Implications of adopting the principle of Informed Consent in Sri Lankan Medical Malpractice law: A critical analysis in light of *Montgomery v. Lanarkshire Health Board* (2015) UKSC 11

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Abstract - *In Sri Lanka the law on medical negligence persists against the backdrop of a culture where the medical profession is one of the most noble and revered of all vocations. A doctor's opinion is always respected and rarely challenged in Sri Lankan society. Its views with regard to healthcare are an embodiment of the phrase "Doctor knows best". However, in recent times there has been a paradigm shift in the doctor-patient relationship due to increased concern for patient rights and especially one's right to self-determination. The objective of this research, is to address this change in social attitude through proposed legal reforms and changes in judicial approach in the area of informed consent. The principle of informed consent has opened new horizons in the protection of patient autonomy, where failure to disclose vital medical information becomes actionable under the law of Delict/Tort. However, due to a paucity in case law, the position of Sri Lankan courts is unclear with regard to the required standard of disclosure to obtain informed consent i.e. whether the mere signing of a consent form is enough to constitute 'informed' consent. This paper proposes expansion of the principle of Informed Consent, in light of the principles set out in the UK Supreme Court's recent landmark judgment; Montgomery v. Lanarkshire Health Board. The study shows through a critical analysis of this case and the socio-legal context of Sri Lanka, how expanding the current law on informed consent will protect patient autonomy and afford an alternative course of legal action, for those who cannot satisfy the traditional 'but for' test or overcome the rigors of the fault based approach, while raising the standard of healthcare and the medical practice which is allegedly in steep decline.*

***Keywords*- Medical Negligence, Informed Consent, *Montgomery v. Lanarkshire Health Board* UKSC (2015) 11**

I. INTRODUCTION

The protection of human rights is considered an issue of paramount importance, gaining increased recognition in every civilized society of the modern world. The Law on Medical Negligence developed as a branch of Tort/Delict with the aim of protecting patient rights which has received special attention ever since healthcare was systemized. Medical negligence or malpractice is defined as "the breach of duty of care towards a patient by an act of commission or omission, resulting in damage or harm or injury to the patient" (Fernando.R, 2013). In order to be successful in such a claim, a plaintiff in Sri Lanka is required to satisfy the 4 elements of the Aquilian action under Roman Dutch Law. In this, Sri Lankan courts adopt a fault based approach where the onus of establishing negligence is on the plaintiff. The plaintiff is also required to establish a direct causal nexus between the defendants act or omission and the final harm. The Supreme Court ruling in *Priyani Soyza v. Arsekularathna* (2001) 2 Sri.LR 293 was subject to heavy criticism by legal scholars since the application of the 'but-for' test for causation made it almost impossible for terminally ill patients to claim damages even where negligence was established. The principle of informed consent provides a ray of hope for such claimants who suffer at the hands of the fault based system and the traditional 'but-for' test. This test requires proof that the doctor failed to disclose all relevant facts and as a consequence the patient was unable to refuse the harmful treatment or opt for an alternative one. In such an instance, the doctor can be held liable even if he performed the treatment with due diligence. The principle is demonstrative of the paradigm shift from the previous doctor centric approach to a more patient rights oriented approach where the violation of a patient's right to self-determination becomes the determining factor in establishing culpability.

As a welfare state, Sri Lanka offers free healthcare services to its citizens. Despite free healthcare in government hospitals, there has been a vast development in the private sector and most middle or upper class citizens resort to paid private healthcare. Especially in urban areas, private clinics and channeling centers receive a torrent of patients with each doctor seeing more than a 100 clients per day. This results in a very limited timespan during which an over-worked doctor gets only a few minutes to examine, explain his findings, describe and prescribe treatment for each patient. This has shown to result in improper treatment, misdiagnosis and other fruits of carelessness and negligence. On the other hand, in rural areas and lower class families, patients who utilize government healthcare services, often face difficulties in

communicating with their doctors either due to illiteracy or a language barrier.

