HEALTHCARE RISK MANAGEMENT

"Reasonable Patient Test" for Disclosure of Information Part I: Open-ended communication to identify patient's real needs

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What is a "reasonable patient test" and why is it important?

When medical treatment is followed by adverse outcomes, patients and/or family members could express grievances against the medical professional and may allege that sufficient information had not been disclosed, particularly the possible risks of the treatment. This might lead to complaints to related medical bodies/authorities for possible clinical negligence and/or commencing litigation to claim for damages. Medical treatments or procedures carry inherent risks and the question is whether medical professionals can disclose all the possible risks even those of remote possibility.

For most of human history until the 1980s, the prevalent idea was that doctors should know what is in their patients' best interest, and patients usually relied on doctors to make decisions regarding their care[1]. Therefore, the doctors would decide how to disclose the risks of the treatments or procedures. It is by no means acting in good faith as doctors do not want to bombard patients with every trivial complication and with a massive amount of information, perhaps with many pages of documents. In doing so, this might result in overwhelming the patient with too much information and them refusing to undergo a "relatively safe" treatment. The courts in Australia (e.g., *Rogers v. Whitaker*[2]), Canada (e.g., *Reibl v. Hughes*[3]), the UK (e.g., *Montgomery v. Lanarkshire Health Board*[4]), and the US (e.g., *Canterbury v. Spence*[5]), have applied the "reasonable patient test", requiring the sufficiency of disclosure to be judged from the perspective of a reasonable patient and NOT of the doctor. In *Whitaker* and *Montgomery*, the assessment of materiality of risk required the medical professional to identify what this particular patient would need and want to know taking into account his/her characteristics and circumstances.

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[1] *Wilson R F (20115). The Promise of Informed Consent. In Cohen G, Hoffman AK and Sahe W (eds). The Oxford Handbook of U.S. Health Law. New York: Oxford University Press.*
[2] *[1992] HCA 58, (1992) 175 CLR 479 (High Court of Australia)*
[3] *[1980] 2 SCR 880 (Supreme Court), Canada*
[4] *[2015] UKSC 11, [2015] AC 143 (Supreme Court (Scotland)), UK*
[5] *464 F.2d 722 (United States Court of Appeal for the District of Columbia Circuit), US*

The "reasonable patient test", also known as "patient-centred test", follows the concept of "patient-centred care", which is not a new concept. The Family Medicine team at Western University in Ontario, Canada, published a series of papers in the 1980s on "the patient-centred clinical approach", and one core value is the identification of patients' priorities so an appropriate clinical decision can be made[6]. The Australian Medical Council has classified communication with patients and encouraging patients to be responsible in managing their health as good medical practice[7]. It is also one of the key indicators in the Australian Safety and Quality Framework for Health Care[8]. In the UK, the General Medical Council has stipulated the need for doctors to determine the extent to which patients want to be involved in decision making, and doctors should provide explanation, advice, and reassurance, which are regarded as training outcomes of medical graduates[9]. In the US, *Salgo v. Leland Stanford Junior University Board of Trustees,*[10] the California Supreme Court gave a rather broad instruction that physicians must disclose to the patient all the facts mutually affecting his/her rights and interests, and the surgical risk, hazard and danger involved. The defendant alleged that jury instructions prejudiced them, and the Supreme Court directed the board's instruction to be scaled back to enable physicians to retain discretions in certain circumstances to not making a disclosure. However, the discretion must be consistent with the full disclosure of acts necessary for informed consent, and the *Salgo* case signalled a shift to secure informed consent taking into account what a reasonable patient would want to know[11]. The Medical Council of Hong Kong has emphasised the importance of proper dialogue and communication between a doctor and a patient. That takes into consideration the individual circumstances that were taken into account in the *Montgomery* case[12].

Effective communication can help apply the "reasonable patient test"

When a doctor actively pays attention to a patient's story, not only does the patient feel that their voice has been heard, but the patient is also more likely to ask questions, receive information about what their symptoms mean, participate in decision making and leave them with the feeling that their issues have not been ignored[13]. Health communication is an important core skill to be acquired by doctors to address a patient's needs for effective care. The goals of a consultation are not just establishing the diagnosis and management by prescription and investigation. If the consultation only reflects the doctor's perspective, it cannot fully address the needs of the patient and might lead to the patient not disclosing their material risks.

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[6] Brown J, Stewart M, McCracken E, McWhinney, IR, Levenstein J. The Patient-Centred Clinical Method.2. Definition and Application. Fam Pract 1986; 3: 75-79.

