The Informed Consent Process in Percutaneous Coronary Intervention: A review

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COLLEGE OF NURSING AND MIDWIFERY Candidate Declaration

Declaration

This is to certify that:

i. The dissertation comprises only my original work;

ii. Due acknowledgment has been made in the text to all other materials used;

iii. No portion of the work referred to in the dissertation has been submitted in support of an application for another degree or qualification of this or any other university or other institutes of learning.

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List of abbreviation/Acronyms

AHA	American Heart Association
BHF	British Heart Foundation.
CVD	Cardiovascular Disease
CASP	Critical Assessment Skill Program
ECG	Electrocardiogram
MESH	Medical Subject Headings
PCI	Percutaneous Coronary Intervention
PEO	Population, Experience, Outcome
PPCI	Primary Percutaneous Coronary Intervention
STEMI	ST Segment Elevation Myocardial Infarction
WHO	World Health Organization

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Abstract

Informed consent is an essential process in observing the ethical issues in a medical facility. However, there is scanty of information on how the process is carried out. Percutaneous Coronary Intervention (PCI)is a widely known revascularization process. The process requires informed consent between the patients and the doctors to be executed. Therefore, the study conducted a systematic review of the available sources in the selected database to determine the patient's and cardiologist's views of the informed consent process in PCI. The findings from the reviews of the 14 papers, most patients did not understand the ethical and legal principles behind the informed consent process in over 50% of the papers. Besides, the patients overestimated the benefits forget the risks associated, and lack information on the available alternative methods. In most scenarios, the patients are unaware of the procedure and the cardiologists fail to involve the patients in the process. The results demonstrated the lack of partnership between the cardiologists and the patients in the decision-making process. Therefore, there is a need for partnership between the patients and the doctors in the informed consent process.

Chapter One

1.0 Introduction

This chapter introduces the research topic broadly and narrows it down to the study's specific objectives. The section entails the definition of percutaneous Coronary Intervention treatment methods, and the informed consent process in percutaneous Coronary Intervention, The sections exhaustively cover the perceptions of informed consent in PCI.

1.1 Background

1.1.1 Prevalence

Cardiovascular disease is an inclusive term for all the conditions affecting the heart and the blood vessels. The main cause of the condition is the increased fatty deposits in the arteries and the possibility of blood clots. This results in the dysfunction of the arteries in some organs like the heart, brain kidneys, and the eyes. The increased fatty deposit in the arteries results in blockage of the arteries resulting in coronary artery disease. Coronary arteries supply blood to the heart muscles to enable the pumping of blood to the rest of the body. When there is a buildup of the fatty deposits in the arteries it causes the narrowing of the blood vessels inhibiting the smooth flow of blood to the heart. If the heart can't get enough blood, it implies that there will be limited oxygen disrupting the proper functioning of the heart subjecting an individual to heart attacks risks, chest pains and discomfort.

According to American Heart Association (AHA) (2020), 1 in 5 heart attacks is silent and the individual will not be aware of it. In addition, every year, about 605,000 American Patients suffer from a first heart attack (American heart Association, 2020). According to the British heart foundation (BHF) (2018), Heart attack causes over 200,000 hospital visits in the United Kingdom each year. Despite the fact that survival rates have improved since

financing for new medicines began, 180 people die in the UK every day from heart attacks. The longer it takes for people who have had a heart attack to see a physician and receive stenting treatment. The lower the chance of survival (European heart journal, 2018).

Heart attacks (Myocardial infarction) is the irreversible death of the muscles of the heart due to prolonged lack of oxygen supply to the heart. An increased number of the heart attacks have been reported in the US every year. Myocardial infarction has been classified into five categories depending on the main underlying condition. The first category is spontaneous Myocardial infarction which is caused by ulceration, fissuring erosion in the arteries reducing blood flow. However, the patient may not have coronary artery disease. The second category is Myocardial infarction secondary to an ischemic imbalance. This occurs due to high demand for oxygen or a decrease in the supply of oxygen.

The third category is Myocardial infarction which results in death due to the unavailability of biomarker values. This is described by the sudden or unexpected cardiac death prior to sampling of the biomarkers. The fourth a) category is the heart attack relating to PCI; this is caused by the increased biomarker values to more than five tiles the 99th percentile of the Uniform Resource Locator for the normal baseline value patients. The fourth (b) category is the heart attack related to stent thrombosis which is the setting of myocardial ischemia in conjunction with an increase or a decrease of the biomarkers. The fifth category is the heart attack (Myocardial infarction) related to coronary artery bypass grafting. This type is caused by the elevation of the cardiac biomarker values which are more than ten times the 99th percentile Uniform Resource Locator in patients with normal baseline values. Definition of Cardiovascular Disease, Coronary Artery Disease, Myocardial infarction, and types.

The World Health Organization (WHO) (2021) defined cardiovascular disease (CVD) as the commonly used term for a group of disorders that can affect the heart and blood supply. Coronary artery disease can be defined as a part of cardiovascular disease in which the buildup of plaque in the arteries that supply oxygenated blood to the heart. Plaque causes narrowing or complete blockage, leading to several conditions such as heart attack (Mayo clinic, 2021). According to National Health Service (2019), a heart attack, known as myocardial infarction (MI), is a medical emergency. The blood supply to the heart is suddenly blocked, usually by a blood clot. During a heart attack, a plaque may rupture and release cholesterol and other substances into the artery a blood clot forms at the site of the rupture. If the clot is large, it can block blood flow through the coronary artery and deprive the heart of oxygen and nutrients (ischemia). As a result, there may be a complete or partial blockage of the coronary artery a complete blockage can indicate an ST-elevation myocardial infarction (STEMI). The health national service (2013-2014) defined ST-elevation Myocardial infarction as the artery supplying the heart muscle is completely blocked by a combination of atheroma and blood clot. A partial blockage can indicate a myocardial infarction without ST elevation (NSTEMI) (ESC 2018).

1.1.2 Typical symptoms of Myocardial infarction.

A typical patient with ST-elevation Myocardial Infarction may present with persistent chest pain or persistent chest discomfort radiating to the neck, lower jaw, or left arm. In some cases, the patient may present shortness of breath, nausea/vomiting, fatigue, palpitations, or syncope (ESC, 2018). Plaque rupture with platelet aggregation and rapid thrombus development occur in acute myocardial infarction, resulting in an abrupt blockage of the coronary artery. These patients complain of severe chest heaviness, diaphoresis, and

nausea. Urgent PTCA is frequently necessary to prevent further cardiac damage (Malik and Tivakaran, 2021).

1.1.3 Treatment of Acute Myocardial infarction

Acute Myocardial infarction can be treated by primary percutaneous coronary intervention (PPCI) or fibrinolysis. Primary angioplasty (PPCI) is the use of the PCI technique to relieve the blockage as the main or first treatment for patients suffering a heart attack. According to the European Society of Cardiology Guidelines, (2018) there are two pathways for the management of Myocardial infarction starting with initiating an Electrocardiogram (ECG) if was a suspension of Myocardial infarction. The first Pathway if the patient was transferred to a PCI hospital, initial ECG and Bloods need to be done and activation of Cath lab in less than 90 mins. As per the ESC guidelines (2018) from diagnosis to wire, time should be less than 60 min (ESC, 2018). However, if the patient was in non-PCI hospitals if the diagnosis conformed maximum of 10 mins the fibrinolysis needs to be administered and to transfer the patient within 60-90 min to a Cath lab facility, and the PCI needs to be done within 120 min (European Society of Cardiology, 2018). In fibrinolysis, or what is known as thrombolytic therapy, the provider will use a lytic agent. It will work to dissolve blood clots that have acutely (suddenly) blocked significant arteries or veins and can have potentially serious or life-threatening consequences (Avgerinos, 2021).

1.2 PCI Evolution

It was developed in the early 1990s. The major complication was bleeding, re-occlusion, and Intracranial hemorrhage (Van de Warf et al., 2009). The other treatment for acute Myocardial Infarction, or what is known as ST-elevation Myocardial Infarction, is percutaneous coronary intervention (PCI). It was developed by Andreas Gruentzig, the

father of modern interventional cardiology, performed the first in 1977 (Smilowitz & Feit, 2016). Shortly after discovering PTCA, the American cardiologist Geoffrey Hartzler introduced primary angioplasty as a treatment for acute MI (Smilowitz & Feit, 2016). Angioplasty was associated with a trend toward a reduced hospital mortality rate, a reduction in reinfection or in-hospital mortality, and less intracranial bleeding (Smilowitz & Feit, 2016).

Percutaneous transluminal coronary angioplasty (PTCA), commonly known as percutaneous coronary intervention (PCI), is an invasive technique that allows free blood flow to the myocardium by opening blocked or stenosis coronary arteries. The obstructions are caused by lipid-rich plaque in the arteries, which reduces blood flow to the heart. Atherosclerosis is the buildup of lipid-rich plaque in the arteries. The patient may be presented with chest pain and dyspnea with exertion (Malik and Tivakaran, 2021). Moreover, the mortality rate of STEMI varies from study to study.