This prevailing social situation has created a huge gap between the doctor and the patient. Patients usually see doctors as robots or medical treatment machines, rattling out their symptoms and then prescribing some form of treatment. The patients in return, resort to signing whatever forms are waived at them and then surrendering themselves to whatever treatment the doctor prescribes. They rarely question any step of the approach, until or unless something goes wrong. The doctor on the other hand, routinely examines the patient and prescribes treatment without any prolonged discussion of the facts, either due to time constraints, due to fear of scaring a patient to a point where he refuses treatment, or due to the assumption that it's an unnecessary burden on a patient since he wouldn't understand or wouldn't be bothered with knowing any medical details. But times are changing and patients are more concerned with knowing what is happening to their bodies and being active participants in the treatment process.

The principle of informed consent was introduced and has developed considerably in countries such as the US to address this change in social attitude. Sri Lankan society is also changing and it is vital that the legal framework also adjusts accordingly to cater to the changing needs of society.

The main research problem revolves around how the principle of informed consent addresses this change in social attitude, from 'doctor knows best' to a patient centric system of disclosure. The paper discusses what the principle of informed consent is, how it defers from other ordinary forms of malpractice, its scope and its constituent elements. It reviews the recent development in English law through a case study of *Montgomery v. Lanarkshire Health Board.* Ultimately it examines the socio-legal implications of adopting this principle in the Sri Lankan context through a critical analysis of the most common objections raised against it.

II. METHODOLOGY

This paper is a qualitative study based on analysis of literature such as textbooks, journal articles and case law as well as information gathered from interviewing 5 practicing doctors, 2 final year medical students and persons involved in hospital administration. The research revolves around a case study of Montgomery v. Lanarkshire Health Board (2015) UKSC 11 and contains a critical analysis of how these English legal principles can be adopted in the Sri Lankan socio-legal context.

III. WHAT IS INFORMED CONSENT?

Informed consent is the process by which the treating health care provider discloses appropriate information to a competent patient so that the patient may make a voluntary choice to accept or refuse treatment. (Appelbaum 2007). Here, the importance of it being a 'voluntary choice' is of great significance. The principle of informed consent was developed to safeguard a patient's autonomy, to ensure that he has a say in what happens to his body.

'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…'
Schloendorff v New York Hospital (1914) 211 N.Y. 125, 105 N.E. 92

The above statement reflects how the roots of this principle can be traced back to the tort of battery which involves an intentional 'unpermitted' act causing harmful or offensive contact with the person of another. (Farlex Free Dictionary 2015) However, consent to such an act absolved the perpetrator of liability and thus proof of informed consent now acts as a defence available to healthcare professionals.

IV. MALPRACTICE VS. ABSENCE OF INFORMED CONSENT

Medical negligence or malpractice with regard to treatment or diagnosis should be distinguished from the absence of Informed consent. The former deals with instances where there is a departure from the standard of care expected from a competent healthcare professional in the performance of his duties. However, a claim based on the absence of informed consent requires that; (1) the physician did not present the risks and benefits of the proposed treatment and of alternative treatments; (2) with full information, the patient would have declined the treatment; and (3) the treatment, *even though appropriate and carried out skillfully*, was a substantial factor causing the patient's injuries. (Moore 1995). Another fundamental difference in these two approaches is with regard to the different patient rights protected by each. Malpractice claims are based on a patient's right to expect competent healthcare devoid of negligence whereas Informed consent seeks to protect his right to self-determination.

