patient's clinical condition, in this context, the patient's IF and treatment of the IF should balance risks and benefits (Kokiko & Watts, 1995). The principles motivating this first part of the model are beneficence and non-maleficence. Respect for autonomy follows this consideration by understanding the wishes and opinions of the patient about his or her IF, which can be accomplished by ensuring informed consent for the patient to make care decisions (Kokiko & Watts, 1995). Third is the life quality, where the decision-maker weighs future function of the patient based on care decisions, which is difficult to determine in the context of IFs and is often subjective. Finally, external factors are considered, including family wishes, scarcity of resources, cost of care, religion, and research (Kokiko & Watts, 1995). While triage focused on priority-setting when resources are limited and the shared decision-making model focused on patient autonomy, this model attempts to consolidate all factors in order for the decision-maker to identify all facets of the clinical case. This model is helpful for mid-level providers or individuals specifically tasked with IF management if they are not limited by time. If mid-level providers are given this specific responsibility of managing IFs, they may have less time constraints than regular healthcare professionals who have to carry out other duties and responsibilities. However, this model may not always be feasible for use by many healthcare professionals caring for patients because IFs are often nonurgent, and this model requires more time and attention than high-volume EDs can manage. This model would work well if management of IFs was delegated to mid-level providers, or if a specific IF coordinator role was developed, as recommended by some literature sources in our previous review.

Emergency care workers have to provide care under difficult circumstances, where time and resources are scarce, and must face decision-making in times of crises, such as pandemics. These situations make decision-making difficult, which is why decision-making is important to consider in preparedness planning, and is helpful to apply to and explore for every day emergency medicine, such as when managing IFs. While IFs are not considered a pandemic or outbreak, it would be helpful to explore the ethical principles and values that the pandemic

influenza preparedness framework (Thompson et al., 2006) is modelled after to inform decision-making. The following ethical values are critical to this framework: duty to provide care, equity, individual liberty, privacy, proportionality, protection of the public from harm, reciprocity, solidarity, stewardship, and trust (Thompson et al., 2006). Some of these values can be applicable to managing IFs in ED settings, including the duty to provide care, equity, individual liberty, solidarity, stewardship, and trust, which we have previously addressed. The duty to provide care is inherent to healthcare professionals and requires meeting the demands of healthcare needs with the competing obligations of their own health (Thompson et al., 2006). Equity, congruent to fairness, holds that if all things are equal, all patients have an equal claim to medical attention (Thompson et al., 2006), which is important when discussing IFs because not all patients have equal health needs. Individual liberty is pertinent to IF management because it respects the principle of autonomy and understanding patient wishes is critical to ethical management. Solidarity is also an ethical value that should be considered when making decisions about IF management because solidarity involves good, open, and honest communication, as well as collaboration within and between healthcare workers and institutions to coordinate healthcare delivery and patient transfers and referrals (Thompson et al., 2006). Promoting solidarity will help to improve collaboration between healthcare workers to manage patient care when an IF is discovered. Stewardship requires ethical governance of healthcare resources, including diagnostic testing in the context of IFs, and resources should be protected to avoid unnecessarily ordering tests to explore the nature of an IF. Finally, trust is critical to ethically managing IFs because patients must be able to trust their physicians, who must be able to trust radiologists and other healthcare professionals, to help make management decisions about IFs.

While several decision-making models have been developed for use in clinical care, only some models are appropriate for emergency care settings because of its distinct characteristics that we discussed. It should be noted that it is not feasible to expect healthcare providers in emergency settings to consider all of these models and each facet of each model, which is why it is important to develop plans and protocols to follow in advance. The appropriate features from these models can be consolidated to inform a model and protocol that would be best suited for managing IFs in ED settings. In the next section, we will return to the case studies outlined in the first chapter and discuss them using these decision-making models and ED-related ethical principles.

Clinical Vignette Discussion

In the first chapter, a series of vignettes were introduced that highlight the complexities of IFs and variance in outcomes following IF discovery. We will briefly discuss these cases here (Table 4.2) to show how they apply to the principles of EDs, and how decision-making models can be used to ethically manage the cases.