In Peterson *et al* (2010) study, 1.27 percent of PCI patients died in the hospital, ranging from 0.65 percent in elective PCI to 4.81 percent in STEMI patients. Due to the age, gender, and history, for example, older patients, females, and diabetic patients are at high mortality risk. While Dominguez *et al* (2021) study, the Patient In-hospital mortality rate after PCI for an elective patient is 0.2%, while for ST-elevation, Myocardial infarction (STEMI) is 6.6%. The American Heart Association (2020), Females had longer door-to-balloon delays and lower rates of medical care based on guidelines than males. Females with ST-segment–elevation myocardial infarction have a greater in-hospital death rate than males (7.4 percent versus 4.6 percent) (Ferreira & Mochly-Rosen, 2012). Thus, it can be concluded that STEMI patients have a higher risk of developing complications than elective PCI patients.

Percutaneous coronary intervention is a popular medical procedure globally. It is a procedure that is used electively or urgently, depending on the state of the patients (Spertus et al., 2015). It is an effective procedure if successfully carried out. It improves myocardial perfusion without coronary artery bypass surgery, which takes time for recovery. It entails the integration of coronary angioplasty with stenting. Its primary function is to unblock the coronary artery and enable blood flow without conducting heart surgery. It is the best option to allow blood flow and prevent chest pains, heart attacks, and deaths.

The effectiveness of the procedure depends on various aspects that the patients determine. For instance, if the patient has coronary stenosis above 50% or has chest pains symptoms that are not responding to medical therapy (EFC, 2014). Besides, it is effective in patients with acute coronary syndromes because it is continually evolving. The combination of PCI and anti-angina medication may reduce the number of patients with chest pains and heart attacks for three years through therapy. However, it does not reduce deaths and the essentiality of other interventions.

Despite the effectiveness of the PCI procedure, it is important for patients to give informed consent prior to the procedure. Informed consent entails proper medical practice and the patient's rights and is a reflection of the ethical principles (Rothberg et al., 2015). The process requires collaboration and coordination between the patient and the doctor in decision-making. For it to be ethically valid, the patients should willingly be informed and have the capacity to make decisions. Part of the information required for informed consent includes the risks, benefits, other optional methods, and the consequences if they tend to avoid the procedure.

However, as much as the patients' needs to be fully aware of the risk and benefits their specific information should be adhered to and properly documented. Despite that most PCI patients tend to concentrate on the benefits overseeing the risks and other treatment options leading to uninformed decision making. Informed consent can seemingly be a single occurrence or a continuous process. The continuous process is considered optimal. The idea of informed consent is different in various medical facilities and the quantity of information provided to the patient is unpredictable. Besides, it's not a simple task as it involves collaboration with various health care professionals. Moreover, its quality is a result of various aspects such as minimal time, the unwillingness of patients, and the level of expertise of the doctors involved.

1.3 History of informed consent

During 1950, the concept of Informed consent was not established. The primary focus of medical ethics was to protect the patients from harm and benefit them. The challenge during that period, they disclosed information without harming patients by revealing their condition too abruptly and bluntly (Informed consent, 2021). Withholding information and even outright deception were regularly justified as morally appropriate means of avoiding such harm. Emphasis on the principle of "first, not harm" even promoted the idea that a health professional is obligated not to disclose information because to do so would risk a harmful outcome.

In 1978, the first guideline of Informed consent was established, and it focuses on the importance of informing the patient about the benefit and risks of the condition (Informed consent, 2021). Paterick *et al* (2008) stated that Medical informed consent is critical to a physician's capacity to diagnose and treat patients. The patient has the right to accept or refuse clinical examination, treatment, or both. Physicians must provide patients with equity

in the covenant by teaching them to make informed decisions. When physicians and patients take informed medical consent seriously, the patient-physician relationship transforms into a real partnership with shared decision-making authority and outcomes accountability (Paterick *et al*, 2008).

1.4 Informed consent

The informed consent process is essential in medical practices; however, there are controversies about ethical purposes. It has been imposed in clinical practice through nonmedical authorities, and it's the primary legal and ethical as opposed to evidence based. Astin *et al*, (2020), the informed consent procedure is based on the notion of patient autonomy, which indicates that individuals have the freedom to choose what happens to them. Before any invasive medical or surgical operation, consent is essential, and for it to be valid, the patient must have the capacity to decide, be well informed, and act willingly.

According to American Medical Association (2021), Informed consent to medical treatment is required by law and ethics. Patients have the right to obtain information about proposed treatments and to ask questions so that they may make well-informed decisions regarding their care. In the patient-physician relationship, effective communication develops trust and facilitates collaborative decision-making. In other words, Informed consent is a process of informing patients about their condition, ensuring that the patient understands the purpose, benefits, and potential risks of medical or surgical treatment, and obtaining the patient's consent to the treatment or procedure (Davis, 2021). In addition, informed consent generally requires the patient or responsible party to sign a statement acknowledging that he/she understands the risks and benefits of the procedure or treatment (Davis, 2021)

Informed consent entails the communication between the patient and the healthcare providers on the agreements on the treatment methods, the risks and the benefits, and the possible alternatives. The patient is entitled to information before deciding on the treatment and the procedures to be undertaken (Dathatri et al., 2014). The informed consent process ensures that the doctor gives the patient access to information concerning the underlying condition and the available treatment options before giving the patient a chance to make a decision. The information given include the state or the underlying patient condition, the risks and the benefits, the recommended treatment option provided by the doctor, and other options available.

The next stage is signing the form to ascertain that all the information provided is accurate and that the patient can make a decision (Glaser *et al.,* 2020). If the patient agrees to proceed with the treatment method, a signature is required to give consent and allow the doctor to proceed with the procedure. This protects the patient from any complications that may arise, and therefore the patient should be keen to go through all the details before signing. The process is a complex one since it is an interaction between the patient and the doctor with different perspectives, attitudes, preferences, and expectations.

Most international research indicates variability on the information given to patients awaiting the PCI procedure. In most cases, there is an overestimation of the benefits, the risks are omitted, and no consideration of the possible alternatives. It is essential to understand the PCI informed consent process before carrying out the procedure.

1.5 Informed concept implications

Informed consent is divided in to three types: Implied consent occurs when a patient passively participates in a procedure without dialogue or formal agreement. In these situations, the principles of effective communication apply, and health practitioners must

present the patient with adequate information to comprehend the operation and why it is being performed. It is not necessary to document implied consent in the clinical record (Kakar *et al,* 2014). Secondly, a verbal consent occurs when a patient orally declares their assent to a procedure but does not sign any written document. This is sufficient for regular therapy, such as diagnostic procedures and prevention, as long as complete records are kept (Kakar *et al,* 2014).

Lastly, Written consent is required for any major intervention, including risks such as anesthesia or sedation, restorative procedures, any invasive or surgical procedures, the administration of drugs with known high stakes, and so on (Kakar *et al,* 2014). Thus, Informed Consent can be obtained for several cases such as in emergency situations, invasive procures, for example, angiogram or surgeries, informed decision-making for healthcare tests, and refusal of treatment.

1.6 Informed consent in emergency

In emergency cases the physicians may commence treatment without previous informed permission in circumstances where a choice must be made quickly, the patient is unable to engage in decision making, and the patient's surrogate is unavailable. In such scenarios, the doctors should notify the patient as soon as possible and gain agreement to continue therapy (American Medical Association, 2021).

From the above information, it can be concluded that applying informed consent in emergency cases is impossible. Some of the challenges when obtaining informed consent are the time, language barriers, and patient's conditions. Selinger (2009) states that all medical investigations and operations require informed consent, which is considered a cornerstone of contemporary medicine. In addition, a medical intervention without adequate informed consent is a criminal offense, and the practitioner may face battery

charges. Treatment against the patient's will, therapy that differs from the one consented for, and treatment after intentionally providing incorrect information are examples of such scenarios (Selinger 2009).

1.7 Informed consent in PCI

According to the American College of Cardiology Foundation (2014), obtaining informed consent prior to emergency treatments is challenging. When a patient presents with STEMI, the patient can be presented with chest pain, swatting, and abdominal pain (common in females), making genuine informed consent impossible. In addition, rapid triage, transfer, and treatment of STEMI patients create a tense environment that, by necessity, restricts a lengthy and comprehensive informed consent procedure.

Nonetheless, the interventionist must attempt to enlighten the patient and family about the risks and advantages of various techniques and balance the benefits of extensive conversation with the benefits of quick intervention. Olsson *et al*, (2021) stated that it is reasonable to ask for verbal consent for STEMI Patients. Thus, consent for primary PCI variates from region to region some countries verbal consent will be sufficient for primary PCI. In other countries, the verbal consent will not be enough, and written informed consent will be indicated.