V. THE SCOPE OF INFORMED CONSENT

In the United States, where this aspect of the law has been well developed, courts have imposed liability on medical professionals who;

1. Performed treatment without any consent at all, either actual or implied. - *Mink v. University of*

Chicago (1978) U.S. District Court, N.D. Illinois, E.D Fed Suppl; 460:713-23

2. Performed treatment of a nature substantially different from what the patient consented to. - *Gaskin v Goldwasser* (1998) 520 NE2d 1085 Ill and *Cobbs v Grant* (1972) 502 P2d 1 Cal

3. Substituted one treatment for another without patient authorization. – (1995) *Tom v Lenox Hill Hosp* (627 NYS2d 874 NY App Div

The fact that a doctor acted in good faith would not excuse his failure to obtain proper patient consent as was illustrated in *Mohr v Williams* (1905) 104 NW 12 Min: The defendant, an ear specialist, obtained informed consent from the plaintiff to operate on his right ear. While the patient was under general anesthesia, the doctor realized that the left ear was damaged more than the right and therefore he proceeded to operate on that instead. After the operation, the plaintiff suffered a hearing impairment and sued for battery. Although it was proven in court that the defendant had not acted negligently in performing the surgery, he was still held liable (despite his best intentions) for failure to obtain proper consent.

VI. ELEMENTS OF INFORMED CONSENT

The biggest hurdle faced by courts in implementing the law on informed consent, is deciding what would actually constitute 'legally acceptable consent'. There is no universal standard in this regard and the judicial approach to informed consent varies with each jurisdiction. However, it is possible to categorize and isolate 5 general elements of informed consent; Competence, Amount and accuracy of information, Patient understanding, Voluntariness and Authorization (Schmerler, 1998). The parameters and legal tests adopted in assessing the above may differ and different jurisdictions will develop their own approach. The position of Sri Lankan courts with regard to certain elements is unclear due to a paucity of case law but the significance of each element in the Sri Lankan socio-legal context can be examined.

- **Competence:** The legal capacity of a person to make a rational choice.
    - ability to comprehend medical information and consequences of decisions
    - ability to communicate decisions
    - Other factors affecting legal capacity such as age and prevailing mental conditions.
- **Amount and accuracy of information:**
    - inheritance of condition and patient-specific risks
    - potential benefits, risks, and limitation of all management options
    - available alternatives
- **Patient understanding:** This is perhaps the most challenging aspect of informed consent; it is the responsibility of the healthcare provider to identify and attempt to overcome such barriers as the following:
    - fear or denial
    - illness
    - lack of education or reduced cognitive ability
    - cultural considerations
    - unscientific beliefs, family myths
    - language barriers
- **Voluntariness:** The patient has to make a personal decision without coercion. He or she cannot simply yield to the suggestion of a family member, doctor, or any other individual.
- **Authorization:** The patient should actively agree to a course of action and that decision should be documented.

VII. MONTGOMERY AND ITS PRINCIPLES, AS RELEVANT IN THE SRI LANKAN CONTEXT

Montgomery v. Lanarkshire Health Board (2015) UKSC 11 was a landmark judgment delivered by a 7 judge panel of the UK Supreme Court, which clearly signaled the deviation of English Law from the traditional Prudent Doctor's Test to the more rights oriented Prudent Patient's Test in assessing disclosure. The court unanimously overturned the majority decision in *Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* (1985) AC 871 which up to this point, laid out the principles governing UK law with regard to the doctor's duty to disclose risks, which is based on the Bolam test (whether the omission was accepted as proper by a responsible body of medical opinion) introduced in *Bolam v Frierm Hospital Management Committee* (1957) 1 WLR 582. Prior to this judgment, there was debate as to whether informed consent had discreetly made its way into English law (Heywood 2004) through cases such as *Chester v Afshar (2004) 4 All ER 587* and *Chappel v Hart (1998) 195 CLR 232.*

The judgment in *Montgomery* has spurned all previously existing ambiguities and given judicial recognition to the fact that the principle of informed consent is now firmly grounded in English Law. It is worth considering to what extent these principles will be relevant in the Sri Lankan context.

Nadine Montgomery gave birth to a baby boy on 1 October 1999 at Bellshill Maternity Hospital, Lanarkshire.

