Informed consent—patients' understanding of risk

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ABSTRACT

AIMS: The central concept of informed consent is communication of the chance of a successful outcome. The risks and benefits are probabilistic concepts derived from populations; they do not map with any certainty to the individual. We tested patients' comprehension of basic probability concepts that are needed for informed consent.

METHODS: Patients (n=478) completed five questions designed to test risk estimates that are relevant to informed consent. The questions posed non-medical scenarios to avoid patients associating them with their clinical care. The questionnaire was in English and was only offered to patients whose nurse felt that they had sufficient English literacy to understand the questions.

RESULTS: Out of a possible total of five correct answers, Asian patients scored lowest, and significantly less than Pākehā/Europeans (average total score 2.6±1.7 vs 3.6±1.4, p<0.001, 95% confidence interval 0.5 to 1.38). The total score for Māori/Pasifika was intermediate (3.2±1.4), yet they had the lowest deprivation index. This discordant finding may be due to poorer English literacy among Asian participants. On multiple linear regression, Asian ethnicity and advancing age were the independent predictors of a low score. Socio-economic deprivation decile and sex were not.

CONCLUSIONS: When answering questions constructed according to best practice, many (but not all) patients have reasonable risk comprehension. Further improvement could target older patients, those of Asian ethnicity and probably all patients where English is a second language. Liberal use of interpreters is suggested.

Patient informed consent is integral to the practice of medicine. The central concept of informed consent is communication of the chance of a successful outcome. The risks and benefits of different therapeutic options are discussed. However, these are probabilistic concepts derived from populations. They do not map to the individual in a way that gives the certainty that we humans prefer. Risk literacy is not universal, as documented in a literature that spans medicine, behavioural psychology and economics.[1–3] We tested patients' comprehension of risk as it relates to informed consent.

Methods

Five questions were constructed that evaluated the understanding of probabilistic concepts that are relevant to informed consent. The questions posed non-medical scenarios to avoid patients associating them with their clinical care. The form of the questions reflect how verbal and written consent is obtained at Te Whatu Ora – Waitematā. They were refined for readability and representativeness with feedback from colleagues and a random sample of laypersons. The average reading ease was 85.2 out of 100, indicating "easily understood by 11- to 12-year-olds".[4] The final version was offered to cardiology patients in various settings, including Te Whatu Ora – Waitematā cardiology inpatients and outpatients awaiting cardiac catheterisation, and at a private cardiac catheterisation laboratory waiting area. The questionnaire was in English and clinical staff were instructed to only canvas participation from patients they judged to have sufficient facility with English. Interpreters were not used. Patients were asked to answer the questions without help from whānau or support persons. The study was approved by the local ethics committee.

Questionnaire

What follows are the questions. Each is accompanied by an explanation of purpose that was not included in the version administered to patients.[5,6]

1. Your plumber has told you that the greater the percentage (%) blockage in your pipes, the greater the need to get them fixed. Which percentage (%) blockage has the highest chance of needing to be fixed?

33%	50%	99%	Unsure

Percentages are often used to present risk to patients. This assesses basic understanding of how risk changes as percentages change.

2. You have seven cards, each with a different day of the week. You pick one card at random.
   What is the likelihood of choosing a Wednesday?

1/7	2/7	3/7	Unsure

Frequencies are the preferred way to present risks to patients. This assesses basic understanding of what a frequency means.

3. Which of the following indicates a greater chance of meeting your favourite movie star at your local cafe?

1 in 10	1 in 100	1 in 1,000	Unsure

This assesses how risk increases with increasing frequency.

4. The chance of catching a fish with your hands is 3 in 1,000.
   10,000 people try catching a fish with their hands. How many are likely to catch a fish?

   ____ people

This assesses how a frequency is applied to calculate expected number of complications.

5. The chance of a person winning a raffle is 4 in a 1,000.
   What is the chance of ***not*** winning the raffle?

4 in a 1,000	100 in a 1,000	996 in a 1,000	Unsure

Both positive and negative framing should be used to describe risk. This assesses understanding of the relationship between positive and negative framing.

Analysis

Demographics were obtained using the National Health Identifier for each patient. Socio-economic deprivation was assessed according to domicile with the New Zealand Index of Deprivation 2018 (NZDep2018).[7] Questions left blank or marked "unsure" were classified as wrong, as only patients judged to have adequate literacy were offered participation ("intention to participate" analysis). Significance was defined as $p<0.05$. SPSS® version 29.0.0.0 (241) was used for analysis. Each correct answer was awarded one point. The total questionnaire score for each patient was the summed score for the five questions (range 0–5). The analysis focussed on the total score, using analysis of variance (ANOVA) with Bonferroni correction for comparison between groups of differing sex, ethnicity and age >70. Pearson's correlation was used to assess for any linear relationship of the total questionnaire score with numeric age and socio-economic decile. Multiple linear regression was used to build a predictive model for total score. Sub-group analysis for individual questions was carried out using Chi-square with Bonferroni correction. Training effect was evaluated by administering the questionnaire a second time to 21 patients, at a variable (unrecorded) number of days after their initial exposure.

