

Mental Health Legal Centre Inc. response to

**The Australian Commission on Safety and Quality in
HealthCare**

**Patient-Centred Care: Improving Quality and Safety by
Focusing Care on Patients and Consumers,**

**Discussion Paper, Draft for public consultation, September
2010.**

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Mental Health Legal Centre

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We commend ACSQHC on its excellent discussion paper. We strongly support the principle of patient-centred care and generally support the paper's recommendations. In our response, we are focussing on the recommendations most relevant to our clients and their experience of the general and mental health systems.

Our organization

The Mental Health Legal Centre Inc (MHLC) is a Victorian state-wide specialist community legal centre. MHLC provides direct legal advocacy, telephone legal advice and referral to callers and community education about mental health and the law for people in Victoria with, or labelled as having, a mental illness. MHLC also undertakes substantial research, law reform and policy work in relation to mental health and the law, the aim of which is to further the rights of people with mental illness in Victoria.

MHLC is a non-profit organisation and receives the majority of its funding from the Victorian Department of Health and Victoria Legal Aid. Additionally, we receive project funding from philanthropic and government sources.

Recommendation 1

If health workers adopted a more patient-centred approach, patients might be more engaged with their treatment and dissatisfaction and complaints could be reduced. Including patient-centred care in strategic and other policy documentation would improve the sharing of information and enhance transparency between healthcarers and patients.

There is a culture in the mental health sector of withholding access to files from patients. People with physical ailments may merely request to see their patient file, but in the mental health sector many barriers prevent people informally accessing their files. These range from a paternalistic belief that patients' illnesses will be exacerbated; staff shortages that prevent staff from spending time to explain file-notes; health-carers viewing themselves as the expert or fear of litigation. This practice of not informing patients about their health-care raises the question of how they can understand and contribute to their treatment plans.

Consumers [patients] told researchers that gaining access to their case file is a major concern. Some consumers stated that they had no knowledge of their right to access their file; others reported that they were not provided with enough time to understand the file's contents...¹

Commonly, patients are compelled to apply for file access under the Victorian Freedom of Information Act 1982 (FOI). The file they receive as a consequence could be

censored under section 33² or withheld on the ground of irrelevancy under section 25,³ which further undermine patients' confidence in their treatment, and their relationship with the health-carer and the health system.

Some people, aware of the contents of their file, were disturbed that the file had documents missing. People were not generally aware of the exemption provisions for some documents.⁴

Another consideration is the procedure followed before some Mental Health Review Board hearings. A mental health service may make an application for non-disclosure under section 26(8) of the Mental Health Act (1986), which, in our experience, the Board usually grants on the basis of confidentiality. This is often due to family members asking the services not to disclose to a patient that they have been in contact with the service or supplied information that would displease the patient.

Services generally make non-disclosure applications as they fear the information has the potential to damage the relationship with their patient, for example, if they have notified child protection. But the result of a successful non-disclosure application is that self-represented patients cannot see their patient files prior to the hearing, which puts them at a serious disadvantage during the course of the hearing. The withheld material may be evidence that assists the patient's case. Conversely, it may be uncorroborated evidence about their behaviour that they wish to challenge. The Board will usually not look at the non-disclosed material. But if it subsequently decides to do so, the patient is unable to influence the Board's view of the material. This does not concord with the principle of natural justice:

One of the demands of natural justice is that the parties are allowed to comprehensively present their case. No access or inadequate access to their file is likely to mean consumers are effectively denied this opportunity.⁵

Almost 96% of patients are self-represented before the Mental Health Review Board.⁶ Even those legally represented are affected by non-disclosure. On approximately one out of five occasions, the application for non-disclosure is only revealed on the day of the hearing, leaving patient and legal practitioner with no time to prepare an appeal/response.

Recommendation 2

It is essential that patient survey tools should accord with a national standard to enable accurate collation and comparison of patient care experience data.

Recommendation 3

We agree that surveys need to incorporate responses that transcend mere satisfaction or dissatisfaction to include the domains of respect, emotional support, physical comfort, information and communication, continuity and transition, care coordination, involvement of people of choice and access to care.

In the Victorian mental health sector, however, it seems that patient satisfaction has not yet been assessed. It has been incumbent on local services to collect data about patient satisfaction, but if it has been collected it is not publicly available on the Mental Health, Drugs and Regions Division page of the Victorian Health Department website.⁷ Additionally, the Chief Psychiatrist's report focuses on assessment of acute mental health services and whether they have met their statutory obligations, not patient satisfaction.

