

A SYSTEMATIC REVIEW OF PATIENT PERSPECTIVE ON THE INFORMED CONSENT DOCTRINE: ETHICAL AND LEGAL REFLECTIONS

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ABSTRACT

Informed consent is an ethical and legal doctrine of patients' right of acquiescence to treatment and the disclosure of adequate information by the physician to facilitate patients' medical decisions. The doctrine seeks to expand the scope of potential legal liabilities of medical practitioners and to promote patients' rights to medical care. A breach of the informed consent doctrine could be actionable in battery or assault when there is bodily trespass without consent and the tort of clinical negligence when there are inadequate disclosures. This article is a desk-top systematic review of primary data from seven independent empirical studies on informed consent from the perspective of the patient in five common law African countries. The publications which were purposively searched and extracted from *Google Scholar* reveal that though majority of patients (at least 79 percent) granted consent for treatment, there was insufficient disclosure of material complications or risks, treatment alternatives or the right of patients to refuse medical treatment if they so wished. Disclosures on material risks were as low as 21.2 percent of patients. The physician's competence in providing adequate information disclosure, demands continual medical training in the practice of the informed consent doctrine. The application of communication strategies that could enhance patients' capacity to understand the informed consent process is recommended. Additionally, clear guidelines from relevant regulatory bodies are recommended to promote patient rights to informed consent and to protect medical practitioners from potential legal liabilities.

Keywords: Informed Consent, Patient's Rights, Disclosure, Autonomy, Systematic Review, Common law

INTRODUCTION

Informed consent, a relatively new patient-centered doctrine in medical care, is derived from the legal doctrine of human rights and the principle of autonomy. This doctrine is defined as the "process of communication between a patient and physician that results in the

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patient's authorization or agreement to undergo a specific medical intervention.”² Informed consent is a partnership and dialogue process culminating in the patient's voluntary agreement or acquiescence to receive (or refuse to receive) medical treatment and the doctor's duty to disclose to the patient, adequate information upon which the latter could make informed decisions concerning his or her health and proposed treatment.

The doctrine seeks to guarantee the protection and promotion of the patient's human dignity and moral autonomy as a “consumer” of health care. It engenders respect for patient bodily integrity and stimulates patients' trust, confidence and cooperation in the treatment process, a *sine qua non* for successful treatment outcomes. It is a practical application of the principle of patient autonomy which was first used by ancient Greek philosophers to describe self-determination or self- rule of an individual. In health care, the principle of autonomy refers to patients' sovereignty over their choice-making decisions. To respect a patient's autonomy is to recognize his right to make his own choices and undertake actions based on his own set of values and belief systems. The doctrine represents the legal basis for patients' consent to treatment which may be provided for in a country's Constitution, in relevant statutory enactments or rules of law such as case law and codes of professional medical practice. As a legal doctrine, informed consent evolved as a judicial precedent of judge-made law. It is the “currency of the law” and “sets the terms for future resolution of cases in an area.”³ Paradoxically, case laws on informed consent in common law jurisdictions in Africa appear not to have been adequately developed.⁴ Though patients' right to informed consent in Ghana is protected by statutory law, it is apparent that reported cases of case law that could establish directly what constitutes a valid informed consent to medical treatment are also rare.⁵

As a fundamental human right of the patient, the informed consent doctrine was developed with the purpose of expanding the scope of legal liabilities of medical practitioners and to promote patients' rights in making autonomous choices. Patients' right to informed consent is guaranteed in Ghana's, 1992 Constitution⁶ and in statutory law:

The patient is entitled to full information on the patient's condition and management and the possible risks involved except in emergency situations when the patient is unable to make a decision and the need for treatment is urgent... The patient is entitled to know the alternative

²American Medical Association. ‘Informed Consent-Background’, Code of Medical Ethics, section 2.1.1 <<https://code-medical-ethics.ama-assn.org>>

³ Emerson Tiller & Frank B. Cross, What is legal doctrine? (2005).

⁴ Sylvester C. Chima, An Investigation of informed consent in clinical Practice in South Africa (2018) p. 4

⁵Ebenezer Adwedaa, Consent to Medical Treatment: A doctor's view on how the Ghanaian Courts may resolve consent Related Information Disclosure Disputes (2014).

⁶The Constitution of the Republic of Ghana 1992, Article 30

treatments and other health care providers within the service if these may contribute to improved outcomes... The patient has the right to know the identity of the caregivers.⁷

By the informed consent medical decision model, it is the patient's right to be provided all information concerning his health condition including available interventions and possible risks to enable him to make informed decisions and choices. And it is the medical practitioner's duty to obtain the patient's informed agreement for all therapeutic treatment or preventive procedures.⁸ A physician's inherent duty of care is to provide his patient with sufficient disclosures on the proposed treatment, such as the expected benefits, available alternative treatments, possible risks or side effects, the likely prognosis, disclosures on the identity of caregivers and hospital charges to guide patient's decision-making choices relating to consulting, medical examination, diagnostic tests, nursing care, surgical operations as well as preventive procedures. The informed consent doctrine also applies to the autonomous patient's right to refuse treatment even if the refusal will result in his or her injury, disability or death.⁹ For informed consent to be valid it requires the patient's comprehension of the disclosures on the proposed intervention and procedures and potential outcomes. The doctrine seeks to expand the scope of potential legal liabilities of medical practitioners and to promote patients' rights to medical care. A breach of the informed consent doctrine could be actionable in battery¹⁰ or assault¹¹ when there is bodily trespass without consent and the tort of clinical negligence when there are inadequate disclosures.¹²

Like most social phenomena or legal theories, informed consent has its own philosophical underpinnings. The doctrine traces its philosophical jurisprudence to the theory of ethical deontology.¹³ The term deontology, derived from the Greek word *deon* meaning "duty, or that which is binding," was propounded by the eighteenth-century German moral philosopher and Sociologist Immanuel Kant (1724-1804). Deontological theory emphasizes duty and responsibility and not necessarily outcomes in justifying the obligation to act in accordance with the rules of morality. According to Kant, right and wrong are determined by adherence to moral obligations and rational thought and not necessarily on outcomes. He emphasized on the principles or motives that animate peoples' (including the physician) actions rather than the consequences. Kant proffered that people are by nature

⁷ Republic of Ghana Public Health Act 2012 Act 851 (Sixth Sched. Sect. 167) Patient's Charter. p. 136

⁸ *ibid*

⁹ *St George's Healthcare NHS Trust v S* [1999] Fam 26, CA

¹⁰ *Airedale NHS Trust v. Bland* [1993] A.C. 789

¹¹ *Collins v Wilcock* [1984] 3 All ER 374

¹² *Sidaway v Board of Governors of the Bethlem Royal Hospital Governors* [1984] 1 All E.R. 1018.

