INFORMED CONSENT REVISITED-

LIFE AFTER THE *HII CHII KOK* DECISION

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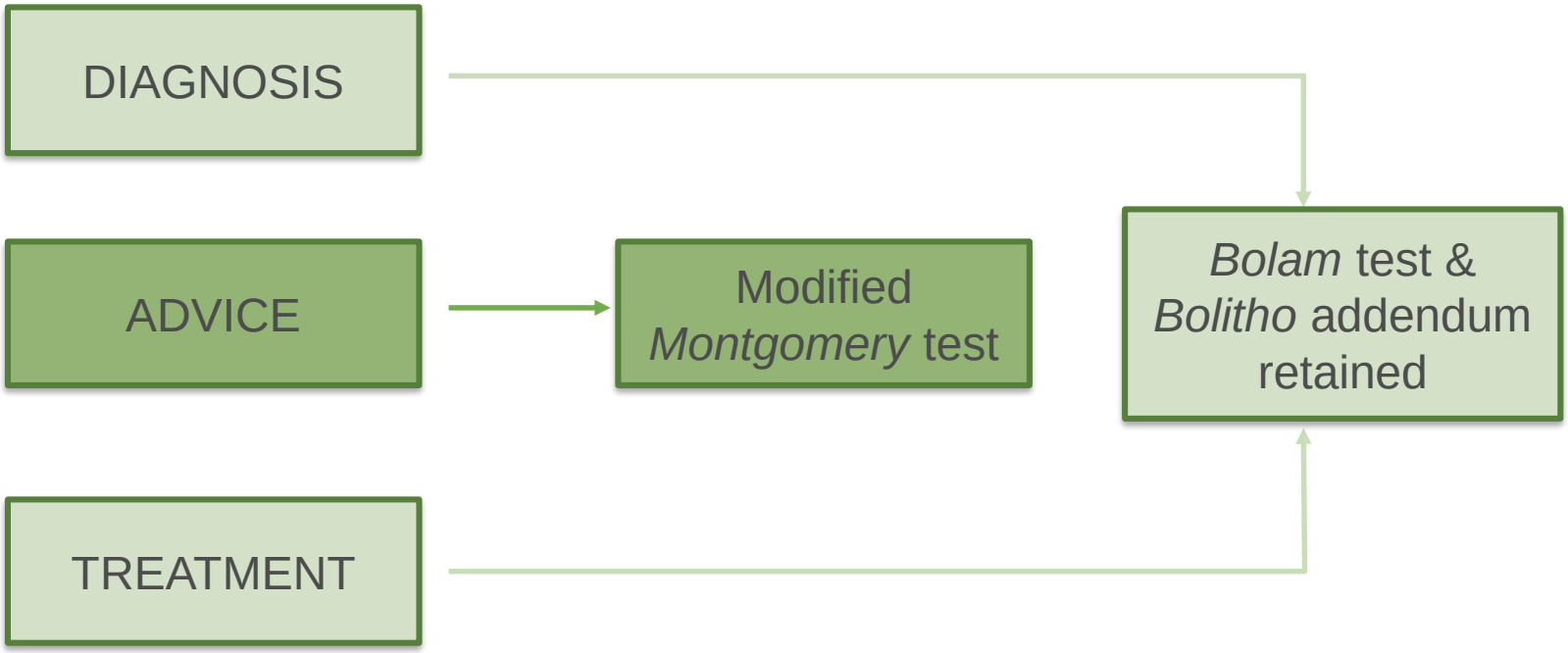
Legal Clinic

Significance of the CA's decision in *Hii Chii Kok*

- A departure from the *Bolam-Bolitho* test and introduction of the modified *Montgomery* test in relation to **Advice**



The Modified *Montgomery* test

A **three-stage inquiry** when considering a doctor's duty to advise:

① Was the information which the patient alleges was negligently withheld from him:

a) information which would be **relevant and material from the perspective of a reasonable patient in the particular patient's position**, or

b) information which the doctor **knew or should have known would have been considered relevant and material** by the particular patient for reasons specific to this patient?

② Was the doctor in possession of this information at the material time, and if not, was the doctor negligent (under his duty of diagnosis or treatment) in not obtaining or having this information?

③ If the information was relevant and material and in the doctor's possession at the material time, was the doctor reasonably justified in withholding the information?

SMC case:

SMC v Dr Ganesh Ramalingam [2018] SMCDT 6

- Dr Ganesh was censured and suspended from practice for 7 months and ordered to pay costs arising from his management of a patient who suffered a colonic perforation following colonoscopy.

- He pleaded guilty to 3 charges: (a) failing to obtain informed consent, (b) failing to keep proper medical records, and (c) failing to undertake an adequate clinical assessment and evaluation of the patient before recommending and proceeding with endoscopy/colonoscopy.

- DT was of the view that this was “an intentional, deliberate departure” from standards expected of doctors. They found that the patient’s decision to have the procedures **was not informed because Dr Ganesh did not tell her why the procedures were needed or that there were alternative treatments such as oral antibiotics.**

SMC case:
SMC v Dr Ganesh Ramalingam [2018] SMCDT 6

- He also failed to keep adequate medical records to characterise the patient's symptoms, state why he had recommended the procedures, or record the advice given to the patient.

- DT questioned why the procedures were carried out within four hours of the consultation when there was no urgency, calling Dr Ganesh's conduct "inexplicable".

- DT wanted to "**send a strong signal to the public that the medical profession does not (and will not) condone a doctor's failure to respect a patient's autonomy**" in deciding the treatment he gets.

SMC case:

SMC v Dr Ganesh Ramalingam [2018] SMCDT 6

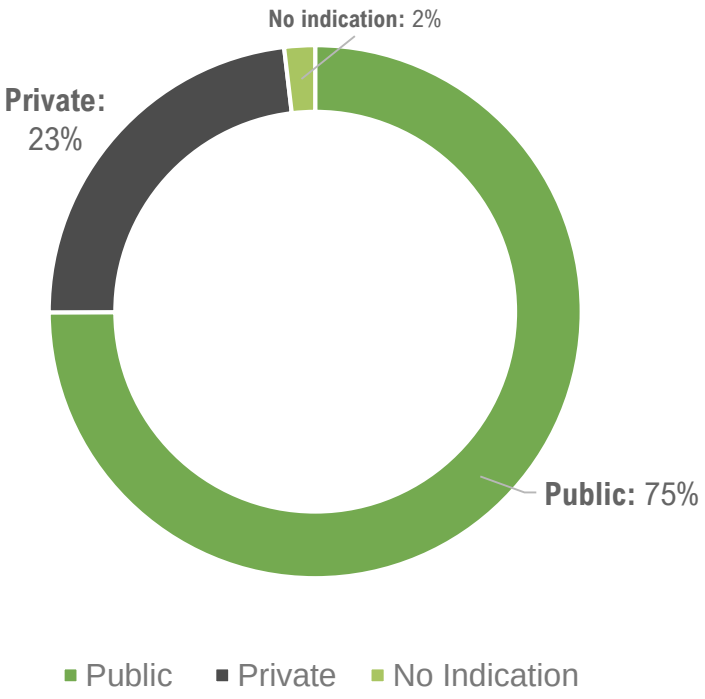
- Sentence was reduced to 7 months because Dr Ganesh pleaded guilty (thereby saving time and costs) and did not offer any "excuses for his shortcoming".

- DT thought that a longer suspension of 12 months was warranted but gave him credit for acknowledging that he deserved a suspension: “This is a manifestation of Dr Ganesh's true remorse for not attempting to downplay his acts of professional misconduct”, adding that “such a posture is not often seen at the DT hearings”.