Recommendation 4

Incorporating "improving patient care experience" as an integral indicator of health service quality improvement is meritorious in theory. But there are several issues attached to such a development.

Firstly, linking service quality to "performance-based payments" has contributed to a number of Victorian hospitals providing misleading data to funding departments.⁸

Second, given that mental health services are already underfunded,⁹ there is a risk that performance based payments could make the situation for patients even worse if services failed to improve patient care experience.

Finally, patient satisfaction may vary over the course of the treatment, so the time at which satisfaction is measured is crucial.

Recommendation 5

Recent research suggests that patients will make use of publicly available data on hospital performance if they are in a position to choose among providers.¹⁰ Mental health patients, however, are referred to the hospital in their local catchment area and

lack choice.¹¹ Information pertaining to their general health options, and those of other patients, would still be useful.

Information about Victorian hospitals is available on the Your Hospitals page of the Department of Health website. Reports on public hospitals are uploaded annually and include patient satisfaction ratings conducted by an independent organisation. The results, however, are aggregated to such an extent that the views of mental health patients cannot be specifically identified.

The Victorian Mental Health Services section¹² of the Department of Health website does not display the results of surveys of mental health patients regarding the domains of patient care experience.

There is further opportunity for policy-makers and regulators to present data on the Victorian Department of Human Services website via its Funded Agency Channel.¹³ The Mental Health, Drugs & Regions Division has uploaded few reports in comparison with other program areas.

The MyHospitals site could be developed as a forum to publicize patient satisfaction on a national basis, but is currently confined to waiting times for emergency department care and elective surgery.¹⁴ A matter of concern is that the accuracy of information on the website – three years in development – has been queried. The Victorian Health Minister David Davis has warned that data submitted by the State's hospitals are unreliable due to acknowledged episodes of misrepresentation to funders. The Federal Health Minister Nicola Roxon has conceded that she and the State ministers cannot personally vouch for the accuracy of data posted in the site.¹⁵ Data on all websites offering a comparative analysis should be audited before being uploaded to ensure its integrity.

It is imperative that a national standard scheme ensures that data are compiled consistently across all health services. Recommendation 2 needs to be put into effect.

Recommendation 6

We support the implementation of a system of regularly collecting and reporting data on patient care experience. We are aware that many mental health patients find engaging in narrative-based feedback cathartic and would be willing to participate.

Recommendation 7

We endorse this recommendation.

Recommendation 8

We endorse this recommendation.

Recommendation 9

We endorse this recommendation.

Recommendation 10

Family involvement

While it is important for health services to develop a patient-centred mission, there seems to be an assumption in the discussion paper that families are naturally supportive of patients and should always be part of that mission. The practice of engaging families as partners may be less applicable in mental health. Given the unfortunate stigma attached to mental illness in our community, some families feel significant shame when a relative becomes unwell. Also, the mental illness may have arisen due to trauma in the family. Additionally, a patient's family may have notified the Crisis Assessment Team, often against the patient's wishes, with the result that the person is put under an involuntary treatment order.

We prefer a focus on sharing information directly with the patient and the people of their choice, who may be friends rather than relatives.

My carer base has never been my family. It is a collection of friends, some being primary carers and another group of close friends who have a wide range of roles and accept a wide range of responsibilities for me.¹⁶

The appointment of patients to boards and advisory committees is useful. But it is inadvisable to rely on this strategy alone. The practice accommodates only patients with the confidence to do it. The telling of stories to board members is also worthwhile, but again should not exclude forums, interviews, surveys and informal feedback.

The involvement of patients in healthcare policies and procedures

Some doctors are also teachers for tertiary institutions and/or clinical researchers. This situation can leave the patient confused about the therapeutic relationship and potentially affect the practice of patient-centred care.

Clinical trials

It is difficult to see how the conduct of some clinical trials is consistent with the notion of patient-centred care. Patients can be asked to participate in clinical trials at their first visit to a hospital or health service at a time they may be distressed by a diagnosis. The reason for this practice may be that researchers require subjects who are treatment-naïve, but the patients may find it insensitive. Patients may also be asked about participating in the same trial several times, which they have reported makes them feel like a commodity rather than a patient.

