ORIGINAL ARTICLE

Parental preferences with regards to disclosure following adverse events occurring in relation to medication use or diagnosis in the care of their children – perspectives from Malaysia

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ABSTRACT

Introduction: Open disclosure is poorly understood in Malaysia but is an ethical and professional responsibility. The objectives of this study were to determine: (1) the perception of parents regarding the severity of medical error in relation to medication use or diagnosis; (2) the preference of parents for information following the medical error and its relation to severity; and (3) the preference of parents with regards to disciplinary action, reporting, and legal action.

Methods: We translated and contextualised a questionnaire developed from a previous study. The questionnaire consisted of four case vignettes that described the following: medication error with a lifelong complication; diagnostic error with a lifelong complication; diagnostic error without lifelong effect; and medication error without lifelong effect. Each case vignette was followed by a series of questions examining the subject's perception on the above areas. We also determined the content validity of the questionnaire. We invited parents of Malaysian children admitted to the paediatric wards of Tuanku Jaafar Hospital to participate in the study.

Results: One hundred and twenty-three parents participated in the study. The majority of parents wanted to be told regarding the event. As the severity of the case vignettes increased, the desire for information, remedial action, acknowledgement of responsibility, compensation, punishment, legal action, and reporting to a higher agency also increased. The findings did not have strong evidence of a relationship with subject's demographics.

Conclusion: This study gives insights into previously unexplored perspectives and preferences of parents in Malaysia regarding open disclosure. It also highlights the opportunity for more research in this area with potentially broad applications.

KEY WORDS:
Parents, medical error, diagnosis, children, disclosure

INTRODUCTION

Open disclosure is the process of providing an open and consistent approach to communicating with the patient and their support person following an adverse incident. This includes health care professionals providing their patients with accurate information about the adverse event, immediate consequences, options to remedy the harm, and preventive measures to avoid future recurrence together with support, and an expression of regret.[1] The landmark report, "To Err is Human," highlighted the significant risk that medical errors pose to patient safety.[2] Open disclosure is an ethical and professional responsibility and is expected by patients.[3-6] To date, the majority of research has come from the developed world, but there is little robust data on this subject from developing countries.[7]

Recent national research into near misses and adverse events show worrying trends. Within the public sector in Malaysia, 69.7% of admissions to non-specialist hospitals and about half of admissions to government specialist hospitals had near misses.[8] With regards to adverse events, 6.3% of admissions to non-specialist hospitals and 15.3% of admissions to specialist hospitals had one or more adverse events. In non-specialist government hospitals, one in five events resulted in death, and about half resulted in disability.[8] In government hospitals, a quarter of adverse events resulted in death and more than half resulted in disability. A recent study involving a review of medical records in twelve government primary care clinics showed that diagnostic errors were present in 3.6% of records and management errors in 53.2%; 39.9% of errors had the potential to cause serious harm.[9] There are no published data on errors from the private sector.

Research to appreciate the impact of cultural and socio-demographic differences is vital to understand the expectations of patients and their families, particularly when adverse events have occurred concerning their children. Little research has been done in this area, but existing results do show a different approach may be required.[10] Recent research

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published in China and Japan suggests that a full apology with acknowledgement of responsibility is required in the event of a medical error.[11,12]
The objectives of this study were to determine:
1. the perception of parents regarding the severity of medical error in relation to medication use or diagnosis.
2. the preference of parents for information following the medical error and its relation to severity.
3. the preference of parents with regards to disciplinary action, reporting to a higher body, and legal action in relation to the medical error.

We hypothesised that parents do want to be informed of the adverse event regardless of severity.

MATERIALS AND METHODS

Study design and setting
A cross-sectional survey was performed in the paediatric wards of Tuanku Jaafar Hospital, the main general hospital in the Malaysian state of Negeri Sembilan. Subjects who were parents of children admitted to the paediatric ward of Hospital Tuanku Jaafar Seremban were invited to participate in the study. Convenient sampling was used. The study was conducted from November 2013 to November 2014.

Study Instrument
We used an adapted version of the questionnaire developed by Hobgood *et al.*[13] Permission was obtained from the publishers to use this questionnaire. The questionnaire consisted of four case vignettes that portrayed a range of medical errors with varying severity. The case vignettes addressed: (1) a medication error with a lifelong complication, (2) a diagnostic error with a lifelong complication, (3) a diagnostic error without lifelong effect, and (4) a medication error without lifelong effect. We also collected demographic information on the following: age, gender, ethnicity, marital status, income level, education level, number of children, preferred place of healthcare, and usual method of paying for healthcare.