Grace received a diagnosis of acute gastroenteritis, which eventually led to an IF in a subsequent ED visit of a "fibroid-appearing" uterus and questionable ovarian mass, diagnosed as a leiomyoma, hydrosalpinx, and dermoid cyst. While the case does not reveal what care she received in the ED, she did receive follow-up care for her IFs and her operations were successful. It is unclear whether there should have been further testing and care in her initial visit, which could have avoided her future operations, but we will assume that it would have made no difference. In the first visit, the care provider gave a diagnosis, which we would hope is accurate, but it should be considered whether more tests should have been done. In her next visit, she had two ultrasounds conducted and it led to positive outcomes because she received care for all IFs discovered in the ED. In this case, the first visit could have included an additional follow-up

Table 4.2. Case studies of incidental findings adapted from the literature.

Case 1 ("Grace")	A 37-year-old woman, Grace, presented with abdominal pain, vomiting, and diarrhea, and received a diagnosis of acute gastroenteritis. One month later she returned with worsening abdominal pain, now localized to the right upper and lower quadrants. An ultrasound was performed because of suspected gallbladder disease. The gallbladder was normal, but a "fibroid-appearing" uterus and questionable ovarian mass were noted. These findings prompted the performance of a subsequent ultrasound, which demonstrated a leiomyoma, hydrosalpinx, and dermoid cyst. Grace had one ovary and both fallopian tubes removed, a left cystectomy, and a total abdominal hysterectomy. Postoperatively, she did well (Kendall & Mandavia, 2001).
Case 2 ("Jack")	A 2-year-old child, Jack, in King County, Washington, hit his head in a fall and underwent a head CT scan initially read as normal. However, repeat interpretation of the scan revealed a tumour that was not reported to the family. Fourteen months later, the child was diagnosed with an ependymoma, a tumour, from which he eventually died. The family sued the hospital and radiologist, and settled the case for $5 million (Onwubiko & Mooney, 2018).
Case 3 ("Tina")	Tina, a healthy 33-year-old woman, presented to the ED complaining of intense abdominal pain, nausea, and a bloating sensation. The physician examines her and detects that her pain is predominantly in the right lower quadrant of her abdomen. Although the provider suspects food poisoning based on the patient's last meal consisting of seafood, the physical examination findings are concerning for acute appendicitis. The provider informs Tina that she will need to undergo an abdominal CT to ensure there is no appendicitis. Tina agrees to the examination, but the provider did

	not mention any risks associated with examination or the potential for IFs. The CT study revealed no appendicitis, but the radiologist notes a one-centimetre "small circumscribed lesion of unknown significance" in her right adrenal gland. The ED provider tells Tina that she has no appendicitis and is safe to go home, but should follow up with her primary care provider for work-up of her IF in the adrenal gland. Tina is relieved about the appendicitis, but is visibly anxious about the IF, which she assumes is malignant. She wishes to ask a provider for more information, but the ED provider has already moved on to another patient. Tina was discharged from the ED (Kole & Fiester, 2013).
Case 4 ("Tom")	A 60-year-old man, Tom, with no vascular risk factors or history of smoking entered the ED reporting numbness and weakness on one side of his body. Tom received a CT angiogram to test for a suspected transient ischemic attack. While analyzing the images, the emergency radiologists noticed a one-centimetre nodule in the left upper lobe of his lung. The patient experienced anxiety and concern for the nodule and a biopsy of the nodule was conducted. During the biopsy, Tom suffered a pneumothorax as well as hypoxia, which led to cardiac arrest. The patient was left with permanent anoxic brain injury. The pathology report later showed that the one-centimetre nodule was benign inflammation (Bioethics Commission, 2013).

with the EP referring the patient to a primary care provider or for subsequent care of her acute gastroenteritis, which is part of the duty to provide care. The emergency care providers could have adopted the Iserson (2015) rapid decision-making model to determine if previous cases of acute gastroenteritis needed follow-up or validation of an accurate diagnosis.