[7] Australian Medical Board. Good medical practice: A code of conduct for doctors in Australia. Medical Board AHPRA, October 2020. https://www.medicalboard.gov.au/Codes-Guidelines-Policies/Code-of-conduct.aspx?TSPD_101_R0=08c403b005ab2000978e9347378b90c7563e80c7b65a7bb4f8e7f52f8264d5a70c6816ce5becc5c40818a6ba11143000672a91c487b1216a1ea13d39cd18ebf47ba401c769efe75f9e6f8deaf1ac50d36f83b932742ed233f28fb168020924da. Access 21 August 2022

[8] Braithwaite J., Healy J., Dwan K. The Governance of Health Safety and Quality. Commonwealth of Australia, 2015.

[9] General Medical Council. Guidance on professional standards and ethics for doctors: Decision making and consent. London: GMC, 2020. Available https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---decision-making-and-consent-english_pdf-84191055.pdf Access 21 August, 2022; General Medical Council Outcomes for Graduates. GMC (Tomorrow's Doctors): Working with doctors Working with patients. London: GMC, 2015. Available https://www.gmc-uk.org/education/standards-guidance-and-curricula/standards-and-outcomes/outcomes-for-graduates Access 21 Aug 2022

[10] 154 Cal. App. 2d 560, 317 P.2d 170

[11] See note n 1 Wilson, 2015

[12] Medical Council of Hong Kong. Code of Professional Conduct for the Guidance of Registered Medical Practitioners. Revised 2016

[13] Lee A. Better Healthcare Communication is essential for advancement of Health Care System. International Symposium on Communication in Health Care on February 12th -13th, 2018 Australian National University, Canberra, Australia

The consultation process would facilitate the communication process to identify the patients' needs including their own ideas, concerns and expectations. The initiation of the consultation can help to set the scene to enable the patients communicating their needs as illustrated by following case.

Case 1

Mr. Sun, age 46, went to see Dr. Moon requesting a referral for a coronary angiogram, as he wanted to know whether he suffered from coronary heart disease. He had no particular symptoms and just wanted a check-up. His wife and children received care from Dr. Moon's family practice from time to time and Mr. Sun sometimes visited Dr. Moon but he tended to seek help from a company doctor near his office.

Dr. Moon mentioned to Mr. Sun briefly that there is a slight risk of allergic reaction with the contrast medium used in the procedure such as a itch, rash and sometimes hives. Mr. Sun did not have a past history of any allergies, so Dr. Moon did not go ask for more details.

Mr. Sun received a CT angiogram and developed an allergic reaction with a rash, dizziness and a nauseous feeling. He also had some difficulty breathing. Whether he was anxious with an allergic reaction or hyperventilation could not be determined, as he did not have a wheezy chest. The reaction settled spontaneously and uneventfully.

Mr. Sun felt dissatisfaction with Dr. Moon, as he should have warned him of the potential serious risk of an allergic reaction, even if it was a very small risk. As Mr. Sun did not have any cardiac symptoms and had good exercise tolerance, he only underwent the check-up because he was asked to by his wife. If he had known the small risk of serious complication, he would not have undergone this investigation, as those resulting symptoms had serious repercussions on his health and well-being.

Should Dr. Moon have identified the material risk to Mr. Sun ?

If Dr. Moon had initiated the consultation with open-ended communication such as *"Mr. Sun, I have not seen you for some time. How can I help you today?",* this would have established good rapport and shown the doctor's interest to know more about Mr. Moon's issues. This is particularly useful for new patients or patients who have not sought care for sometime.

After Mr. Sun made a request for referral for a CT angiogram, Dr. Moon again should have adopted open-ended communication: *"Tell me, why you are worried about your heart?"*

It would have been best to allow time for Mr. Sun to speak. Apart from understanding the reasons, this would have also allowed Mr. Sun to talk about his lifestyle, cardiac symptoms, past medical illness, and social history from a broader perspective.

If Mr. Sun did not have any significant symptoms, lifestyle factors, family history or past medical history putting him at risk of cardiovascular disease, Dr. Moon should have recommended alternatives to evaluate cardiovascular risk factors such as an assessment of blood pressure, cardiovascular status, obesity, lipid level, diabetes mellitus, renal function, etc.

The most important way to prevent arteriosclerotic cardio-vascular disease (ASCVD) is to promote a healthy lifestyle. The main causal, and modifiable ASCVD risk factors are blood apolipoprotein-B-containing lipoproteins (of which low-density lipoprotein, LDL, is most abundant), high blood pressure, cigarette smoking, and diabetes mellitus, and adiposity is another important risk factor[14]. If the prevalence of an unhealthy lifestyle is still high, the ASCVD risk factors are often poorly treated.