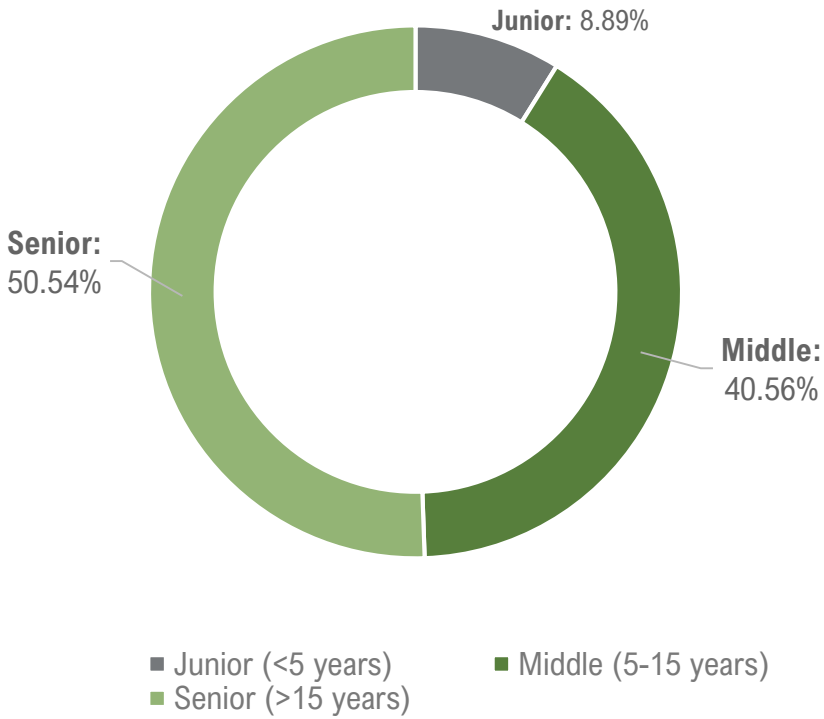
How the modified *Montgomery* test has influenced the practice of medicine in Singapore: The survey responses

- A total of **643** responses were analysed

Public v Private Institutions



Number of years in practice



Summary of survey responses

1. Majority of the respondents who completed the survey are aware of the modified *Montgomery* test [87.25%].

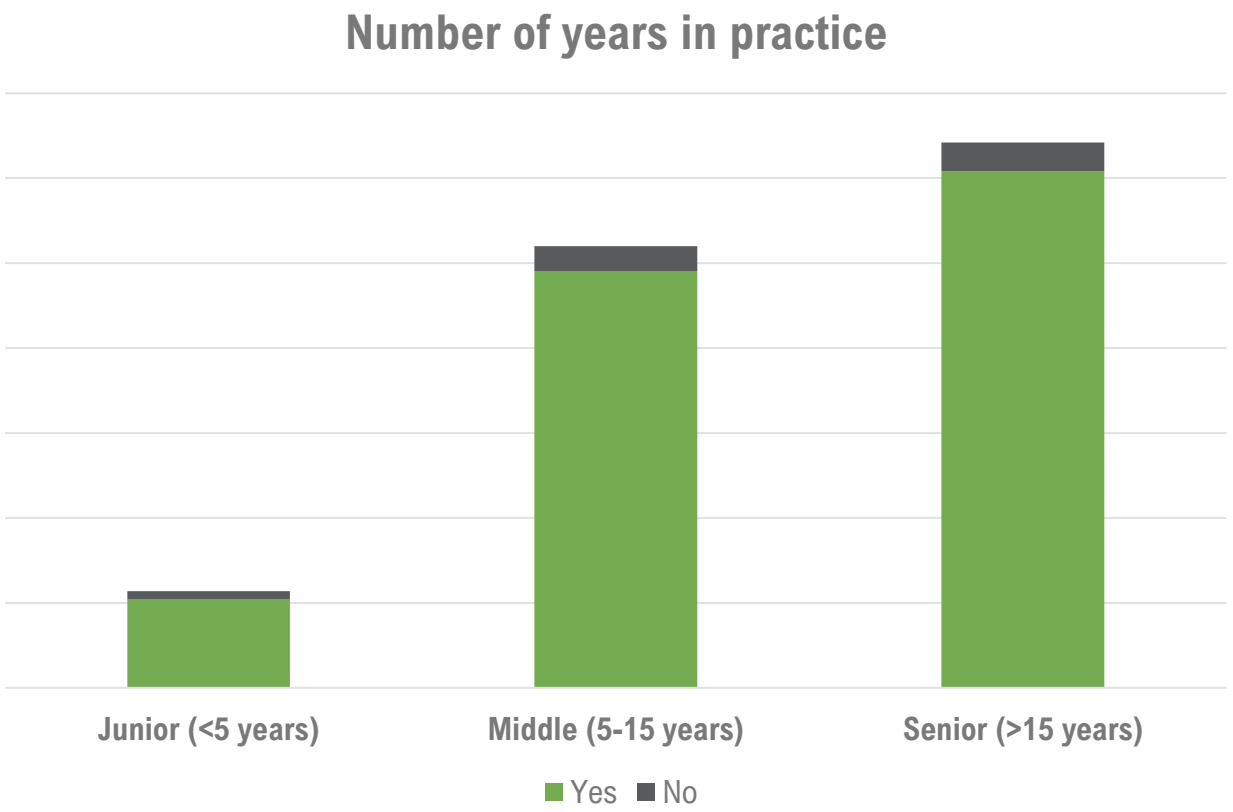
2. The respondents are quite evenly split as to whether the modified *Montgomery* test is a good development.

3. Less than half of the respondents are both aware that the test has changed the law with regard to informed consent and have changed their practice as a result [43.70%]. A sizeable proportion of the respondents are aware of the change in law, yet have not changed their practice as a result [27.37%].

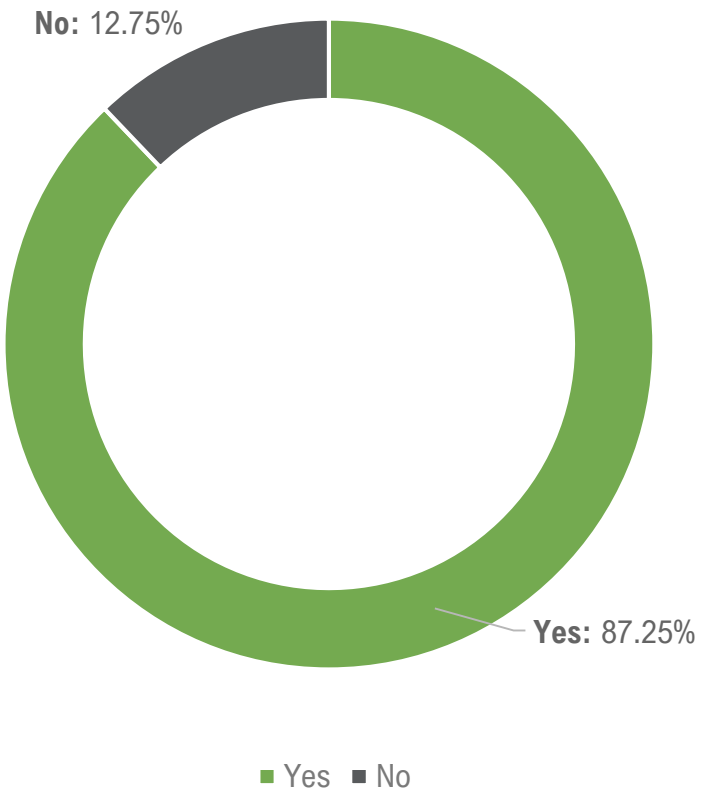
4. A significant number of respondents do not appear to have an accurate understanding of the modified *Montgomery* test – e.g. 53.03% of the respondents thought that a patient needs to be informed of *all* risks associated with the proposed treatment.

5. A large number of respondents [~23%] felt that having more time with patients would help them to cope with the additional requirements needed to satisfy the modified Montgomery test.

Do you take consent for medical procedures from a patient?



Are you aware of the modified *Montgomery* test as set out in the Singapore Court of Appeal decision of *Hii Chii Kok?*



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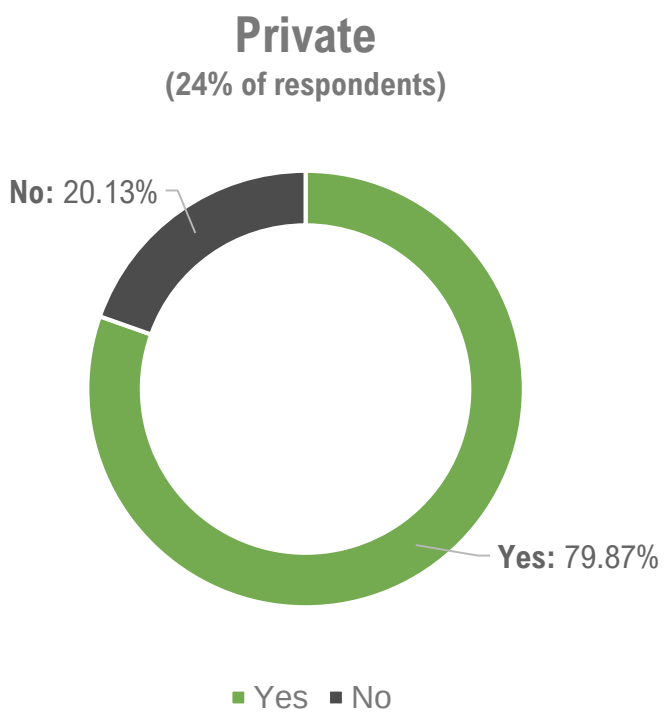

