Preface

From ancient times, and throughout the medieval era and into the modern age of civilization, the doctor-patient relationship, including the clinical decision-making always had some degree of association with what we now term ‘the principle beneficence’. Beneficence means ‘to do good; to actively pursue the good for one’s patient’ (Veatch 1988: 34).

Throughout the history of medicine, doctors have possessed the scientific expertise and the absolute power to dictate and impose their decisions on the vulnerable and trusting patients. In modern times, this “paternalistic” view of doctors/medicine has changed and is now viewed in a harsh light. Nowadays, doctors are ethically bound to take the wishes and desires of their patients or proxies into consideration in the decision-taking which will affect the patients’ health or treatment. The previously held notion that doctors should unilaterally make all the medical choices without the input from the patient (or the patient’s family) is referred to as ‘strong paternalism’ (Van DeVeer 1986).

In medical ethics, this idea has been replaced by forms of either weak paternalism (where input from the patient or

proxy is taken into consideration however, the doctor takes a lead in decision-making) or “anti-paternalism” where the adult competent patient, in full knowledge and understanding of the pros and cons of his or her illness or condition makes his or her own informed choice and the doctor follows this directive (Dworkin 2009 and Bernstein et al 2000: 53).

From the onset of surgical procedures in practice, patients were often subjected to what we, as doctors, now consider as intolerable, unsafe and untested forms of surgery with no diagnostic or prognostic value and certainties. Technological advances in the form of e.g. anesthesia, antibiotics, radiography and outcomes assessments have resulted in an improvement in the morbidities and mortalities often encountered- particularly in the field of orthopaedic surgery (Calne 2000: 34-67).

Over the years, the empirical research studies on the surgical outcomes have greatly increased the knowledge of what the patients might practically expect in the course of their surgical treatment. This means that both the risks and benefits can be better predicted and patients have become increasingly

involved in such discussions before surgery (Jones 2007: 115-120). This could also be attributed to the increased exposure to the advanced technology mediated medical information and landmark litigation cases that has changed the face of the doctor – patient interaction and which appeared to threaten the doctors (Bunch 2000: 71).

The moral considerations pertaining to the surgical treatment of patients has also evolved with time. The principle of 'beneficence', which may be linked to strong paternalism, meant that the doctor, whilst making all the decisions, was presumed to be always acting in the best interests of the patient. The shift in the practice of medicine is linked to societal shifts and so with the changing mores and the advent of a 'human rights' mentality which became most prominent in the 1960's. The idea that competent adult patients should have the weightiest say in their own healthcare came into being (Ibid: 76-77).

Beneficence remains an important principle in medical ethics but the link to the 'benevolent doctor' has become blurred. Now, in the surgical treatment of patients, there is the realization of the importance of an informed consent, but it is

interesting that more emphasis seem to be placed on the assurance that the informed consent form is fully documented and filed than on the doctor – patient relationship aspect of the process which Bunch (2000: 71) views as a question of satisfying the legal requirement at the expense of what is supposed to be a novel intention.

Although the practice of orthopaedic surgery has its own history and evolution alongside the development of the concept of an informed consent, not much is being taught or practiced regarding it in our South African medical schools or during the specialist training of orthopaedics. This is most probably the same elsewhere in the world.

For example, in a past study by Wenger and Lieberman (2000: 78), orthopaedic surgeons were found to have insufficient understanding of the proper ethical conduct concerning how one obtains an informed consent. Hence the strong need to interrogate this very important subject and get it firmly entrenched within the field of orthopaedic surgery. The informed consent process should be an accepted routine and included in standard practice.

Towards that end I looked at the history and evolution of informed consent in orthopaedic surgery in the following way:

1. The history and definition of an informed consent.
2. The legal considerations and prevailing regulations.
3. Theory and ethical analysis.
4. The decision-making capacity, impediments and enhancement thereof.
5. The current and future within the practice of orthopaedic surgery.

Informed consent in orthopaedic surgery is not fundamentally different from that practiced in the other surgical sub-specialties but does have very important essential elements that call for a special attention and scrutiny. Drawing from the earlier common procedures such as an emergency life saving limb amputation, this specialty has evolved in the areas of emergency trauma and elective surgery as well as the related research.

Beyond the dispute over the surgical site, there are now a vast assortment of various anatomical metal and non-metal implant materials for fixing the broken bones, joints

replacement surgery, tumour limb salvage procedures and the reconstruction of ligaments that have taken the field of medicine by storm and have important implications to the practice of orthopaedics, the surgeon and the assumed beneficiaries, the patients.

The planning, approaches and choices related to orthopaedic surgery have become so diverse and highly specialized and consequently increased the knowledge gap between the surgeon and the anxious and vulnerable patient. The patient would also need to understand that planned secondary procedures or surgical revisions following implant failures or unforeseen complications is an unfortunate and not so uncommon occurrence in the field of orthopaedic surgery.

The above carries serious ethical and legal implications concerning the approach to obtaining informed consent and the contents thereof. First, the surgery is almost always invasive and accompanied by the insertion of some foreign element that adds a third party to the relationship between the doctor and patient viz; the implant manufacturer. The patient in this instance relies solely on the treating surgeon not to misrepresent both the implant and the implantation equipment

used for the elected surgical procedure. Also, the healing period for the adult long bones is often protracted, taking an average of 3- 24 months to complete(Webb and Hardy 1996: 813) and the rehabilitation would extend the recovery period even further which carries the burden of a prolonged poor mobility and self care. That would also often necessitate the need of some form of external economic support. All these factors call for not only competency in the surgical techniques but good communication skills and the ability to get the patient to understand his or her condition and voluntarily agree to the proposed surgical intervention and the possible consequences that may emerge (SAOJ 2008: 14-15; Strauss 2008: 10-11).

CHAPTER 1: Informed consent in Orthopaedics – a brief history

The treatment of patients has always followed a series of clinical decisions e.g. what the leading diagnosis may be, the tests indicated to rule out the other differential diagnoses or authenticate the initial judgment, and factors such as age and the general medical condition. Clinical decisions in surgery are based on the best possible diagnosis; the surgeon is the expert whose skills and knowledge are essential to a good patient outcome. To paraphrase Jones in his article: Surgeon's silence: A history of informed consent in orthopaedic practice: he says *'The interaction between the surgeon and the patient is fundamental in this process and is normally complicated by the fact that patients are given narcotics or sedatives for pain, anaesthetized for the purpose of surgery rendering them incapable of any decision-making during that time'* (Jones 2007: 115).