1.9 When to make a decision

To recap the definition of PCI is an invasive intervention to return the blood flow by opening the blood vessels (University of California San Francisco, 2022). The performing surgeon needs to educate the patient on the benefit, risks, complications, and pain of any invasive intervention. In addition, the Doctors duty is to gain the patient's agreement to the intervention and verify patient understanding (Brezis et al.,2008). Thus, The Doctors need to make sure the patient is competent, eligible to consent, and free from any forces, such

as pain, unhealthy environment (noise, family pressure), and if the patient is ready to receive the information.

In an emergency such as a heart attack taking informed consent can be challenging due to time limits and other factors such as pain and disease conditions. According to AHA (2011), guidelines address the challenge of applying informed consent for STEMI patients in which the patient will be presented with distress and sedated in some patients. Performing valid informed consent for this patient will be impossible. In addition, Rapid triage, transport, and treatment of STEMI patients create a tense environment that, by necessity, limits a lengthy and comprehensive informed consent procedure. In our review, Probyn *et al.* (2017) stated that for acute cases such as MI, the interventional cardiology would take a short time for discussion as consenting takes place immediately before the intervention.

1.10 Communication in the consent process

According to Stanton (2003), Communication consists of the sender, receiver, and the appropriate environment. In other words, it is the process of receiving messages, orders, and information from the sender in the proper environment that helps in understanding the statements and information provided. Similarly, Alsheikh and Iqbal (2020) defined Communication as a two-way process involving voice, writing, or nonverbal methods to create a common interpretation for those engaged. On the other hand, Pick *et al.* (2014) defined communication as creating a shared understanding between the sender and the receiver. It is not only receiving messages. A safe and high-quality healthcare system relies on effective communication between health professionals and patients. Communication can be divided into verbal and non-verbal communication, speaking, and written communication. (Willkomm, 2018). In oral communication, when the person speaks with others either face to face, or by smartphones and recently with intelligent applications.

Non-verbal communication is when the person uses body language such as eye contact, facial expressions, and body movement (Willkomm, 2018). Thus, using non-verbal communication when the Doctor will discuss the patient's condition and the patient eyes will be full of questions and trying to find the answer—finally, written communication such as written informed consent and documentation process—for example, referral letters Medial reports. (Willkomm, 2018). Thus, effective communication is a core element when communicating with Patients, Families, and other healthcare providers as a healthcare provider.

1.11 Conclusion

In summary, we know that the acute and elective PCI informed consent process is complex and variable and could be improved. To identify how we can optimize the informed consent for PCI, the reviewer needs to understand the experiences of patients and doctors, in the context in which the interactions take place. Given this knowledge gap, the aim of this dissertation is to explore the experience of informed consent in PCI for Patients undergoing PCI and the cardiologist experience.

Chapter two

Methodology

2.0 Introduction

The chapter entails the exploration of data collection procedures and the importance of the reviews. The part covered under the chapter includes the literature review definition, the data collections procedures for the review, which include the inclusion and the exclusion criteria, and the databases used to get the data.

2.1 Aims of the review

A literature review entails the analysis of the currently available literature on the research topic. The literature involves academic papers, journals, books, and articles concerning the subject. It is a critical evaluation of the study topic by covering the existing research, conceptions, and evidence and the critical evaluation and discussion of the content. It sets the theoretical background of the study and helps the researcher to put the study in its context. Citation of the previous studies implies that the researcher has incorporated the other works into the study.

Getting the right sources of information on the topic, synthesizing, and documenting it helps the healthcare providers, decision-makers, and other consumers help in the management of healthcare information (Forbes, 2003). Therefore, systematic reviews are helpful in guiding the doctors and medical personnel in their practice and help in informed decision-making in policy formulation. The review helps in identifying what has been done and what has not been done and identification of gaps in the study area (Lobiondo-Wood and Haber, 2018).

The review process begins by stating the state of science on the topic and synthesizing the merits and demerits of the available studies on the research topic. Another review process is the illustration of the conceptual framework that guides the study to determine if the study needs to be replicated or redefined and the generation of questions and hypotheses. After the completion of the review, the research should come up with a new study design that will fill the gaps, make conclusions, and provide recommendations that will impact policy implementation.

According to Kumar (2021), the initial stage of the literature review is the formulation of the question. The PEO acronym is applied to guide the review, which stands for the population, Experience, and outcome of interest. The study's aim is to explore the experience of patients and cardiologists on informed consent in Percutaneous Coronary Intervention. The methodology will entail the identification of the keywords that will aid comprehensive research that will exhaust all the available sources and evidence on the topic.

2.2 Inclusion/ exclusion criteria

This stage involves selecting the required studies that will be included in the review. This sets the context of the research review. The process ensures that the study materials are selected through the required methods and logic. The inclusion and exclusion criteria have been illustrated in the following table 1

Table 1 Inclusion and Exclusion criteria

Criteria	**Inclusion criteria**	**Exclusion criteria**
Population	Patients that have elective or emergency PCI Cardiologists	Below 18 years

Experience	Informed consent in percutaneous Coronary intervention	Informed consent for participation in research trials
Outcome	Experience Views opinions	
Research time frame	2010-2022	Previous studies before 2010
Type of study	Both qualitative and quantitative studies will be used Peer-reviewed articles	Commentary case studies

Population

The population will entail cardiac patients that have elective or emergency PCI and the cardiologists. The patients and the cardiologists should be 18 years and above.

Experience

This criterion analyses the patient's and the cardiologist's perception of the informed consent process in PCI.

Outcome

This part assesses the perceptions of the patients who went through PCI or who were about to go through the PCI medical procedure. Moreover, it will assess the cardiologist's perceptions of the informed consent process in PCI. The outcome will also entail the clinical procedure of the informed consent process and PCI.

2.3 Type of studies

The study will explore both qualitative and quantitative studies that fall under the inclusion and exclusion criteria. Qualitative research provides extensive information of the topic under research. Qualitative research provides an in-depth understanding of the social aspects in their natural environment. Qualitative study in this context will highlight the experiences of patients and cardiologists. The commentary and case reports will be excluded in this research.

According to Pieper and Puljak (2020) the restriction caused by language in review results to language bias which is referred to as systematic bias. This is whereby the study papers are selected based on specific language. However, this will not be a limitation for qualitative study. The study will use English language to discuss the findings and provide recommendations.

2.4 Search strategy

It is essential to widen the search process to maximize on the retrieval of extensive content. The initial step in the process is identifying the key words of the research topic. The search strategy should also contain phrases and truncated words and subheadings where applicable. Moreover, Booleans operators such as" and "or" can be used together with the search topic. Depending on the topic search time may be minimized by the use of search filters such as those that are developed and authenticated by the scientists in the Health Information Research Unit (HiRU) of McMaster University under a deal from the National

Library of Medicine (Rethlefsen *et al.*, 2021). The filters can also be found in PubMed's Clinical Queries and Health services Research Queries.

The database has search limits that allow one to narrow results to get the articles that are more synonymous with the research questions. The limits include the article's publication type, publication dates, Language, subject, and sex among others.

2.5 Electronic database search

The key electronic databases explored for the study were PubMed, Medline, Cochrane Library, and CINAHL complete. The four databases were essential for this research because of limited information on the research topic. Besides, the use of more databases increases the quantity and quality of information leading to conclusive findings. PubMed is a free resource that facilitates the search and retrieval of biomedical and life sciences to improve global and individual health. It contains more than 29.9 million biomedical literature citations and abstracts (Pourmarzi, D., & Sharami, 2017). Medline is the largest component of PubMed (Khare *et al.,* 2014). It entails citations from the Medline, and articles indexed with (Medical Subject Headings) MeSH.

The Third database is Cochrane Library (Wiley). Cochrane Reviews base their conclusions on the findings of research that fulfill particular quality standards because the most trustworthy studies will give the best evidence for making healthcare decisions. Cochrane Review authors use measures to limit the influence of bias in various stages of the review process. Such as: Identifying relevant research from a variety of sources (including unpublished sources), Selection of studies for inclusion and assessment of their strengths and weaknesses using established criteria, Data collecting that is systematic, and Data

synthesis that is appropriate. The reviewer selected these databases to look for quality studies and peer-reviewed papers. In addition, Cochrane Library was used to roll out and exist papers about the research question.

The last database used in this paper is CINAHL Complete, considered the world's most comprehensive nursing and allied health research database, including full text for almost 1,400 indexed journals and indexing for over 5,400 publications in nursing and allied health professions (Verd, 2021). The database has about 4.1 million documents dating back to 1937 (Verd, 2021).

These databases were searched using a combination of appropriate free text words and controlled terms (Medical Subject Heading (MeSH) or MeSH-like terms). The search was structured using the PEO format where population (P) terms (Patient undergoing PCI, nurses, and doctors) were combined with Experience (E) terms (perception, view, opinion) and outcome (O) terms (' The experience of informed consent for clients, Nurses and physicians ') (Licquirish et al., 2019). The identified terms were then combined using appropriate BOOLEAN operators such as 'AND' and 'OR.' According to Kumar (2019), using the BOOLEAN operators is adequate to narrow the search and identify the relevant references.