¹³G. Garbutt & P. Davies 'Should the Practice of Medicine Be a Deontological or Utilitarian Enterprise?' (2011).

rationale, autonomous, free, and equal and thus emphasized moral worth, and underscored the moral duty of the physician towards the patient.¹⁴ Kant's *means-ends imperative* recognizes that human beings have inherent and ultimate value and must be respected and not used as means to utilitarian end. Every human being (including the patient) is therefore inherently worthy of respect and dignity.¹⁵ This philosophy focuses on intentionality and is consonant to the "blame and shame" medical culture. It establishes a deeper sense of duty towards the patient. Considered patient-centered, Kantian deontology is in contrast to the philosophy of utilitarianism (or consequentialism) propounded by the nineteenth century English philosopher John Stuart Mill, who emphasized outcomes rather than duty and responsibility.¹⁶

Additionally, the informed consent doctrine was primarily derived from the fundamental libertarian ethical concept of patient autonomy in the *Schloendorff* case of the classical jurisprudential American judgment of Judge Benjamin Cardozo, sometimes labeled a 'transatlantic' doctrine and widely cited as the case law precedent for seeking consent from patients prior to any medical or surgical intervention.¹⁷ Writing for the court, Judge Cardozo opined what has since 1914 become the cornerstone and *stare decisis* in the doctrine of autonomy and by extension the application informed consent:

Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages, except in cases of emergency where the patient is unconscious, and where it is necessary to operate before consent can be obtained.

Historically, the Hippocratic Oath of the 5th Century ancient Greece and earlier codes of medical ethics which predated the informed consent doctrine, were predicated on the ethical principles of paternalism and non-maleficence. Power balance was skewed in the physician's favour. The physician on account of his professional training and skill was considered a "superman" and all-knowing. The patient was not deemed to have the competence or the authority to oppose or disagree with the decisions of the physician. The

¹⁴ Immanuel Kant, *Fundamental Principles of the Metaphysics of Morals*. Sect. I & II (see Andrew Bailey, *First Philosophy, Fundamental Problems and Readings in Philosophy*, 2002, *Broadview Press*, pp. 634-666).

¹⁵ Chase M. Donaldson, 'Using Kantian Ethics in Medical Ethics Education.' (2017).

¹⁶ J. Mandal, D.K. Ponnambath & SC Parija 'Utilitarian and Deontological Ethics in Medicine.' (2016).

¹⁷ *Schloendorff v Society of New York Hospital* (1914) 211 NY 125

(The plaintiff in *Schloendorff* case Mrs. Mary Schloendorff had visited a hospital suffering from an unknown stomach disorder and consented to be examined under anesthetics. Her physician removed a fibroid tumour while she was unconscious without her consent. Her arms developed gangrene after the operation, allegedly due to the operation resulting in the amputation of her fingers. The surgeon was found guilty of assault since the surgery was not an emergency.

autonomy of the patient was thus restricted and his right of choice or decision-making was disregarded or at best suppressed. Full information disclosures as required of the practice of modern informed consent doctrine were not known. The physician-patient fiduciary relationship was based on a bond of faith and trust in which the physician was required to act in good faith for the benefit of the patient and to hold back on actions that will harm his patient. The ethical principle of non-maleficence succinctly captured in the Hippocratic Oath as “*primum non nocere*” (i.e. *first do no harm*), was itself considered a disguised paternalistic principle. Patients’ rights to informed consent became prominent in the later part of the 20th century. Contemporary debate on informed consent began with clinical research ethics issues following the Nuremberg war atrocities perpetrated by Nazi doctors under the pretense of medical research during the World War II. The final judgment of the tribunal that tried the offending Nazi physicians thus culminated in the codification of the 1947 Nuremberg Code.¹⁸ The elements and principles of the Code were subsequently adapted by the World Medical Association and infused into the Declaration of Helsinki as a statement of ethical principle for medical research involving human subjects.¹⁹

The first reported use of the phrase “informed consent” was in the *Salgo* case in California, USA.²⁰ The phrase was used to describe the duty of care of the doctor in that case in which an apparently competently performed aortography resulted in a permanent paralysis of the plaintiff’s leg. In reference to the alleged breach of the doctor’s duty of care to the patient-claimant, J. Bray in his statement asserted that:

A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment. Likewise the physician may not minimize the known dangers of the procedure or operation in order to induce his patient’s consent.”²¹

As a legal principle in English common law, the informed consent doctrine was gleaned and distilled by Lord Scarman in the *Sidaway* case from the common law positions in the US and Canada, providing the standard for the scope of disclosures.²² A breach of human bodily integrity is considered an affront to the principle of autonomy which is founded on the

¹⁸Nuremberg Code (1947) (see British Medical Journal No. 7070 Vol. 313,1996 p. 1448

¹⁹World Medical Association, Declaration of Helsinki, Ethical Principles for Medical Research involving Human Subjects. *Bulletin of the World Health Organization*, 2001.

²⁰*Salgo v Leland Stanford Junior University Board of Trustees* 154 Cal. App. 2d 560 (1957)

(The plaintiff’s testimony was that he was not informed of the aortography to be performed, a claim the defense conceded to but argued that the patient would have been frightened and probably refused consent if there was full disclosure. The court overruled the defense and ruled that sufficient disclosure of risks and complications was necessary for the patient to have made autonomous choices).