Jack, the two-year-old who fell and hit his head, had a tumour that was not reported to the family. If the CT had been performed in the ED, the EP should have confirmed that the family was aware of the information found incidentally. Using the shared decision-making model with the parents (Probst et al., 2017) as well as the R.O.L.E. model (Kokiko & Watts, 1995)—which is useful for mid-level providers—emergency care providers could have determined that discussing a child's condition and findings with the family upheld the duty of care as well as the reasonable person standard for disclosure. In this case, it seems that the tumour was revealed after repeat interpretation, which could mean that it was after the family and patient left the ED. In this scenario, if mid-level providers were responsible for managing IFs in the ED, they could have developed a way to contact the family and patient to inform them of this significant finding, which could have minimized the harm that ensued. There is literature that recommends delegating responsibility to mid-level providers or developing a specific role to manage IFs, indicating that this can be done in this case (Biegler N. et al., 2012; Daoud et al., 2017; Huynh et al., 2008; Paluska et al., 2007; Sperry et al., 2010).

In Tina's case, a physical examination was done that led to a suspicion that Tina has acute appendicitis. The EP conducted an abdominal CT to confirm the suspicion, but again, the

limited time in the ED did not allow for the provider to discuss the risks associated with the CT or with the IFs. In this case, the EP did not discuss details about further care, but recommended for the patient to seek primary care for follow-up of an incidental lesion in her adrenal gland. In the ED, the EP must assess the patient's capacity, in order to gauge whether the patient will seek follow-up care as recommended. To clarify, it is not the EP's responsibility to make sure the patient seeks follow-up, but that they comprehend the recommendation to seek follow-up. While difficult without developing and building trust between the patient and physician, this could have been accomplished using the Probst et al. (2017) shared decision-making model to engage the patient in a discussion about care decisions. Using this model would also help to ensure the patient has comprehension of care. In the ED, the EP may transfer responsibility of the patient to a different healthcare provider while they attend to another patient, and a mid-level provider can confirm that their primary care provider—if they have one—is aware of the lesion, which requires solidarity and collaboration between other healthcare professionals. Alternatively, the mid-level provider can use R.O.L.E. as a model to make certain that patients have enough information and comprehension about the IF and the recommendation to seek further care, which is especially important in this case where Tina wanted to ask more questions, but the care provider had already moved onto another patient. Classification of findings would also have been useful here because if it was found that the lesion was benign, it could have been more accurately explained to Tina to avoid the needless anxiety that she experienced. If the lesion had unknown significance, it would have been prudent for the care provider to transfer her care to someone who can validate the lesion and discuss its significance further.

Finally, in Tom's case, it is unclear what was causing the original symptoms of numbness and weakness on one side of Tom's body because the case study focused on the incidental lung nodule instead of the original purpose for which the CT angiogram was sought. Focusing on the IF instead of the original purpose of care can be a concern for following up on IFs since the original purpose for a test may be more urgent than the IF, but can be overlooked if an IF is discovered. It is likely that there was insufficient time in the ED to explain to Tom the risks and benefits of receiving a biopsy. There was also time constraints for emergency care providers to determine the materiality of the lung nodule. If the risks and benefits of following up the nodule with a biopsy had been adequately explained, it is possible that the harm he experienced could have been avoided, although not a guarantee. In this case, better triage practices could have been implemented to classify the significance of the findings and the Probst et al. (2017) shared decision-making model could have been adopted to discuss decisions with the patient. If the EPs

had transferred Tom's care to another care provider, they may have been able to diagnose the nodule as benign by taking the time available in other settings to assess its materiality. Alternatively, if EPs delegated the task of managing the lung nodule finding to a mid-level provider or IF coordinator, the R.O.L.E. model could have been used (Kokiko & Watts, 1995). Using that model, the patient could have been more appropriately informed of the potential risks and benefits of the subsequent testing, and there could have been more adequate follow-up. Although it does not guarantee that the patient would not have chosen to seek further diagnostic tests including the biopsy, there could have been increased assurance that the patient understood the risks involved and that the duty to provide care was upheld. The ethical values of solidarity and trust should have been at the forefront of decision-making in this case. In the ED, the EPs must determine if Tom had the capacity and competency to consent to further testing through the shared decision-making model (Probst et al., 2017). The initial CT angiogram was within the role of the EP to determine the original purpose for which Tom entered the ED, but through the values of solidarity and trust, as well as justice, the subsequent testing of the nodule could have been delegated to another care provider to ensure that other patients in the ED receive necessary care. Overall, when considering the outcomes of these cases, it is helpful to refer back to the principles of emergency medicine that make IF management particularly challenging and adopt and adapt the methods and models relevant to emergency medicine. When searching for solutions to manage IFs ethically, it is also important to consider how to avoid the challenges caused by time constraints, determining capacity to consent, and the limited physician-patient relationships in the ED.