Age is the main risk factor for ASCVD and women under 50 and men under 40 are almost at low 10-year ASCVD risk. In general, apparently healthy people under age 50 at 'low to moderate risk', maintaining healthy lifestyles and modifying any risks is sufficient. For those at 'high risk', treatment of underlying ASCVD risk factors should be considered.

If Mr. Sun had been found to be at high risk, Dr. Moon should have then discussed the risk and benefits of undergoing more intensive investigation. Apart from a CT angiogram, a treadmill test (exercise ECG) could also have been an option. Mr. Moon could then have been given adequate information to make a decision.

If Mr. Sun had been given the balance of risk and benefit, Mr. Sun could have then been asked whether he would accept the possible risks and what risks he would be particularly afraid of. By adopting an open dialogue, not only can more clinical information be elicited, but more alternatives can be generated for a patient to consider. This can help to unfold the patient's underlying agenda.

The principle of OARS (Open-ended questions, Affirmation, Reflective listening, and Summarising) helps patients to present their perceptions and doctors to summarise. The consultation should emphasise connection with patients by focusing on a patient before a greeting, listening intently, agreeing on the importance of various matters connected to presented complaints, and exploration of emotion[15]. This approach can help a doctor to come into agreement on the important matters related to a particular consultation. This would have led to less intensive and invasive investigations, and managed the important ASCVD risk factors, as well as avoided complications in Mr. Sun's case.

Bombarding patients with all possible risks

There is another case of Mr. Worry with acute appendicitis, in which the surgeon bombarded the patient with all possible complications.

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[14] Visseren FLJ, Mach F, Smulders YM, et al. ESC Guidelines on cardiovascular disease prevention in clinical practice. Eur Heart J. 2021;42(34): 3227-3337. doi: 10.1093/eurheartj/ehab484.

[15] Zullamn DM, et al. Practices to Foster Physician Presence and Connection With Patients in the Clinical Encounter. JAMA 2020;323:70- 81.

Case 2

Mr. Worry had right side abdominal pain and was admitted via the casualty department. He was seen by surgeon, Dr. Cut, who made the provisional diagnosis of appendicitis. Dr. Cut advised to observe for a few hours and revealed the clinical condition again (this case happened over 2 decades ago when imaging was not widely used and diagnosis was based on a clinical assessment supported by laboratory tests).

Mr. Worry had increasing abdominal pain more localised to his right side, with fever. Dr. Cut reviewed him again and found increasing tenderness and rigidity with rebound tenderness over the right lower quadrant of the abdomen. Dr. Cut told Mr. Worry to undergo an appendectomy (laparoscopic surgery was not widely available at that time). Mr. Worry was worried about complications from surgery. Dr. Cut told him that complications included bleeding, infection, damage to surrounding healthy organs, and blocked bowel. All these would be possible, so Mr. Worry should think about it. Mr. Worry could not make the decision, so he called his family doctor, Dr. Kind.

Dr. Kind went to see Mr. Worry and asked to talk to Dr. Cut. Dr. Kind also examined Mr. Worry and his clinical findings were highly suggestive of acute appendicitis. When Dr. Cut came, he repeated the findings. Dr. Cut also mentioned that Mr. Worry had mentioned abdominal pain on and off for sometime. This would be a good opportunity to open up the abdomen to see if anything was wrong. Mr. Worry became more confused and worried as he had only mentioned an episode of bad abdominal pain that took place sometime ago. Dr. Kind asked whether he could have a moment with Mr. Worry.

Dr. Kind told Mr. Worry that he was highly likely to suffer from appendicitis. The only treatment could be surgical removal, and would not be resolved with medication. There would be the possibility of complications, as raised by Dr. Cut. However, if not treated, it would lead to perforation of the infected appendix, leading to peritonitis, which would be life-threatening. Dr. Kind asked Mr. Worry if he had any other concerns regarding the surgery. Mr. Worry then asked how likely it would be for the appendix to perforate. The answer given was "very likely" if left untreated. Mr. Worry then opted for surgery.

This case has illustrated that bombarding a patient with all possible risks without an attempt to allow the patient to express their ideas, concerns and expectations might lead to refusal of a potentially life-saving treatment. A patient should be communicated the risk of complications of undergoing treatment versus the risk of complications of not having treatment, to enable the patient to weigh the benefits and risks. Further more, a patient should also be asked his/her preferred mode of treatment. This would not only unfold the underlying concerns and expectation, but also clarify whether the preferred treatments would be available and feasible.