The questionnaire asked subjects on their perception on whether each case was a medical error, their perception of severity, and who or whom they preferred to learn of the event from. Each case is then followed by a series of questions that examine their desire for information, acknowledgement of responsibility, remedial action, compensation, legal action, and action by a regulatory body.

Prior to the adaptation process, we performed a pilot test for feasibility and suitability on a group of 20 volunteers (10 couples). The volunteers were Malaysians who had children under the age of 18 and they were recruited opportunistically by the researchers. The volunteers were asked to complete the questionnaire and respond to the following statements using a Likert scale: "strongly disagree," disagree," "neutral," "agree," or "strongly agree."
- I was given clear instructions on how to complete the questionnaire
- The instructions on how to complete the questionnaire were clear and easy to understand
- The case scenario was easy to understand
- This case scenario could have happened in Malaysia
- This scenario could have happened to my child at some point in my life
- I could picture myself as the parent of this child
- The questions were clear and easy to understand

The responses from the volunteers indicated that 70% or more of them "agreed" or "strongly agreed" with each of the statements above.

Next, we translated the original questionnaire into the Malay language (as 60 per cent of hospital attendees are Malays) using the protocol proposed by the World Health Organization.[14] After the Malay questionnaire had been forward and back-translated, both English and Malay questionnaires were pre-tested with cognitive interviewing to contextualise the questionnaire for the Malaysian context. All researchers underwent training prior to cognitive interviewing.

The researchers performed cognitive interviews on parents at Tuanku Jaafar Hospital that would have met the inclusion criteria. These parents were excluded from the study subsequently. Both questionnaires underwent repeated cycles of cognitive interviewing followed by revision based on comments from the subjects. The final contextualised questionnaire was achieved after four cycles of cognitive interviewing. The final version of the questionnaire is shown in the appendix. During the actual study, subjects were offered assistance when completing the questionnaire, but none of them requested such assistance.

Subject Information and Sample Size
Demographic data were collected from each of the parents (Table I). Using epidemiological software available in openepi.com, we estimated that we would require 384 subjects to take part in this study to achieve a confidence interval of 95%.[15]

Analysis
Similar to the study by Hobgood *et al.*, we collapsed the responses to: "strongly agree/agree," "neutral," and "disagree/strongly disagree." We also analysed the subject's responses for any relationship with their demographic details using Pearson's chi square test. For the subject's desire to seek legal action (questions 11 and 12), we compared subjects who rated case severity as "severe" versus "mild-moderate;" we combined the responses to "neutral/disagree/strongly disagree" and "strongly agree/agree."

RESULTS

Subject Demographics
Table I shows the demographics of the subjects. Not all the details were complete as subjects were not obliged to provide all demographic information that was requested. Of the questionnaires received, only questionnaires from 123 parents were suitable for further analysis, the remainder having to be excluded due to incomplete data. From the remaining 123 subjects, each case vignette was individually analysed and only completed case vignettes were included (Figure 1).

Table I: Demographic details of subjects (total number = 123)

Demographic detail	Demographic category	Number of subjects (percentage)
Age	20 to 29 years	29 (23.6)
	30 to 39 years	59 (48.0)
	40 to 49 years	14 (11.4)
	50 and above	1 (0.8)
	Not stated/declined*	20 (16.3)
Gender	Male	30 (24.4)
	Female	81 (65.9)
	Not stated/declined*	12 (9.8)
Ethnicity	Malay	83 (67.5)
	Chinese	13 (10.6)
	Indian	22 (17.9)
	Others	3 (2.4)
	Not stated/declined*	2 (1.6)
Marital status	Married	118 (95.9)
	Divorced	2 (1.6)
	Widowed	2 (1.6)
	Not stated/declined*	1 (0.8)
Income per month (in Malaysian Ringgit)	<RM1000	27 (22.0)
	1000 to 2999	42 (34.1)
	3000 to 4999	27 (22.0)
	5000 to 9999	16 (13.0)
	Above 10000	2 (1.6)
	Income not stated/declined*	9 (7.3)
Educational level	None	2 (1.6)
	Primary	5 (4.1)
	Secondary	72 (58.5)
	Tertiary	40 (32.6)
	Not stated/declined*	4 (3.2)
Occupation	Pensioner	4 (3.3)
	Professional	35 (28.5)
	Self Employed	22 (17.9)
	Skilled Manual	15 (12.2)
	Unskilled Manual	10 (8.1)
	Housewife	32 (26.0)
	Unemployed	2 (1.6)
	Not stated/declined*	3 (2.4)
Normal place of preferred healthcare	Private	12 (9.8)
	Government	68 (55.3)
	Combination	39 (31.7)
	Not stated/declined*	4 (3.3)
Normal method of paying for healthcare	Self	69 (56.1)
	Insurance	26 (21.1)
	No payment usually required	26 (21.1)
	Not stated/declined*	2 (1.6)