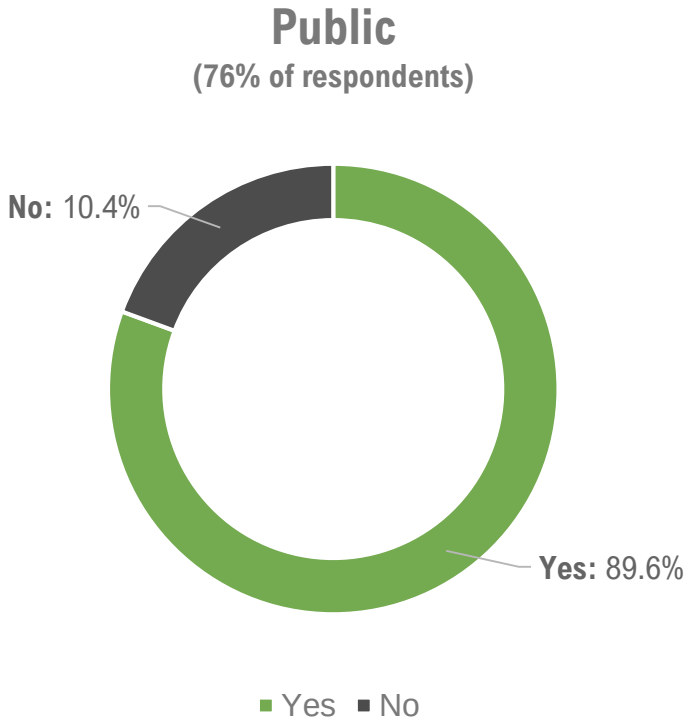

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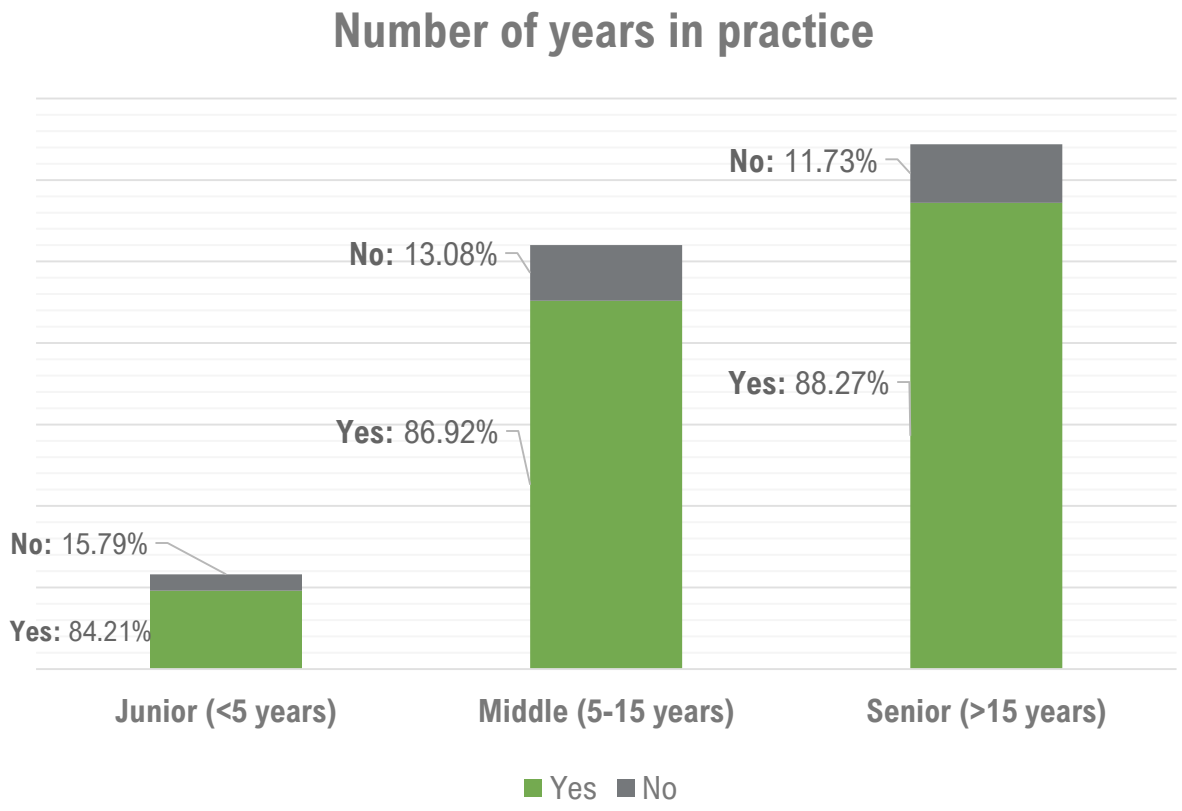
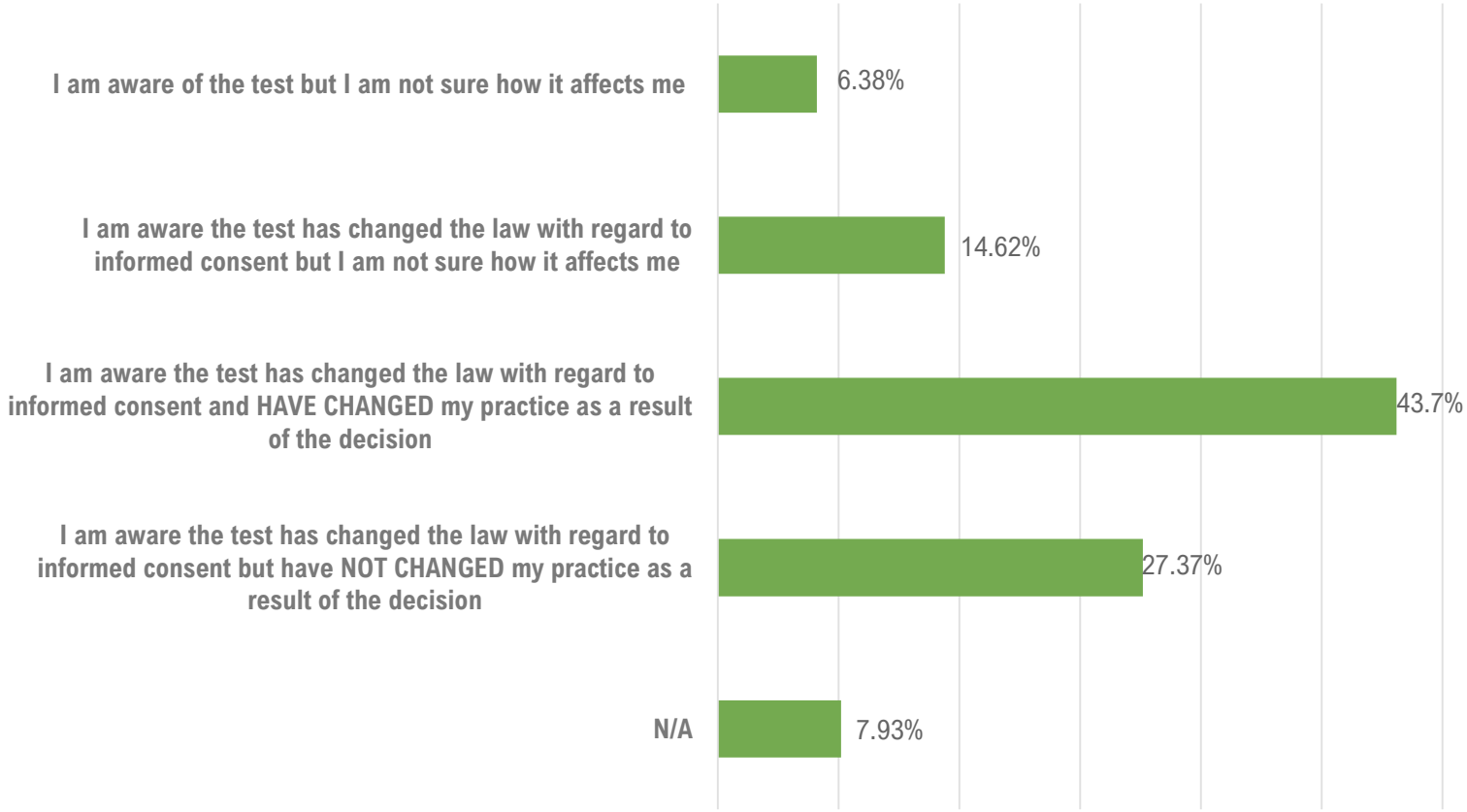
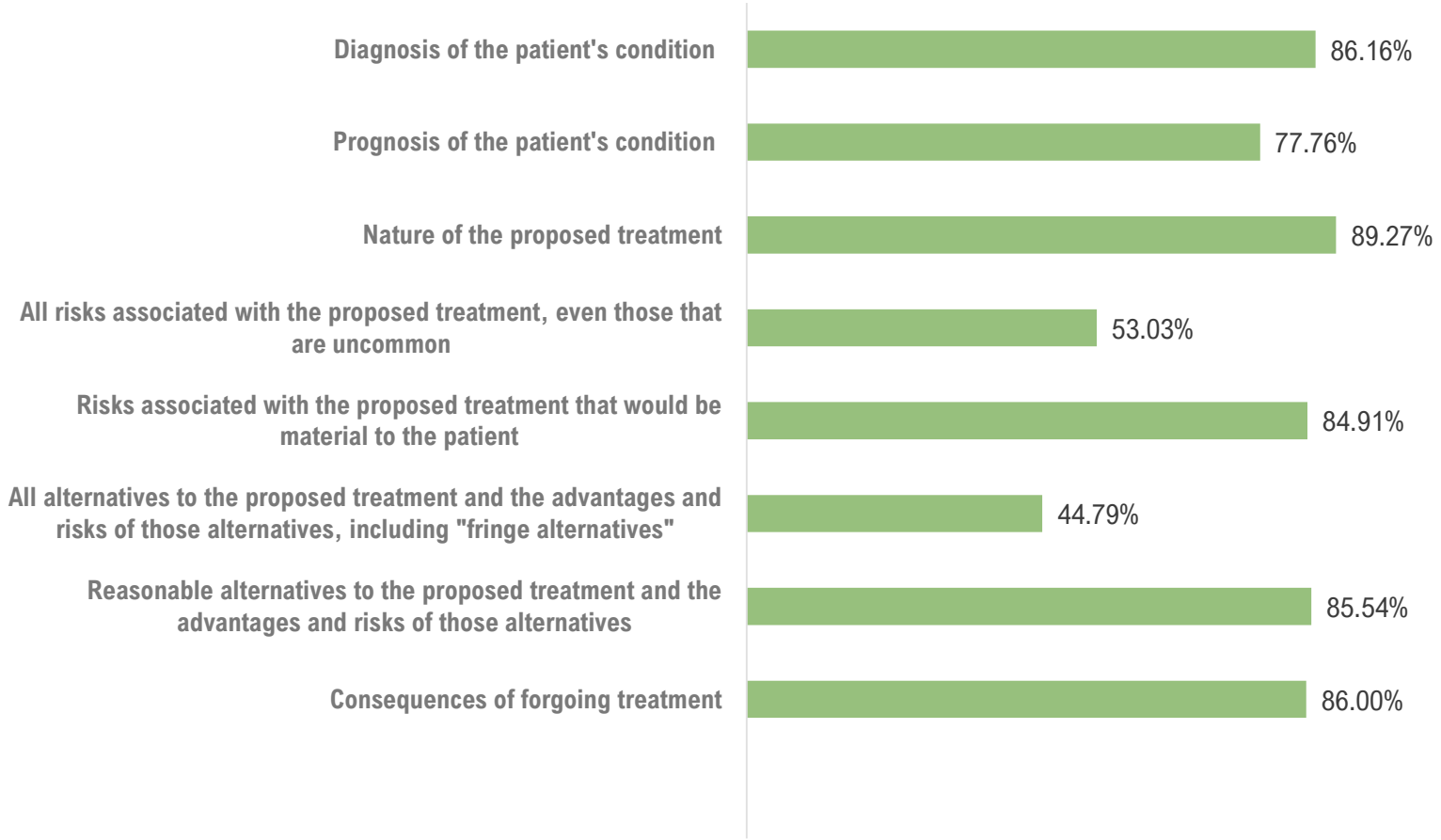