Other disciplines of medicine, such as internal medicine do not have the same difficulty as the patients treated here, in the main they are not faced with known periods of

incompetence. In the framework of informed consent, it is this fact of incompetence what sets the practice of surgery apart from that of general medicine.

The rapid evolution of orthopaedics as a specialty with sub-specialties using a vast array of surgical techniques, implant materials of many sorts, plus in some countries, the legality of direct patient advertising, internet information, and “organized medicine” have brought about an even more complicated surgeon-patient relationship(Dorr 2003: 11-13). With this kind of scenario, it is beyond any argument that it is in this very difficult and increasingly complicated field of orthopaedics that informed consent should be made a reality that is embraced and put into practice.

Over the past few decades, several authors have eloquently traced, analyzed and written on the evolution of informed consent (Faden et al. 1986; Mazur 1986).This debate did not unfold in a vacuum, but within a well set background of the distorted doctor – patient relationship and the disregard of the basic human rights that could not escape the scrutiny, criticism and sanctioning of a developing society. Those ensuing debates were dictated by the prevailing conditions

and they further fed into how society was to realign itself in the peoples' daily practical lives and relationships including the then strongly paternalistic one between doctors and patients. In came the four areas that became crucial in shaping the course of events and the development of informed consent viz;

1. Philosophical debates around the respect of the individual's autonomy as expressed amongst many others by yesteryear philosophers such as Kant and Mill. In relation to the doctors, this gained further expression in the historical landmark in the form of the Hippocratic Oath. The patient was hence forth recognized to have the right to choose what he or she found to be good and satisfying. In that manner, the dignity of the individual was restored, and it was never accepted again that the duty of the doctor extended beyond his or her expertise to advice and intervene as understood and accepted without duress by the patient (Kant 1964; Mill 1952).

2. The uncovered fraudulent early research activities that lacked the respect for the participants and the World

War II atrocities brought about decisions that also helped in the evolution of the informed consent. Of note, The Nuremberg Code (1947), Belmont Report (1979) and the Declaration of Helsinki (1964) assisted in laying down the foundation for the informed consent as clear ethical principles and guidelines for human research were formulated (Grodin 1992: 121-133, Belmont Report 1976-1979, Helsinki Declaration 1964 & Ellenberg 1997: 629 - 636).

3. The litigation and successful legal challenge of the beneficence-based clinical judgment as the sole determinant of treatment of 1914 (McCullough et al 1998: 17-18). This landmark judgment set in the New York Court affirmed the autonomous decision making of the individual, Mrs. Schloendorff who was surgically violated by a surgeon who took it upon himself to proceed with surgery on her against her wishes whilst under anaesthetic. It was this particular case and the equally significant subsequent ones that crafted additional pillars for a fortified informed consent when the two important legal concepts of (a) Professional standard vs. Reasonable person standard and (b)

Defining the four components of the legal doctrine of the informed consent that called for the necessity for a full risk disclosure came to the fore (Jonsen et al 1982).

4. The death of paternalism as an accepted norm and standard was seriously challenged by the principle of respect for autonomy and the stipulated transparent informed consent process. The self centeredness of the doctors was eroded as the professional privilege and authority became submerged in a manner that balanced the scales in the favour of the vulnerable patients (Veatch 1995: 5-12).

The above historical developments heralded in the era of enlightenment that was coupled with a number of bio-technological breakthroughs that assisted in modernizing the practice of surgery in general but orthopaedics in particular. That had the benefit of enhancing the general medical knowledge, exposed the intolerable and unsafe surgical procedures which further entrenched the importance of informed consent. Again, the discovery of tools such as the x-

rays imaging enhanced the capability of orthopaedic surgeons to make timely and proper diagnoses of bony pathologies which were previously not that easy (Rang 2000).

In and around 1918, a surgeon by the name of Ernest Amory Codman initiated a noble idea, the *"end result concept"* which systemically looked back at the operated patients, insisted on thorough patients' follow up visits and did clinical audits as a means of studying the surgical outcomes especially with regard to the possible risks and benefits. This became a milestone of great significance to the development of clinical medicine as it profoundly deepened the knowledge of what the patients could expect in the course of the proposed surgical interventions as the surgeons could now prognosticate the outcome based on the available scientifically audited work and experience (Jones 2007:118).

It was the beginning of the establishment of the so called standard of care and the current popular evidence based medicine which was to have a significant bearing and influence on the legal issues that I will be addressing in the next chapter.

Chapter 2: Legal Issues in Informed Consent

As a result of the historical background given in the previous chapter, a platform and reason for decent discussions prior to surgery between the surgeon and the now empowered patient was established and became the subject of interest and scrutiny.

The interest in the current medical developments and knowledge then, as well as the reasons behind decisions and the nature of agreements reached, has established new grounds for the legal disputes and judgments. That heralded in the legal framework of the informed consent as the surgeon-patient unity of will was brought into question. Here are some of the critical sequential landmark court decisions that contributed to the evolution and shaping of the informed consent concept:

1. The Duty to Inform Decision of 1767

Mr Slater (England) sued his treating orthopaedic surgeons, Mr. Baker and Mr. Staplton for deliberately refracturing his

tibia in an attempt to correct a malunion without his permission. The court ruled that there was a *"requirement to inform"* the patient of an intended treatment (Faden 1986). Interestingly there was no emphasis on the right of the patient to make a final decision on the matter affecting his treatment.

2. The Assault and Battery Decision of 1905

In the case of **Mohr V Williams** a patient who had consented for surgery on one ear only, had the opposite done as well, which was found to be a decision taken unilaterally by the surgeon whilst the patient was under anaesthesia. The court determined that the action was unlawful and constituted battery of the patient. The surgeon's duty to inform and secure the patient's consent before surgery was affirmed (Mohr v. Williams 1905).

3. The Right to Self Determination Decision of 1914

In the landmark decision on the need and value of an informed consent Judge Benjamin Cardozo in the case of

Schloendorff v. The Society of New York Hospital (1914) ruled that

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

This was a very strong reprimand for the previous practice of surgery where the unilateral decisions and actions of the surgeon were paramount and unchallenged. The key role of the patient, Mrs. Schloendorff and her autonomy was restored after having been subjected to a uterine fibroid excision that she did not consent for. The surgeon had obviously exceeded his professional mandate and authority which limited him to performing only an examination under anaesthetic and nothing more. The right thing to do or the surgeon's fiduciary role at the time of the patient's anaesthetic induced lack of capacity to determine her wish, was to consciously protect the interests and values of the patient as represented in the

discussions and agreement prior to the primary theatre procedure.