²¹ *Salgo v Leland Stanford Junior University Board of Trustees* 154 Cal. App. 2d 560 (1957)

²² *Sidaway v Board of Governors of the Bethlem Royal Hospital Governors* [1984] 1 All E.R. 1018.

premise that every human being (including the patient), has an inviolability right to determine what shall be done with his or her own body.²³ The patient must be told the truth (i.e. veracity principle) of his condition. Even for the terminal stage patient, making truthful disclosures to him or his legal decision-making proxy is important for him to spend a fulfilling terminal stage and die a dignified death.²⁴ By nature and scope, informed consent may be implied, oral or written.²⁵ A presupposition of implied consent arises when a patient voluntarily visits a health facility for treatment or his demeanour so suggests.²⁶ A written consent such as the use of a hospital consent form could be an admissible *prima facie* evidential material in court. The validity of consent may however not necessarily be determined on the basis of the form or manner it is given, though the use of consent form constitutes good practice of documentation and of legal value for reference.²⁷

A breach of a duty of care owed to a patient may constitute an actionable tort of trespass to the bodily integrity of the patient. Providing medical care to a patient without his informed consent or in spite of a refusal of consent may tantamount to a violation of his bodily integrity which could be actionable in the tort of battery or/and assault. An action for battery results from a non-consensual touching of a patient owed a duty of care by the medical practitioner which may or may not cause physical harm to the patient. On the other hand, assault is an intentional act such as a surgical operation performed under general anesthesia which may cause the patient to apprehend the infliction of imminent and unlawful force on his person, resulting in emotional anxiety or fear. Evidence of compliance to the tenets of the informed consent doctrine could potentially operate as a defense to a legal action in battery or assault. Under Ghana's criminal law, an act of battery could be a misdemeanour of an intentional physical trespass to a person or the use of non-consensual or unpermitted force on a patient's body:

A person makes an assault and battery upon another person, if without the other person's consent, and with the intention of causing harm, pain, or fear, or annoyance to the other person, or of exciting him to anger, he forcibly touches the person, or causes any person, animal, or matter to forcibly touch him.²⁸

²³ *Schloendorff v. Society of New York Hospital* (1914) 211 NY 125

²⁴ Y. Aoki *et al.*, 'Significance of informed consent and truth telling for quality life in terminal cancer patients' (1997)

²⁵ General Legal Council Guidelines: 'Seeking Patients' Consent. The Ethical Considerations,' sect. 27-32 (see A. Hockton, 2002 pp. 219-220)

²⁶ *O'Brien v. Cunard S.S. Co.* [1891] 28 N.E. 266 Supreme Judicial Court of Massachusetts (In *O'Brien* a patient who held her arm for a smallpox vaccination was assumed to have given an implied consent).

²⁷ *St George's Healthcare NHS Trust v S* [1998] 2 F.L.R. 728

²⁸ Republic of Ghana *Criminal Offences Act*, Act 29, Chapter 4, Sect. 86

Most empirical studies on informed consent in developing countries particularly Africa, have vastly been focusing on the perspectives of the physician and in particular the surgeon; or on informed consent in clinical trials and biomedical research. Relatively, not many studies have focused on informed consent from patient perspective. This review paper sought to reveal patients' perspective on informed consent practices in common law jurisdictions in Africa. The justification for this study across common law jurisdictions in Africa is on the basis that *common law* permits courts to set precedents by their rulings and to afford the opportunity for their adaptation by other common law courts on similar cases. As the adage goes, he who feels it knows it. Literature search was conducted in *Google Scholar* for systematic reviews that had been conducted exclusively from patients' perspective on informed consent in common law jurisdictions in Africa. This produced no positive result hence this article. This constituted a knowledge gap and an empirical starting point for synthesizing and analyzing existing primary data on patients' perspective on informed consent to answer the four research questions. What is the nature and scope of information disclosures to patients by medical practitioners? What is the extent of patients' levels of understanding of the disclosures? To what extent do patients consent to treatment? What are the exceptions to the practice of informed consent doctrine? The outcome of this review potentially has relevant epistemological value for health policy formulation in common law jurisdictions.

MATERIALS AND METHODS

This medico-legal desk-top article is a systematic review of seven selected empirical articles published on informed consent practices from patients' perspectives in five common law jurisdictions in the African Region, namely Ghana, Nigeria, South Africa, Kenya and Uganda. Each of the primary studies applied a cross-sectional survey methodology in interviewing large samples of patients respectively. In this study, a literature search was conducted on "*patient perspective of informed consent practices in common law African countries*" in *Google Scholar*. This yielded over 83,200 articles which were then screened for eligibility to select relevant articles written in English Language that met the inclusion criteria. Seven articles which adequately satisfied the inclusion criteria were purposively selected. Together they studied a total of 2,052 patients as respondents in various hospitals in the five selected common law countries. Conversely, articles that did not meet the inclusion criteria were excluded. Categories of patients interviewed in the reviewed articles were out-patients, cesarean delivery patients, elective surgical patients, post-operative patients or dental patients respectively as listed in Table 1 of the secondary data summarized for the ensuing analysis. The secondary research methodology used has a number of merits. It is relatively economic in comparison with primary and the evidence

available from systematic review is “always more reliable than any single piece of evidence.”²⁹

Table 1: Synthesized Secondary Data in Sampled Empirical Studies

Author(s)	Methodology/Sampling	Key Findings
Joseph Ochieng <i>et al.</i> , (2015) ³⁰	Descriptive Survey of post-operative patients at three university teaching hospitals in Uganda. Sample size was 371 patients.	<ul style="list-style-type: none"> - Over 81 % of patients consented to the surgical operation - 17 % did not give their consent - 80% reported having been given explanations on their surgery - But 43.9% could not ask questions before treatment - 20% of patients not satisfied with information provided before and after surgery.
David Nono <i>et al.</i> , (2022) ³¹	Cross-sectional descriptive study of 324 adult dental patients in the Dental Outpatient Department of Mulago Teaching Hospital in Kampala, Uganda.	<ul style="list-style-type: none"> - 85.3% patients consented before the start of dental procedures. - Only 5.3% of dentists obtained written informed consent - 93.7% were oral consent. - 96.3% of patients were satisfied with explanation on treatment - 93.5% of patients were informed of other treatment options .
J Muthoni Ntonjira (2012) ³²	The study was a cross-sectional survey of 383 adult patients scheduled to undergo elective surgery at the Kenyatta National Hospital in Nairobi, Kenya.	<ul style="list-style-type: none"> - 97.2% of patients consented & informed of nature of surgery - 98.2% were given the reason for surgery - 89.4% of the patients informed of the benefits of the surgery - 76.7% informed of anaesthesia administered - 78.8% of patients not informed of possible complications - 76.3% not informed on any anaesthesia related complications - 78.4% of patients felt satisfied with the IC process - Only 8.8% of patients informed of treatment alternatives.