Results

Of the 478 respondents, 12 were from a private cardiac facility. The remainder were from Te Whatu Ora – Waitematā public hospitals, mainly North Shore Hospital. Eleven respondents chose to remain anonymous. Anonymous patients were not more likely to leave questions blank. Blank answers varied from 3.6% (Q1, Q2) to 5.6% (Q3). Sixteen patients gave a reason for leaving questions blank, seven cited language (five Asian, two Other European) and three were not comfortable with numbers.

Baseline characteristics are in Table 1. Female respondents comprised 31% of the total, Māori comprised 7%, patients over age 70 comprised 44% and those over age 75 comprised 28%.

Results for the total questionnaire score are in Table 2. Asian patients scored lowest, and significantly worse than Pākehā/Europeans (total score 2.6±1.7 vs 3.6±1.4, $p<0.001$, 95% confidence interval 0.5 to 1.38). See Figure 1. Yet, Asian patients' deprivation decile was intermediate, at 4.9, compared with 6.2 for Māori/Pasifika and 4.2

Table 1: Baseline characteristics of the 478 patients.

Demographic		n (%)
Age	≤70	256 (54%)
	>70	211 (44%)
	Anonymous	11 (2%)
Sex	Female	150 (31%)
	Male	317 (66%)
	Anonymous	11 (2%)
Deprivation index	Upper tertile (1–3)	171 (36%)
	Mid tertile (4–6)	187 (39%)
	Low tertile (7–10)	105 (22%)
	Anonymous or data not available	15 (3%)
Ethnicity	Asian	47 (10%)
	Māori/Pasifika	70 (15%)
	Pākehā/European	349 (73%)
	Anonymous or data not available	12 (3 %)

Table 2: Total questionnaire score.

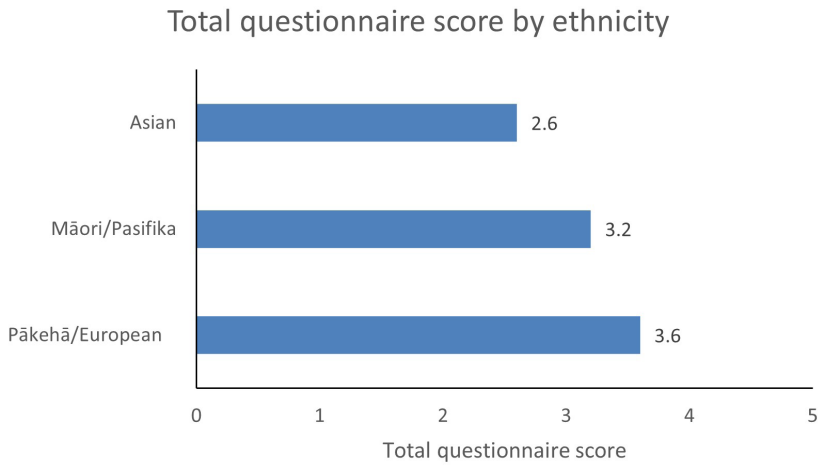
Demographic		Mean ± std deviation
Total		3.4±1.4 (range 0–5)
Age	≤70	3.6±1.4
	>70	3.2±1.5
	Anonymous	3.4±1.6
Sex	Female	3.3±1.4
	Male	3.5±1.4
	Anonymous	3.4±1.6
Deprivation index	Upper tertile (1–3)	3.5±1.4
	Mid tertile (4–6)	3.4±1.4
	Low tertile (7–10)	3.3±1.5
	Anonymous	3.3±1.8

Table 2 (continued): Total questionnaire score.

