Legal Disputes over Duties to Disclose Treatment Risks to Patients: A Review of Negligence Claims and Complaints in Australia

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Introduction

The 1972 case of Canterbury v Spence [1] ranks among the best-known court decisions in American and international health law. Mr Canterbury, a 19-year-old typist for the Federal Bureau of Investigation, became paraplegic and incontinent following spinal surgery. He sued, alleging that the surgeon, Dr Spence, had failed in his duty to outline the risks of this outcome. Dr Spence countered that he owed no duty to warn of such an unexpected complication. The enduring significance of the case lies in the decision by the District of Columbia Court of Appeals to reject the traditional customary standard for assessing negligence (what would a reasonable practitioner have done?), and opt instead for a new patient-centered standard (what would a reasonable patient want to know?).

In the 40 years since Canterbury, appellate courts of many US states [2] and many countries—including the United Kingdom [3], Canada [4], Australia [5], Malaysia [6], Ireland [7], and New Zealand [8]—have considered similar cases, disputes in which patients and doctors square off over whether a particular treatment risk ought to have been disclosed. Our aim was to detail the treatments, risks, and adverse outcomes at issue in these cases.

Analysis

Setting

Avant Mutual Group Limited (Avant) and the Office of the Health Services Commissioner of Victoria (HSC) provided data for our analysis. Avant is Australia’s largest provider of medical indemnity insurance, covering approximately 55% of the country’s registered medical practitioners. The HSC, established in 1987, has statutory responsibility for resolving complaints against health care providers in Victoria, Australia’s second most populous state with 5.2 million residents. Patients must initiate complaints in writing but do not require legal representation. The system is free and open to all and is advertised widely in health care facilities.

Data

The sample frame consisted of all malpractice claims (n = 7,846) brought against doctors insured by Avant in three states (New South Wales, Victoria, and Queensland) between 1 January 2002 and 31 December 2008, and all conciliated complaints (n = 1,898) lodged with the HSC in Victoria during the same period. We have previously described our method for screening claims and complaints in this sample frame to determine


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Abbreviations: HSC, Health Services Commissioner of Victoria

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which ones met the definition of a
informed consent dispute [11]. We recap
definitions of key terms in Box 1.
Data collection proceeded in two steps.
We first undertook an initial review of
cases in the parent study [11] and then
followed up with an in-depth review
reported here. In the follow-up review,
one investigator (MMB) returned to Avant
and HSC offices between August and
November 2010 and re-examined the
hardcopy files associated with all cases
flagged in the initial review as meeting the
study definition of a disputed duty case.
We confirmed that the cases met the study
definition and collected supplementary
information, including details of patients’
allegations and health outcomes, doctors’
responses, and the undisclosed risks in
dispute. Probabilities associated with the
clinical risks in selected cases were subse-
sequently obtained through a series of
Medline searches and literature reviews
(one per case).
We did not attempt to judge whether
the patient’s or doctor’s position in the
disputed duty cases was the correct one.
Doing so would have required more
information than was available to us in the
case files. The case outcomes are not an
appropriate proxy for merit. With
claims, cases were typically resolved by
out-of-court negotiation. Moreover,
allegations about deficiencies in the con-
sent process often co-existed with other
types of allegations, yet legal outcomes
were generally “global”, not tethered to
specific allegations. With complaints, the
HSC runs a dispute resolution process; it
generally does not rule on the merit of
patients’ allegations or practitioners’ re-
sponses.
The ethics committee at the University
of Melbourne approved the study.

Findings

Frequency of Disputed Duty Cases
A total of 3.4% (263/7,846) of malprac-
tice claims and 11.5% (218/1,898) of
conciliated complaints involved disputes
over informed consent. Three-quarters
(375/481) of informed consent disputes
involved allegations that risks had not
been disclosed (Figure 1). However, most
of these cases (80%, 330/375) were not
disputed duty cases because they did not
involve disagreements between patients
and clinicians over whether a risk ought
to have been disclosed.

Rather, factual disagreements predomin-
ated. These were chiefly factual disputes
about whether the risk had been disclosed
before treatment (e.g., “I would have
discussed the risks of thrombosis associated
with this contraceptive”) or whether the
patient’s poor outcome was due to materi-
alisation of the undisclosed risk (e.g.,
“There was no causal connection between
the iodine discogram and her thyroid
disease”). In addition, in several cases the
doctor conceded that the risk was not
disclosed but should have been (e.g., “I
didn’t disclose the risk of bile duct injury. I
apologise for this and think the case should
be settled.”).