²⁹ J.A. Muir Gray (2001) p. 127

³⁰ Joseph Ochieng *et al.*, 'Informed consent in clinical practice: Patients' experiences and perspectives following surgery.' *BMC Research Notes* (2015)

³¹ David Nono *et al.*, 'Assessment of the Informed Consent Process in the Provision of Dental Care in Mulago hospital, Uganda' *BMC* (2022)

³² Ntonjira J. Muthoni, 'A cross-sectional study of the practice of obtaining informed consent for elective surgery at the Kenyatta National Hospital.' (2010).

<p>SC. Chima (2015)³³</p>	<p>A cross-sectional survey study of 404 patients attending randomly selected public hospitals in (Durban), KwaZulu-Natal province in South Africa.</p>	<ul style="list-style-type: none"> - 73% of patients gave IC verbally, "written" (19%); and 5% used both methods. - 76% legal surrogates consulted before decision-making. - 91% of patients satisfied with information received & did not feel coerced. - 81% informed of the diagnosis - 61% informed of benefits of treatment - Only 57% patients informed of the risks - 78% favored disclosure of all material risks - 41% informed of treatment options - 28% informed of right of refusal. - 8% afraid to ask questions for fear of losing free treatment.
<p>P Theletsane <i>et al.</i>, (2021)³⁴</p>	<p>A descriptive study on day 2-3 post caesarean delivery patients conducted in 3 tertiary hospitals in academic healthcare setting in Pretoria, South Africa. The sample size was 250 patients.</p>	<ul style="list-style-type: none"> - 92.4% patients were informed why the operation was necessary. - 75.6% informed of the name of the operation. - 80.4% informed of the type of anaesthesia - Only 29.2% informed of risks - Most common risk disclosed was risk of bleeding. - 88.4% of patients alerted on the possibility of blood transfusion. - 59.2% informed of their right to refuse the caesarean procedure. - 36.8% were informed of delivery alternatives for future pregnancies to avoid caesarean delivery.
<p>OO. Ogunbode <i>et al.</i>, (2015)³⁵</p>	<p>Descriptive cross-sectional survey of 150 patients who had caesarean delivery at Department of Obstetrics and Gynaecology, College of Medicine, University of Ibadan. Nigeria</p>	<ul style="list-style-type: none"> - 64.0% caesarean patients (and 28.6% husbands) gave consent. - 81.5% caesarean patients consented in the labour ward - 75.3% satisfied with the consent form. - Profuse bleeding (86.0%) and blood transfusions (88.7%) most disclosed risks. - Postoperative care less discussed. I.e. start of oral intake (25.3%) and suture removal (18.7%). - 91.3% of patients satisfied with the information provided.

³³ SC. Chima, "Because I want to be informed, to be part of the decision-making": Patients' insights on informed consent practices by healthcare professionals in South Africa." (2015).

³⁴ P. Theletsane *et al.*, 'Exploring the Adequacy of Obtaining Informed Consent for Caesarean Deliveries - A Patient Perspective.' (2021).

³⁵ OO Ogunbode *et al.*, 'Informed consent for caesarean section at a Nigerian University Teaching Hospital: Patients' Perspective.' (2015)

Alexander A. Oti <i>et al.</i> (2016) ³⁶	Descriptive cross-sectional survey of 170 patients who were undergoing elective surgery from selected surgical departments of Komfo Anokye Teaching Hospital in Kumasi, Ghana.	<ul style="list-style-type: none"> -79% patients made to sign or thumb print consent form without any explanation on treatment options or possible complications -75% patients did not know or had never heard of IC doctrine - 60% were not informed of their diagnosis. - 42% said doctors know best, so should choose treatment for patients. - But 58% of patients wanted to be part of the decision making concerning their care.
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Source: Systematic Review Matrix, Author (2023); IC= Informed Consent

RESULTS AND DISCUSSION

This section synthesizes and reviews the four thematic areas of the secondary data in Table 1 above, namely information disclosure to patients, patients' understanding of disclosures, and patients' consent to treatment and exceptions to the clinical practice of informed consent doctrine.

Information Disclosure

The informed consent doctrine demands that patients are provided with sufficient information upon which to make autonomous decisions and choices. In Ghana, the law makes it obligatory for medical practitioners to comply with the duty to obtain patients' informed consent prior to providing treatment and to disclose full information of any proposed treatment plan including possible collateral risks to the patient.³⁷ In the English case of *Taylor*,³⁸ Popplewell described any act of consent without any explanation to the patient as 'window dressing.' Similarly, *Brazier* succinctly likened it to a "hollow vessel."³⁹ Denying patient information or providing him or her with manipulated information or information under duress is a violation of his right to informed consent and an infringement on his human dignity and bodily integrity. This review has revealed that with the exception of the dental respondents in *Nono et al.*, a significant majority of patients in the other six primary studies were neither informed of material risks or complications of treatment, treatment alternatives nor patient's right to refuse medical treatment. In *Nono et al.*, 96.3 per cent of patients commended their dentists for satisfactorily explaining to them the treatment they had received, 93.5 per cent admitted having been provided information on

³⁶ Alexander Acheampong Oti *et al.*, 'Informed consent under the Ghana Health Service Patients Charter: Practice and Awareness' (2016).

³⁷ Republic of Ghana. Public Health Act, 2012 Act 851 (Sixth Sched. Sect. 167) Patient's Charter.