The reference list of identified studies (citation tracking) was searched to identify other relevant studies but not from the specified databases. According to Butler, Hall, and Copnell (2016), the reference lists of relevant articles, particularly other literature reviews on the topic, may reveal citations that were missed during a database search. The protocol should specify if this sort of search will be conducted and if essential journals are manually searched for possibly relevant papers, these should also be specified.

2.6 Data collection and analysis

2.6.1 Data extraction strategy

Studies identified from the literature search were assessed for eligibility by the reviewer (FA) against the inclusion/exclusion criteria. According to Mathes, et al. (2017), the extraction of data is a crucial stage in performing a systematic review. The terms data collecting, and data collection are frequently used interchangeably. Data extraction is defined as any sort of data extraction from primary research into any form of standardized table. It is one of the most time-consuming and important activities for ensuring the validity of Systematic review outcomes. In a systematic review, data extraction serves as the foundation for the results and conclusions. Recent research, however, found a relatively high rate of data extraction mistakes in systematic reviews (Mathes et al., 2017). Therefore, to deduce the data extraction mistakes a standardized data extraction form was used.

2.6.2 Analysis of risk bias within studies

Risk bias assessment promotes transparency of the study findings. Biasness could result from the findings conclusion or overestimation of the intervention effects. It is mostly caused by limitations in the study design. Qualitative articles will be evaluated using the Critical Assessment Skills Programme (CASP) tool (Long *et al.,* 2020).

CASP tool for qualitative studies consist of ten questions intended to help the reviewer to think through these topics in a systematic manner and it is divided into three Section (Critical Appraisal Skills Programme, 2018). (See table 1). The first two questions are screening questions that may be rapidly answered. If the answer to both is "yes," it is worthwhile to move on to the following questions. There is some overlap between the questions, and you are required to record a "yes," "no," or "can't tell" response to the majority of them. Following each question, a number of italicized prompts are provided.

These are intended to remind the reviewer of the significance of the question. Fill in the blanks with your explanations for your replies (Critical Appraisal Skills Programme, 2018).

Table 2 CASP Qualitative Studies Checklist (Critical Appraisal Skills Programme, 2018)

Section A Are the results valid?	1. Was there a clear statement of the aims of The research? 2. Is a qualitative methodology appropriate? 3. Was the research design appropriate to address the aims of the research? 4. Was the recruitment strategy appropriate to the aims of the research? 5. Was the data collected in a way that addressed the research issue? 6. Has the relationship between researcher and participants been adequately considered?
Section B What are the results?	7. Have ethical issues been taken into consideration?

	8. Was the data analysis sufficiently rigorous? 9. Is there a clear statement of findings?
Section C Will the results help locally?	10. How valuable is the research?

2.6.3 Data synthesis

A narrative synthesis will be used in ~~this qualitative~~ review. Sylvester et al. (2013) defined narrative review as a conventional method of evaluating existing material to arrive at a qualitative interpretation of past knowledge. It may also be described as an attempt to summarize or synthesize published on a specific topic without seeking generalization or cumulative knowledge from what has been examined (Sylvester et al., 2013).

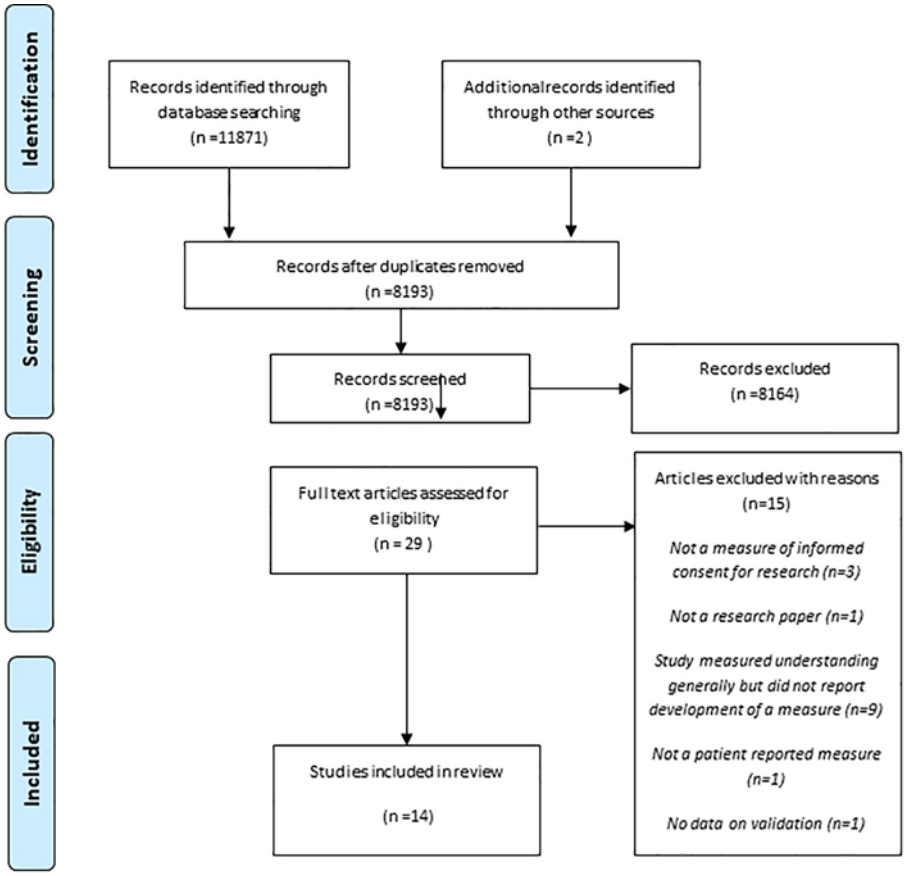
2.7 Conclusion

The chapter outlined the review's aim and data collection, the definition of a literature review, inclusion and exclusion criteria, and databases utilized in the search. In addition, discussion of the search strategies used—a discussion on data extraction strategy. However, the bias tool used for paper quality to minimize or eliminate bias in articles involved a researcher bias and article bias.

Chapter Three

3.1 Results

The search process resulted in the identification of 8192 research papers. The screening was done on the titles and abstracts and 29 full texts were retrieved for more assessment. Out of the 29, 14 met the inclusion criteria. The search process has been summarized in figure 1.



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). *P*referred *R*eporting *I*tems for *S*ystematic Reviews and *M*eta-*A*nalyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

Figure 1 Prisma flow chart

The study literature yielded 14 content analyses that showed that some of the essential components of the search were not included such as information on benefits (Whittle *et al.*, 2014) risks (Terranova *et al.*2012) alternatives (Whitney *et al.,*2003), and numerical differences.

Table 3 Summary of the included papers

Study	Lee et al.(2012)	Whittle et al. (2014)	Larobina et al.(2007)	Goff et al.(2014)	Howard et al.(2014)	Rothberg et al.(2014)
Number of participants	347	663	90		82	23
Average age/range (years)	69	63.8	62(PCI) 68(CABG)	64	65	
Location	Two city hospital, USA	3 VHA, 1 University, USA	Single tertiary			
interventions	PCI (elective)	PCI and CABG (elective)	PCI and CABG (Elective and	Angiogram and PCI	PCI	Angiography and PCI
Outcomes measured	Patient understanding of intervention (expected benefits and alternatives)	Expected treatment benefits	Expected treatment benefits and alternatives	Results of conventional and directed qualitative content analysis	Healthcare providers can improve informed consent	Presence of 7 elements of informed decision making and
Assessment used		Interview with questionnaire	Interviews and	Qualitative content analysis	Qualitative study (Survey)	Cross-sectional

Study	Astin et al., 2020	Rothberg et al., 2010	Howard and Shen	Spatz et al., 2016	Spertus et al., 2015	Kureshi et al., 2014	Probyn et al. (2017)	Dathari et al. (2014)
	118 cardiologists, 326 patients	180			1117	991		102
Number of participants	England	Academic setting	Florida, Maryland, and New Jersey	UK	US centers	US academic and community hospital	England	
						3		
Average age/range (years)	PCI	Elective coronary catheterization and	PCI	Informed consent	PCI	PCI	Elective and Acute PCI	PCI Elective outpatient
	The percutaneous coronary intervention informed consent process requires	Patients' and cardiologists' beliefs about	The number of PCIs in patients without a	The UK case serves as a reminder that at the heart of a reasonable	A personalized consent document improved	Patients' perceptions of the urgency and benefits of percutaneous		Successful identification of all PCI risks
	Cross-sectional surveys	Survey	Survey	survey	Survey	interviews	Interviews	Questionnaires
Location								
interventions								

Probyn et al. (2017)	Dathari et al. (2014)	Rothberg et al.(2014)	Howard et al.(2014)	Goff et al.(2014)	Larobina et al.(2007)	Whittle et al. (2014)	Lee et al.(2012)
	102	23	82		90	663	347
England			65	64	62(PCI) 68(CABG)	63.8	69
					Single tertiary hospital,	3 VHA, 1 University, USA	Two city hospital, USA
Elective and Acute PCI	PCI Elective outpatient cardiac catheterization	Angiography and PCI	PCI	Angiogram and PCI	PCI and CABG (Elective and non-elective	PCI and CABG (elective)	PCI (elective)