Nine percent (45/481) of informed
consent cases were disputed duty cases.
All findings reported hereafter pertain to
this special group of cases.

Treatments and Adverse Outcomes
In more than two-thirds of disputed
duty cases, the treatment rendered was a
surgical procedure (31/45). The rest
involved medications (7), anaesthetic pro-
cedures (3), obstetric care (3), and a
washout of tear ducts performed by a
general practitioner.

Table 1 shows the types of adverse
outcomes for patients that resulted from
materialisation of the undisclosed risks. In
a third of cases (15/45), patients com-
plained of not being warned of the risk
that further surgery would be needed; in
nearly three-quarters of cases (33/45) the
complaint centered on not being warned
about one of four outcomes: chronic pain,
impaired vision or hearing, poor cosmetic
result, and infertility or sexual dysfunction.

The dominance of these five outcomes
among disputed duty cases is striking;
collectively, they featured in 84% of

Box 1. Key Definitions
A claim is a written demand for compensation.

A conciliated complaint is a complaint the HSC considers too complex or serious
to be resolved through facilitated communication alone, and so refers it to formal
conciliation. (Approximately 20% of all complaints lodged with the HSC proceed
to conciliation.)

An informed consent dispute is a claim or complaint that alleges a deficiency,
either in the quality or quantity of information provided to the patient about a
treatment prior to a decision about whether to undertake it, or in the process
through which the patient was asked to consider such information and make a
decision.

A disputed duty case is a type of informed consent dispute, one that involves a
head-to-head disagreement between a patient and a doctor over the need to
explain certain risks. These are situations in which a patient (or the patient’s
representative) alleges that a particular risk should have been disclosed before
treatment, and a doctor responds that the disclosure was unnecessary or
inappropriate.

Summary Points

- Doctors, especially surgeons, are often unsure which clinical risks they should
disclose and discuss with patients before treatment. Leading medical
malpractice cases in many countries have centered on this issue.
- In a sample of nearly 10,000 malpractice claims and conciliated health care
complaints from Australia, we identified 481 disputes over informed consent, 45
(9%) of which were “disputed duty cases”—disagreements between patients
and doctors over whether a particular clinical risk should have been disclosed
before treatment.
- Two-thirds of disputed duty cases involved surgical procedures, and the
majority (38/45) of cases related to five adverse outcomes: the need for further
surgery, poor cosmetic result, impaired vision or hearing, chronic pain, and
infertility or sexual dysfunction.
- The most common justifications doctors gave for non-disclosure were that the
risk was too rare to warrant discussion or the specific risk was covered by a
more general risk that was discussed.
- Although most informed consent disputes appear to involve disagreements
about who said what and when, not stand-offs over whether a particular risk
ought to have been disclosed, doctors may routinely underestimate the
importance of a small set of risks that vex patients.

Findings

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Rather, factual disagreements predominated. These were chiefly factual disputes
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The dominance of these five outcomes
among disputed duty cases is striking;
collectively, they featured in 84% of
disputed duty cases. (It is also worth noting that several of the leading court cases, detailed in Table S1, involved this same group of outcomes.) What these outcomes have in common is important quality-of-life implications for patients. Our findings suggest that doctors may underestimate the premium patients place on understanding the risks of them in advance of treatment.

The adverse outcomes enumerated in Table 1 are essentially physical in nature. Patients in approximately a third of cases (17/45) also alleged psychological harm, in the form of depression or an anxiety disorder, associated with the adverse outcome.

Doctors’ Justifications for Non-Disclosure

Table 2 shows the distribution of cases by type of justification doctors gave for not having disclosed the risk. Examples of selected cases are also shown. The “risk too rare” and “subset of general risk” justifications for non-disclosure were particularly common; collectively, they appeared in nearly two-thirds of the disputed duty cases.

Risk too rare. The most common justification for non-disclosure (18/45 cases) was that the risk was too rare. These were cases in which doctors argued that the outcome the patient experienced occurs too infrequently in clinical practice to warrant disclosing it during the informed consent process, or the risk was so rare that it was unknown to the doctor.