Conflicts of Interest

Where a trial participant's treating doctor is also the research scientist, there is a potential conflict of interest.¹⁷ This practice of this dual role could impact upon patient-centred healthcare:

Respect for both physician and patient autonomy may conflict with the scientific principles necessary for good research.¹⁸

In many public hospitals, the treating doctor recruits patient for clinical trials in which they are involved. Best practice would be for an independent researcher, doctor or nurse to act as recruiters.

The National Statement on Ethical Conduct in Human Research (2007) (The National Statement) says:

3.3.16 In clinical research, where patient care is combined with an intent to contribute to knowledge, the following matters should be carefully weighed:

- (c) the possible effects of an unequal or dependent relationship between the treating health professional or researcher and the potential participant (see *Chapter 4.3: People in dependent or unequal relationships*).

Chapter 4.3: Examples may include relationships between:

...health care professionals and their patients or clients

3.3.17 Where the researcher is also the treating health professional, it should be considered whether an independent person should seek the consent of potential participants.¹⁹

The excellent Code of Ethics devised by the Australian Medical Association (AMA) “has grown out of other similar ethical codes stretching back into history including the Hippocratic Oath”.²⁰ Although not all doctors are members of the AMA, and the Code of Ethics is not binding on members, it is nonetheless used as the ethical yardstick for the legal system.²¹

The Code says:

1.2 Clinical Research

- c. Recognise that considerations relating to the well-being of individual participants in research take precedence over the interests of science or society.

The therapeutic obligation means that patients’ care should not be compromised by research methods such as randomisation or double-blinding. The latter technique involves neither the doctor nor the patient knowing which medication is being taken by the patient.

According to the National Statement:

Research methods intended to avoid or reduce bias include randomisation and ‘blinding’ participants and researchers to the identity of agents being compared...Researchers who propose to use such methods should be aware of the ethical issues that may arise in the design and conduct of such research. In particular, paragraphs 3.3.3 and 3.3.6 will apply in all situations, while other paragraphs may be relevant depending on the nature of the research and the relationship between the researcher and potential participants.²²

Randomization can mean that the patients’ individual circumstances are not taken into account:

The combination you will receive has been chosen at random by a computer and your doctor has no influence on the treatment chosen for you.²³

Or:

Neither the doctor nor the study participant can decide which treatment the participant receives.²⁴

Or:

By going into this study, you and your doctor accept that we don't know which is the best treatment option and are prepared to be randomly allocated [through this study] to a treatment regimen, that is, give up your right to choose your treatment.²⁵

Some physicians claim that “randomized trials fail to elevate the interests of the individual patient above the goal of potential benefits to future patients”.²⁶

Eligibility and Exclusion

Sometimes eligible patients are excluded from drug trials they want to be involved in unless they consent to providing extra tissue for other future trials. This process circumvents the usual requirement for informed consent for each trial the researchers undertake. It can leave patients feeling disempowered and is contrary to sound ethical practice and to patient-centred care.

The trial could provide the only access to new, unlicensed drugs for patients who have had a sub-optimal response to licensed drugs and could be at risk of serious illness. Such a trial had this proviso for participants:

If you do not agree to having [extra] blood taken for future research relating to the treatment of HIV you will not be able to participate in this study.²⁷

An example for another trial stipulated:

By consenting to take part in this study, you also consent to the collection, storage and testing of 10 ml of blood for further research into how your genes might affect the metabolism of antiretroviral drugs.²⁸

These terms are distinct from the acceptable practice of providing patients with the option of donating additional tissue:

You can still take part in this study even if you do not agree to these additional blood draws [for future research].²⁹

Under sections entitled “Justice”, The National Statement says:

3.3.6 The research methodology should provide a rationale for the selection of participants and a fair method of recruitment. (see paragraph 1.4).³⁰

1.4 In research that is just:

(a) taking into account the scope and objectives of the proposed research, the selection, exclusion and inclusion of categories of research participants is fair, and is accurately described in the results of the research;

(b) the process of recruiting participants is fair;

(e) there is no exploitation of participants in the conduct of research

Informed consent

Some studies rely on the “extended” consent of patients instead of specific informed consent.

Principle 2.2.14 of The National Statement explains that:

Consent may be:

(a) ‘specific’: limited to the specific project under consideration;

(b) ‘extended’: given for the use of data or tissue in future research projects that are:

(i) an extension of, or closely related to, the original project;

or

(ii) in the same general area of research (for example, genealogical, ethnographical, epidemiological, or chronic illness research);

(c) ‘unspecified’: given for the use of data or tissue in any future research.