³⁸ *Taylor v. Shropshire Health Authority* [1998] Lloyd's Rep. Med.395

³⁹ *Brazier*, M. (2003) p.107

other treatment options; while over 95 percent were granted the opportunity to ask questions. However, in *Ochieng et al.*, albeit 80 per cent of respondents reported that they were satisfied with the adequacy of disclosures and explanations on their surgical treatment, a significant 43.9 per cent could not ask questions before treatment. In *Ntonjira*, overwhelming majority of patients (97.2%) conceded having been informed of the nature of surgery, the reasons for the surgical procedure (98.2%) and the anaesthesia to be administered (76.7%). Yet only 21.2 per cent were informed of the possible complications or risks involved in the surgical operation. As low as 8.8 per cent were informed of alternatives to the proposed mode of treatment. In *Chima*, 91 per cent were satisfied with the adequacy of information disclosed to them and did not feel coerced into granting informed consent. Nonetheless, though seemingly low, a notable 8 per cent felt intimidated and could not ask questions for fear of losing the benefit of free treatment. A significant 43 per cent of patients experienced no disclosures on potential risks, no disclosures on treatment alternatives (59%) or right of refusal (72%). This is despite the fact that it was the desire and wish of as high as 78 per cent that material risks were disclosed to them. Similarly, in *Theletsane et al.*, only 29.2 per cent were informed pre-operatively of all the risks in caesarean deliveries i.e. the risk of bleeding and blood transfusion. The inadequacy of information disclosures could have had potential actionable implications if patients' conditions had subsequently developed complications.

In *Ogunbode et al.*, material risks of profuse bleeding (86.0%) and blood transfusions (88.7%) were commonly discussed among doctors and patients. Not surprisingly, 91.3 per cent of patients said they were satisfied with the information provided. However, disclosures on postoperative care including commencement of oral intake and details on suture removal were mostly not disclosed, a finding largely corroborated by an earlier Nigerian study from the perspective of practicing surgeons.⁴⁰ On the other hand, *Oti et al.*, revealed in their study that information on potential complications, risks or treatment options were not disclosed to as high as 79 per cent of the elective surgical patient-respondents, although 58 percent wished they had enjoyed their right to informed consent and had been part of the decision-making process of treatment.

With those findings a critical question that may be asked is how much information disclosure should be considered sufficient for an informed consent process? In the English case of *Sidaway*,⁴¹ Lord Scarman argued that:

The doctor's duty arises from his patient's right. If one considers the scope of the doctor's duty by beginning with the right of the patient to make his

⁴⁰ T.O. Ogundiran & C.A. Adebamowo, 'Surgeon-Patient Information Disclosure Practices in Southwestern Nigeria.' *Journal of Medical Ethics* (2010)

⁴¹ *Sidaway v Board of Governors of the Bethlem Royal Hospital Governors* [1984] 1 All E.R. 1018.

own decision whether he will or will not undergo the treatment proposed, the right to be informed of significant risk and the doctor's corresponding duty are easy to understand; for the proper implementation of the right requires that the doctor be under a duty to inform his patient of the material risks inherent in the treatment.

According to Lord Scarman, consent granted in the absence of sufficient information may be considered a vitiated consent. Informed consent must include an explanation on the nature of treatment, potential benefits of the treatment, material risks and side effects, alternative treatments and the right to refuse treatment. A breach of duty to warn the patient on the material risks in medical or surgical treatment according to Lord Scarman, could elicit an action in medical negligence. On the other hand, J. Bristow in his statement in *Chatterton*,⁴² opined *inter alia* that providing the patient with information in broad terms is sufficient and a valid consent to negate any subsequent action in battery, as long as the patient understood the broad nature of the treatment proposed. J. Bristow further asserted that:

In my judgment, once the patient is informed in *broad terms* of the nature of the procedure which is intended, and gives her consent, that consent is real, and the cause of the action on which to base a claim for failure to go into risks and implications is negligence, not trespass.⁴³

Under common law, *broad term* standard may be equated to the 'reasonable person' standard,⁴⁴ which requires the physician to disclose all information that a reasonable person might want to have prior to deciding to accept or refuse treatment. Additionally, the patient must be given the opportunity to ask any questions he may be interested or curious to ask. The clinician must respond as fully, accurately, objectively and honestly as possible. When material risks in a treatment are not fully disclosed to the patient or his legal proxy, then the patient (potential claimant) has not validly consented, and the medical practitioner may be liable for an action in clinical negligence. The onus of proof may however be on the claimant to prove that the physician owed him a duty of care and that the defendant's

⁴² *Chatterton v. Gerson* [1981] 1 All ER 257

⁴³ *Sidaway v Board of Governors of the Bethlem Royal Hospital Governors* [1984] 1 All E.R. 1018. (The claimant Mrs. Sidaway had in October 1974 suffered paralysis from injury to her spinal cord as a result of a surgical operation on her by neuro-surgeon Falconer. She alleged that she was not warned of the inherent material risk. The claim was an action in clinical negligence, even though the claimant admitted she had granted consent for the operation. Her claim was rejected by the House of Lords. In rejecting the claim, Lord Scarman applied the 'prudent patient' test on the basis that the claimant had not succeeded in proving that the defendant in causing him harm was negligent in his duty).

⁴⁴ *Hall v Brooklands Auto Racing Club* [1933] 1 KB 205, 217. (Refer Michael A. Jones (2002) p. 192: "The reasonable man is not a paragon, neither is he a clairvoyant. He is the ordinary man, or the man on the Clapham omnibus.")

carelessness or negligence caused him harm.⁴⁵ This principle was further affirmed by Lord Scarman's in his dissenting judgment in the *Sidaway* case.⁴⁶ It is this *broad term* principle which the court may have adapted in the *Frank Darko* case in Ghana.⁴⁷

Lord Bridge in his statement advocated that providing a patient sufficient information is a matter of clinical judgment and that the level of disclosure of information can be decided using the *Bolam Test*.⁴⁸ By the *Bolam* standard, the physician is required to meet the standard of competence of the reasonable professional, exercising the skill of his profession in accordance with a practice accepted at the time as proper by a responsible body of medical opinion. However, Lord Scarman in his statement rejected the relevance of *Bolam test* to disclosure of material risks. He proffered that a right balance between clinical decision-making and the patient's right to informed consent could be attained by applying the "prudent patient" test derived from the *Canterbury case*.⁴⁹ Subsequently, the English House of Lords' in its judgment in *Bolitho*⁵⁰ emphatically established that the body of medical opinion relied upon in *Bolam* must be "responsible, reasonable and respectable," and that it ought to be necessarily logical and be subject to judicial review. the objective standard for a full informed consent disclosure that conforms to the principle of respect for an autonomous patient is the 'reasonable patient standard' *to wit*, the "material information" a reasonable or an average patient would expect to know to be an informed participant in the decision making process.