4. Knowledge and Consent Decisions of 1935, 1957 and 1972

(a) In 1935 an orthopedic surgery patient, **Mr. Fortner** was misdiagnosed to be having a distal femur sarcoma whereas he actually had a syphilitic osteitis. He was subjected to the inappropriate cancer treatment and the court itself failed to bring to the fore the question of the patient's right to autonomy on the one hand and knowledge and informed consent on the other (Faden 1986).

(b) The 1957 court ruling in the case of **Sago v. Leland Stanford Jr University Board of Trustees**, found that the right to the material information to enable the patient to make an informed consent to a risky trans-lumbar spine procedure that left him paralysed was undermined. In this case the nature and the quality of the surgeon's disclosure came under scrutiny and it laid the foundation for the interrogation of the so-called professional community or professional standard

and its adequacy in empowering the layman or ordinary patient to make an informed decision.

(c) The case of **Canterbury v. Spencer in 1972** was another important landmark in that the court rejected the professional community standard disclosure in favour of the reasonable person standard. Therefore, the information that needed to be given to the patient by the surgeon was required to suit and be understood by the reasonable patient.

These early developments in the history of the informed consent were vital to the refinement of its current form and content. It was mainly driven by the legal and ethical debates of the day and each stage corresponded with the level of such debates at the time.

The obligation on the part of the surgeon to disclose information to the patient is the first key element to the process of the informed consent. In the ancient past, the surgeon occupied a position of authority and practiced a beneficence based approach to patient care. He was expected to seek for the patient the balance of goods over harms, as those goods and harms were understood and balanced from a rigorous clinical perspective (Beauchamp

1994).The unilateral actions of the surgeon over the passive and vulnerable patient did in fact do harm to the patients in many instances (Jones 2007).

The landmark court case of Mrs. Schloendorff in 1914 assisted in defining the concept of the simple consent to surgery. The basic question that had to be answered was whether the patient agreed to surgery or not. The surgeon was still expected to act in the beneficent manner and in the best interest of the patient but with the simple consent from the patient. This case and the subsequent ones alluded to above here, went on to further define and refined the common law of the patient's rights to an informed consent.

The law has since then evolved to include the two critical questions to satisfy the requirement for the informed consent (McCullough 1998) and those are as follows:

a) Did the surgeon provide the patient with adequate information to assist in the decision making?

For the information to satisfy the requirement it has to be volunteered, tailored according to the patient's intellectual capacity as well as to demonstrate respect for his or her values, virtues, culture and interests. Furthermore, it must

empower the patient with the knowledge to make him or her to understand their condition and the proposed intervention.

The standard for ensuring effective communication of the complex medical explanation that will make an ordinary person or layman to understand fully is not that of the professional standard but that of the standard reasonable person or patient. This should be in the non-technical language and which will give the patient more than what he or she already knows and with the relevant comprehensible material information.

b) Did the patient consent to the surgical intervention?

The patient's preference is what should prevail at the end unless there are ethically compelling reasons against that like if an irrational decision is taken which does not match that of a standard reasonable patient or person. The patient possesses the sole right and authority to decide over what should happen to his or her body. After receiving the appropriate information and explained to, the patient may make a determination that he or she would not benefit from

the proposed procedure and decline in line with exercising his or her rightful and autonomous authority.

The South African Law and Statutory Regulations

The Constitution of the Republic of South Africa (RSA Constitution 1996) is the supreme law of the land and any law or conduct inconsistent with it is invalid, and the obligations imposed by it must be fulfilled. Our constitution is based on the Bill of Rights which is contained in Chapter 2 of the same Constitution and it is considered to be one of the most modern and enviable in the world because of its progressive nature and content. It is from this constitution that we derive the culture of respect for the dignity, interests, virtues and values of the individual.

The right to information and that of choice by the individual are strongly embedded in it and so is the right to a proper informed consent. It is in Section 12(2) of the Constitution that we find stated the following:

Everyone has the right to bodily and psychological integrity, which includes the right to make decisions regarding

reproduction, to security and control over his or her body and not to be subjected to medical or scientific experiments without his or her consent.

This important national and legal document, seeks to empower and give the individual the effective authority to rule over oneself. It is the supreme law of the country that embodies the values of respect for the individual and his or her autonomy and furthermore acts as a shield and protection for the possible violations that may occur.

The National Health Act

The National Health Act 61 of 2003 does have a prescription on the concept of informed consent as gazetted on the 23rd July 2003 under Chapter 2, Sections 6-9 and can be summarized as follows:

The user of the health facility is entitled to a disclosure of his or her health status unless if his or her interests are going to be jeopardized.

The user is to be informed of the range of the investigative diagnostic procedures and the proposed treatment interventions.

Information on the benefits, risks, costs and consequences associated with the different options must be voluntarily discussed with the patient.

The right to refuse health services and the implications, risks and obligations thereof must be explained to the patient.

Patients are to be addressed in their own languages and their level of literacy and understanding is to be taken into account.

One cannot treat a patient without an informed consent unless ordered to do so by the Court of Law in certain special circumstances for which the interest of the patient would reign supreme.

The above is a clear enhancement of the respect of the right of the individual, his or her values and the interests as contained in the Constitution. This means that any deviation from what is stipulated by the law on the aspect of autonomy and informed consent may be punishable in a Court of Law.

The South African Law is quite particular about guaranteeing the right to an informed consent and prescribes the minimum requirements in order to satisfy its conditions. It places the onus squarely upon the surgeon to adequately inform the

patient about all the material risks of the proposed surgical intervention in a manner that a reasonable patient would be able to fully appreciate and understand and feel equipped to exercise his or her authority in the decision making. The surgeon is thus expected to make a full disclosure of both the benefits and risks that the patient will attach enough significance to and carefully weigh. Therefore, the informed consent will make a strong legal impression if it is found to be comprehensive enough attesting that the patient was well informed, had enough knowledge and appreciation of the potential risks carried by the procedure and finally exercised his or her authority to give the go ahead for the procedure to be performed.

The courts and our law are often relied upon in the adjudication of the difficult situations where the surgeon may have exceeded the professional mandate or the patient's best interest is denied or is under threat and needing protection or circumstances where legal authority for the substitute consent is needed amongst others.