Future Directions

As evidenced by our literature review, policy and guidance review, and ethical discussion, there are several avenues that need to be explored to improve the landscape of ethical management of IFs. There are many directions that research and practice initiatives can go that would complement these findings, including conducting qualitative research. Future research should elucidate the preferences and expectations of ED patients with regards to disclosure of IFs as well as management of care following these discoveries. Qualitative research can ask patients who previously received incidental results about their experiences in the ED, who disclosed the information, how it was disclosed, how care was managed inside and outside the ED, and what their preferences would be in similar occurrences in the future. While difficult, it would improve the understanding of the topic to follow patients who had IFs that were not disclosed to them.

This research can be done by choosing a population where the finding was not initially disclosed to them, but disclosed at a subsequent visit, and retrospectively measure their health outcomes and patient experiences. This research can also be done by reviewing cases of College complaints that patients have made against physicians concerning IFs. Alternatively, interesting research might include prospectively or retrospectively measuring the outcomes and comparing patients who were and were not notified of an IF in the ED setting, or who did and did not follow up on IFs, and exploring their care trajectories to assess health outcomes. Research such as this should be conducted in different settings for comparative purposes, for example in both the United States and Canada, where the differences in healthcare systems may lead to different research findings.

In addition to focusing on patients as the target of qualitative research, other qualitative research could focus on other stakeholders' preferences and opinions, including EPs, emergency radiologists, mid-level providers, and policymakers, among others. One way this could be accomplished is using a Delphi approach with questionnaires to assess policy and guidance opinions of these stakeholders. The literature explored in this critical interpretive literature review did not yield results discussing the preferences and concerns of these stakeholders and thus, the themes and ethical dilemmas surrounding IFs cannot be known unless future research is conducted to understand the roles and expectations of these key players.

The literature surrounding IFs in ED settings has focused almost exclusively on findings stemming from diagnostic and imaging tests. However, there are other ways in which IFs can be learned and other kinds of IFs that require further exploration and discussion. For example, there may be IFs that are incidental to physicians, but not to patients, such as cases involving abuse or suicidality. These IFs can be learned without purposefully looking for them, through simple discussions with or basic physical examinations of patients in the ED, which are ethically challenging to manage without protocols or guidelines. While rare, IFs from laboratory testing or genetic testing are possibilities in the ED that require further academic discussion. From here, it would be appropriate to explore extending the application of the definition of IFs to potentially including psychosocial findings and also findings that patients are already aware of, which requires its own realm of ethical discussion.

In the research domain, it would be of interest to consult different informed consent documents to learn how researchers define and explain IFs to study subjects in order to consolidate a uniform definition for research contexts. It would also be of interest to measure if and how study subjects understand IFs because improving their understanding of IFs and the

risks and benefits may be translatable to other populations, including ED patients. Further discussion on distinguishing between research and care is also critical to ethically decide whether research-context guidance on IFs can be appropriately and safely applied to care settings.