What do you understand about the modified *Montgomery* test with regard to how it impacts the practice of medicine?



Based on my understanding of the modified *Montgomery* test, a patient needs to be informed of the following (tick all that apply)



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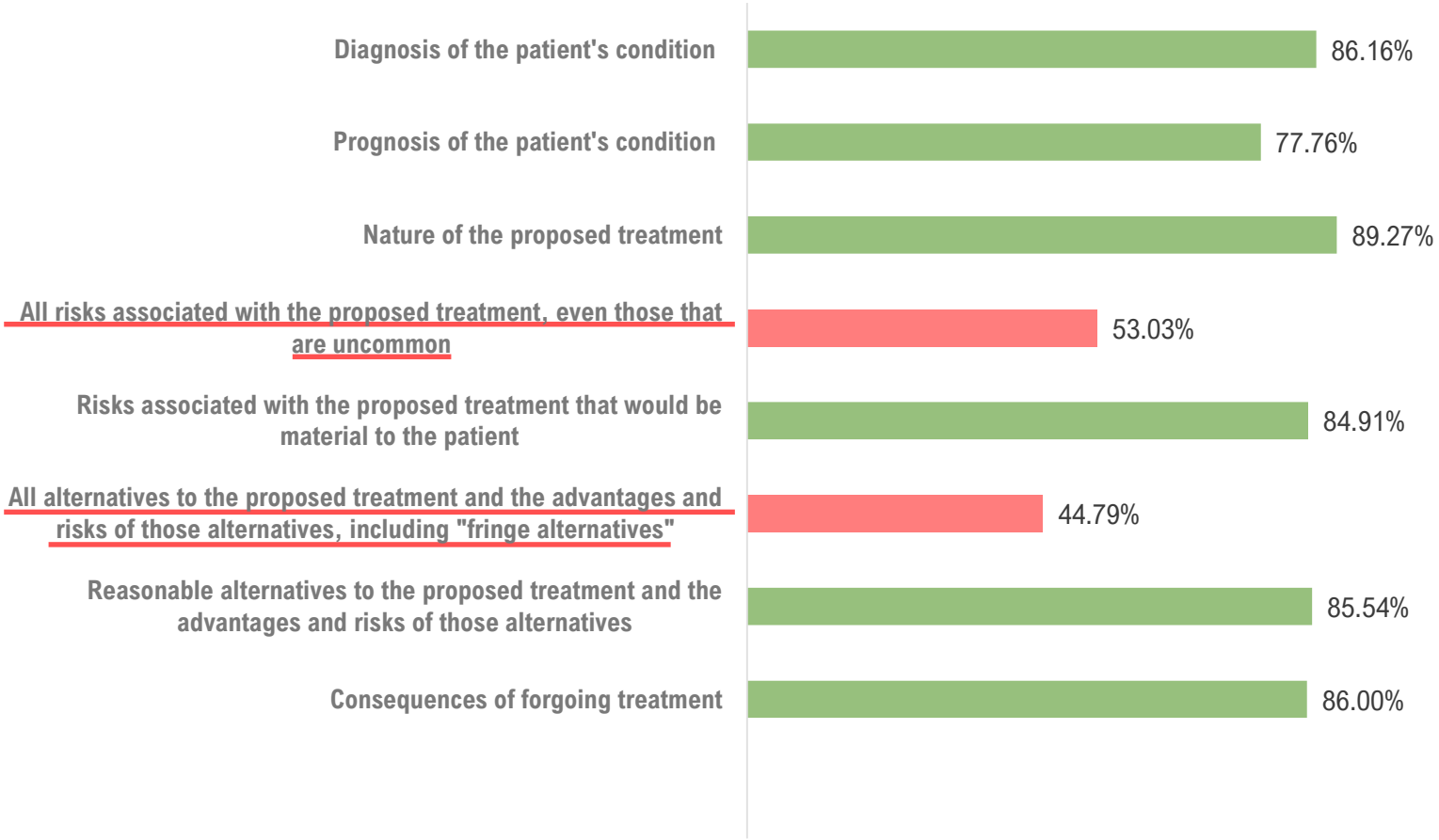
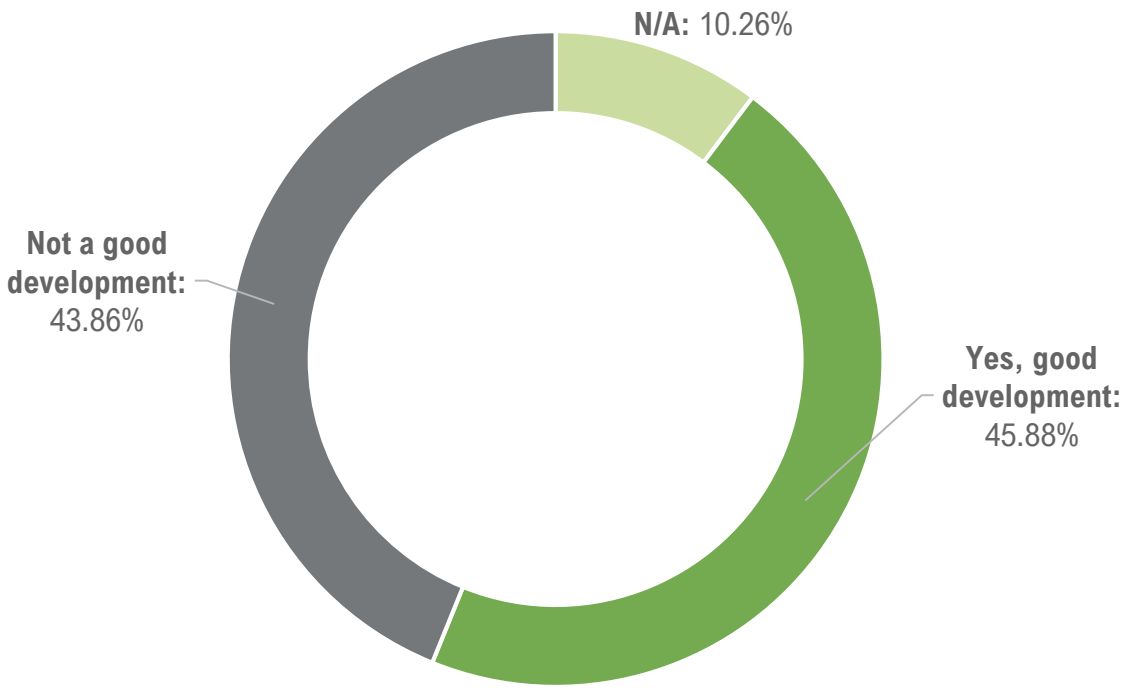