Patient Understanding of Disclosures

In Ghana, a valid informed consent demands that the patient understands the nature of the proposed medical intervention, the material risks, side effects, and alternative treatments, right of refusal to treatment and potential consequences of refusing treatment.⁵¹ The challenge of comprehension arises when disclosures are lacking, inadequate, untimely or not skillfully communicated. For disclosures to be comprehensible to patients, they must be communicated in a manner that patients could understand. In this review patients' understanding of disclosures is a challenge.⁵² Another difficulty is the lack or inadequate

⁴⁵ *Chatterton v Gerson* [1981] 1 All ER 257

⁴⁶ *Sidaway v Board of Governors of the Bethlem Royal Hospital Governors* [1984] 1 All E.R. 1018.

⁴⁷ *Frank Darko v. Korle-Bu Teaching Hospital* (2008)

⁴⁸ *Bolam v Frein Barnet Hospital Management Committee* (1957) W.L.R. 582.

⁴⁹ *Canterbury v. Spence* (1972), 464 F. 2d 772

⁵⁰ *Bolitho v City and Hackney Heath Authority* [1998] A. C. 232

⁵¹ Republic of Ghana. Public Health Act, 2012 Act 851 (Sixth Sched. Sect. 167) Patient's Charter. pp. 135-138

⁵² Alexander A. Oti *et al.*, 'Informed consent under the Ghana Health Service Patients Charter: Practice and Awareness' (2016).

opportunities doctors afford patients to ask questions for explanation before treatment. This challenge was revealed confirmed by *Ochieng et al.*, and *Chima*.

According to *Chima*, lack of or inadequate understanding arise due to a number of factors. This may include language barriers, absence or lack of interpreters, heavy workload of doctors, time constraints and lack of or inadequate literacy on the part of patients.⁵³ These challenges are not significantly different from those found by *Oti et al.* As alluded to in *Ogundode et al.*, it is arduous to translate or explain medical diagnoses, potential risks and treatment alternatives in local African languages in the process of obtaining patients' informed consent. In any case, consent forms in the studied common law countries are largely filled in English language. According to *P. Theletsane et al.*, language forms a major challenge to the informed consent process. The informed consent process needs to be simplified in a local language of patients if need be to enhance the understanding and participation of patients.⁵⁴

It is curious that despite the inadequacies of disclosures in the primary studies reviewed, some patients felt satisfied with the current practice of informed consent, an apparent indication that many patients did not fully understand the purpose and scope of the informed consent doctrine. The matter in issue may be inadequate communication skills on the part of medical practitioners which may account for inadequate information disclosure. This was opined by *Chatterton* that inadequate information disclosure "could be due to that fact that most practitioners do not know much about the process of informed consent and the consequence of insufficient disclosure."⁵⁵ There is therefore the need to prioritize counseling of patients on their right to informed consent. Against the backdrop of inadequate patient understanding in the informed consent process, it was found in a systematic review of communication interventions in California that the use of a wide range of communication interventions such as written information, audio visual/multimedia interventions, extended discussions, and test/feedback techniques could help to improve patient comprehension of information disclosures.⁵⁶

Patient Consent to Treatment

This section reviews the nature and scope of consent granted prior to medical intervention. Consent to medical treatment includes patients' acquiescence to consultation, medical examination, diagnostics, surgical operation or dental procedures and services. Table 1

⁵³ Sylvester C. Chima. 'Evaluating the Quality of Informed Consent and Contemporary Clinical Practices by Medical Doctors in South Africa: An Empirical Study.' (2013).

⁵⁴ OO Ogunbode *et al.*, 'Informed consent for caesarean section at a Nigerian University Teaching Hospital: Patients' Perspective.' (2015)

⁵⁵ *Chatterton v Gerson* [1981] 1 All ER 257

⁵⁶ Yael Schenker *et al.*, (2011)

revealed that a huge majority, between 79 and 97.2 per cent of patients in the reviewed studies granted consent prior to medical treatment. Also high as between 81 and 85.3 per cent of the surgical and dental patients in the two Ugandan studies granted consent before treatment. In *Ntonjira*, 97.2 per cent of elective surgical patients granted consent while 78 percent “felt satisfied with the current process of obtaining informed consent.”⁵⁷ In *Chima*, 97 per cent of respondents said they granted consent prior to treatment. Legal surrogates (76%) played a key role in medical decision-making. Similarly as high as 92.4 per cent of cesarean delivery respondents were reported to have granted consent in *Theletsane* while in *Ogunbode et al.* a significant majority of cesarean delivery respondents (81.5%) said they or their husbands, the latter as legal surrogates granted consent. Majority of respondents (75.3%) in *Ogunbode et al.* expressed satisfaction with the quality of consent form signed and considered them well written and simple to read. On the contrary, *Oti et al.*, found that though 79 per cent of patient-respondents granted consent “the doctor only asked them to either sign or thumbprint the consent document.”⁵⁸ Moreover, 75 percent of respondents said they either did not know or had never heard of the doctrine of informed consent, an indication of the inadequate extent of education on patients’ right to informed consent.⁵⁹

An important matter in issue is whether the consent granted by patients meet the legal standard of valid and free informed consent. The common law principle in *Chatterton*,⁶⁰ is that it is not a real informed consent for a patient to sign a consent form to undergo a surgical operation without any explanation from the doctor. A completed consent form whether signed or thumb printed is not necessarily a substitute for the necessary dialogue that must ensue to achieve valid consent, full disclosure or free refusal. The capacity or competence of the patient has to be established before he or she can be made to sign the form. In order for a patient to exercise his right to consent, it is essential that it is established that he has the mental capacity to comprehend the substance of information disclosed, and the capacity to voluntarily engage in the informed consent process.⁶¹ For consent to be valid and free, it must be offered intentionally and voluntarily by the patient without any coercion, deception or duress.⁶² An autonomous patient’s consent to accept or refuse treatment could be described as valid and free only when it is granted voluntarily without pressure or undue influence of any third party.⁶³ Ghana’s criminal offences law provides that “consent is void

⁵⁷ J. Muthoni Ntonjira (2012)

⁵⁸ Alexander A. Oti et al., (2016)