For future practice, it would be worthwhile for emergency healthcare professionals to seek feedback, validation, and consensus from experts and form working groups to develop ethical guidance. Deciding on criteria for when IF disclosure is not morally obligatory or permissible in the ED would be helpful for healthcare professionals to navigate uncertainty. Instruction on if and when these healthcare professionals can override patient preferences on identification and disclosure of IFs is also imperative. While ethical management of IFs can be more readily determined for competent adult patients, moral attention on pediatric patients and incompetent adults is still required. Exploring the rates of follow-up for regular care in these populations can help to inform what is to be expected for follow-up of IFs in ED settings as well as other care contexts. Understanding the demographics of patients who visit the ED as well as the interactions between healthcare workers and these populations would add to the transcultural considerations on this subject. It would also be important to explore whether the potential for knowledge imbalances in vulnerable patient populations can affect whether and how IFs are managed for these individuals in the ED and how to improve the quality of their care. Another question that should be explored to improve systemic healthcare concerns is asking whether IFs are common because patients do not have primary care providers (Ray, 2018). Understanding why IFs are being discovered in EDs can help to understand how to avoid such occurrences to improve patient flow in EDs and to promote the importance of primary care.

At the policy level, explorations of the economic aspects of IFs are only at a preliminary stage. What are the costs involved with following up with IFs? What are the costs to the healthcare system when an IF is discovered in the ED versus a primary care clinic? How does the cost compare between learning of and following up with a benign or insignificant IF versus following a wait-and-see procedure and treating the IF only when it becomes more serious in the future? There are several cost-related questions that would be of interest to explore in order to understand where the line should be drawn between upholding the duty of care and overdiagnosis. Ethicists should deliberate about the extent to which costs should be a factor in deciding on disclosure or follow-up care and treatment decisions. The burden of extra costs for IFs has been a growing concern, especially with the increase in medical imaging utilization and when diagnoses are indeterminate (Berland et al., 2010). The problem of costs is also a public health concern because of increases in wait times and ED length of stay, which shows a scarcity

of time and resources because of the high volumes in EDs, rendering the issue of cost containment to be a high priority (Canadian Institute for Health Information, 2018). Future work should explore whether the potential for increased improvements in diagnostic testing will affect and lead to increases in IF frequency and whether that will help to solve or exacerbate the problem of IF management, which would then make IF management more ethically important with each passing milestone in the evolution of diagnostic testing. The promises of diagnosis that lead to lifesaving treatment and the pitfalls of anxiety, overdiagnosis, and the dangers of testing are what make IFs an ethical conundrum, and discussions should centre around whether the lack of ethical management of IFs are a human or system failure.

Conclusion

To understand the importance of determining ethical management of IFs, consider the COVID-19 outbreak, which is causing global concern, infecting thousands and killing hundreds within only weeks of its first case. The growing panic surrounding how to navigate the complexities of this health crisis is not dissimilar to previous epidemics, like SARS or Ebola. It is events such as these that show why being able to ethically manage IFs, especially in EDs, is critical. If we can identify how to navigate and manage the problem of IFs as well as have policies and protocols to justify management decisions, it will make this problem easier to manage in EDs. Therefore, healthcare professionals and policymakers can prioritize medical and ethical attention required by other serious scenarios, like natural disasters and epidemics.

As we have explored, the issue of IFs is common in EDs, which has proven to be a significant setting to explore because of its distinct characteristics and moral challenges. Although the nature of IFs are that they are normally unanticipated and thus not always easy to predict the risks and benefits, we have demonstrated that an attempt should be made by emergency care providers and other relevant stakeholders to identify the challenges of IFs in order to determine whether, when, and how they should be identified, disclosed, and managed. The principles of respect for autonomy, veracity, beneficence, non-maleficence, and justice should be considered when managing these discoveries.

In this thesis, we established and clarified the definition of IFs and through the literature review and subsequent discussion, we explored what the literature presents on the topic of IFs, which was more focused on frequency of findings than ethical considerations. Relevant codes of ethics, policies and guidelines from health professions and other professional bodies, research-context guidelines, and legislation, were identified and examined to understand current practices

and expectations surrounding IF management as they apply to themes of autonomy and informed consent, beneficence and non-maleficence, justice, veracity and disclosure, standard of care, continuity of care, and guidance development. These reviews allowed us to identify the ethical challenges that require research and policy reform to inform future directions in this field. These results advance the field because it has provided a critical perspective on the importance and value of understanding IFs in this setting and because IFs are commonly found without there being standards of practice in the ED. For individuals working in ED settings as well as policymakers, this research has laid out avenues for improvement of IF management by considering the values and principles distinctive of EDs. This review has implications for the development of ethical guidance in ED settings to manage IFs in a way that promotes patient welfare while also maintaining justice in the healthcare system.