Do you think the modified *Montgomery* test is a good development?



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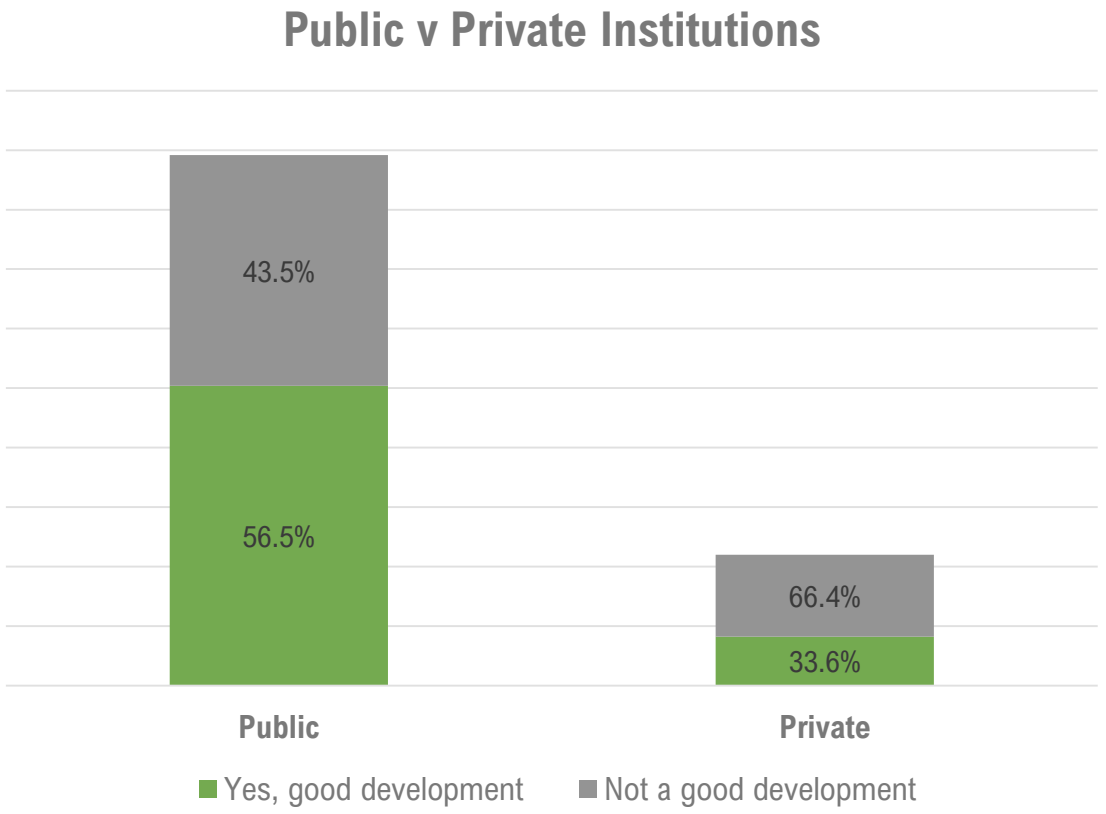

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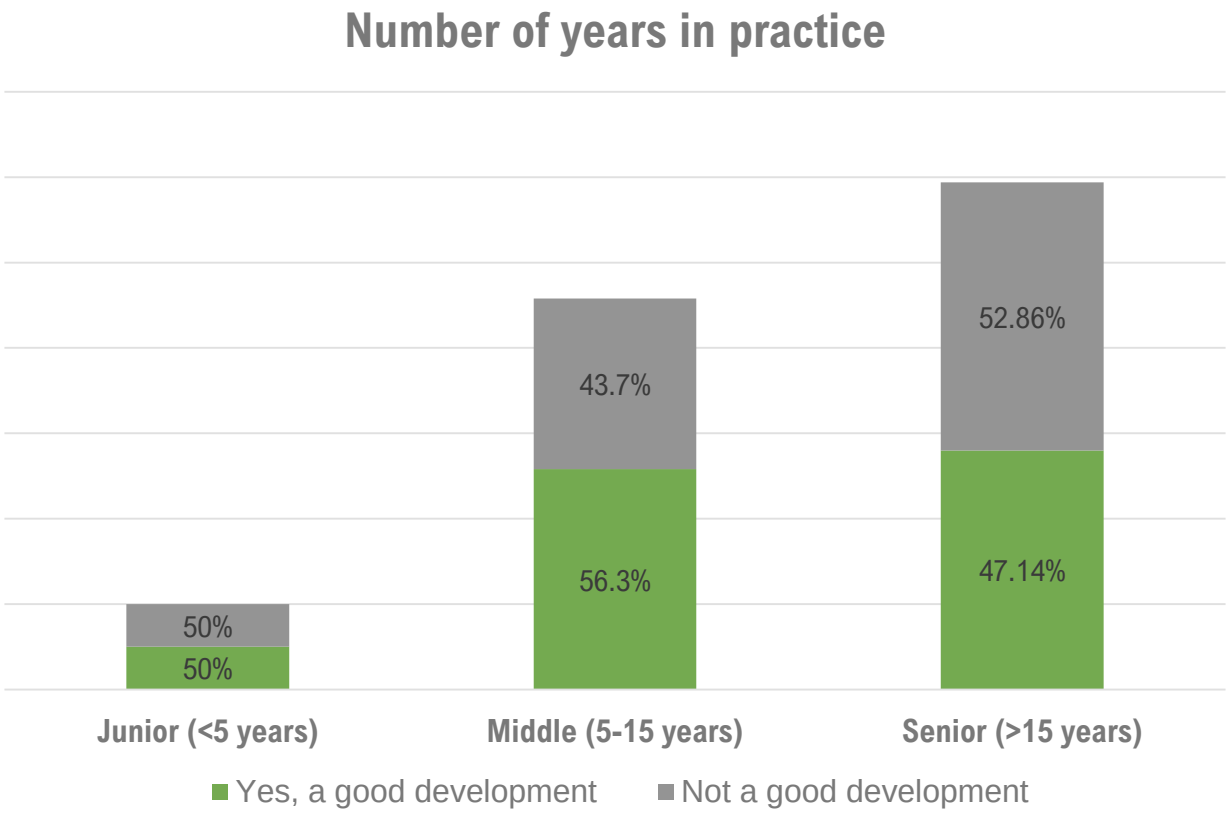


Do you think the modified *Montgomery* test is a good development? -- YES

- Of the respondents who think the modified *Montgomery* test is a good development, the most common reasons given are as follows (starting with the most common):

  - ✓ Patients will be better informed and empowered to make decisions
  - ✓ More patient-centric and more focus on autonomy, less paternalism / improve the standard of consent taking
  - ✓ Individualist approach can help cater to different patients
  - ✓ Patients are more educated now and information is more easily available anyway

- However, many also qualified their response by citing various difficulties and problems with the modified *Montgomery* test.