Mrs Montgomery was a woman of small stature, who suffered from insulin dependent diabetes mellitus. Dr McLellan an employee of the board, failed to disclose that there was a 9-10% risk of shoulder dystocia (the inability of the shoulders to pass through the pelvis) during vaginal delivery by such diabetic mothers. The doctor's policy was not to advise diabetic women about shoulder dystocia as, in her view, the risk of a grave problem for the baby was very small, but if advised of the risks of shoulder dystocia women would opt for a caesarean section. During delivery, as a result of shoulder dystocia, the baby was deprived of oxygen for 12 minutes and sustained physical injury. As a result, following his birth he was diagnosed with both cerebral palsy and Erb's palsy which caused severe brain damage and disabilities.

The claimant sued for damages on the basis that as a small diabetic woman, she had not been warned about the risks involved in a vaginal delivery and, had she been warned, she would have opted for the safer option of a caesarean section. The claim was rejected by the court of first instance as well as on appeal to the Court of Appeal (Scotland) which followed the *ratio* set out in *Sidaway.* On appeal to the Supreme Court of UK, a unanimous ruling allowed the appeal and awarded damages in the sum of £5.25 million.

A. The Doctor-Patient Relationship

The court in *Montgomery* paid special attention to the paradigm of the doctor-patient relationship existing in the modern world and declared that it had changed dramatically since *Sidaway.* Lord Kerr highlighted the court's view that;

"…patients are now widely regarded as persons holding rights, rather than as the passive recipients of the care of the medical profession. They are also widely treated as consumers exercising choices….It would therefore be a mistake to view patients as uninformed, incapable of understanding medical matters, or wholly dependent upon a flow of information from doctors. The idea that patients were medically uninformed and incapable of understanding medical matters was always a questionable generalization…" (At 75-76)

This reflects how society is continuing to change in such a way that the previously existing belief; 'the doctor knows best' is losing ground and giving way to the notion that "the patient needs to know too".

Lord Kerr in *Montgomery* commented on how the internet and other media have made medical information more accessible to the general public and therefore it is now a mistake to view patients as "uninformed and incapable of understanding medical matters". He also commented on how all pharmaceutical products require labels and instructions that that can be understood by an ordinary person. (At 76) This gives rise to the question as to whether a similar view can be adopted in the Sri Lankan context as well, since the biggest hurdle faced by doctors as discussed previously, is the patients' inability to understand medical matters. Sri Lanka currently boasts a literacy rate of 92.6% (Department of Census and Statistics 2015) which is the highest in South Asia and above par for a 3rd world country. This, coupled with the fact that education is free and mandatory for children from 5-14 years of age (Education Act 1998) means that a vast majority of Sri Lankans have the capacity to understand if explained in simple terms. The doctors who were interviewed stated that they usually encountered problems when communicating with the older population of the lower class. On the other hand they observed that the youth from the same social class were quite competent with regard to these matters and even those who were less so would understand a procedure once time was taken to explain it in simpler terms.

Thus, it can be inferred that although Sri Lankan society cannot be directly compared with developed countries in the west, there is a clear indication that patient understanding has improved exponentially over the past few years and that it can no longer be safely assumed that most patients are ignorant. Doctors also indicate that now there is increased concern by patients with regard to what treatment is performed and they expect a higher standard of care especially in the private sector. In the midst of such social changes where patient autonomy and doctor responsibility are growing in importance, it is only fitting that the legal system adjusts accordingly.

B. The Standard of Disclosure

Following *Montgomery*, the law now generally requires that a doctor must take "…reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments." (At 82)

The test for 'materiality' was given special attention by the court which analysed previous approaches adopted by both English and foreign judiciaries. The view expressed by Lord Scarman in the dissenting judgment of *Sidaway (At 889-890)* and the approach adopted by the Australian High Court in *Rogers v Whitaker* (1992) 175 CLR 479 At 489-490 were taken into account and the court in *Montgomery* held that 'Materiality' was to be judged by reference to the individual circumstances of the case and whether a reasonable person in the patient's position would be likely to attach significance to the risk, or whether the doctor is or should be aware that the particular patient would be likely to attach significance to

it. (At 87) This requires consideration of the patient as an individual.