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Appendices

Table 2.1A. Details on critical interpretive literature review search strategy.

Search strategy	Date searched	Number of records	Detailed search strategy
The Journal of Emergency Medicine; Academic Emergency Medicine; Emergency Medicine Journal; Trauma; Annals of Emergency Medicine; Journal of Emergencies, Trauma, and Shock; The American Journal of Emergency Medicine (Journal Handsearching)	25 September 2019	N/A	
ProQuest Dissertations and Theses Global	7 October 2019	845	"incidental finding" OR "incidental findings" AND emergency
PubMed (Database searching)	7 October 2019	2189	("incidental findings"[mesh] OR (incidental*[tw] AND finding*[tw]) OR incidentaloma*[tw] OR unsolicited finding*[tw] OR unsolicited result*[tw] OR unsolicited discover*[tw] OR unsolicited outcome*[tw] OR unsolicited diagnos*[tw] OR unsought for finding*[tw] OR unsought for result*[tw] OR unsought for discover*[tw] OR unsought for outcome*[tw] OR unsought for diagnos*[tw] OR off-target finding*[tw] OR off-target result*[tw] OR off-target discover*[tw] OR off-target outcome*[tw] OR off-target diagnos*[tw] OR incidental* finding*[tw] OR incidental* result*[tw] OR incidental* discover*[tw] OR incidental* outcome*[tw] OR incidental* diagnos*[tw] OR unanticipated finding*[tw] OR unanticipated result*[tw] OR unanticipated discover*[tw] OR unanticipated outcome*[tw] OR unanticipated diagnos*[tw] OR unintended finding*[tw] OR unintended result*[tw] OR unintended discover*[tw] OR unintended outcome*[tw] OR unintended diagnos*[tw] OR ancillary finding*[tw] OR ancillary result*[tw] OR ancillary discover*[tw] OR ancillary outcome*[tw] OR ancillary diagnos*[tw] OR unexpected finding*[tw] OR unexpected result*[tw] OR unexpected discover*[tw] OR unexpected outcome*[tw] OR unexpected diagnos*[tw] OR unrelated finding*[tw] OR unrelated result*[tw] OR unrelated discover*[tw] OR unrelated outcome*[tw] OR unrelated diagnos*[tw]) AND ("Emergency Service, Hospital"[Mesh] OR emergency[tw] OR er[tw] OR ed[tw] OR triage[tw] OR trauma[tw])

Scopus (Database searching)	7 October 2019	2399	TITLE-ABS-KEY (incidental* W/3 finding*) OR incidentaloma* OR TITLE-ABS-KEY (unsolicited OR “unsought for” OR off-target OR incidental* OR unanticipated OR unintended OR ancillary OR unexpected OR unrelated PRE/0 finding* OR result* OR discover* OR outcome* OR diagnos*) AND TITLE-ABS-KEY (emergency OR {er} OR {ed} OR triage OR trauma)
Web of Science (Database searching)	7 October 2019	1176	(TS= (incidental* NEAR/3 finding*) OR TS= incidentaloma* OR TS= (“unsolicited finding*” OR “unsolicited result*” OR “unsolicited discover*” OR “unsolicited outcome*” OR “unsolicited diagnos*” OR “unsought for finding*” OR “unsought for result*” OR “unsought for discover*” OR “unsought for outcome*” OR “unsought for diagnos*” OR “off-target finding*” OR “off-target result*” OR “off-target discover*” OR “off-target outcome*” OR “off-target diagnos*” OR “incidental* result*” OR “incidental* discover*” OR “incidental* outcome*” OR “incidental* diagnos*” OR “unanticipated finding*” OR “unanticipated result*” OR “unanticipated discover*” OR “unanticipated outcome*” OR “unanticipated diagnos*” OR “unintended finding*” OR “unintended result*” OR “unintended discover*” OR “unintended outcome*” OR “unintended diagnos*” OR “ancillary finding*” OR “ancillary result*” OR “ancillary discover*” OR “ancillary outcome*” OR “ancillary diagnos*” OR “unexpected finding*” OR “unexpected result*” OR “unexpected discover*” OR “unexpected outcome*” OR “unexpected diagnos*” OR “unrelated finding*” OR “unrelated result*” OR “unrelated discover*” OR “unrelated outcome*” OR “unrelated diagnos*”)) AND TS= (emergency OR “er” OR “ed” OR triage OR trauma)
PubMed Central	11 October 2019	7827	incidental finding*[all fields] OR incidentaloma*[all fields] OR incidental discover*[all fields] OR incidental*[ti] AND (emergency[tw] OR er[tw] OR ed[tw] OR triage[tw] OR trauma[tw])
Injury; Emergency Medicine International; The British Journal of Radiology; Emergency Radiology; BMC Medical Ethics; Journal of Medical Ethics; American Journal of Bioethics; Bioethics; Journal of Law, Medicine and Ethics (Journal Handsearching)	29 October 2019		