Lee et al.(2012)	**Study**	Astin et al., 2020	Rothberg et al., 2010	Howard and Shen (2014)	Spatz et al., 2016	Spertus et al., 2015	Kureshi et al., 2014
347	**Number of participants**	118 cardiologists, 326 patients	180			1117	991
69	**Average age/range (years)**	England	Academic setting	Florida, Maryland, and New Jersey	UK	US centers	US academic and community hospital
Two city hospital, USA	**Location**						3
PCI (elective)	**interventions**	PCI	Elective coronary catheterization and possible PCI	PCI	Informed consent	PCI	PCI

Spertus et al., 2015	Kureshi et al., 2014	Probyn et al. (2017)	Dathari et al. (2014)	Rothberg et al.(2014)	Howard et al.(2014)	Goff et al.(2014)	Larobina et al.(2007)	Whittle et al. (2014)
1117	991		102	23	82		90	663
US centers	US academic and community hospital	England			65	64	62(PCI) 68(CABG)	63.8
	3						Single tertiary hospital, Australia	3 VHA, 1 University, USA
PCI	PCI	Elective and Acute PCI	PCI Elective outpatient cardiac catheterization	Angiography and PCI	PCI	Angiogram and PCI	PCI and CABG (Elective and non-elective	PCI and CABG (elective)

Lee *et al.* (2012)	**Study**
347	**Number of participants**
69	**Average age/range (years)**
Two city hospital, USA	**Location**
PCI (elective)	**interventions**
Patient understanding of intervention (expected benefits and alternatives)	**Outcomes measured**
Not reported	**Assessment used**

Astin et al., 2020	Rothberg et al., 2010	Howard and Shen (2014)	Spatz et al., 2016
118 cardiologists, 326 patients	180		
England	Academic setting	Florida, Maryland, and New Jersey	UK
PCI	Elective coronary catheterization and possible PCI	PCI	Informed consent

Howard *et al.* (2014)	Goff *et al.* (2014)	Larobina *et al.* (2007)	Whittle *et al.* (2014)
82		90	663
65	64	62(PCI) 68(CABG)	63.8
Not reported	Not reported	Single tertiary hospital, Australia	3 VHA, 1 University, USA
PCI	Angiogram and PCI	PCI and CABG (Elective and non-elective	PCI and CABG (elective)
Healthcare providers can improve informed consent	Results of conventional and directed qualitative content analysis	Expected treatment benefits and alternatives offered	Expected treatment benefits
Qualitative study (Survey)	Qualitative content analysis	Interviews and questionnaires	Interview with questionnaire

Kureshi *et al.,* 2014	Probyn *et al.* (2017)	Dathari *et al.* (2014)	Rothberg *et al.* (2014)
991	Not reported	102	23
US academic and community hospital	England	Not reported	Not reported
3	Not reported	Not reported	Not reported
PCI	Elective and Acute PCI	PCI Elective outpatient cardiac catheterization	Angiography and PCI
Patients' perceptions of the urgency and benefits of percutaneous coronary intervention, assessed by interview	Not reported	Successful identification of all PCI risks	Presence of 7 elements of informed decision making and the decision to undergo angiography and possible PCI
interviews	Interviews	Questionnaires	Cross-sectional analysis

Spatz *et al.,* 2016	Spertus *et al.,* 2015
Not reported	1117
UK	US centers
Not reported	Not reported
Informed consent	PCI
The UK case serves as a reminder that at the heart of a reasonable patient standard is respect for patients' informational needs; preferences, values, and goals; safety; and autonomy	A personalized consent document improved the process of informed consent and shared decision-making
survey	Survey

Rothberg et al., 2010	Howard and Shen (2014)
180	Not reported
Academic setting	Florida, Maryland, and New Jersey
Not reported	Not reported
Elective coronary catheterization and possible PCI	PCI
Patients' and cardiologists' beliefs about benefits of PCI. All cardiologists reported beliefs about PCI for patients in hypothetical scenarios	The number of PCIs in patients without a diagnosis of AMI or unstable angina in Florida, Maryland, and New Jersey declined from 48,000 in 2006 to 40,000 in 2008 (17 percent).
Survey	Survey

Blanchared *et al (2020)*	Astin *et al.,* 2020
82 participants	118 cardiologists, 326 patients
Single academic medical center in US	England
United state	Not reported
PCI	PCI
Informed consent for percutaneous coronary Intervention: a Patient perspective of a complex Process	The percutaneous coronary intervention informed consent process requires improvement to ensure that patients are more involved and accurately understand treatment benefits to make an informed decision
Exploratory descriptive study	Cross-sectional surveys

Chapter Four

4.1 Critical appraisal

Overall, all of the studies ranged in quality from medium to high. Although the overall results were positive, there were certain methodological issues that should have been addressed. None of the included studies commented on whether the researcher-participant connection was taken into account or if it had any effect on patients' responses. Because half of the studies examined did not mention their recruiting approach, it was unclear how this may have impacted their results. Despite these constraints, the research proved to be of medium quality. Table 3 displays the quality evaluation findings.

The sample size of the participants in all studies varied from a small sample size of 23 participants to and large sample size with a number of 1117 participants. In addition, Howard and Shen (2014); Spatz *et al.,* 2016; Goff *et al.* (2014) did not provide clear information about the number of participants in the studies. According to Clancy (2019), a small sample size may make it difficult to evaluate whether a specific outcome is a real discovery, and a type II error may emerge in some situations. However, the average age for the participants across the studies ranged between the age of 62 to 69 years old

Location:

All the studies selected were done in Europe, for example, 3 studies were examined in United states centers, 2 studies in England, one single study took place in northern England, and one study was done in the UK.

Assessment tool used:

One study used an exploratory, descriptive study as an assessment tool. Two studies used a cross-sectional method. Moreover, seven studies used a survey as an assessment tool for the studies, and three studies selected an interview as an assessment tool; however, one study did not report the method used for the study.

Interventions:

All the 14 studies highlighted the topic of PCI, and some studies highlighted the focus on PCI and CABG. in addition, one study Focus on elective PCI only, one study was focus on Informed consent.

Outcomes measured

It can be seen the first outcome measured is Patient understanding of intervention (expected benefits and alternatives), Secondly, Expected treatment benefits, next to that

Expected treatment benefits and alternatives offered moreover, Presence of 7 elements of informed decision making and the decision to undergo angiography and possible PCI

Successful identification of all PCI risks.

Table 3 critical appraisal

Study	Was there a clear statement of the aims of the research?	Is a qualitative methodology appropriate?	Was the research design appropriate to address the aims of the research?	Was the recruitment strategy appropriate to the aims of the research?	Was the data collected in a way that addressed the research issue?	Has the relationship between researcher and participants been adequately considered?	Have ethical issues been taken into consideration?	Was the data analysis sufficiently rigorous?	Is there a clear statement of findings?	How valuable is the research?
Lee *et al.*(2012)	Y	Y	Y	Y	Y	?	Y	?	Y	Y
Whittle *et al.* (2014)	Y	Y	Y	Y	Y	?	Y	?	Y	Y
Larobina et al.(2007)	Y	Y	Y	Y	Y	?	Y	?	Y	Y
Goff et al.(2014)	Y	Y	Y	Y	Y	?	Y	?	Y	Y
Howard et al.(2014)	Y	Y	Y	Y	Y	?	Y	?	Y	Y
Rothberg et al.(2014)	Y	Y	Y	Y	Y	?	Y	?	Y	Y
Dathari et al. (2014)	Y	Y	Y	Y	Y	?	Y	?	Y	Y
Probyn et al. (2017)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Kureshi et al., 2014	Y	Y	Y	Y	Y	?	Y	?	Y	Y
Spertus et al., 2015	Y	Y	Y	Y	Y	?	Y	?	Y	Y
Spatz et al., 2016	Y	Y	Y	Y	Y	?	Y	?	Y	Y
Howard and Shen (2014)	Y	Y	Y	Y	Y	?	Y	?	Y	Y
Rothberg et al., 2010	Y	Y	Y	Y	Y	?	Y	?	Y	Y
Blanchard et al., (2020)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Astin et al., 2020	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y

Chapter Five

5.1 findings

The studies reported a qualitative mode of data collection and analysis. The studies reported congruity between the search methodology and data collection modes, the results, and the conclusion was concurrent with the study methodology.

5.2 Synthesized findings

A total of 14 papers from the included studies were selected for the review. The papers were synthesized into six Themes. The first one was that the patient's characteristics had an impact on the informed consent process. Secondly, the patients and the doctors agreed that the transfer of knowledge was an important concept in the consent process. Thirdly, the consent process was all about good communication between the doctors and the patients. Fourth, the patient's self-view as model patients hindered their participation in the process. The fifth, trust which could be built or broken during the process had an impact on the decision-making process. Lastly, the patient's participation in the process was controlled by their physical conditions and their perceptions of the available treatment option.