Do you think the modified *Montgomery* test is a good development? -- NO

- Of the respondents who think the modified *Montgomery* test is *not* a good development, the most common reasons are as follows (starting with the most common):

  - × Too subjective – difficult or impossible to know what is material to the patient / the patient can retrospectively claim it was material
  - × Defensive medicine and increased litigation
  - × Requires too much time for consent taking
  - × Too complex – information overload for the patient / the patient will not be able to understand as he/she is not medically literate
  - × Doctors are the professionals for a reason / patients will make the wrong or poor decisions
  - × Patients can forget/hide/fail to share information about themselves
  - × Patients will be dissuaded from undergoing procedures by obscure risks
  - × Uncertainty in practice and of what the doctors must do
  - × Erodes trust between the doctor and the patient

Selected Comments

- ✓ “In principle the concept is good, moving towards personalized care. Patients need to understand with greater autonomy on their part, comes responsibility too for their own choices.”

- ✓ “It is a reflection of the cultural and educational advancements in society and is inevitable”

- × “It is idealistic to assume that medical education can be taught in a few 10-20 minutes consultations to the public when it take many years to train highly intelligent individuals. It is equally idealistic to assume that the doctor can understands the patient's needs and priorities when parents who know the child from birth often misunderstand their own child's needs and priorities. Given the doctor cannot assume to understand the patient in a few meetings, s/he cannot impart what may be relevant in that time, but to enrol the patient into medical school before implementing treatment”

- × “While I agree that informed consent (in general) can be done better, the concept of "material" information/risk seems too arbitrary, and subject to interpretation that can be construed against the clinician”

Selected Comments

- "A lot of times, giving the patient too much information will result in the patient feeling inundated, and result in the patient in making a poor decision from a doctor's point of view, do we then still proceed with that decision?"

- "Patients seem to have too much rights"

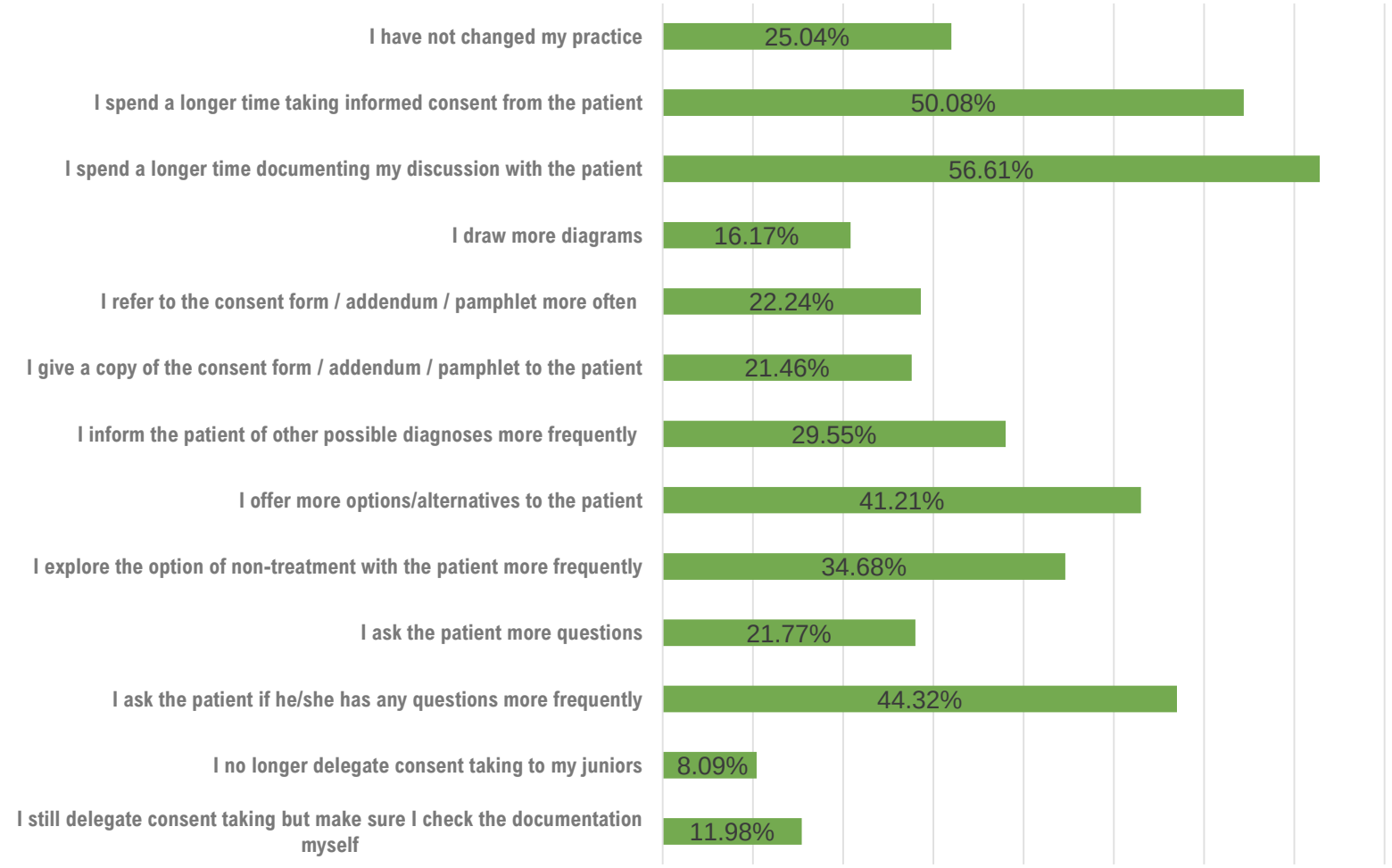
- "Impossible to achieve in clinic. Impossible to ever fulfill this law. Most patients don't have the intellectual capacity to process everything also. Aunties and uncles don't even speak good Chinese or English or dialect. The law wants us to explain every single possible risk in a clinic session - I am not going to give a tutorial on medical problems during the clinic session, and we have to take into consideration time constraints. Doctors will never win against any law suit under this law"

- "Much of the modified montgomery test is based on the assumption that patients have a high level of medical literacy. Unfortunately, medical literacy among the Singapore population is generally low. When applied in a situation in which patients have low medical literacy, the consequences can be very harmful to patients, who end up choosing inferior treatments…or worse forego proven treatments because of erroneous beliefs…"

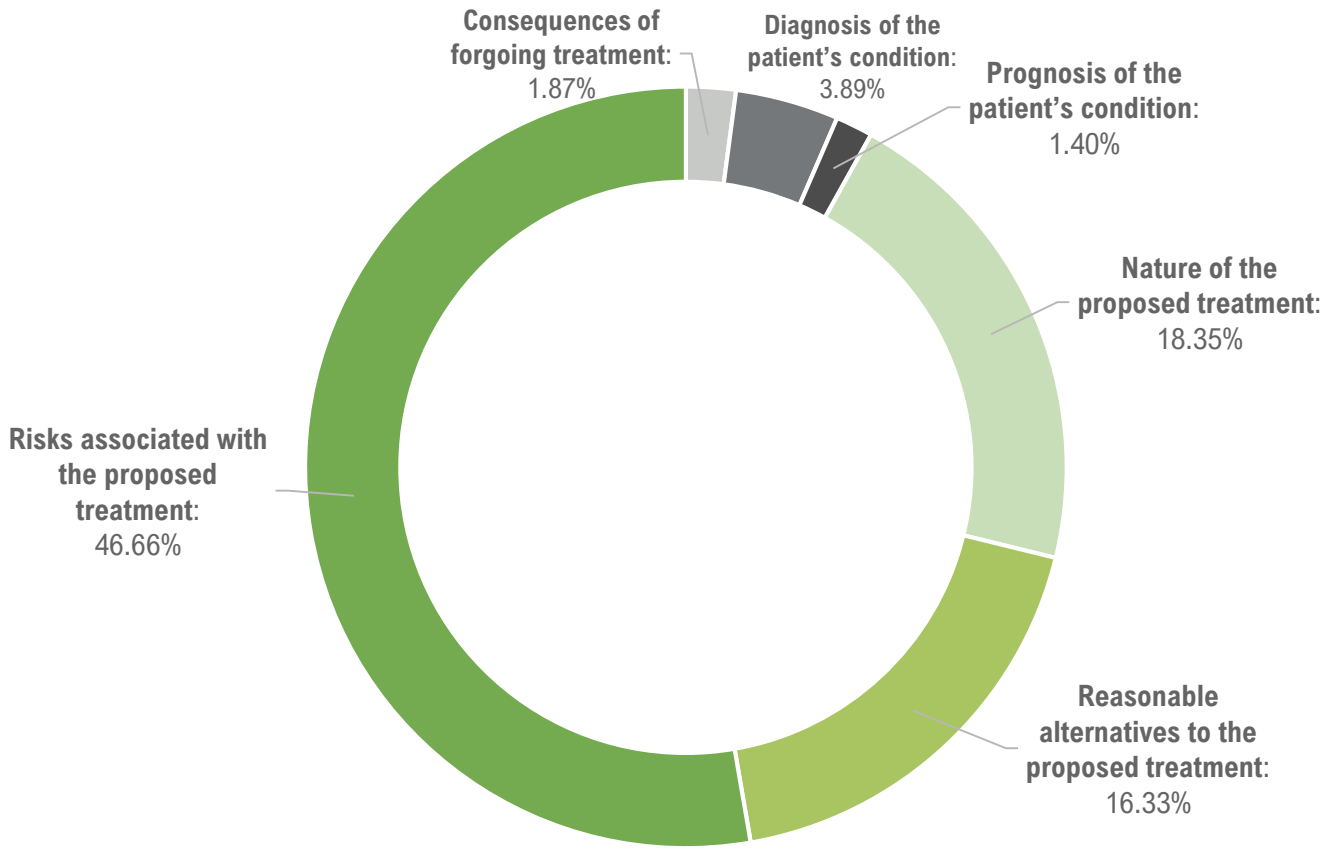
Doctors Who Blame the Lawyers and the Legal System