The Health Professions Council of South Africa (HPCSA)

The HPCSA, which is the statutory body for the Health Professionals, in its ethical guidelines booklet 10 (HPCSA 2007), seeks to guide and direct the health care practitioners on the principles of good clinical practice during the informed consent process. This is an important comprehensive document that refers to the South African Constitution, the National Health Act, various statutes and the common law.

Orthopaedic surgeons have much to draw from this document as it clearly sets out the standard of competence, care and conduct with regard to the informed consent process and its requirements. Both the legal and ethical considerations are stipulated in a fairly comprehensive and balanced manner. The following are what I consider to be the most relevant areas for the orthopaedic surgeon to note:

1. **Providing sufficient information** with regard to the patient's health status, the proposed intervention, uncertainties of the diagnosis and treatment, subsidiary treatments, the procedures' risks and benefits as well as the consequences thereof (Sect.3.1, pgs.1-3, Sect. 3.4, pg.4 & Sect.6, pg.6).

2. The ethical and legal obligations for the surgeon with regard to the **disclosure of the material risks and benefits** to assist in the assertion of the patient's autonomy (Sect.3.1, pg.2 & Sect.3.3, pg.4).

3. The **effective communication** of the needed information and the deepening of the patients' understanding (Sect.2.3, pg.1, Subsects.3.1.4 & 3.1.6, pg.3, Sect 3.2, pg.3 & Sect.3.4, pg.4).

4. The **legal definition of the informed consent** and as to who is supposed or allowed to obtain the consent (Sects.4&5, pg.5).

5. Ensuring the **patient's voluntary decision making** through giving a balanced view of the surgical options and the declaration of the possible conflict of interest (Sect.7, pg.6).

6. The approach to the **emergency** surgical intervention (Sect.8, pgs.6-7).

7. The **competency** of giving an informed consent, the surrogate or substitute consent and the handling of the children's consent (Sect.9, pgs.7-9).

8. The **“Best Interest” Principle** and the intervention of the Court of Law (Sect.10, pg.9).

9. The **Express and Implied consent** and the importance and circumstances of reviewing the informed consent are explained (Sects.13, 15&16, pgs.10&11).

In the following Chapter I will further define the informed consent and its components in relation to the ethical arguments that make up its foundation.

Chapter 3: Ethics and Informed Consent

An informed consent is an essential part of the autonomous decision making process of the surgical patient. It involves the documentation of a dynamic decision making process and its conclusion which is made up of the two pillars, the ethical and the legal process (McCullough 1998: 15-37; Jones et al 2007: 903-918). Moreover, it is perceived as a morally essential course of action to form a strong therapeutic alliance between the surgeon and the patient for the purposes of sharing responsibility in the decision making.

This is crucial in that during the intra-operative, anaesthetic and passive participatory phase of the relationship, the patient will be relying on the operating orthopaedic surgeon to represent his or her interests as agreed to in the informed consent. This is a mutual decision making process with both the patient and the surgeon playing an active role. The surgeon exercises a fiduciary duty in the beneficence manner by sharing the clinical knowledge with the patient and respecting the patient's autonomy and human rights. Ultimately, the patient decides on what is right for herself or himself. The informed consent process goes along with the

Kantian philosophy which places emphasis on the respect for the persons and embarking on the good actions for the good results (Rachel 2007: 130-140). According to the ethical debates and scholars in the field of ethics, there are three key elements to the informed consent process which are as follows:

a) The disclosure of the information by the surgeon

For the patient to be able to make sense of his or her problem and make a final decision on what is to happen, he or she has to be empowered with the information from the treating orthopaedic surgeon. After going through the history taking , clinical examination and performing whatever tests are necessary, the patient has to be told in the ordinary layman's language as to what the diagnosis is and the implications thereof as far as the natural progression of the illness is concerned. The information provided must appreciate the patient's background, values and culture and distressing disclosures must be handled with the sensitivity they deserve (Haslam 2004: 13-16).

In other words, what the patient is told must be tailored to the individual's intellectual and emotional status. The surgeon will

have to disclose what the suggested treatment plan is and the other available alternatives including the conservative forms of treatment. The risks and benefits of the proposed surgical intervention must be discussed without any exaggeration or bias of either the recommended option or the alternatives.

Any uncertainties concerning the knowledge, outcomes or available expertise need to be declared so that the patient can fully appreciate the problem at hand and if there would be a benefit from a second opinion expert the patient must be referred appropriately.

b) The patient's comprehension of the disclosed information and implications

The patient should have the ability to receive the new information given, absorb and retain it for him or her to arrive at an independent decision. The law makes an emphasis on the important role the surgeon must play in the informed consent process, whereas ethics clearly defines the roles for both surgeon and patient. The patient must be able to grasp, digest the information and make sense out of it and have the opportunity to ask relevant questions. It is at this level when it becomes the duty of the surgeon to assist in filling up any

knowledge gaps and correcting the misconceptions and errors that may be made in the process. The surgeon has an obligation to assist the patient through this process without being coercive or else it will go against one's fiduciary duty to guide or advise the patient.

An evaluation of the surgeon's information and its depth is made as well as the extent to which the patient has been able to understand the salient points thereof. The pros and the cons in relation to the natural disease progression and the risks and benefits are evaluated and weighed accordingly as well as all the discomfort, pain and physical limitations that follow surgery. It is obvious that only an informed and competent patient who is also being guided by the surgeon and those close to him or her that will come to a rational conclusion.

Interactions of this nature will reinforce the rapport and therapeutic alliance between the patient and the surgeon and help build trust as well as the confidence. Following all of these points, the patient is the final decision maker and the person with the final authority to give the go ahead for the surgical intervention.

c) The decision making

This is an important step where the patient has to exercise the autonomy to determine what should happen with his or her own body based on the information that is disclosed. As much as the surgeon is an authority in the field, only the patient has the authority to make a final decision and hence need to appreciate the consequences thereof. The patient needs to have a cognitive understanding by being able to make an analysis of his or her situation before and after surgery and the effects or changes that will occur around his or her life and work out on the coping strategies.

Through the evaluative understanding the patient must look into the proposed surgical intervention and evaluate it against the other possible options and also his or her own values and interests (Faden 1986).

At the end of the above, the patient should be able to take a responsibility and sign an informed consent document that states that his or her condition has been explained to him or her and that the nature of the surgical procedure is well understood as far as its goals and expected outcomes (Jones 2007: 907-911).