* Some subjects declined to provide information in certain demographic areas

Table II: Subject's perception on severity of error, and who/whom to learn from regarding the event*

	Severity of Error			Preference of who/whom to learn from regarding event		
	Minor (%)	Moderate (%)	Severe (%)	Nurse (%)	Doctor (%)	Team specialised in breaking bad news (%)
Case 1	3 (3.8)	15 (19.0)	61 (77.2)	3 (3.8)	60 (75.9)	16 (20.3)
Case 2	18 (24.7)	24 (32.9)	31 (42.5)	3 (4.1)	57 (78.1)	13 (17.8)
Case 3	31 (57.4)	19 (35.2)	4 (7.4)	0 (0)	51 (94.4)	3 (5.6)
Case 4	33 (57.9)	18 (31.6)	6 (10.5)	8 (14.0)	46 (80.7)	3 (5.3)

* Only those subjects stated that the cases were medical errors were analysed here (see Figure 1)

Table III: Subject's preference for information, remedial action, and acknowledgement of responsibility

		Q3. "I would want to be told about the event as soon as it was discovered" (%)	Q4. "I would want to know all the details of the event" (%)	Q5. "I would want to know that something had been done to prevent this from happening to another child" (%)	Q6. "I would want an apology for the event" (%)
Case 1	Strongly agree/agree	68 (86.1)	69 (87.3)	74 (93.7)	51 (64.6)
	Neutral	6 (7.6)	8 (10.1)	5 (6.3)	17 (21.5)
	Disagree/strongly disagree	5 (6.3)	2 (2.5)	0 (0)	11 (13.9)
Case 2	Strongly agree/agree	63 (86.3)	61 (83.6)	62 (84.9)	45 (61.6)
	Neutral	4 (5.5)	8 (11.0)	6 (8.2)	19 (26.0)
	Disagree/strongly disagree	6 (8.2)	4 (5.5)	5 (6.8)	9 (12.3)
Case 3	Strongly agree/agree	46 (85.2)	44 (81.5)	40 (74.1)	36 (66.7)
	Neutral	3 (5.6)	8 (14.8)	14 (25.9)	10 (18.5)
	Disagree/strongly disagree	5 (9.3)	2 (3.7)	0 (0)	8 (14.8)
Case 4	Strongly agree/agree	47 (82.5)	45 (78.9)	42 (73.7)	29 (50.9)
	Neutral	5 (8.8)	11 (19.3)	12 (21.1)	19 (33.3)
	Disagree/strongly disagree	5 (8.8)	1 (1.8)	3 (5.3)	9 (15.8)

Table IV: Subject's desire for compensation, perspective on physician responsibility, and punishment

		Q7. "I would want the financial compensation for the medical expenses associated with the event" (%)	Q8. "I would want financial compensation beyond the medical expenses associated with the event" (%)	Q9. "I believe the physician is the party most responsible for this event" (%)	Q10. "I would want the responsible party to be punished for the event" (%)
Case 1	Strongly agree/agree	57 (72.2)	42 (53.2)	59 (74.7)	51 (64.6)
	Neutral	16 (20.3)	25 (31.6)	14 (17.7)	17 (21.5)
	Disagree/strongly disagree	6 (7.6)	12 (15.2)	6 (7.6)	11 (13.9)
Case 2	Strongly agree/agree	45 (61.6)	34 (46.6)	54 (74.0)	42 (57.5)
	Neutral	17 (23.3)	24 (32.9)	15 (20.5)	21 (28.8)
	Disagree/strongly disagree	11 (15.1)	15 (20.5)	4 (5.5)	10 (13.7)
Case 3	Strongly agree/agree	22 (40.7)	18 (33.3)	40 (74.1)	23 (42.6)
	Neutral	22 (40.7)	29 (53.7)	10 (18.5)	22 (40.7)
	Disagree/strongly disagree	10 (18.5)	7 (13.0)	4 (7.4)	9 (16.7)
Case 4	Strongly agree/agree	20 (35.1)	19 (33.3)	33 (57.9)	24 (42.1)
	Neutral	21 (36.8)	24 (42.1)	16 (28.1)	25 (43.9)
	Disagree/strongly disagree	16 (28.1)	14 (24.6)	8 (14.0)	8 (14.0)

The majority of parents were below 50 years of age (83%), Malay (67%), married (96%), and female (66%). Ninety-one percent of parents had received at least secondary school education. The types of occupation held showed a wide distribution, the largest group being those who were professionals (28%). Most of the parents preferred government health services as opposed to private healthcare and the majority of parents paid for their healthcare themselves, regardless of whether they sought healthcare privately or via the public sector.