⁵⁹ *Taylor v. Shropshire Health Authority* [1998] Lloyd’s Rep. Med.395

⁶⁰ *Chatterton v. Gerson* [1981] 1 All ER 257

⁶¹ *St George’s Healthcare NHS Trust v S* [1998] 2 F.L.R. 728

⁶² *Re T (An Adult) (Consent for Medical Treatment)* [1992] 2 FLR 458

⁶³ *Freeman v Home Office* [1984] 1 All ER 1036

if it is obtained by means of deceit or of duress”⁶⁴ and “by undue exercise of any official, parental, or any other authority.”⁶⁵ Otherwise, a competent surrogate or family member should be made to provide substitute consent. In the Ghanaian case of the minor *Frank Darko*, the court did not find the hospital negligent when the left knee of the plaintiff was operated on instead of the right knee. In its ruling, the court pronounced that the patient’s family proxy had signed a *broad consent* form which authorized the surgical team to take any measures necessary for the purpose of the operation.⁶⁶ Notwithstanding the legalities of the informed consent doctrine, the physician’s duty of disclosure and to obtain the patient’s informed consent to treatment is not absolute. It has its exceptions in clinical practice.

Exceptions to Informed Consent Doctrine

This section discusses the main ethical and legal exceptions to the strict practice of informed consent in which failure of the medical practitioner to obtain informed consent may be justified. This includes situations of emergency that demand swift action to save the life of a patient; when the doctor envisages that disclosure of information could harm the patient; a scenario of patient waiver; and the incompetent state of the patient to grant informed consent. Generally, with the exception of patient waiver, the rest of the stated situations of exceptions to the informed consent process primarily rest on the strength of the doctor’s clinical judgment. In emergency situations such as treating motor traffic accident victims or conducting emergency cesarean delivery, prompt treatment is necessary to prevent avoidable deaths or any serious harm to the patient.⁶⁷ In such circumstances, treatment of a patient by the doctor under the paternalistic model to act in good faith to enhance the patient’s right to life becomes imperative. Delaying treatment in order to obtain informed consent could jeopardize the patient’s health or life. Additionally, in emergency situations *implied consent* could reasonably be assumed for the patient since any reasonable person would most likely consent to treatment under such circumstances.⁶⁸ According to Lord Brandon, the lawfulness of the treatment of unconscious patients in emergency situations without consent may be invoked under the common law *Principle of Necessity*.⁶⁹ In corroborating Lord Brandon’s assertion, Lord Goff in *Re F*,⁷⁰ opined that medical treatment in medical emergency situations is legally agreeable under the principle of necessity because it is an action to preserve the patient’s life, health and well-being. It is

⁶⁴ Ghana’s Criminal Offences Act, Act 29 (1960) Sect. 14 (b)

⁶⁵ *ibid* Sect. 14 (c)

⁶⁶ *Frank Darko v Korle-Bu Teaching Hospital*, (see Joel Tetteh Zutah, et al., *Licensed to kill? Contextualising medical misconduct, malpractice and the law in Ghana*. 2021)

⁶⁷ OO Ogunbode, et al., (2015)

⁶⁸ *Mohr v Williams* (1905) N. W. 12 (Sup. Ct. Minnesota)

⁶⁹ *Re F* [1990] 2 A.C. 1 (Refer A. Hockton, 2002 p. 9)

⁷⁰ *Re F* [1990] 2 A.C. 1 (Refer A. Hockton, 2002 p. 9)

also in concordance with the ethical principles of beneficence and non-maleficence. Although standards of informed consent generally apply in emergencies as in non-emergencies, emergency medical practitioners are more predisposed to the practice of paternalism in the application of the *Principle of Necessity*.

The second exception to the informed consent doctrine is when the doctor envisages that disclosures particularly on potential risks, complications or side effects could physically or psychologically harm the patient. This exception is derived from the American common law doctrine of *therapeutic privilege* originating from the *Canterbury* case.⁷¹ Under this doctrine the doctor may be permitted in some circumstances to at his own discretion withhold from the patient information on diagnosis, nature of treatment or material risk of treatment, if in his professional opinion he can prove the reasonableness of non-disclosure; and that disclosure in that circumstance is not only non-therapeutic but could precipitate a psychological harm to the patient. Lord Scarman proffered in *Sidaway* that “that there is the need that the doctor should have opportunity of proving that he reasonably believed that disclosure of the risk would be damaging to his patient or contrary to his best interest.” In circumstances warranting its invocation, the therapeutic privilege doctrine may be an action of defense against allegations of lack of or inadequate disclosure. But could the mitigating factor of therapeutic privilege be a justification for a deficit in the disclosure of risks and complications to patients? In *Pearce* case,⁷² Lord Woolf cautioned medical practitioners to inform patients of their right to disclosures on any “significant risk.” As noted earlier, Ghana’s Patients’ Charter also provides that medical practitioners do a full disclosure of any proposed treatment plan especially material risks in simple comprehensible language to the patient.⁷³ Though it may be argued that therapeutic privilege practice could be regarded as acceding to the ethical principle of non-maleficence, it may also be considered a breach of the autonomy of the patient on the grounds that it could be overused or misused as an excuse for non- disclosures.

The sufficiency of information disclosed to a patient may also vary depending on the patient’s own wishes or desires. An autonomous patient may either refuse to consent or may waive his or her right to informed consent. It could be a self-waiver of the patient or waiver by his or her surrogate decision maker. In the American *Miranda* case,⁷⁴ the Supreme Court defined waiver as the intentional and voluntary relinquishing of a known right. According to *Oti et al.*,⁷⁵ 42 per cent of respondents stated that doctors “know best,” so should be made to choose the treatment plan for patients. That perspective of

⁷¹ *Canterbury v. Spence*(1972) 464 F. 2d 227

⁷² *Pearce v United Bristol Healthcare NHS Trust* (1999) 48 B.M.L.R 118

⁷³ Republic of Ghana. Public Health Act, 2012 Act 851 (Sixth Sched. Sect. 167(2)) Patient’s Charter.

⁷⁴ *Miranda v Arizona* (1966) 384 US 436.