Disclosing information and meeting the needs of patients

There are some guidelines that would assist clinicians in putting the new consent process of *Montgomery*[16] into effect as the law requires. They can be summarised as follows[17]*:*

1. The assessment of materiality of risk is fact-sensitive. Statistics/percentages of risks are relevant, but not necessarily decisive.
2. A small risk of serious harm may be expected to be of significance to most patients, and particularly for patients undergoing non-urgent, avoidable, or purely cosmetic treatment.

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[16] *See note n3 Montgomery*

[17] *Badenoch J and Lee A (2023) Disclosure of information and informed consent: Montgomery v. Lanarkshire Health Board. In the history, significance and practical effect of the decision, and its perils and pitfalls for clinicians. In J Chiu, A Lee, KW Tong (Eds), Healthcare Law and Ethic: Principles & Concepts. Hong Kong: City University Press.*

3. A risk, however remote, may be of particular significance to a patient whose life or livelihood would be especially adversely affected if the risk materialised, e.g. risk of damage to the voice of a singer or the finger of a concert pianist.
4. The purely 'mechanical' approach without explanation will not suffice.
5. There must be genuine dialogue between a doctor and a patient in every case, and the genuine dialogue requires the doctor:
    (i) to use understandable language and check that it is understood;
    (ii) to avoid excessively detailed information – keep it simple;
    (iii) so far as possible, to avoid technical jargon;
    (iv) to tailor the discussion to the individual patient.
6. The dialogue should take place without pressure for instant decision or under stress due to symptoms.
7. Physical or emotional distress may be a barrier to free choice, as the patient may not be fit to give reasoned consent. Consent purportedly given in such circumstances may not be regarded in law as true or valid.
8. The required extent of disclosure is reasonable and not an exhaustive recitation of a catalogue of risks of very minor and/or transient side-effects, i.e., found in the small print of drug data sheets, will not be required and should generally be avoided altogether. Reasonableness is the key, and the courts can be expected to apply the test of reasonableness in all cases. Common sense should prevail.
9. The person who advises/prescribes/carries out the treatment should, whenever practicable, provide the information and obtain the consent.
10. A doctor who is not good at communication must recognise his or her weakness, and take steps to acquire the necessary skills.
11. Lack of time for adequate dialogue with the patient must be overcome, because it is the patient's basic and fundamental right to make a true and free choice. Without adequate information, the patient's choice is not real and the consent is not valid.
12. The doctor's own position: If asked directly by the patient what choice they would make for themselves or for their child, the doctor may answer truthfully, but with words carefully chosen to avoid exerting, or appearing to exert, undue pressure. The doctor could say, "It is entirely your decision. You and I are quite different people, but I would choose, and I would want my loved ones to choose, to undergo this (or that) treatment".

Is the "reasonable patient test" unreasonable to physicians?

The "reasonable patient test" requires identification and disclosure of material risks, which can be demanding on physicians. However, there are guiding principles and skills for more effective risk communication as discussed in this paper. Moreover, it further reinforces the concept of "patient-centred care". It is not demanding the impossible.

In Part II, there will be more analysis of cases applying *Montgomery* in the UK, Singapore and Hong Kong, and a review of cases/legislations in other common law jurisdictions applying the "reasonable patient test" for the consent process. It will provide deeper insights showing that the consent process requiring disclosure of material risks is consistent with common law principles and also principles of good clinical practice.

Key messages:

1) The “reasonable patient test” follows the concept of “patient-centred care”, which is not a new concept. Good quality of care requires doctors to provide explanation, advice, and reassurance.
2) The goals of a consultation are not just establishing the diagnosis and management by prescription and required investigation. It should also facilitate the communication process and identify a patient’s needs, including their own ideas, concerns and expectations. The initiation of the consultation can help to set the scene to enable the patient communicating their needs as illustrated by the previous cases.
3) There are some guidelines to assist clinicians to adopt “patient-centred test”, such as:
    a) Be fact-sensitive in the assessment of the materiality of risk.
    b) Statistics are relevant but, not necessarily important for every decision.
    c) Remote risk can be of significance to a patient if their life or livelihood could be adversely affected if the risk materialised.
    d) The extent of disclosure should be reasonable, not exhaustive, and should avoid a mechanical approach.
    e) The dialogue should take place without the pressure for instant decision or the stress of extreme symptom. There should be awareness that emotional distress can be a barrier to free choice. Lack of time is never a valid excuse/defence.
4) Open communication can allow patients to tell what is on their minds, so material risks can be identified.
5) Physicians have the duty to inform patients of alternative treatments.
6) Time pressure cannot be an excuse for inadequate disclosure of information as it is the patient’s basic and fundamental right to make a true and free choice.