There are other important aspects of the informed consent that are worth mentioning that do feature extensively in the legal, philosophical and medical literature which are:

Voluntariness: This aspect refers to the necessary autonomous decision making process that is devoid of interference in terms of coercion or being frightened in favour of one intervention against the other. If need be the patient must be allowed to take time to go and consult with the close friends or relatives and be encouraged to seek a second opinion when necessary. The patient need to work through all this at his or her own pace and of course be appropriately advised if there is a sense of urgency that he or she needs to be aware of such as in the case of a malignant tumour.

Competence or decision making capacity: The patient has to be competent in order to successfully go through an informed consent process. Every adult patient must be presumed to have the decision making capacity until proven otherwise. The competence will vary according to the complexity of the decision to be made (Haslam 2004: 16; HPCSA 2007: 7, 8).

The competence can be affected by the legal age of consent, psychiatric illness, head injury, drug or alcohol intoxication or the administration of either narcotics or sedatives. The patient lacking the necessary decision making capacity may have the substitute or surrogate consent given through a relative or a nominated person who would have to put himself or herself in the position of the affected person and be able to represent his or her interests in the manner consistent with his or her values and aspirations. The curator may be authorized to consent or in some instances the “Living will” will give a necessary directive (HPCSA 2007: 7).

The “Best Interest Principle”: This is applied to those patients who lack the decision making capacity and looks at the reasonable options for the individual against the following criteria as advised by the Health Professions Council of South Africa:

- The presence and suitability of the clinically indicated options.
- Identify if the patient is in possession of a “Living Will” with the specified directives.

- Assess the interests, values and priorities that the patient's acquaintances might know about the patient.

- The patient's preferences as told by the relatives or friends.

- The choice must not compromise future options for the patient.

With reference to children, the South African Constitution in Section 28(2) states that "A child's best interests are of paramount importance in every matter concerning the child".

Hence both the parents and doctors are expected at all times to act in the best interests of the child when a decision needs to be taken on the surgical or medical intervention. If this principle is found to be undermined, the courts can be approached for a resolution in favour of the right of the child.

Types of consent

When a patient has given either a verbal or written consent it is considered to be an "Express Consent" as opposed to what is called an "Implied Consent" which refers to assumption of agreement based on the patient's positive actions. (Wenger

2000: 79, 80; Haslam 2004: 13-14; Ellenberg 1997: 632; HPCSA 2007: 10-11).

The latter is not always the case and hence one has to be careful and ask for permission for every new step throughout the process.

The Health Professions' Council of South Africa, which is aimed at protecting the patients and guiding the health professionals, is well placed and it is within its mandate to set out the ethical and legal guidelines in order to harmonize the doctor – patient relationships. The core of its guidelines revolves around the critical issues of the entrenchment of the patient's autonomy and insistence on the part of the health care workers to think and act ethically as they execute their beneficence duties and mandate.

Chapter 4: Awareness, Knowledge and Teaching of the Informed Consent Process in Orthopaedic Surgery

There is a great concern amongst the various authors surveyed about the lack of understanding of the informed consent process amongst the orthopaedic surgeons as indicated by the following:

In a survey conducted by Wenger et al (1998: 198-205) to evaluate the knowledge of ethical issues among a group of 102 orthopaedic surgeons and to assess the ability of handling ethical dilemmas, it was found that there was a significantly poor understanding and knowledge regarding the skills of obtaining the informed consent despite the fact that it was being practiced on a daily basis.

The authors identified the knowledge gaps as far as certain important ethical questions which they attribute to the possible lack of teaching in those areas as they also do acknowledge that in the overall since the introduction of Ethics as a subject at some of the medical schools that were included in their study the moral reasoning has since then remarkably improved.

The actual clinical skills around the informed consent process had however not been properly taught to the trainees. They further point out that doctors need to acquaint themselves with the law and avoid misinterpreting it as that may bring them into conflict with the expected ethical conduct. On the other hand the proper ethical analysis and resolutions are often on the correct side of the law. In this study almost half of the respondents failed to apply the informed consent properly which indicates that the simple awareness is not good enough if the process is not fully applied. The failure to practice the proper application of the process is likely to result in an illegal or fraudulent document.

McCullough et al (1998: 15) also point out at the lack of formal teaching of the necessary clinical skills that the orthopaedic surgeons need during their critical formative training years. They also lament the lack of supervision of the junior staff members who are often mandated to obtain the consent for surgery. This poor attention to the informed consent dialogue is not scrunitised for the areas of weakness or where improvements are necessary. As a lot of the clinical skills are learnt in the field of practice, the lack of proper supervision and coaching in this area will in turn lead to poor

delivery and improper practices. The supervisors themselves are found to be non-compliant as they fail to make the necessary follow-ups, reviews or corrective measures. The consequence of this is that the patient's autonomy is undermined and it also weakens the necessary therapeutic alliance which is supposed to benefit both the surgeon and the patient.

Clearly, in the absence of a proper shared decision- making process, there would be a lack of the vital emotional and intellectual preparation and readiness on the part of the patient who would be subjected to an uncertain, psychologically and physically traumatizing experience.

The study conducted by Braddock et al., (2008: 1830-1838) aimed at exploring the quality of the informed decision making in the orthopaedic surgical practice. Here, the authors observed that the informed consent process was being promoted in several fields of medicine but that little was known about the actual practice in orthopaedic surgery as no guidelines existed in this field. In essence, this study was looking at the most effective and time efficient orthopaedic surgery specific strategies or guidelines that would effectively

communicate the material information needed by patients aimed at encouraging their full participation in the consenting process. This was with the hope to emerge both ethically and legally compliant and the patients being able to make a proper informed consent with the necessary authority. What the authors seem to have achieved here is to put forth their case that the time constraints should not be seen as an impediment for obtaining a good quality informed consent but instead advocated for the improved communication methods to advance the desired ideal.

The patients used in their study were elective surgery patients and they established a practice of deliberately slowing down the decision making process and saw the patients on numerous occasions prior to the anticipated surgical procedures until they came to terms with their own decisions.

Singh and Mayahi (2004: 339-341) reported on a study carried out amongst orthopaedic consultants in the United Kingdom to establish the level of adherence to their Health Department's informed consent guidelines. They found that out of the 110 cases looked into, 53 patients' consents were obtained by the most junior staff members with the serious

omissions relating to some of the specific complications and the surgery related risks. This goes to show that delegation of duty does not mean a total abdication as that kind of transfer of responsibility can be viewed as a virtual negligence of duty on the part of the involved senior surgeons.