- “I have dedicated my life to helping patients, but with each passing year this country is moving to the terrible medical legal environment that doctors have to endure else where. With each day that passes we are all aware that there are lawyers that would love to pounce on us and destroy our lives.”
- “Public and legal services will still find a way to blame doctors for mishaps.”
- “With the modified Montgomery, the law opens up more reasons for unhappy patients to initiate legal proceedings or worse still allows rogue lawyers to instigate a case.”
- “It is somewhat amusing to see how the legal community around the world are unquestionably following this idiotic decision like mindless morons.”
- “…complicates and confuses everyone: patients, doctors, policy makers, judges. benefits only predatory lawyers”
- “Absolutely unworkable. Can only have been dreamt up by people who have never had to care for a single patient in their lives.”

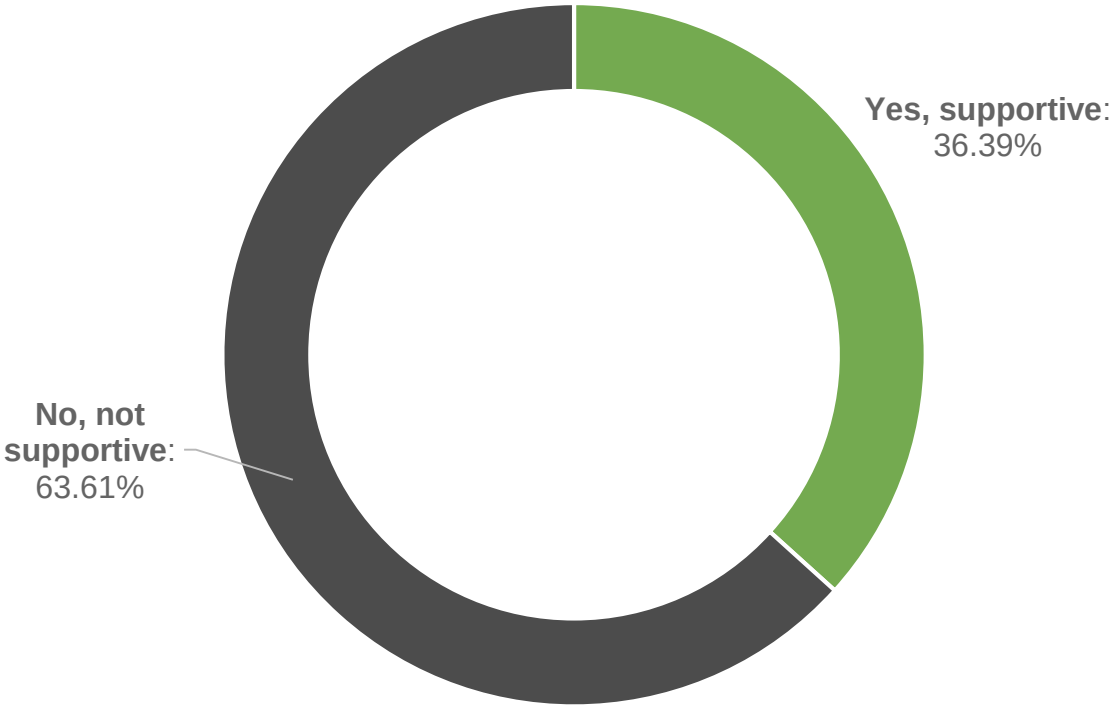
As a result of the modified *Montgomery* test, I have changed my practice in the following ways (tick all that apply)



As a result of the modified *Montgomery* test, I tend to spend the most amount of time explaining the following:



Are you supportive of audio/video recording of the consent taking process?



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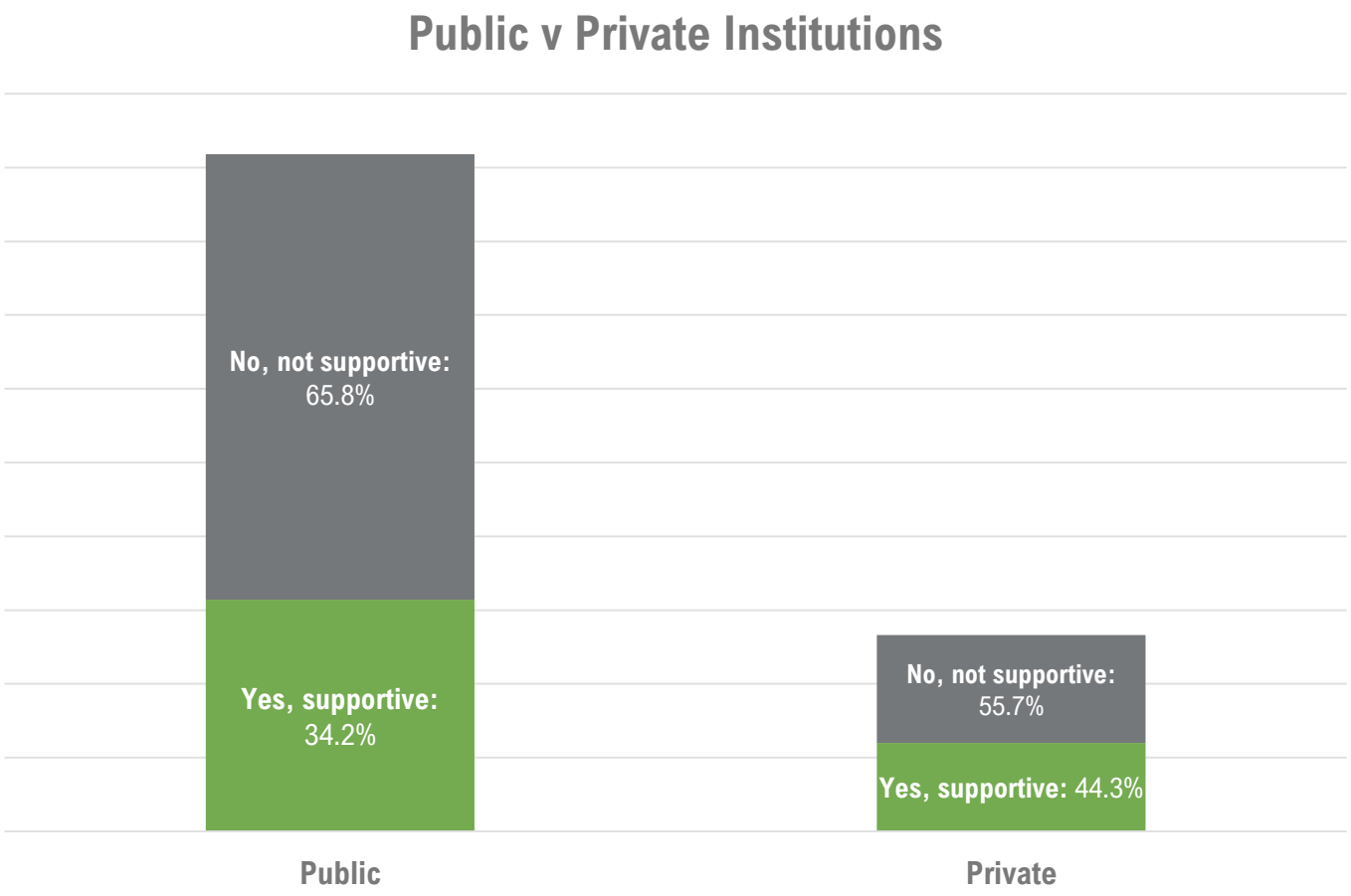

Are you supportive of audio/video recording of the consent taking process? -- YES

- Of the respondents who are supportive of audio/video recording of the consent taking process, the most common reasons are as follows (starting with the most common):

  - ✓ More certainty and less misunderstandings, objective evidence of what was explained to the patient
  - ✓ Saves time

- Some respondents noted that many patients are already recording consultations

Are you supportive of audio/video recording of the consent taking process? – NO

- Of the respondents who are *not* supportive of audio/video recording of the consent taking process, the most common reasons are as follows (starting with the most common):

  - × Erodes the trust between the patient and the doctor / defensive medicine
  - × Lack of resources (e.g. equipment, storage, etc.)
  - × Infringement of confidentiality and privacy
  - × Written documentation is sufficient
  - × Potential for abuse if the recording is taken out of context or altered / does not capture the whole consent taking process
  - × Time consuming
  - × Intrusive, troublesome, stressful and uncomfortable (for the doctor)

Selected Comments

- ✓ “Easier documentation. I don't need to type a long conversation, long consultation. It helps to serve as documentary proof of a confrontative and difficult and abusive patient”
- ✓ “It is logistically hard to implement and archive in a busy setting. Nevertheless this may be inevitable and should be made an acceptable alternative or adjunct to extensive documentation.”
- ✓ “Recordings can be used for teaching and research purposes, where appropriate.”
- × “Feels like an interrogation”
- × “A lot of time wasted in administrative tasks that really is just adding an additional workload for doctors. Keep in mind that a lot of consents are taken in the wards, where video/audio equipment is scarce, often not working well, and a plain hassle to maintain and procure.”