⁷⁵ Alexander A. Oti et al., (2016)

respondents could be interpreted as a willingness to waive their right to informed consent. Few questions may arise when patients effectively waive their right to grant informed consent. Does an act of waiver itself synchronize with the doctrine of informed consent? Should a waiver be considered as exercising the right of choice? Or is there a need for the medical practitioner to enquire further about the reason behind the waiver? By the US Supreme Court's ruling, patients may have the right to waive their *Miranda rights*⁷⁶ to grant informed consent as long as it is voluntarily done without coercion or duress and that there is enough documentation to that effect.

The fourth exception to the informed consent doctrine is when the patient has no competence or capacity to grant informed consent. This includes patients who are either minors, have mental disorders or are incompetent adults such as the terminally ill. Common law permits that where a patient is a minor; or is an adult patient who lacks autonomous competence, the consent of a competent legal adult representative with parental, family or guardian responsibility be granted the right to provide informed consent on behalf of the patient, provided the exercise of consent "is in good faith for the benefit of the person on whose behalf it is given."⁷⁷ As a general rule, any person with a parental responsibility has the right to grant consent on behalf of a child. The right of parents to make treatment decisions on behalf of and in the best interest of their children is guaranteed in both statutory and common law.⁷⁸ Additionally, the doctor's actions must be in accordance with his duty of care to the patient. The courts may however declare the *Gillick* competence age at which a child attains the age of majority by which to make his decisions.⁷⁹ *Gillick* competence is a developmental concept in which a child, though under 16 years, is one with sufficient developmental maturity and intelligence to understand and retain information on the nature and implications of planned medical procedures. Under English common law, a *Gillick*-competent child below the age of 16 years may give consent on his own behalf. However, the more high-risk a medical procedure is the less likely to presume for a child a state of *Gillick* competence.

In Ghana⁸⁰ and in South Africa,⁸¹ the legal age for granting consent is 12 years and above, although by definition a child is a person below the age of 18 years.⁸² Doctors are sometimes confronted with a challenging dilemma when treating a child whose parents on

⁷⁶ *Miranda v Arizona* (1966) 384 US 436 .

⁷⁷ Republic of Ghana Criminal Offences Act, Act 29, Chapter 2, Sect. 14(d)

⁷⁸ *R (A Minor)(Wardship: Medical Treatment* [1992] 1 F.L.R 190)

⁷⁹ *Gillick v West Norfolk AHA* [1986] 1 A. C.

⁸⁰ Republic of Ghana Criminal Offences Act, Act 29, Chapter 2, Sect. 14 (a)

⁸¹ S.C. Chima (2018) p. 383

⁸² Republic of Ghana. The Children's Act, 1998, Act 560, Sect. 1

the basis of their religion do not believe in pharmacological therapy ('*kyir bentua*' in local Fante language) or blood transfusion (e.g. Jehovah's Witnesses) and thus may not grant consent for the treatment of the child. Nonetheless, Ghana's 1992 Constitution makes it mandatory for any medical practitioner to provide treatment to a patient even when he has no competence to grant his or her own consent. Ghana's Constitution provides *inter alia* that "A person who by reason of sickness or any other cause cannot give his consent shall not be deprived by any other person of medical treatment...by reason only of religious or other beliefs"⁸³ The concept of competence and the informed consent doctrine are particularly important in psychiatric practice. Although assessing competence in informed consent practice is a general legal concept, the clinician in psychiatric practice most often makes his or her own clinical assessment of the patient's competence to grant informed consent because most of their patients may have mental disorders. Ghana's statute law also provides that "A person who by reason of a mental disorder is unable to give consent shall not be deprived by another person of medical treatment, education or any other social or economic benefits"⁸⁴ The psychiatrist or the clinician's determination of the patient's recall capacity, mental capacity to comprehend disclosures, and the determination of the legal surrogate or proxy with the responsibility for decision-making for the incompetent patient become essential in the informed consent dialogue. The doctrine of informed consent also places high professional obligation on the clinician to be receptive to cultural sensibilities during doctor-patient relationship and to have adequate understanding and appreciation of the nature and legal implications of their duty of care to the patient.

CONCLUSION

The doctrine of informed consent seeks to expand the scope of potential legal liabilities of medical practitioners and to promote patients' rights to medical care. The invocation of informed consent in medical practice is primarily the responsibility of the doctor *to wit* the protection of patients' right to informed consent as a conduit to engender patients' trust, confidence and cooperation in the therapeutic process. It also seeks to protect and promote the principles of patients' autonomy and human dignity. This study aimed at revealing a synthesized perspective of patients on the practice of informed consent doctrine in five common law African countries including Ghana. Literature search showed that most empirical studies on informed consent in Africa have been focusing on the perspective of the physician, the surgeon; and informed consent in clinical and biomedical research. An empirical starting point was thus auspicious for a systematic review of existing primary data on informed consent from the patients' perspective. This review has shown that a very

⁸³ Republic of Ghana, 1992 Constitution, Article 30

⁸⁴ Republic of Ghana. Mental Health Act, 2012 , Act 846, Sect. 56

significant majority of patients were generally not informed of material risks or potential complications of treatment, treatment alternatives or patient's right to refuse medical treatment. Though at least 79 per cent granted consent for treatment, there was insufficient disclosure of material complications or risks, treatment alternatives or the right of patients to refuse medical treatment if they so wished. Disclosures on material risks were as low as 21.2 percent of patients. For those who contended that they granted consent, eyebrows could be raised on how informed and valid their consent was. The ethical and legal exceptions to informed consent doctrine were also discussed to show that the doctrine has its elastic limitations. There is the need to avail patients with the knowledge on procedures and implications involved in the use of consent forms and to make full disclosures on risks, alternative treatments and the right to refuse any treatment. On the other hand, there is the need for continual medical or dental education for medical practitioners on patients' rights and in particular to integrate informed consent in medical education curricula. Communication skills of medical practitioners in informed consent must be improved to support information disclosures and to enhance patients' levels of understanding with the aim of stalling potential litigious relationships between the medical practitioner and his or her patient. The informed consent process needs to be simplified in local languages of patients if need be to enhance the understanding and participation of patients. Accurate documentation of consent processes in clinical practice must be an additional priority. Additionally, clear guidelines from relevant regulatory bodies are recommended to promote patient rights to informed consent and to protect medical practitioners from potential legal liabilities.

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CONFLICT OF INTEREST

Author hereby declares no conflict of interest.

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