5.3.1 Patients inherent characteristics influenced the decision-making process

From the findings, the patients and doctors agreed that various intrinsic patient features had a noteworthy effect on the decision-making process. This shows that the informed consent process varies for every patient due to their different inherent features (Dathari et al. 2014).

Drive for surgery

Most patients and doctors reported having a predetermined liking for the treatment alternative or a driving force towards treatment before the treatment process is carried out. Various aspects had an impact on the motivation of the patients like the past experience during the treatment process or healthcare, the belief that the available treatment option was the best option irrespective of the truth, and the cultural beliefs about the treatment option (Dathari et al., 2014; Spertus et al. 2015; Spartz et al., 2016).

Anxiety

In some studies, the patients discussed how anxiety significantly affected their informed consent decision-making process. Anxiety had an impact on the ability of the patients to synthesize information prior to making a decision (Rothberg et al., 2010; Rotheberg et al., 2014; Spartz et al., 2016; Probyn et al., 2017). The patients and doctors believed the anxiety could be reduced through an effective and efficient consent process. The patients should be advised to relax before going through the process so as to make the right decision.

The forms of decision making and choices

Some issues arose from different preferences of the patients for knowledge and involvement in the consent process. Some patients desired to have all the information concerning their diagnosis, the available treatment methods, and the benefits and the risks of the available options to get the required information to be in control in the consent process (Rothberg *et al.,* 2010; Rotheberg *et al.,* 2014; Spartz *et al.,* 2016). However, some other patients did not see the need to get information about the risks or benefits of the treatment method and left the entire process to the doctor.

Diagnosis

Some of the findings showed that the health conditions of the patients had an impact on the consent process, or the patient participated in the decision-making process. The type of illness experienced by the patient affected the participation process of the informed consent. The diagnosis affected the patient's views on the informed consent process (Astin et al., 2020)

5.3.2 Importance of knowledge in the consent process

Most studies Dathari *et al. (*2014); Spertus *et al.* (2015);Spartz *et al.* (2016) ; Astin *et al.* (2020) demonstrated the importance of knowledge sharing during the consent process. According to the knowledge findings, three categories were identified. The first one was the patients feeling adequately informed, secondly, the level of disclosure, and lastly, some patients resorted to seeking information from other sources apart from the consent consultation. This shows that the consent process is different for various patients. Kureshi *et al.* (2014); Probyn *et al.* (2017); Astin *et al.* (2020) confirmed that low knowledge levels impaired the patient's participation in the consent process and at the same time some did not wish to be more informed. In situations where the patients did not consider the knowledge as important, the decision was left in the hands of the doctor and that was influenced by the doctor-patient relationship.

Not fully informed

Both the patients and the doctors felt inadequate in terms of knowledge which impaired their full participation in the decision-making process (Probyn et a., 2017; Goff et al., 2014; Astin et al. 2020). Some factors that had an impact on knowledge levels were time allocated to the consent process, the desire of the patient for knowledge, and the experience of the

doctors. The patients perceived knowledge as their comprehension of their condition, available alternatives, and the outcome of the treatment method.

Essential levels of disclosure

The patients and the doctors felt that some information was not to be shared eligible during the consent process (Probyn *et al.,* 2017. Both doctors and patients were uncomfortable discussing issues like mortality during the consent process despite the importance of raising such issues. The patients required the doctors to disclose all the information so that they did not seek more clarification (Probyn *et al.* 2017).

5.3.3consent was perceived as communication skills between the doctors and the patients

Patients and doctors expressed their concerns towards the necessity of clear communication during the consent process (Rothberg et al., 2010; Rothberg *et al.,* 2014; Probyn *et al.* 2017) . They both agreed that it was a process, and a lot was involved during the process. However, most of the patients considered the process as troublesome but also unavoidable.

Clarity and free jargon

Patients expressed the need for clear information conveyed to them in a simple manner. Moreover, the medical terms used by the doctors made it hard for them to comprehend the consent process. They expressed their fear of participating in the decision-making process due to the manner in which the information was communicated to them which increased their fear and anxiety. Doctors on the other hand tabled their frustration in the delivery of information concerning the outcome of the treatment and ended up using technical terms

to present information with no further explanation (Dathari *et al,* 2014; Rothberg *et al.,* 2014).

Process

The consent process was described in various ways, and it was meant to cover various purposes. It was defined as a lawful entity, learning process, and a consensus between the patient and the doctor (Astin et al., 2020). Therefore, the doctors and the patients agreed that the process was a ritualistic information communication the process but was essential from a lawful view and that the knowledge had to be conveyed to patients despite their preferences.

5.3.4 Patients personal views

Patients expressed a sense of anxiety in that their actions or character would be seen as deviating from the perceived model patient (Probyn et al 2017; Astin et al., 2020). The perceived model patient was not objecting to the doctor, not posing questions concerning g the consent process, and not wasting the doctor's time with any inquiries.

Time pressure

Patients did not want to waste the doctor's time by asking questions concerning the consent. These were mostly observed in public medical facilities and resources strapped to healthcare. In such scenarios, the patients preferred the use of a medical facility in a public place being informed of the patient needs in the waiting room (Astin et al., 2020). Some studies demonstrated the need for sufficient time required during the consent process (Probyn et al., 2017: Dathari et al., 2014; Lee at al., 2012). The doctors complained that time was an obstacle in relaying information to the patients as they would like the patient to agree to the process without being coerced.

Compliance with expert advice

Most studies revealed that the patients relied on the doctor's recommendation for treatment methods (Probyn et al 2017; Astin et al., 2020 and Blanchared et al., 2020) Patients believed that being too curious would be seen as being out of character. This led to signing of the consent form without really understanding the contents and agreeing to treatment methods without further inquiries. The patients believed and highly trusted in the doctor's opinions and they assumed that they were not equipped with the desired knowledge to question the treatment options.

Trust

Trust was a major aspect in almost all the studies. The patients and the doctors agreed on the essentiality of trust in the doctor-patient connection in the organization. Some factors such as the medicine and the treatment influenced the trust levels of the patients.

Trust in doctor

The doctor's trust was an important aspect of the consent process in several studies. According to (Probyn *et al* 2017; Astin *et al.,* 2020) some patients confirmed that trust was developed via proper communication confirming that the doctors had their best welfare at heart, and this was made possible through recommendations from friends, family, and the doctor's expertise. The patients believed that the doctors had the capacity to make them aware of the information in order to make the right choice. Also, the doctors affirmed that building trust was essential in the consent process in case of any complications during the treatment process.

Trust built during the early stages built more confidence in the doctor's decision. In some other studies, the patients did not trust the doctors but went ahead with the treatment process because of their condition. The patients trust in doctors had a great impact on the treatment methods preferred by the patients and they relied on the consent of the doctors instead of getting information about the consent process.

5.3.5 Decision-making process was influenced by others

Some aspects concerning the decision-making process were identified. First, the patients outlined the influence of other people besides the doctors in the consent process. Second, the patients assumed that they did not have much influence in the consent process and agreed on the available treatment method. Lastly, the physical condition of the patients influenced their capacity to partake in the consent process (Astin et al., 2020).

Important others

Some studies (Probyn et al., 2017; Astin et al., 2020,) outlined the role of the family who was important in the consent process. From the studies, the patient's choices and well-being in the hospitals were influenced by the suggestions from family and friends who accompanied them. Therefore, patients recognized the support of friends and family for their contribution to the consent process.

Choice

Most patients did not regard other treatment options. Those in emergency and critical conditions believed that the treatment option suggested by the doctor was the realistic one. Presentation of other available options was considered irrelevant. Their belief in surgery overweighed the other treatment options as they are considered to be not effective. Patients felt that they were not well informed to explore other options and were contented

with the doctor's choice (Spertus et al., 2015; Spartz et al., 2016; Rothberg et al., 2010; Rothberg et al., 2014; Dathari et al., 2014; Kureshi et al., 2014).

Physical state

From the findings, some aspects such as fear, anxiety, and medications all had a significant impact on the ability of the patient to fully participate in the decision-making process (Astin et al., 2004). Under these conditions, the doctor was obliged to make the decision, and even if they gave the consent it was informed.

5.3.6 Communication

The reviewed articles have shown a gap in patient understanding of the intervention in stable PCI. According to Astin et al. (2020), some patients will not be able to recall the information provided to them. However, some patients agreed that they received information about the intervention. In addition, some patients will not understand the information they received from the cardiologist. Supporting this argument, Kureshi et al. (2014) and Blanchard et al. (2020) some patients had a poor understand and recall of the information. In addition, patients overestimate the benefit of PCI and thought of PCI as a cure for their heart diseases and to prevent further heart attacks.