Selected Comments

- “It reflects that there is a level of distrust between patient and physician, and this can only lead to a bad doctor-patient relationship. Just like in a marriage, you don’t record everything your spouse says.”

- “We certainly do not like patients video recording our clinic sessions, so I don't see how they might feel comfortable when we do the same. This may result in adversarial / transactional relationships developing between both parties and in the long run”

- “Are you kidding? There is a doctor patient relationship. Please don't kill it!”

- “Simply because like in complaints, the opposition lawyer can then obtain the recording and twist things to their advantage. No explanation can be 100% perfect. It has to be reasonable but you can then get hung on missing out the most minor things or even in your phrasing”

In your opinion, what will help you cope with the additional requirements to satisfy the modified *Montgomery* test and how would you like to learn more about informed consent?

- The most common responses (starting with the most common):

  - ✓ More time and manpower (e.g. dedicated scribe) / lower KPIs and increased fees (in view of increased time) [~23%]
  - ✓ Training for doctors (i.e. lectures, seminars, dialogue, road shows, workshops, role play, etc.) [~ 20%]
  - ✓ Standardised consent forms, checklists, pamphlets, and/or information sheets for patients [~16%]
  - ✓ Institutional, government, national, SMC and/or SMA guidelines, protocols and support [~13%]
  - ✓ Case studies [~4%]
  - ✓ Pre-recorded videos for patients to watch [~3.5%]
  - ✓ Education of the public/patients [~3%]
  - ✓ Reverse modified *Montgomery* test / change the law back [~1%]
  - ✓ Time to retire / nothing as it will never be satisfied [~1%]
  - ✓ More reasonable patients [<0.5%]

Selected Comments

- “(1) Voice dictation of clinic notes (2) Electronic notepad capable of drawing and storing electronic diagrams”

- “a video explaining the procedure with animation and diagrams can be made as mandatory viewing by the patient and family members and they will then sign off on the video using their thumb print or some other biometric ID”

- “a willingness for singaporeans to pay for the increased consultation time it takes for a doctor to comply with Montgomery”

- “Standardized templates/ information material for patients for common procedures- "Things I may like to know about my XXXXXX””

- “More forums and case study talks by medico legal bodies and also from the judges”

- “Short videos on such informed consent legalities as podcasts can be shared to our normal emails or social media channels.”

Selected Comments

- “Refresher course for doctors. Departmental effort to consolidate and unify the process of informed consent taking amongst the doctors.”

- “More competent interpreters familiar with medical terminology in the language being translated, and able to speak all Chinese dialects, Malay & Tamil as well as Mandarin”

- “(1) Frequent email newsletter & updates on latest changes in the medicolegal landscape. (2) Website or smartphone app updates with online mini-courses or podcasts. (3) Regular workshops or talks during departmental meetings.”

- “To have sample consent forms, sessions on demos and recommendations , regular updates , access to guidelines e.g. online or booklets”

- “Public education. The public need to be aware that they have a role to play in deciding medical treatment and should be involved more in decision making which is also known as "shared decision ""

Selected Comments

- “The ministry just has to reassure that doctors will not be left on the lurch when s**t hits the fan”
- “The government and upper management should remove KPI's that requires us to see X number of patient per unit time. Every patient is unique and we need to really spend time talking to them...”
- “Nothing. We are screwed. We need to challenge the ruling and prove that a group of peers and not judges should decide if adequate informed consent was obtained.”
- “Time, more time, my learned friend.”
- “I would like to suggest that the judges try to walk a day in our shoes before suggesting more ways that make doctors' work even harder than it is now”
- “I need to stop practising”
- “Retirement”

Back to the SMC case:
SMC v Dr Ganesh Ramalingam [2018] SMCDT 6

- DT considered Dr Ganesh's failings to amount to "serious negligence":

> *"It was agreed that Dr Ganesh's failure to obtain the informed consent of the Patient before performing the Procedures on her would amount to such serious negligence that it objectively portrays an abuse of the privileges which accompany registration as a medical practitioner."*

- However as part of Dr Ganesh's mitigation plea, the DT was asked to take into account the "**Active steps voluntarily taken to improve clinical care and medical practice"**.

Back to the SMC case:
SMC v Dr Ganesh Ramalingam [2018] SMCDT 6

"To demonstrate his determination not to repeat the mistakes, Dr Ganesh has voluntarily taken active steps to improve his clinical care and medical practice. In doing so, Dr Ganesh has acknowledged his shortcomings and shown a commitment to improve in order to provide the best care to his patients. The steps taken include:

1. ***Use of Pamphlets and Visual Aids when obtaining informed consent**. Utilising teaching aids such as pamphlets and information sheets to better explain treatment options. The pamphlets are given to patients after their consultation with Dr Ganesh. Clinic assistants have also been trained to go through the pamphlets with the patients and ensure that they have no further questions before they leave the clinic. If patients have further queries, they would be directed back to the consultation room for further discussion with Dr Ganesh. This reduces the risks of error or failure in handwritten documentation.*

Back to the SMC case:

SMC v Dr Ganesh Ramalingam [2018] SMCDT 6

2. ***Ensuring sufficient elapse of time for the signing of the consent form**. Effort is made to ensure that patients are given as much time as they request to review the consent forms before signing them. Dr Ganesh will reiterate the nature, risks and complications, and alternatives of the treatment options before the patients sign the consent forms (i.e. advice is given thrice). Even after patients sign the consent forms, they are informed that they have the liberty to cancel the procedure if they decide not to proceed.*

3. ***Ensuring patients' records are properly and accurately captured**. During consultations, Dr Ganesh contemporaneously documents the discussion with his patients. The case notes are typed into the 'Clinic Assist' system. At the end of each day, Dr Ganesh would double check the 'Clinic Assist' system to ensure that all the patients' records are properly and accurately captured.*

4. ***Instituting a 24-hour hotline**. Dr Ganesh has also set up a 24-hour hotline on which patients can contact him personally if they have any queries or doubts regarding their procedure or medical condition."*

In Conclusion

- Doctors can and must meet the challenges of the new modified *Montgomery* Test.

- We need to have meaningful discussions about the resources doctors need to improve their practices, rather than to lament, seek to blame the lawyers and the Courts, or contemplate retirement.

- While public sector doctors do indeed face great pressure in their practice and have limited time allotted for each patient they see, they also have certain advantages:

    - They can tap into shared resources (both “intra-hospital” and “inter-hospital”).
    - They can implement hospital-wide practices for counseling patients, with a view to raising standards and making their practices more consistent.

In Conclusion

- Rather than wait for the perfect solutions to present themselves, the medical profession needs to start taking incremental steps towards improving doctors' communication with their patients.
    - Teach doctors that how they talk to and advise their patients is just as important as their diagnostic and treatment skills.
    - Instruct doctors on how to communicate more effectively e.g. step up training, increase the usage of educational materials and pamphlets, give the patients time to digest the information etc.
    - Provide resources to help doctors document the discussions more comprehensively and efficiently.

In Conclusion

- Give doctors MORE TIME to interact with their patients.
- Understand that STANDARDS are more important than FEES. Patients will not see the value of paying for a longer consultation unless they feel they are benefitting from the advice they get.
- Doctors need to be the first to change their mindset – yes it is important to also educate patients, but doctors must not forget that *they are the educators.*

In Conclusion

- If you / your colleagues have not already completed the survey, you may do so at the following link:

https://www.surveymonkey.com/r/H2YJJQ6

Thank You

Legal Clinic