In addition to the studies cited above, there is an interesting study that explored the so called closed claims analysis applied to complex legal issues of which in this instance the focus was on the orthopaedic malpractice claims of two insurance companies reported by Bhattacharyya et al (2005: 2395-2400). The primary aim was to isolate those factors related with the successful litigation or successful legal defense in the 28 cases of the claim of an inadequate informed consent spanning over 24 years. This study was done in the backdrop of an acknowledgement that the orthopaedic surgeons do routinely obtain an informed consent albeit there was a lack of information to guide them in the effective methods of obtaining a legally and ethically sound patient authorization.

The conclusion of this study and the lessons to draw from it was that the surgeon himself or herself must routinely obtain

an informed consent in the rooms, document the process in the patient's clinical notes file and in the operative notes. The documentation of the clinical findings, the final diagnosis and the agreement with the patient is certainly one very good form for future reference and a defense that every surgeon has to uphold. A case in point here was the dramatic decrease in the indemnity risk when the principle was routinely adhered to.

To my knowledge, there is no published local South African study on the informed consent practices involving the field of orthopaedic surgery. The local experience and practices would predictably be a mirror image reflection of the researched findings from the other parts of the world. The following are my own personal observations:

a) The formal teaching of Ethics and the practical guidelines on obtaining an informed consent at the clinical departmental level is lacking.

b) The job of obtaining the consent is often relegated to the most junior staff member, the Intern or the nursing sister and with no direct supervision by the involved surgeon.

c) I am not aware of a routine conscious review of the signed consent by the surgeon who finally performs the surgery.

d) The final document itself is not comprehensive enough and hence does not conform to what is supposed to be the acceptable ethical and legal standard.

Having noted the above, I would however also point out to the heavy patients load that is a norm in our public hospitals and the shortage of staff that often limit not only the access of patients to the most senior staff members for the clinical assessment but also to the quality discussions prior to surgery for the purposes of reaching sound and better informed decisions. However, the routine ward rounds and patients intake meetings are useful discussion platforms that expose each and very member of staff equally. That does serve to empower them with the fair amount of knowledge and skill to be able to convey a reasonably good and informative message to the consenting patient.

This is often done around the patient who may be overwhelmed by the highly technical language often used in the discussions. At the conclusion of the deliberations

normally the patient would be given a quick and concise briefing and requested to sign a surgical consent form. This seems to concur with the concerns and experiences from the other parts of the world that are even better resourced than we are (Craven 2003: 51-52).

There is certainly a need to focus on the informed consent as it occupies the centre of the relationship between the surgeon and the patient and presents the interesting ethical and legal challenges that impact equally on both. The increased awareness amongst orthopaedic surgeons will be in line with the needed response to the raised concerns and may lead to the establishment of the operational guidelines and compliance with our Constitution, Health Act and the Health Professions Council of South Africa's regulations.

It is with the above background that I wish to next dwell into the specifics relating to the orthopaedic surgery field in particular with the aim of helping to define and refine the pertinent aspects and processes that I believe to be essential to the proper implementation of the legal and ethical informed consent process.

Chapter 5: The Informed Consent Process in Orthopaedic Surgical Practice

All the surgical specialities do definitely need to practice a proper informed consent process in order to adhere to the principle of ensuring that our patients remain firmly in authority in the exercise of their autonomy. In that way we, as doctors or surgeons will be giving recognition and value to their basic human rights (McCullough et al.1998: 4).

Orthopaedic surgery is not only a rapidly developing discipline, but it is also extremely busy and technically highly demanding. The almost routine usage of the metal fixatives / prostheses brings to the fore the ethical concerns of the possible experimentation with humans especially in the absence of credible long term research or outcome studies to give us the guarantees of no future complications (Holt et al 2006: 226 – 229).

The surgeon's level of honesty and areas of potential conflicts of interest raise the moral and ethical concerns that must be explicitly addressed in the informed consent process. These discussions are mainly about the metals that are implanted

into the active human bodies, the expected wear and tear that would as expected ultimately result in even longer revision surgery or removals in the future. For that reason, the informed consent must be appropriately adjusted to include the future that could be either predictable or otherwise as based on the available historical outcomes of each particular implant that the patient must be made aware of.

As the return to normal life may be long and frustrating following orthopaedic surgical procedures, proper pre-emptive counseling is always necessary so that the expectation should match the real outcome. The orthopaedic related complications can be a disaster best avoided in the first place but a warning given to the patient prior to surgery is equally important. It satisfies the obligation to disclose and allow the patient the right to form his or her own opinion and make a decision with all the available facts at hand. Of all the complications, major examples viz; post-operative bone sepsis, poor bone union, bleeding, deep vein thrombosis and iatrogenic neurological or vascular damage deserve a special mention (Singh and Mayahi 2004: 339; Easley 2005: 77-81).

The other much more serious problem scenarios that carry dire medico-legal implications to make an even stronger case for a properly obtained informed consent in orthopaedic surgery relate to the following:

Wrong level, site or side surgery which emphasizes the importance of cross checking or review of the informed consent on a routine basis by the surgeon, scrub sister, anaesthetist and assistant surgeon or other members of the operating team. This does happen in the foot and ankle surgery, knee arthroscopic surgery, multilevel spine surgery or any other situation where the limbs or digits can be easily mixed up unless clearly marked pre-operatively (HPCSA 2007: 7 & Easley 2005: 77-78).

Wrong limb amputation represents one of the most serious negligence malpractice case scenarios which could be avoided if the proper informed consent practices are adhered to.

Post spinal surgery paralysis and the so called failed back syndrome.

The function versus the expected cosmetic outcome*:* Pre-operative patient education is needed to correct any unrealistic expectations (Lindseth 2000: 61 – 65).

The routine usage of the following standard equipments in the practice of orthopaedic surgery, predispose patients to the specific complications that are not seen with the other surgical disciplines:

The ***tourniquet*** used for the creation of the bloodless field if incorrectly inflated or timed can result in the loss of a limb arising from either the skin, neurological or vascular damage (Easley 2005: 80; MPS Casebook 1 2005: 16).

The ***traction tables*** used for the manipulation and reduction of the fractured long bones exert point pressures resulting in complications such as the perennial ischaemic necrosis or pudendal nerve palsy and male impotence.

The ***intra-operative multiple x-rays irradiation*** of patients is seldom mentioned in our informed consent records as a potential harm.

The potential for ***thermal burns*** or tissue necrosis resulting from the diathermy, detergents, bone cement and drilling or sawing procedures must be borne in mind.