Perception of error and severity of error

Figure 2 shows a summary of the perception of each subject on whether each case was a medical error. We excluded those subjects who indicated that the case vignette was not a medical error from further analysis (Figure 1). Subjects perceived the error was of greater severity when complications occurred and the majority preferred to learn of the event from the doctor (Table II).

Preference for Information, Remedial Action, and Acknowledgement of Responsibility

The desire for more information and remedial action was higher in the first two cases where the severity of the outcome was greater; whereas the desire for an apology was similar across all four cases (Table III). We did not find significant evidence of a relationship between these areas and the subject's demographics.

Table V: Subject's preference for legal action and reporting to other agencies

		Q11. "After being informed of this event, I would seek legal action"	Q12. "If I was not informed of the event, and I learned about it through different means, I would seek legal action"	Q13. "I believe the responsible party should be reported to an agency that can monitor care quality"	Q14. "I believe the responsible party should be reported to an agency that can punish them"
Case 1	Strongly agree/agree	52 (65.8)	67 (84.8)	58 (73.4)	50 (63.3)
	Neutral	23 (29.1)	8 (10.1)	19 (24.1)	23 (29.1)
	Disagree/strongly disagree	4 (5.1)	4 (5.1)	2 (2.5)	6 (7.6)
Case 2	Strongly agree/agree	40 (54.8)	50 (68.5)	46 (63.0)	38 (52.1)
	Neutral	27 (37.0)	19 (26.0)	21 (28.8)	24 (32.9)
	Disagree/strongly disagree	6 (8.2)	4 (5.5)	6 (8.2)	11 (15.1)
Case 3	Strongly agree/agree	24 (44.4)	23 (42.6)	26 (48.1)	18 (33.3)
	Neutral	27 (50.0)	30 (55.6)	25 (46.3)	28 (51.9)
	Disagree/strongly disagree	3 (5.6)	1 (1.9)	3 (5.6)	8 (14.8)
Case 4	Strongly agree/agree	26 (45.6)	25 (43.9)	26 (45.6)	19 (33.3)
	Neutral	22 (38.6)	24 (42.1)	24 (42.1)	24 (42.1)
	Disagree/strongly disagree	9 (15.8)	8 (14.0)	7 (12.3)	14 (24.6)

Table VI: Relationship between case severity and desire for legal action

Case	Severity	Q11. "After being informed of this event, I would seek legal action"				Q12. "If I was not informed of the event, and I learned about it through different means, I would seek legal action"			
		Strongly Disagree/ Disagree/ Neutral (%)	Strongly Agree/ Agree (%)	$\chi 2$	p	Strongly Disagree/ Disagree/ Neutral (%)	Strongly Agree/ Agree (%)	$\chi 2$	p
1	Minor/Moderate	6	12	0.01	0.93	6	12	5.95	0.01
	Severe	21	40			6	55		
2	Minor/Moderate	20	22	0.23	0.62	15	27	0.81	0.36
	Severe	13	18			8	23		
3	Minor/Moderate	28	22	0.05	0.82	29	21	0.09	0.76
	Severe	2	2			2	2		
4	Minor/Moderate	28	23	0.05	0.82	20	31	4.24	0.04
	Severe	3	3			5	1		

Compensation, Physician Responsibility, and Punishment

The desire for financial compensation, attributing responsibility to the physician, or punishment is not as high as the desire for information, remedial action, or apology but the pattern is not as clear cut – the subject's agreement in these areas do increase in proportion to the severity of the case. Furthermore, the physician is assumed to be the most responsible party in these events, the likelihood of responsibility being attributed to the physician increasing with the severity of the case (Table IV). We did not find significant evidence of a relationship between these areas and subject's demographics.

Preference for legal action and reporting to other agencies

The desire for legal action was higher in the cases with significant complications, but this desire increased further when disclosure came from different means. The desire for reporting to other agencies was also higher with case one and two, although the desire to punish was relatively lower in comparison (Table V). For Case 1, we found a significant relationship between the desire of subjects for legal action if they were not informed of the event (question 12) and their perception of case severity. A weak relationship was also noted in Case 4 (Table VI), suggesting that the subjects did not desire legal action even when the case was perceived to be more severe.