The law lords also warned doctors against 'bombarding the patient with technical information' which they would not be able to comprehend and routinely requiring them to sign a consent form.

A common problem faced by doctors throughout Sri Lanka is the difficulty in explaining a course of treatment to a patient and getting him to understand what exactly he is consenting to, due to the knowledge gap between the two parties. On interviewing several practicing doctors, it was found that most just mention the name of the procedure or explain it in a single sentence before asking the patient to give their written consent. The doctors argued that detailed explanation would prove redundant because a majority of patients in Sri Lanka would not understand and secondly that such explanation would usually scare a patient into refusing even low risk treatment. Describing his personal experience, a doctor recalled that a patient had once refused a routine CT scan involving injection of contrast dye after he had mentioned the minimal risks involved. He goes on to say that now he rarely explains the procedure since more patients might refuse it. Although these arguments do have merit, and the doctor is acting with the best of intentions, it is reflective of the traditional belief that 'the doctor knows best'. In a changing society where patient rights and especially patient autonomy is receiving increased attention, it is now accepted that a patient should have adequate knowledge regarding a procedure and the right to decline it even though the risk is almost negligible in the doctor's eyes. As Lord Kerr stated; "The assessment of whether a risk is material cannot be reduced to percentages." (At 89) Lady Hale also stated that; "A patient is entitled to take into account her own values, her own assessment of the comparative merits...whatever medical opinion may say" (At 115) What the court was implying here was that a risk which is 'material' for one individual may not be so for another and thereby requires a bespoke consent process.

Elaborating on what information a doctor is required to disclose, the court held that;

"…the doctor's advisory role involves dialogue, the aim of which is to ensure that the patient understands the seriousness of her condition, and the anticipated benefits and risks of the proposed treatment and any reasonable alternatives, so that she is then in a position to make an informed decision." (At 90)

C. Objections to Informed Consent

Lords Kerr and Reed noted that there would be certain arguments made against the approach that they set out (para 92). These are 3 arguments quite likely to be raised in the Sri Lankan context in objection to adopting the principles of *Montgomery*:

- Some patients would rather trust their doctors than be informed of all the ways in which their treatment might go wrong (Doctor knows best)
- It is impossible to discuss the risks associated with a medical procedure within the time typically available for a healthcare consultation
- These principles would result in the practice of 'defensive medicine'
- Will increase litigation (Floodgate argument)

With regard to the first argument, as explained earlier, Sri Lankan society holds the medical profession in good stead and thus most patients have complete faith in their doctors and would in most cases, surrender themselves to any treatment. As a result, most doctors assume this to be the case with all patients. However, as social attitudes change, this proves to be an inaccurate assumption. In addressing this argument, the court in *Montgomery* acknowledged that '…a doctor is not obliged to discuss the risks inherent in treatment with a person who makes it clear that she would prefer not to discuss the matter.' However it maintained, that the decision as to whether or not such disclosure was necessary, is not left to the doctor but to the patient, and was definitely not to be assessed using the Bolam test. The court provided an exception to this rule, where the doctor could refrain from disclosing risks if '…in the reasonable exercise of medical judgment, she considers that it would be detrimental to the health of her patient' (para 85). However, the court stressed that this exception (termed 'therapeutic privilege' or 'doctor knows best') should not provide the basis for the general rule. Ie. Unless the patient makes it clear that he doesn't want to know the risks, it is the doctor's legal duty to disclose.