General risk was disclosed. The next most common justification (11/45 cases) was that the risk not discussed was encapsulated in a general risk that was discussed. In a quarter of cases, for example, the doctor mentioned generic risks such as bleeding or infection without providing specific information regarding possible consequences for the patient. In another case, a doctor had warned the patient of the risk of an allergic reaction to phenytoin, but had not specifically mentioned the risk of Stevens-Johnson syndrome and blindness. These findings are consistent with research suggesting that clinicians tend to be overly general in their descriptions of some risks, and struggle with discussing serious complications in specific terms [12].

Other justifications. Each of the other types of justification applied to relatively few cases. Doctors defended non-disclosure in five cases by arguing that the risk was obvious and a reasonable patient ought to have been aware of it. In four cases, the doctor argued it was sufficient to have advised the patient of the average recovery time for a procedure and been silent on risks of delayed recovery; all of these cases involved cosmetic procedures.

Doctors in a further four cases argued that the need for disclosure was obviated by the fact that the benefits of the treatment clearly outweighed any risks, and disclosing the risk in question would have imposed an unnecessary burden on the patient; all of these cases involved surgical procedures. Arguments that it is unnecessary or inappropriate to “burden” the patient with information about procedures they are about to undergo are paternalistic; they hark back to an earlier era in which there was greater deference to the medical profession, and such exercises of “therapeutic privilege” were common and accepted [13,14].

The final three cases were unusual in that the adverse outcome was patently due to negligent care. The patients in these cases alleged a failure to warn of the risk of the outcome and the doctors argued the risk was not one they needed to disclose. (Technically, the doctors were probably correct, because there is no legal duty to warn of risks arising from negligent care.)

Rare Risk Cases

Table 3 provides details of the treatments, adverse outcomes, and risk probabilities for the 18 disputed duty cases in which the doctors’ justification for non-disclosure was that the risk was too rare to warrant it. Our literature review indicated a wide span in these probabilities, ranging from complications described in only a few case reports (e.g., testicular loss following varicocele repair) to well-recognised adverse outcomes occurring in over 1% of cases (e.g., fetal laceration during caesarean delivery of a breech baby).

There was no obvious pattern to this wide variability. We had expected an inverse correlation between risk frequency and severity in this group of cases, but...
found no evidence of one. Nor was there evidence of convergence on a standard risk threshold: the probabilities appeared to vary across several orders of magnitude, from less than 0.01% to greater than 1%.

**Discussion**

**Disputed Duty Cases in Context**

Landmark court battles [1,3,4,5,6,7,8] over informed consent have centred on what legal standard of care should apply in head-to-head disputes between patients and doctors over whether a treatment risk warrants disclosure. To the best of our knowledge, this is the first study to examine this type disagreement at the population level. The finding that nine out of ten legal disputes over informed consent did not turn on such a disagreement highlights a general point: highly publicized legal cases—those at the apex of the “dispute pyramid”—can easily distort understanding of the much larger number of “garden variety” disputes and grievances that sit beneath them [15,16].

The finding also has a practical message for practicing clinicians: malpractice claims and complaints over informed consent are not uncommon events, but when they arise they are most likely to centre on mundane factual disagreement over who said what and when, not contests over what should have been disclosed. This underscores that for the informed consent process, like most other areas of clinical practice, regular and careful documentation of interactions with patients is a prudent risk-management strategy. Documentation of the details of consent discussions in the lead-up to surgical procedures is particularly important, as the vast majority of informed consent disputes involve complications following operations [2,11].

Despite their rarity, disputed duty cases are of special interest for several reasons. From a legal standpoint, these are the types of cases that define and test the standard of care to which doctors must adhere in obtaining informed consent. From a medical standpoint, the clinical details of disputed duty cases may point to an important “penumbra” of treatment risks—outcomes about which there is division or uncertainty among doctors as

### Table 1. Physical health outcomes associated with undisclosed risks that materialised in disputed duty cases.

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>n (%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Further surgery required</td>
<td>15 (33%)</td>
</tr>
<tr>
<td>Chronic pain</td>
<td>13 (29%)</td>
</tr>
<tr>
<td>Poor cosmetic result or delayed wound healing</td>
<td>9 (20%)</td>
</tr>
<tr>
<td>Impaired vision or hearing</td>
<td>8 (18%)</td>
</tr>
<tr>
<td>Infertility or sexual dysfunction</td>
<td>7 (16%)</td>
</tr>
<tr>
<td>Paralysis</td>
<td>3 (7%)</td>
</tr>
<tr>
<td>Other</td>
<td>12 (27%)</td>
</tr>
</tbody>
</table>

*Total sums to greater than 45 because categories are not mutually exclusive.