DISCUSSION

Data is scarce on the expectations of patients or their relatives when medical errors occur in Malaysia. The results of the study highlight several key issues. The study suggests that subjects had differing understanding of what constitutes a medical error. A number of the subjects continued to indicate the severity of the error despite indicating that the case vignettes were not medical errors. This limitation of knowledge with regards to medical errors has been demonstrated in other Asian studies.[16]

This study did not show a significant difference in the perception of the case vignettes based on the subject's demographics, but sample sizes could have affected the results. Although the subject's demographics suggest a reasonable education level, health literacy continues to be a real concern in Malaysia in spite of overall improvement within Asia.[17,18] Lower health literacy rates generally indicate poorer health, and in the case of this study, could potentially impact patient's expectations in the handling of situations that go wrong.

Although there were only slight differences between the perception of error between cases (Figure 2), the more severe cases resulted in a greater desire for information, remedial action, compensation, attribution towards the physician, punishment, legal action, and reporting to a higher agency. Studies elsewhere also report similar findings.[11,13] This study suggests that the subjects desired open disclosure and their desire for further action was dependent on the severity of the case. It was interesting that the desire for an apology showed little difference between cases, suggesting that "saying sorry" alone isn't enough, particularly when complications have occurred. Unfortunately, the small sample size did not allow statistical inferences to be between the demographic characteristics of subjects and their responses.

As expected legal action was more likely with increasing case severity, this study suggests that even more subjects would seek legal action if open disclosure did not take place and they discovered the error through alternative means (Tables V and VI). This is an important consideration for clinicians as the fear of legal action is a major barrier when considering open disclosure.

This study also shows that subjects are doctor-centric, preferring to learn about the event from a doctor in all four cases but also attributing the error to the physician more than any other party. This is a real concern for the following reasons. Presently, little is understood on the perspective of doctors in Malaysia on open disclosure, even though the need for open disclosure is required by the Malaysian Medical Council.[4] A related study on shared decision making showed that doctors in Malaysia are poorly prepared for shared decision making and there are significant gaps in education, research, and local policy.[19] Generally, doctors in Malaysia continue to maintain a paternalistic role in their approach towards patients.[19] Shared decision making is a key component in patient-centered care and in the prevention and handling of errors.[20] Evidence shows that poor handling of adverse events may adversely impact doctors, leading to emotional and job-related stress.[21] For doctors, the fear of litigation following an adverse event continues to be a major barrier, even more so when it comes to open disclosure and extending an apology.[22] Studies in the United States demonstrate that open disclosure may reduce liability costs and time to resolution, but no studies within the region show similar promise.[23,24]

Limitations of this study

Firstly, this study was limited to patients recruited from the government public health service and only from the paediatric wards of a government hospital. The private sector warrants consideration for future research. The private sector in Malaysia is growing rapidly, including policies encouraging medical tourism, but there are concerns that regulation and enforcement within private establishments is still lacking.[25,26] Additionally, significant challenges were faced by researchers to enlist subjects during the recruitment process due to the sensitive nature of this study. Further research should incorporate a broader recruitment strategy that represents parents of children who have experienced different experiences, illnesses, and a variety of backgrounds (e.g. private and public sector). Secondly, this study examined the perspectives of individuals but the outcome of a collaborative decision-making between family members remains unknown. The prevailing culture in Malaysia favours collective decision making within families in contrast with Western society. This in turn has its implications on decision making autonomy as well as the perception and expectations in the course of medical care, even when things go wrong.[22,27,28]

Finally, whilst this study focused on open disclosure, it brings to the forefront valuable areas that need to be addressed such as health literacy, cultural awareness, patient centeredness and shared decision-making, medical education, consistency in the health care system in both the public and private sectors, and improvements in the legal framework.

CONCLUSION

This study demonstrates that open disclosure is essential to parents whose children have experienced an error in the diagnosis or management of their health condition. For clinicians, this study brings further insight into the expectations of parents during the process of open disclosure, particularly in relation to information provided, acknowledgement of responsibility, remedial action, compensation, punishment, legal action, and reporting to a higher agency.

ETHICAL & INSTITUTIONAL APPROVAL

The study received ethical approval from the International Medical University's Joint Research and Ethics Committee as well as the Medical Research and Ethics Committee in Malaysia (Ref no. NMRR-14-250-19376). The study also received approval from the Department of Paediatrics and the Medical Director of Tuanku Jaafar Hospital, Malaysia. The results of this study do not reflect events within the hospital itself.

PERMISSIONS

Permission has been obtained from the publishers to use the questionnaire by Hobgood et al. (reference no. 13) for the purpose of this study.

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