The second argument becomes quite relevant in the Sri Lankan context and is especially so in urban areas where popular practitioners treat more than a hundred patients a day with only a few minutes spent with each patient. Lord Kerr's rebuttal took into to consideration that the General Medical Council (which creates the code of conduct for doctors in the UK) has for a long time adopted a similar view with regard to disclosure in their guidelines, as those proposed by the court. He stated that "...it is nevertheless necessary to impose legal obligations, so that even those doctors who have less skill or inclination for communication, or who are more hurried, are obliged to pause and engage in the discussion which the law requires." (At 95) A similar counter argument can be made

in the Sri Lankan context as well, since the Sri Lanka Medical Association's code of conduct specifies the necessary care to be taken in examination and treatment and makes 'great disregard for professional duties' ground for a disciplinary inquiry. (Article 2, SLMA Code of Conduct for Members) Thus, it can be argued that it is not excessive to impose a stronger legal obligation to carry out duties which a healthcare professional is already required to perform.

The third and final argument deals with the implications of switching to a patient centric system of disclosure. Lords Reed and Kerr addressed the argument by pointing out the fact that a system which requires the patient to make the ultimate choice would actually be less likely to encourage litigation than a system where the patient relies solely on his doctor's decision. (At 93) The same applies to the defensive medicine argument since the doctors would be under a lesser threat of litigation once consent has been obtained. The fear of doctors resorting to defensive medicine has always posed a threat when widening the scope of medical malpractice law. However, it can be argued that in imposing strict limitations and greater fear of litigation, it will make them more accountable, hence encouraging them to act with greater care and diligence. Countries such as the US, Canada and Australia which keep doctors on a short leash, have shown that although a doctor who is less willing to take risks might lose a patient or two, the overall utility (lives saved) is higher, since more patients would have died due to negligence. As for the floodgate argument, this would affect Sri Lanka substantially since the litigation process takes quite a long time as it is. However, as argued by the court in *Montgomery,* if a patient makes the final call in consenting, he will be less encouraged to sue. Obtaining such consent would enable the doctor to plead the defense of 'Volenti non fit injuria' (voluntary assumption of risk) which is part and parcel of Sri Lankan law and is used to vitiate delictual liability. Doctors should also not forget that therapeutic privilege is still available to them, to act as an exception to the general rule in cases where disclosure would be detrimental to the patient's life.

In addition to these three objections raised in *Montgomery,* a major legal objection which would arise in the Sri Lankan legal system, is that the law of delict is based on Roman Dutch Law principles and the judiciary, in the past, has shown reluctance in the past to deviate from its fundamental elements. In *Priyani Soyza v. Arsekularathna* (2001) CA No. 173/94 (F), Vigneswaran J., when invited by counsel to expand Roman Dutch Law principles, expressed the view that 'no court should ignore these fundamental principles'. Further, in *Chissel v. Chapman* 56 NLR 121 Gratiaen J. stated that;

"In England, " less timorous" common law judges sometimes find themselves free to invent a new cause of action to meet a new situation...But those of us who administer the Roman-Dutch law cannot disregard its basic principles although (on grounds of public policy or expediency) we may cautiously attempt to adapt them to fresh situations arising from the complex conditions of modern society." (At 127)

Thus, the Sri Lankan judiciary in the past has shied away from expanding these principles in previous medical negligence cases. However, it can be argued that this proposed expansion falls within the exception of a 'fresh situation arising from complex conditions of modern society' proposed by Grataen J. Moreover, informed consent is already an accepted part of the law which merely requires more clarity regarding the standard of disclosure.

VIII. CONCLUSION

As argued throughout this paper, in modern society, patients are no longer passive recipients of healthcare, but demand the right to know and decide what happens to their bodies. "The issue is not whether enough information was given to ensure consent to the procedure, but whether there was enough information given so that the doctor was not acting negligently and giving due protection to the patient's right of autonomy" (Herring 2012). With only a handful of cases decided in the area of medical negligence and neither of those judgments dealing in depth with the principle of informed consent, it is high time for legal reform or at least judicial review through expansion of prevailing principles to afford more predictability and certainty to the law. The principles expounded in *Montgomery* are quite relevant to Sri Lanka, and its adoption by the judiciary will help to not only protect patient autonomy and the right to self-determination but also increase healthcare standards and the preserve the sanctity of the medical profession.

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