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### Table 2. Doctors’ justifications for non-disclosure of risk in disputed duty cases.

<table>
<thead>
<tr>
<th>Justification Type</th>
<th>n (%)</th>
<th>Case Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rare risk</td>
<td>18 (40%)</td>
<td>Cyclosporin leading to tinnitus and hearing loss</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rectal prolapse repair leading to inability to ejaculate</td>
</tr>
<tr>
<td>Subset of general risk</td>
<td>11 (24%)</td>
<td>Migration of gastric reflux collar leading to cardiac tamponade</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Phenyltoin leading to Stevens-Johnson syndrome causing blindness</td>
</tr>
<tr>
<td>Obvious or implied risk</td>
<td>5 (11%)</td>
<td>Cosmetic eyelid surgery leading to post-operative infection</td>
</tr>
<tr>
<td>Duration of risk</td>
<td>4 (9%)</td>
<td>Cosmetic breast surgery with poor wound healing after one year</td>
</tr>
<tr>
<td>Risk clearly outweighed by benefits</td>
<td>4 (9%)</td>
<td>Abdominal lipectomy leading to post-operative infection and scarring</td>
</tr>
<tr>
<td>Risk of negligence</td>
<td>3 (7%)</td>
<td>Gastric lap band leading to perforation of right ventricle by liver retractor</td>
</tr>
</tbody>
</table>

*Excerpts from doctors’ justificatory statements:

- “It is not our practice to mention all rarely reported side-effects of every medication that is prescribed.”
- “I would not specifically have warned of potential sexual difficulties because the incidence should be relatively low.”
- “I had mentioned Angelchik collars had been known to migrate. I had certainly not mentioned this exceedingly rare complication.”
- “I did not warn him specifically of Stevens Johnson syndrome though I did discuss allergic reactions in general.”
- “Although I may not have highlighted problems of infection, most people, particularly if they are married to a doctor, would be aware that any operation can be complicated by infection.”
- “Most would be healed within a couple of months. The maximum time I would have expected would be six months.”
- “Infection is a solvable problem and the patient would still be in a better position than before the surgery.”
- “I did not mention specifically perforation of the heart, but this could be understood as this has never been reported before.”

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to the appropriateness of disclosure and warning. From a patient standpoint, disputed duty cases may highlight certain types of risks that patients tend to prioritise more highly than doctors do. What lessons does an analysis of such cases have for how doctors should approach the informed consent process?

What to Disclose: A Balancing Act

The clinical reality is that standardised consent forms are widely used, particularly for common procedures, and they tend to present exhaustive enumerations of risks. Anglo-American courts do not accept that merely handing such forms to patients as a valid way to obtain informed consent. Consequently, clinicians must determine which risks to discuss and emphasise. For busy doctors this necessitates choices because time is limited and effort devoted to consent discussions has opportunity costs [17].

One approach is to focus discussion on risks of outcomes above a certain incidence. The notion of a 1% risk threshold appears to have some currency in clinical practice. However, it has no firm basis in either law or available evidence regarding patients’ attitudes to risk [18,19,20]. Courts regard the probability of a particular adverse outcome as an important element in determining what qualifies as a “material” risk that must be disclosed, but it is one of several elements.

The severity of the outcome associated with a risk also matters. It is reasonable to think of rarity and severity as considerations that operate in tandem, on a sliding scale. Small risks of catastrophic outcomes usually warrant emphasis, as do high risks of relatively minor adverse outcomes, but not low risks of minor outcomes.

Distinctive characteristics of individual patients may also dictate the breadth and depth of discussion about certain risks; the extreme example of a hand operation on a concert pianist helps to illustrate the point. A less obvious consideration is the treatment’s urgency. Details of risks tend to matter more toward the elective end of the treatment spectrum than the urgent or emergent end, which may help to explain the prominence of cosmetic treatments among the disputed duty cases in our sample.