Table 3.1A. Detailed references to sub-themes for each source document for codes of ethics (grey) and guidance from health professions and other professional bodies (white).

Themes	American College of Emergency Physicians – Code of Ethics (2017)	American College of Radiology – Code of Ethics (2019)	American Medical Association – Code of Medical Ethics (2001)	American Nurses Association – The Code of Ethics for Nurses with Interpretive Statements (2015)	Canadian Medical Association – Code of Ethics and Professionalism (2017)	Canadian Nurses Association – Code of Ethics (2017)	Ordre des infirmières et infirmiers du Québec – Code of Ethics of Nurses (2002)	The Quebec Code of Ethics of Physicians (2019)	American College of Emergency Physicians: Policy Statement – Interpretation of Diagnostic Imaging Tests (2018)	Canadian Association for Emergency Physicians: Position Statement – Recommendations for the Use of Point-of-Care Ultrasound (PoCUS) by Emergency Phvsicians in Canada (Lewis et al.. 2019)	Canadian Association of Radiologists – CAR Standard for Communication of Diagnostic Imaging Findings (Butler et al., 2010)	The Canadian Medical Protective Association: Duties and responsibilities - Improving patient handovers (2016)	The Canadian Medical Protective Association: Safety of Care – Avoiding pitfalls in the emergency department: Recognizing and managing risks of diagnostic error (2018)	The Canadian Medical Protective Association: Safety of Care Effectively managing hospital test results — Key to timely diagnosis and patient safety (2012)	Choosing Wisely Canada – " Unnecessary Care in Canada" (2017)	Collège des Médecins du Québec: " Safety Framework for the Follow-up of Diagnostic and Screening Test Results" (2012)	College of Physicians and Surgeons of Ontario: Policy Statement – Disclosure of Harm (2003)	College of Physicians and Surgeons of Ontario: Policy Statement – Test Results Management (2011)	Bioethics Commission for the Study of Bioethical Issues: Anticipate and Communicate (2013)
Autonomy and informed consent																			
Autonomy and self-determination	1			1		1	1							1					
Comprehension of care			1		1	1	1	1											
Explain risks and benefits			1	1	1			1											
Informed consent	1			1	1	1	1	1											
Informed consent if time allows*																			
Informed consent not required in emergencies	1		1																
Provide accurate treatment options	1		1	1	1														
Respect competent decision to accept or reject treatment					1														
Respect preferences for not receiving health information			1			1													X

Beneficence and non-maleficence																	
Act on and review significant findings in timely fashion			1									1					
Beneficence*																	
Duty*																	
Non-maleficence					1									X			
Patient well-being and welfare	1			1	1	1											
Provide care unless dangerous							1										
Provide care when emergent			1				1	1									
Continuity of care																	
Communicate with other healthcare professionals			1						1	X		1	1				
Continuity of care			1		1										1		
Follow-up with patients			X					1							1	1	
Obtain consultation to identify materiality*																	
Obtain consultation when appropriate		1	1					1									
Refer for transfer of care			1								1						
Guidance development																	
Anticipate possibility of IFs																	X
Communication plan			1						X								X
Guidance development and evidence-based practices					1								1				X
Management plan									X						1		X
Prepare educational materials																	X
Justice																	
Allocation of time to patients			1														
Justice																	X
Resource allocation						1								X			
Steward of resources	1																