5.8 Cardiologists' communication styles

Communication styles have an impact on the patient's decision to participate in the consent process. some of the studies confirmed that the cardiologists use technical language in discussing the consent process (Rotheberg *et al.,* 2014; Dathari *et al.,* 2014; Spertus *et al,* 2015). Besides, they were not keen on listening to the patients' views and worked on the assumptions that the patients understood or were informed about the process. In most

scenarios, the patients complained that the doctors used technical terms that they could not understand making them to agree without comprehension.

The doctors interrupted or ignored some of the questions posed by the patients. Other studies (Whittle., 2014; Goff et al.,2014; Lerobina et al., 2007) confirmed that the patients asked questions but were not patient enough to wait for the docctors response ignoring their concerns. Besides, the doctors did not agree to with the patient's values concerning the consent process and they dismissed their cultural beliefs. Some of the proposed methods of communication methods is confirming the understanding of the patients after the discussion process the recommended method was the teach-back (Tamariz et al., 2014).

However, some cardiologists were kind to the patients, and they would offer their support through positive feedback on their concerns (Spertus et al., 2015;. They were also concerned about the patients' emotional state and their perceived values. Besides, they were concerned with the well-being of the patients and encouraged them to be confident in the process. They also acknowledged how complex the process was and gave hope to the patient. Some employed humor to enhance personal connection with the patient. Lastly, some gave the patients written documents for the patients to read and understand the consent process.

In some findings from the reviews, most cardiologists did not inform the patients that PCI could not minimize death risks, or that the benefits disappear after 5 years (Howard et al., 2014; Lee et al., 2012; Astin et al.., 2020). Lack of a clear consent that the benefits are minimized to an early reduction of angina symptoms the patients may be convinced that narrowing the artery could prevent an MI. patient's choices to pursue PCI is determined by

the doctor's explicit or implicit statement of the benefits. In some studies, the doctors did not mention the risks of the process.

Chapter Six

6.0 Discussion

6.1 Introduction

The chapter entails a wider analysis of the study findings. The chapter explores the main implications of the study findings and compares them with previous studies to show correlations or disparities. The chapter will discuss the two themes on patients' views of informed consent in PCI according to the findings and relate to other studies and provide recommendations. The same will be applied to the cardiologist's views of the informed consent process in PCI themes

6.2 Informed consent

Informed consent is a complex that involves information transfer from the doctor to the patient to allow the patient to process the information and make informed decisions. The available research emphasizes on increasing the patient's knowledge to minimize anxiety during the decision-making process. From the reviews done, the study does not outline the ambiguity of the consent process.

All the studies documented that the patient's knowledge of the informed consent process was important. Knowledge from the reviews is defined as the understanding of other treatments available, and the risks and benefits associated with the treatment method. However, this is not consistent with other research which focuses on the impartial measures of a patient's memory in the achievement or failure of the process (Probyn et al., 2017). Most patients stated that it was better to feel informed and understand the process as opposed to being given particular details (Vallance et al., 2004; Montori et al., 2014)). Therefore, preceding studies should concentrate on the evaluation of the interventions to

improve informed consent by focusing on patients understanding as opposed to the current focus on the remembering of the amount of information provided.

The review suggests that it wasn't easy for the patients to differentiate credible sources of data from the less incredible ones. Moreover, the language used in most of the educational methods was not easy for them to comprehend (Montori et al., 2014). 50% of the studies both patients and doctors emphasized the significance of trust in the relationship between the patient and the doctor, the patient and the organization, and the patient and the medicine (Goff et al., 2014). However, trust is not easy to measure but various tools can be used to determine the levels of trust between the patient and the doctor (Schmid et al., 2008; Braddock et al., 2010).

Currently, the consent process is viewed as dangerous and obsolete in most cases. The perceptions have been magnified by (Pop and Hexum, 2013) where trust seems to be abused in the medical profession. According to (Krumholz, 2010) the consent process entails the spoken part and the action part apart from the perceived knowledge transfer. Additionally, fully informed consent is difficult to achieve since the doctors may not understand the complexity of the process, and if they comprehend, they may not fully participate due to their physical condition and anxiety. The studies also emphasize the importance of trust in ensuring a quality informed consent process.

6.3 Patients perceptions

Patients did not have a choice during the consent process due to autonomy. Despite most studies addressing the issue, there is a lot that needs to be done before its cooperation in the decision-making process (Braddock et al., 1999). Patients recognized the important role played by family and trusted friends in making the right choice during the consent process. Patients adhered to the treatment methods even if they contradicted their opinions and

ideals or without being fully informed. This was attributed to the lack of knowledge, limited time, and the fear of being perceived as poor by the doctors. An important component of the consent is that it should be free from coercion (Morgan et al., 2000). Despite there being no evidence of coercion from the reviewed studies, some aspects such as the limited time, social classes, and the patient's own perception of being inadequate resulted in forced decision in an indirect way.

Inherent patient characteristics played a major role in determining the success or failure of the consent process. The inherent characteristics were termed as anxiety, the diagnosis, and the need for information by the patient. Anxiety arises from interventions to improve the consent process. According to the review, the baseline anxiety of the patient prevents them from being involved in the consent process from the initial stage. From the view, it is clear that the patients vary when it comes to the type and quantity of consent and therefore one-sided approach cannot be applied to all the patients.

The patients' needs and desires should be pre-determined before the process as opposed to the doctor disclosing the information that has already been determined. This could be solved by creating core information sets. The consent should be developed through an agreement among the patient family, the healthcare professionals, and support members. Some patients may not want to be involved in the consent process, but the core information sets help in the determination of the information which is most likely important to the patients and the doctors.

The review outlined a misunderstanding of the benefits and risks of the interventions by the patients. The patients expect survival benefits and prevention of the reoccurrence of myocardial infarction, but this cannot be ascertained (Windecker et al., 2014). It was also observed that the patients are not well informed of other alternatives which is a

requirement prior to the informed consent process. The misunderstanding is caused by the patient and doctor-related factors. From the patient's perspective, it is the emotional state, being over-optimistic, and too much information that brings confusion in understanding the process (Lidz et al., 1998).

The Elective and acute patients differed in the treatment method in relation to the information given despite focusing on the results of the treatment process as opposed to the treatment method. The elective patients were more concerned with recuperating while the acute patients focused on not dying and preventing of possible attacks in the future. A section of patients who had gone through angiograms had an idea of what the PCI process will entail. However, some patients displayed their discontent when the PCI process was not achieved, and instead other methods were suggested.

The patients believed that the medical authority had the ability to supersede their autonomy for decision-making. This made them to comply with the available treatment recommended by the health services to get better. From this perspective, the consent process is seen as a delivery of information process as opposed to the usual discussion and decision-making process. This doesn’t give the patients a chance to decide on the treatment they would prefer, besides, they are not equipped with the required knowledge to make them decide on the best treatment option.

The reviews show that patients had the choice of agreeing to or rejecting one treatment method which was available. This was attributed to the fact that alteration of treatment w, not an option, and this was outlined in the early phases of the informed consent. Also, when it was essential to prevent the possibility of heart attacks in the future. They agreed to be given enough information however they believed that to get well they had to select the

treatment option suggested to them. Both the acute and the elective patients were obligated to the decision.

6.4 Cardiologist's views of the informed consent in PCI

Cardiologists perceived the informed consent process as a continuous process that supported the patients in decision-making and helped them maintain their code of conduct. The consent process was aligned to guiding the medical practice, patient care, and legal protection. Cardiologists with minimal expertise in the consent process were reassured that the patient's operator was during the treatment procedure. In the review, the doctors did not have prior information about the patient and so they were to decide on the information received by the patient before.

Due to tight schedules, most cardiologists met the patients on the day of the treatment procedure whereby the consent process is done prior. At this point the doctors as the patient if they have understood or if they have concerns to raise. After responding to the patients' questions, it was automatic that they have understood the process. Therefore, the signing of the consent process was not a discussion process but a supported decision-making process between the patient and the doctor. The doctors perceived the informed consent process as a legal procedure against any litigation.

Cardiologists were at the center of the consent process by discussing with the patients about the consent and the signing process. The duration of the discussion relied on the patient's willingness to participate. Also, emergency cases resulted in too little time allocated to the consent process. It was not common for patients to make inquiries despite the efforts by the doctors to determine if they have understood the process. The doctors confirmed that the patients trusted their opinion and agreed to the treatment method. However, the patients and doctors highly valued the discussion prior to the signing of the

consent. For cardiologists, the discussion led to the development of a good patient-doctor relationship before the treatment process.

Cardiologists involved in the consent process before the PCI process did not have a patient-doctor relationship. Therefore, they did not have enough time with the patients, and knowledge of the patient and that led to the creation of assumptions about the information provided before the discussion process. The process was not easy especially when the patients are referred to another hospital. The doctor's views of the informed process were different from the patient's views. The doctors highly regarded the consent process, and this could be attributed to the legal measures involved.