Ethnicity	Asian	2.6±1.7*
	Māori/Pasifika	3.2±1.4
	Pākehā/European	3.6±1.4*
	Anonymous	3.3±1.6

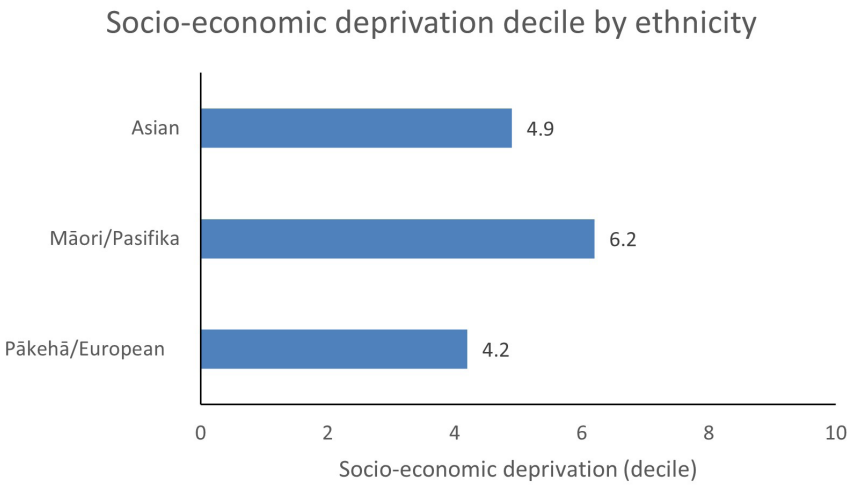
*ANOVA with Bonferroni correction, p<0.001

Figure 1: Overall questionnaire score by ethnicity.



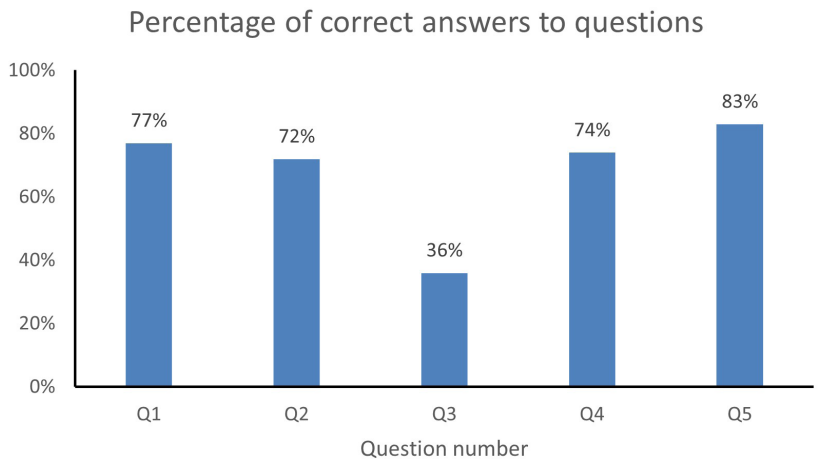
* Asians scored less than Pākehā/European, p<0.001.

Figure 2: Socio-economic deprivation decile by ethnicity.



Differences not significant.

Figure 3: Percentage of correct answers to questions.



*Percent correct for question three was less than for the other questions, p<0.001.

for Pākehā/Europeans. See Figure 2.

Multiple linear regression was run to predict total questionnaire scores from age, socio-economic deprivation score, sex and ethnicity. The prediction was statistically significant with $F(6, 455) = 9.08$, $p<0.001$, R^2 0.11. Age ($p<0.001$) and ethnicity ($p=0.001$) contributed significantly to the model, but deprivation score and sex did not. These findings were robust; they did not change with different methods or different orders of entering variables.

Regarding individual questions, the proportion of correct answers ranged from 36% for question three to 83% for question five (Figure 3). The Appendix contains tables of scores for individual questions by sub-group. The significant differences for individual questions are similar to those for total questionnaire scores, with significantly lower scores for Asian ethnicity (compared with Pākehā/European, 3/5 questions) and age >70 (2/5 questions).

There was no evidence of a learning effect, with no change in overall score when the questionnaire was answered a second time ($p=0.5$).

Discussion

This study tests risk comprehension in patients judged by their nurse to have sufficient English literacy to understand and answer the questionnaire.

Asian patients scored lower than other ethnic groups. Given that their social deprivation index was not the lowest, we surmise that this is due to other factors. Even though their nurse felt that they had sufficient English skills, it is likely that risk concepts need a higher level of literacy. Also, there are reports that Asian people perceive risk differently to Westerners.[8]

The total score for Māori/Pasifika was significantly lower than Pākehā/Europeans', but not as poor as Asian ethnicity.

Besides Asian ethnicity, the other independent predictor of a low score was advancing age.

Question three had the poorest proportion of correct responses, at only 36%. This is notable as it was testing the most evidence-based format of presenting risk as a frequency.[5] However, the denominator varied, and other researchers have found poorer comprehension when this is done.[9] This is a reminder to keep the same denominator throughout the informed consent process.

The other four questions had a correct response rate of 72–83%. This was from questions as a stand-alone event. Evidence suggests that comprehension of risk improves when consenting is a process, rather than a single event. It should include not only written information but also discussion with the consenting doctor to put risks and benefits into context, plus time for questions. It may be that risk presented as "two in a 1,000 chance of a serious complication" would be better comprehended if spelt out in full, as "out of every 1,000 patients undergoing this procedure, around

two will experience a serious complication".