The orthopaedic theatre team is very often comparatively expanded in that in addition to the surgeon, assistants, anaesthesiologists and the nursing staff you may have the radiographer for operating the C-arm x-ray machine as well as the company implants technician or representative who are seldom declared to the patient pre-operatively. For common decency, the protection and respect for the patient, it should be a standard practice to inform the patient prior to surgery that there will be additional people unknown to him or her present during the surgical procedure.

What I have done here is to demonstrate that for the orthopaedic surgeon, in his or her quest of fulfilling the beneficence duty and the promise to care and mend there are numerous important orthopaedic specific omissions that are often taken for granted and in the process undermining the patient's right to a proper informed consent. It is indeed those areas that weaken the legal and ethical standing of our orthopaedic standard of care practice that need to be

highlighted and corrected to suit the correct and embedded informed consent process.

The typical orthopaedic patient would present with pain, deformity and a loss of function or some form of disability. This may be as a result of an acute emergency or non-emergent trauma or a chronically established musculoskeletal condition. In exercising his or her beneficence role, the orthopaedic surgeon would conduct a meticulous problem searching interview with the patient and perform a clinical examination to arrive at some decision and then embark on the appropriate line of investigations, which may include x-rays, other forms of imaging and laboratory tests.

The interpretation of all these, will then culminate in a clinical judgment or a diagnosis which would normally include the proposed form of intervention according to the available standard of care treatment, it is not the surgeon's right to decided on what should finally happen but that of the patient based on the material information disclosed to him or her which would normally outline the preferred treatment option as well as the other alternatives and the expected outcomes or the associated risks and benefits. The patient is in a

position of authority to decide on what is to happen to his or her own body and the surgeon is simply an authority on the subject at hand, the particular orthopaedic ailment and its prescribed remedies (McCullough et al. 2005: 4-5).

From the outset the patient and the surgeon enter into a relationship based on the unspoken assumptions and implicit promises (Marshall and Smith 1998: 40). In presenting his or her problem to the surgeon, the patient's personal and private matters are shared and presumed to be held in confidence. The patient's disclosure is vital to assist the surgeon to perform his or her role which is essentially to come up with a diagnosis and proposed treatment plan. The surgeon has the ethical duty to maintain the confidentiality at all times and this earns him or her respect, confidence and trust from the patient that is important for the therapeutic alliance and compliance.

To attain a suitable agreement on the way forward, a shared decision making process gets underway with each party playing its own role either legal or ethical or both. Whilst the law places an emphasis and certain demands on the role of the treating surgeon, the ethics demands a balanced

approach with each party playing a significant role. The orthopaedic surgeon is called upon to act in a beneficent manner with the honesty that respects the ethical and legal elements of the process in assessing the patient and arriving at a diagnosis that should eventually help the patient.

Furthermore, he or she must use a reasonable man or patient standard to voluntarily disclose the information that will explain the clinical judgment in a clearly understandable manner and outline the envisaged orthopaedic surgical intervention. The exact nature of the surgery that will be done on the bone or joint, the metal implant fixatives or prosthesis has to be clearly explained to the patient. The same would go for the expected effect on the body, durability of the implant and the return to normal function. As to whether any secondary surgery would be indicated and as to how soon that will be, are some of the questions that the orthopaedic surgeon will have to address openly with the patient.

The message must be conveyed in a manner that will empower the patient to meaningfully participate in the decision making process. The material risks, specific complications and all that the treatment plan entails as well as

the post-operative outcome have to be declared so that the patient can have a clear picture as to whether to decline or accept the proposed orthopaedic surgical intervention. The prognosis and the available alternative remedies or expertise must be shared with the patient who is supposed to be in authority as far as making a final decision over his or her own life.

The patient's cognitive and evaluative understanding of the disclosed information and overall situation is crucial for the right decision to be reached. Effectively employing the simple non-technical language as well as the orthopaedic anatomical models, brochures, audiovisual material and samples of orthopaedic implants, a clear message can be driven home to assist in formulating a better simulation of what is being proposed (Easley 2005: 78; Haslam 2004: 14).

If the support splints or walking aids are to be used post-operatively, they have to be explained and demonstrated to the patient before the anticipated surgery and furthermore the expected duration of usage must be disclosed. The patient must be encouraged to freely pose questions and concerns because it is out of that, that the unrealistic expectations ,

misconceptions and errors of judgment can be revealed early for them to be corrected.

It is the duty of the surgeon to honestly guide but not coerce the patient towards a decision that will benefit him or her. The patient's values, virtues and interests remain paramount and should enjoy respect at all times.

The aim is not to quickly clone an orthopaedic surgeon but to provide a reasonable and sufficient base for the well informed rational decision making by the patient. It remains the duty of the orthopaedic surgeon to repeatedly continue identifying the knowledge gaps and educating the patient around his or her condition for the benefit and success of the informed consent process.

The elective surgery provides a good opportunity to spend more time with the patient or see him or her repeatedly which will give the patient even more opportunity to think over the surgeon's proposal, to be able to ask further questions in order to allow him or her to consent or decline the surgical intervention. When there is a sense of urgency and a need for a speedy consent as in an emergency situation, for the purposes of either saving life or a limb, the patient must be

made explicitly aware of such in order to elicit an appropriately timed response (DiGiovanni et al 2000: 613-624).

In the report by Coughlin and Shurnas (2003: 904-908), they found that regardless of the level of education, the patients in the overall tended to fail in recalling what was disclosed to them by the surgeon. The following are some of the objective signs for assessing the depth of understanding by the patient:

1. *A patient who is well orientated and able to relate his or her signs and symptoms to the surgeon's clinical judgment and proposed surgical intervention.*

2. *The patient who actively participates in the discussion and posing relevant questions that are goal orientated with the eagerness to reach a decision.*

3. *The patient correctly echoes what he or she has been told without even being prompted and has no problem in recalling the essential elements of the discussion.*

4. *In the case of an emergency the patient responds appropriately with a sense of the required urgency.*

5. *The ability to correctly brief his or her relatives or associates on the situation is an indicator that the patient has a firm grasp of the process and its contents.*

Once a common ground has been reached as far as the understanding of the clinical orthopaedic judgment, the proposed surgical intervention and risks, benefits and consequences it carries and the alternatives have been disposed of, then the patient is allowed to decided whether the procedure can proceed or not. It has to be understood from both sided that this final decision rests exclusively with the well informed patient who holds the right to autonomy that has to be respected at all times.