The doctors and the patients had similar opinions on the treatment methods and the risks that should be shared during the consent process. The doctors were required to provide detailed information on the likelihood of death, and complications both major and minor. After discussions, the doctors are required to provide alternative methods and discuss the risks and benefits in a way that the patients would understand. Cardiologists have the capacity to ensure that the information is shared in a meaningful way.

Therefore, cardiologists need to be empowered in communication skills to be able to relay the risks and the alternative measures in the decision-making process. In another finding the informed consent process the doctors and the patients agreed that alternative measures should not be tabled during the consent process. However, the patient's understanding of the available treatment options is central to informed decision-making. Doctors not sharing the alternative options are against the set guidelines. The patients should be fully aware of the treatment options available to make the right choice during the process.

In most cases, the doctors are the ones who provide the information and made the decisions, and the patients are obliged to do that. This is attributed to the concept that the doctor is perceived as an expert while the patient is a passive decision-maker. The doctors viewed the patients as diagnoses, and they were seen as the role in the cardiology team. Their role was to reassure the patients of the treatment procedure and ensure that the patients fully understood the procedure. Doctors complained of communication barriers, especially for the patients who did not understand English.

The language barrier had an effect on the consent decision-making process. It was difficult for the doctors to explain the risks and the benefits because the patients did not understand the language. Communication barriers made the patients be referred to another doctor. The referral meant that the doctor had to work on assumptions of the prior information of the patient which was not sufficient to provide an informed decision making. Also, the language barrier left the patient with limited information not sufficient to make an informed decision.

The doctors found it difficult to communicate to the patients about the possible uncertainties of the treatment process. This was attributed to the fear of the patient's reaction resulting in the presentation of information with little or no explanation. The consent is perceived as an education process, legal framework, and ritual that is realized by patient-doctor communication. Therefore, it was necessary for the patient to get full information from the doctors despite the patient's objection.

Both doctors and the patients from the review confirmed that they had predetermined choices before engaging in the informed consent process. This was attributed to various aspects such as the prior experience of surgery or healthcare, the belief that the provided treatment option was the only option, and lastly the cultural beliefs. From the findings, the

cultural beliefs of the treatment process made it difficult for the doctors to effectively elaborate on the consent process.

The patients trust in the institution built their trust in the treatment process. For instance, when the patients were full of anxiety towards the treatment process, the doctors used the hospital records to assure them of the positive results of the treatment method being offered to them. Cardiologists are always optimistic of the PCI process despite little evidence available of the treatment process. Doctors recommend PCI despite the prognosis and patients are not always aware of the prognosis. Also, the way information is given to the patients by the cardiologists has a strong influence on the decision-making process. The patients should be well informed before selecting the treatment option.

Strengths and limitations

The systematic review had its limitation such as the indexing of the literature is not consistent with most databases. The limitation was overcome by increasing the research to enhance the possibilities of getting the right tittles. However, some studies were found through searching the references of the included studies. This implies the possibility of available research that has not been captured in this review. The studies researched are only in English which led to limitations in content since non-English papers would have yielded more information. Nevertheless, since the study was in English other languages would have been a challenge.

The study builds on the limited research available on informed consent in PCI (Hauptman et al., 2013).and contributes to a new perspective on the existing knowledge as previous studies have reflected. The study expounds on the existing and dated research, and it is based on English practice. The qualitative findings may not be replicated in other study

areas, but the methods enhance the trustworthiness of the study results. Therefore, despite being a systematic review that relies on the assessment of previous studies it is able to bring out the gaps and provide suggestions for future studies.

Informed consent is a common right of the patient worldwide for all the critical procedures. Therefore, the findings from this study are applicable in all the healthcare settings where the informed consent is essential. The systematic review was considered a tiresome method, compared to other qualitative and interpretive studies it is subjective, and if properly done it contributes to the development of new insights. Major findings and conclusions can be drawn from the studies which may provide direction for future studies.

The study assessed the methodology process using the specified steps to assess the credibility and reliability of the study sources. Filters were applied to increase the data sources search and through a range of databases that had information that related to the study topic. Also, the studies covered a wider geographical area implying that the findings could be applied to various settings.

Implications of the research

The main barriers to informed consent according to the research are time and the delivery of service. From the review of the previous studies, the issues that were observed over 10 years ago are the same reason affecting the decision-making process of the informed consent. Most studies highlighted that the decisions concerning the treatment methods were made by the cardiologists and the patients were requested to sign making the consent process much more of an event than the process that it is. Despite meeting the legal requirements, it does not enhance the collective responsibility and support in decision making.

The study has shown that patients begin treatment process without a proper understanding and discussion of the risks and the benefits of the process. The patients are also not aware that the risks are not similar and they differ in the way they are presented across medical centers. More research is required to focus on the understanding of settings of the decision making at the PCI referral stages to optimize supported decision making. The patients and the doctors should be educated through resources to increase their awareness on their roles in the decision-making process.

It is evident from the reviews that the decision making process is enhanced when the doctors are motivated and are assured that it will have a positive influence in the medical process and the patients outcomes (Legare *et al.,* 2008). This has a positive impact on the roles and the relationships between the patients and the doctors. This in turn streamlines the patient's attitudes and behaviors that encourages or discourages them to participate in their healthcare during the consent process.

Conclusion

From the review the informed consent process is complex and it differs across countries. Informed consent process enables the patients to decide on the treatment methods they wish to undertake. However, from the findings it is a formal process in PCI that confirms the patients understanding of the treatment process. The patient's decision on the type of the treatment process is based on trust and obligation. From the reviews it is clear that the cardiologist have the capacity to support patients to be active or inactive during the process.

The setting of the healthcare services and the patient's views of their responsibilities in the consent process shows difference in the legal and the ethical principles of the informed consent process and the present practice. Besides, the emphasis of the consent process has shifted from the doctors decisions of what information to share concerning the process to the patients' needs to understand the process. There is need to develop means by educating the patients to empower them to make the right decisions. Therefore, there is need to develop a new approach to informed consent process.

Providing education to patients has the potential to support the consent decision making process and impact the patients positively across the globe. From the research reviews some studies confirmed that the doctors and the patients were not involved in all the informed consent process stages. There is need for the patients and the doctors to be involved from the start to the signing of the consent. More research needs to explore the connection between supported decision making and informed consent in all the informed consent stages to underpin the strategies that can improve the service. Much needs to be done to make the process a collective decision making process as opposed to it being an event.

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Appendix

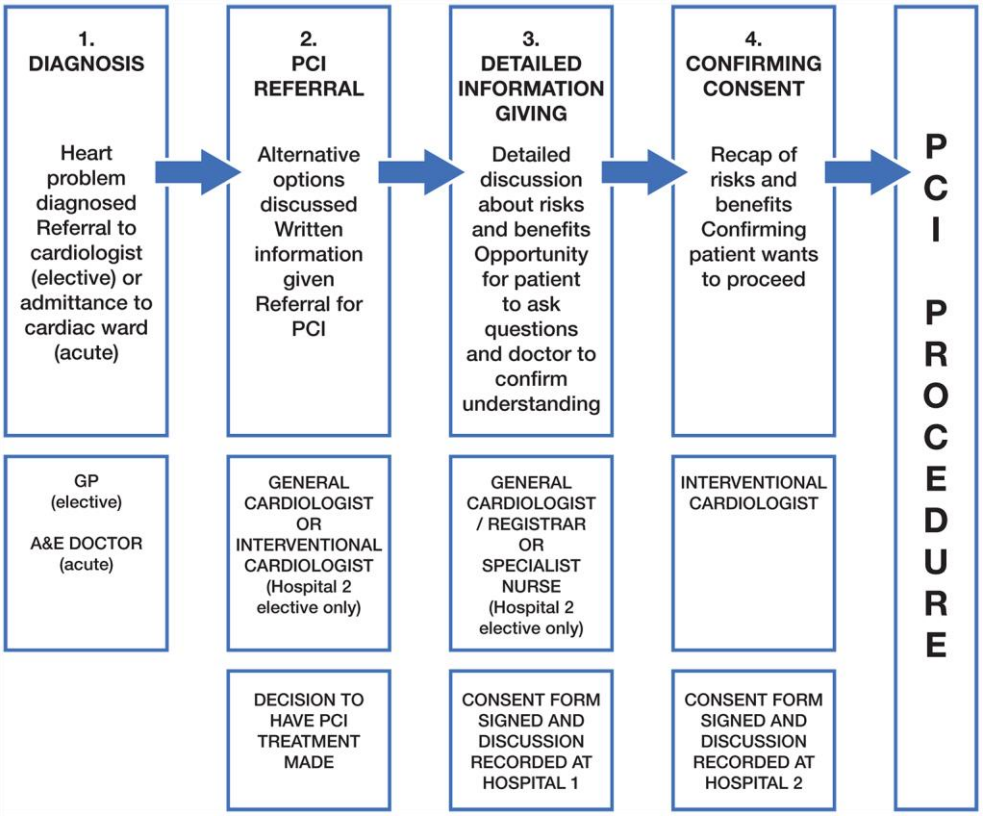

Figure 2 PCI process