Thus, it is likely that correct understanding would be higher still after these patients underwent the entire consent process. This is encouraging for the studied group of patients. However, we can surmise that patients not included in this study because their nurse felt that they had insufficient English comprehension would fare worse. Asians were the only ethnic group where the proportion doing the questionnaire differed from the proportion going through the cardiac catheterisation facility. Asians comprised 10% of the questionnaire population, but 15% through the cardiac catheterisation facility. This suggests that nurses informally assessed one in three Asians to have insufficient comprehension and did not offer questionnaire participation. Thus, many non-participants were Asian with poor English literacy. This supports liberal use of interpreters for informed consent, although we are yet to administer the questionnaire to a sample of interpreters.

Evidence summary of strategies to improve patient comprehension of risk[1,5,6,9–12]

- Start off with the bottom-line message before presenting details and numbers.
- Explain the risk as well as the reasons for it.
- Use numerical estimates but also images (pie charts for risks greater than 1%, icon arrays for risks less than 1%).
- Qualitative descriptions (high/medium/low or likely/unlikely) in verbal discussion can help place numerical estimates into context, but they are subjective—"low" risk can mean different things to the doctor and patient, and can lead patients to misinterpret risk.
- It may help to provide a benchmark risk for comparison, such as the risk of a car accident or drowning.
- Use non-unitary numerators if using frequencies and the same denominator for all frequencies.
- Use absolute, not relative, risk.
- Use both positive and negative framing.
- If possible, individualise risks by showing how they differ in sub-groups, e.g., inpatient versus outpatient, risks with age (best done during discussion with, and tailored to, the individual patient).
- Avoid the "lawyer's list" of all imaginable complications. Less is more when it comes to risk comprehension.
- Multimedia can improve comprehension.

Limitations

The questionnaire was only in the English language. We did not record the time taken to complete the questionnaire; this may have varied between groups. Patients' highest level of education was not sought, so as not to reduce participation because of associated shame (whakamā).[13] This study focussed on numerical estimates of risk, as these are integral to the concept of informed consent. However, this is only part of the overall process of clinical informed consent. Patients' comprehension of the questions may have differed if the written questionnaire was supplemented with verbal discussion. Healthcare and legal professionals place great emphasis on patient exposure to numeric risk estimates, as tested in this study. However, even educated, numerate individuals tend to base their decision on the overall gist of the information, as conveyed descriptively, which includes the flavour of the human interaction between patient and consenter.[5,6,14,15] Of course, this exposes the patient to any bias in the verbal presentation.

Conclusions

When answering questions constructed according to best practice, many (but not all) patients have reasonable risk comprehension. Further improvement could target older patients, those of Asian ethnicity and probably all patients where English is a second language. Liberal use of interpreters is suggested.

COMPETING INTERESTS
Nil.

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Appendices: Tables—individual question scores in sub-groups

Appendix Table 1: Response to individual questions grouped by age.

Age (n)	Q1 (%)	Q2 (%)	Q3 (%)	Q4 (%)	Q5 (%)
Not specified (11)	64	64	36	82*	91
≤70 (256)	78	76	*43**	*80*[§]	86
>70 (211)	76	67	*27**	*67*[§]*	78

Superscripts *[§] indicate pairs that differ significantly from each other.

Appendix Table 2: Response to individual questions grouped by sex.

Sex (n)	Q1 (%)	Q2 (%)	Q3 (%)	Q4 (%)	Q5 (%)
Not specified (11)	64	64	36	82	91
Female (150)	74	72	*27**	75	80
Male (317)	79	72	*40**	74	84

Superscript * indicate pairs that differ significantly from each other.

Appendix Table 3: Response to individual questions grouped by ethnicity.

Ethnicity (n)	Q1 (%)	Q2 (%)	Q3 (%)	Q4 (%)	Q5 (%)
Asian (47)	*62**	*49**	19	64	68*
Māori/Pasifika (70)	66[§]	64	40	66	81
Not specified (12)	67	67	33	75	92
Pākehā/European (349)	*81*[§]*	*76**	37	77	*85**

Superscripts *[§] indicate pairs that differ significantly from each other.

Appendix Table 4: Response to individual questions grouped by socio-economic decile.

Decile (n)	Q1 (%)	Q2 (%)	Q3 (%)	Q4 (%)	Q5 (%)
High 1–3 (171)	75	79*	33	78*	85
Mid 4–7 (187)	77	70	35	76	81
Low 7–10 (105)	80	65*	39	64*	82

Superscripts * indicate pairs that differ significantly from each other.