Standard of care																				
Document and report IFs							1		X		X									
Ensure accurate diagnosis						1														
Ensure care is useful and accurate		1		1		1								1						
Order appropriate and necessary tests				1										1						X
Veracity and disclosure																				
Communicate truthfully	1			1																
Disclose				1		1												1		
Disclose important findings		X					1													
Disclose in timely fashion		1					1							1						
Disclose to patients and healthcare professionals							1		X											
Disclose unless there is harm				1																
Disclose verbally							1													
Encourage preference specification for disclosure		1																		
Exceptions to disclosure						1														
Non-disclosure is unacceptable*																				
Promote trust and fidelity					1															
Tailor to patient needs for disclosure		1																		

X: reference explicitly discusses sub-theme in the context of IFs

*There is no reference that discusses this sub-theme in this table, but the row is kept to maintain consistency. If not discussed in this table, the sub-theme is included in one of the references in Table 3.2A.

Table 3.2A. Detailed references to sub-themes for each source document for research-context guidance (grey) and legislation (white).

Themes	European Medicines Agency – Guideline for good clinical practice E6(R2) (2015)	Food & Drug Administration: Guidance For Industry Investigator Responsibilities – Protecting The Rights, Safety, And Welfare Of Study Subjects (2009)	Medical Research Council - Framework on the feedback of health-related findings in research (2014)	"Practical approaches to incidental findings in brain imaging research" (Iles et al., 2008)	The Royal College of Radiologists – Management of Incidental Findings Detected During Research Imaging (2011)	Tri-Council Policy Statement – Ethical Conduct for Research Involving Humans (CIHR, 2018)	Act Respecting Health Services and Social Services (Quebec – 2019)	The Charter of Human Rights and Freedoms (Quebec –2019)	The Civil Code of Quebec (2019)	The Criminal Code of Canada (2019)	Health Care Consent Act (Ontario – 2018)	Universal Declaration on Bioethics and Human Rights (2006)
Autonomy and informed consent												
Autonomy and self-determination*												
Comprehension of care							1					
Explain risks and benefits									1			
Informed consent				X		X			1		1	1
Informed consent if time allows									1			
Informed consent not required in emergencies									1		1	
Provide accurate treatment options									1			
Respect competent decision to accept or reject treatment*												
Respect preferences for not receiving health information*												
Beneficence and non-maleficence												
Act on and review significant findings in timely fashion*												
Beneficence												1
Duty									1	1		
Non-maleficence									1	1		1
Patient well-being and welfare*												

Provide care unless dangerous						1	1	
Provide care when emergent						1		
Continuity of care								
Communicate with other healthcare professionals*								
Continuity of care*								
Follow-up with patients*								
Obtain consultation to identify materiality				X	X			
Obtain consultation when appropriate			X					
Refer for transfer of care	X							
Guidance development								
Anticipate possibility of IFs		X	X	X				
Communication plan		X	X					
Guidance development and evidence-based practices		X						
Management plan		X	X		X			
Prepare educational materials*								
Justice								
Allocation of time to patients*								
Justice*								
Resource allocation*								
Steward of resources*								
Standard of care								
Document and report IFs			X					
Ensure accurate diagnosis			X					
Ensure care is useful and accurate*								
Order appropriate and necessary tests*								

Veracity and disclosure					
Communicate truthfully*					
Disclose	X	X		1	
Disclose important findings			X		
Disclose in timely fashion		X			
Disclose to patients and healthcare professionals*					
Disclose unless there is harm*					
Disclose verbally		X			
Encourage preference specification for disclosure*					
Exceptions to disclosure				X	
Non-disclosure is unacceptable			X		
Promote trust and fidelity				1	
Tailor to patient needs for disclosure*					

X: reference explicitly discusses sub-theme in the context of IFs

*There is no reference that discusses this sub-theme in this table, but the row is kept to maintain consistency. If not discussed in this table, the sub-theme is included in one of the references in Table 3.1A.