An honest, patient-centered informed consent process begets a strong rapport, mutual trust and therapeutic alliance that will enhance the post-operative compliance and successful rehabilitation programme.

What emerges from this exercise is that an informed consent is not a simple event that requires only a stroke of a pen but a carefully negotiated process that begins at the orthopaedic surgeon’s consultation rooms, out-patients department,

emergency casualty department or from whatever point of first contact (Fleeter 2010: 1-3; Haslam 2004:14). Hence it is an evolving process that must be well documented to meet its standards as both a legal and ethical document. It represents an agreement based on a legitimate and shared decision making process of which both the surgeon and the patient or their representatives can always refer back to.

As much as the actual informed consent form has its own identifiable format, every record of interaction between the patient and the surgeon can be regarded as its acceptable addendum. This asserts the importance of keeping the proper clinical documents, namely, the clinical notes from the consultation rooms or out-patient department, the well written theatre notes as well as a well crafted and signed consent form itself. The latter, is considered to be a valuable clinical tool for both the patient and the orthopaedic surgeon and for it to make sense it should compose of the following (Haslam 2004: 14, Bhattacharyya 2005: 2395-2400, HPCSA 2007: 10; Jones 2007: 908):

- The identity of both the patient and the operating surgeon.

- The diagnosis.
- The proposed procedure, anticipated length of time and the fact that it has been explained to the patient by the surgeon.
- The benefits and risks clearly stated that they have been explained to the patient by the surgeon.
- The expectations.
- It must be signed by both the surgeon and consenting patient.
- It must be dated and witnessed.

The informed consent is not a document to be rushed unless in an extreme emergency situation.

According to Bhattacharyya (2005: 2399 – 2400) the following would be the ideal environment for completing an informed consent:

- A relaxed non-threatening environment like in the doctor's rooms or ward or out-patient department.
- Where questions can be freely asked.

- Where the patient can always come back for further explanations.

- Where the patient can be able to think it over and be at liberty to change his or her mind if necessary.

- Where confidentiality can be maintained such as behind closed doors, the curtains or screen.

Obtaining consent for surgery in the hospital corridor, at the receiving bay or inside the operating theatre is not correct and should be discouraged. It appears like an ambush and is threatening or coercive and further undermines the patient respect and autonomy.

It is preferable that either the operating surgeon or member of the surgical team who has been part of the patient's pre-operative preparations, who is also knowledgeable and skilled be the one that obtains the informed consent. The delegation of this very important process to the other most junior members of staff who are short of those criteria is inappropriate as they will not be able to address the patient's concerns and ask or answer the pertinent questions which will

in turn make the patient lose confidence and trust in the system or the operating team. It is at this stage that the surgeon must inform the patient about the composition of the operating team, the role of the different members and their level of participation in the surgery and what the overall intra-operative plan will entail (Bhattacharyya 2005: 2399, HPCSA 2007: 5; Singh and Mayahi 2004: 340; Kocher 2002: 148 - 150).

Concluding Remarks

In the past few chapters I have tried to capture the issues around the informed consent process and further attempted to narrow it to the aspects pertaining to the discipline of orthopaedic surgery in particular with the aim of making a strong case for bolstering the efforts of ensuring that the process of informed consent become embedded within this vastly developing field of surgery.

In chapter 1 I have looked at the history of the informed consent and came to a conclusion that the balance of forces regarding the doctor – patient relationship has over the years evolved and turned around as society was in the process of shaping itself into a rights centered home for the individual that slowly gained human rights and the highly cherished autonomy. I was able to clearly demonstrate through the evidence of the researched Ethics, Philosophy and Legal material used that it has involved a battle of ideas in contention to sway history in a certain direction. From a balanced look of things it appears as if the result show a *triumph of humanity over darkness* of the past.

In chapter 2 I focused on the legal issues where I traced the trail of land mark court cases decisions that progressively and successfully affirmed the fundamental question of the right for the consenting and competent adult person to determine his or her own destiny. The right to know and to be informed or empowered with the material information that would allow one to take informed decisions over one's own health and well being has been made law that protects the individual and his or her autonomy.

I further related this vital development within the South African Law, National Health Act and the Health Professions Council of South Africa that seeks to uphold the highest ethical and legal standards within the health profession as a whole. With regard to the respect of the individuals and their autonomy, the treatment of people in a manner that would bring them to the level of understanding health issues affecting them, a standard information of what to tell has been determined and that is that of a reasonable person.

Chapter 3 took us through the ethical issues involving amongst others, the disclosure of information by the surgeon, comprehension thereof, decision making and competence of the individual all of which form the important areas around the consent process. It needs to be restated here that the surgeon has a duty to conduct him or herself ethically and legally when interacting with the patients by ensuring that the patient is constructively engaged in the informed consent process without being paternalistic.

In Chapter 4 and 5 I have looked into the level of awareness and practices concerning the informed consent process and was able to prove that a lot leaves much to be desired in terms of our local and some of the international bad practices. Most of the reviewed literature expresses the views and the concerns that the teaching and the practice of the informed consent process within the orthopaedic surgery discipline is deficient (Wenger 2000, Jones 2007: 903 and Braddock 2008: 1830).

There is a general consensus that an informed consent is a fundamental, legal and ethical requirement in the practice of orthopaedic surgery, be it in the area of emergency trauma, elective surgery or related research. Its ethical basis is derived from the bioethical key principle of the respect of the patient's right to autonomy, virtues and values as well as the overall interest that accords one the human dignity. This has in essence matured from the earlier utilitarian approach to the treatment of patients when the paternalistic surgeon's fiduciary role prevailed with a supreme authority at the expense of their feelings and interests.

The ethical approach to the informed consent clearly defined the participatory roles for both the surgeon and the patient whereas the legal approach places the emphasis on the surgeon. Informed consent has become a standard legal testimony describing the information disclosed to the patient that is aimed at empowering him or her in the decision making process. It is a binding document born out of the shared responsibility and again reflects the agreement

between the patient and the surgeon before the procedure is embarked upon.

It is therefore quite important that the information given to the patient is clear and comprehensible. Of utmost importance is that it must be viewed and practiced as a complete patient information disclosure process that is educative and empowering instead of a simple document signing event.

It is imperative that orthopaedic surgery as a fast developing and innovative discipline embraces the correct informed consent principles and practices and strive to raise the level of awareness amongst its trainees and practicing surgeons. Adopting such good practices with the prescribed ethical and legal framework, it will significantly improve our surgical standard of care, quality of research and be of immense benefit to our patients.

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