To this recognised set of factors, our analysis draws attention to five outcomes that appear to trigger the majority of disputed duty cases—the need for further surgery, poor cosmesis, impaired vision or hearing, chronic pain, and infertility or sexual dysfunction. These are outcomes that clinicians may give too little weight and attention in the consent process.

Limitations

Our analysis has several limitations. First, we examined legal disputes over the duty to disclose certain risks; this sample of cases may be unrepresentative of wider disagreements between patients and doctors in this area because they are refracted through the lens of patients’ claiming and complaining behaviour [21]. Second, we were constrained by the information set available in claim and complaint files. Finally, the generalisability of our findings may be influenced by differences in medico-legal systems and, in particular, the prevailing legal standard for informed consent. Since 1992, Australian courts have applied a patient-centred standard [5,22]; the same standard prevails in around half of the states in the US [2] and in a number of other countries [4,6,7,8], where the decision in Canterbury v Spence has proved to be influential.

Conclusion

The rationale for informed consent springs from the ethical principle of autonomy—the notion that it is patients themselves who should make the final decision about which course of treatment to follow. Increasingly, doctors are expected to advise and empower patients to make rational choices by sharing information that may bear upon the decision, including risks of undesired outcomes. Occasionally, doctors and patients will disagree about whether a particular risk has an important bearing on treatment choices. Improved understanding of these situations helps to spotlight gaps between

| Table 3. Characteristics of 18 disputed duty cases in which doctors’ justification for non-disclosure was risk too rare. |
| --- | --- | --- |
| Treatment | Risk That Materialised | Probability of Risk |
| Topical steroid for eczema | Steroid induced rosacea | >1% [23] |
| Rectal prolapse repair | Inability to ejaculate | >1% [24] |
| Caesarean for breech baby | Fetal laceration requiring surgical repair | >1% [25,26] |
| Prolonged prednisone for erythematous eruptions | Avascular necrosis requiring hip replacement | >1% [27] |
| Laparoscopy for endometriosis | Removal of ovary and tube to control bleeding | 0.1 to 1% [28] |
| Cyclosporin for psoriasis | Tinnitus and hearing loss | 0.1 to 1% [29] |
| Inguinal hernia repair | Testicular necrosis requiring orchidectomy | 0.1 to 1% [30] |
| Spinal anaesthetic for caesarean | Paraesthesia and weakness in leg | 0.01 to 0.1% [31] |
| Laryngeal mask airway | Loose teeth requiring dental surgery | 0.01 to 0.1% [32,33] |
| Laparoscopic gastric banding | Cuff leak after 15 months requiring surgery to replace band | 0.01 to 0.1% [34] |
| Flucloxacillin | Hepatitis | <0.01% [35] |
| Bilateral inguinal hernia repair | Infertility due to azospermia | <0.01% [36,37] |
| Vaginal delivery of 4.5 kg baby | Diastasis of symphysis pubis | <0.01% [38] |
| Varicocele repair | Testicular infarct requiring orchidectomy | Case reports [39] |
| Vasectomy | Sperm granuloma requiring surgical excision | Case reports [40] |
| Coronary angiogram and angioplasty | Damage to aortic valve requiring emergency cardiac surgery | Not available |
| Dilatation/washout of tear ducts | Lacrimal duct stenosis leading to inflammation and impaired vision | Not available |
| Pelvic osteotomy for scoliosis | Cosmetic deformity (prominent lateral hip) | Not available |

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what patients want to hear and what doctors perceive patients want (or should want) to hear. It may also be useful information for doctors eager to avoid medico-legal disputes.

Supporting Information

Table S1 Leading court cases on informed consent from 7 countries.

References

6. Hong Chuan Lay v Dr. Eddie Soo Fook Mun (1998) 7 MLJ.

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Author Contributions

Analyzed the data: MB DS. Wrote the first draft of the manuscript: MB DS. Contributed to the writing of the manuscript: AJG RG AG. ICMJE criteria for authorship read and met: MB AJG RG AG DS. Agree with manuscript results and conclusions: MB AJG RC RG AG DS. Coordinated the collection of data at Avant: RC.