Extended consent for tissue donation for unknown future trials is sometimes “piggy-backed” onto a trial requiring specific informed consent:

By consenting to take part in this study, you also consent to the collection, storage and testing of 10 ml of blood for further research into how your genes might affect the metabolism of antiretroviral drugs. This has not been planned yet...³¹

Some researchers seek extended consent for additional current trials, not just future trials, within the Patient Information form for a current trial. They thereby avoid obtaining informed consent for trials that could be explained in detail to potential participants:

About 108mL of the blood will be stored during the first 48 weeks of the study. These blood samples will be stored for [additional] current and future medical research that relates to the treatment of HIV.³²

The AMA Code of Ethics says:

1.2 Clinical Research

- d. Make sure that all research participants or their agents are fully informed and have consented to participate in the study...³³

Language

Information should be supplied to patients in plain language. Here is a paragraph from a Participant Information and Consent Form:

Multiple methods have been used to measure HIV-1 “fitness” (or how strong a virus is) and co-receptor usage in vitro; however, many of these methods are time-consuming and expensive. HIV gains entry to cells by attaching to the CD4 receptor and a chemokine co-receptor. There are 2 chemokine co-receptors that HIV is able to use: the CCR5 and CXCR4 co-receptors. Drugs that block CCR5 co-receptors will have no effect in patients whose HIV virus uses the CXCR4 co-receptor. With the availability of new drugs that can block co-receptors and viral entry (currently only CCR5 antagonists are available in clinical trials), we therefore urgently need tests that can rapidly determine which co-receptor a person’s virus uses. The aim of this project is to develop a rapid, cost-effective assay to assess viral “fitness” and co-receptor usage of patient HIV viruses. These assays will then be used to investigate viruses isolated from patients who have failed treatment. The tests may also be developed for use by clinicians to assist in tailoring anti-retroviral treatment to the needs of each patient.³⁴ [“Fitness” was the only term explained in the document.]

Even purported plain language materials can be difficult for some patients to understand. For example:

Previous experience has shown that the ready availability of stored samples of human blood or tissue has enabled researchers to investigate mechanisms of disease processes and evaluate new diagnostic tests.³⁵

Or:

...using DNA [not explained in document] it may be found that only people with a certain gene [not explained in document] are susceptible to developing an HIV complication such as lipodystrophy (changes in body fat storage and increases in blood cholesterol [not explained in document] and triglycerides [not explained in document]) when they take certain antiretroviral [not explained in document] drugs.³⁶

Many public hospitals fail to provide patient information or signage in community languages. As well, clinical trial information and consent forms where informed consent is required may not be provided in the participant's most comfortable language: "I have read, or have had read to me in a language that I understand, this document and I understand the purposes, procedures and risks of this research project as described within it".³⁷ A document could have been read to the participant by someone who didn't comprehend the English version, particularly medical terms, or who was unable to translate the information accurately. Any clinical trial material requiring a participant's informed consent should be provided in community languages or should be thoroughly explained by a qualified interpreter in their first language.

Non-disclosure of fees/interests

The fundamental ethical values of medicine are based on the belief that physicians are competent, are compassionate towards the sick, and will put the interests of patients before their own.³⁸

The National Statement says:

3.3.18 [A Human Research Ethics Committee] should be satisfied that:

- (a) payment in money or incentives of any kind, whether to researchers or participants, does not result in pressure on individuals to consent to participate;
- (b) research participants are adequately informed of the funding arrangements of the research and given the option of knowing the details of any capitation payments to researchers or clinicians.

Doctor/researchers may not disclose that they receive capitation fees or other funding for recruiting their patients into clinical trials, as it is not mandatory to do so in Australia. Best practice would be for mandatory disclosure of all capitation fees, or payments in lieu, made to doctors or researchers by trial sponsors prior to or during the course of a clinical trial.

Privacy, confidentiality and disclosure of information

The sections of Patient Information and Consent forms explaining disclosure of patients' personal information can be contradictory and confusing. For example:

Any information that can identify you will remain confidential and will only be used for this project. Data will be kept in a locked office in a secure building with limited access, indefinitely. It will only be disclosed with your permission, except as required by law.

Your health records and any information obtained during the study are subject to inspection (for the purpose of verifying the procedures and data) by the authorised representatives of the Alfred Hospital Human Research and Ethics Committee, the Sponsor...or as required by law. By signing the attached Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.³⁹

Clinical teaching

Some doctors at hospitals and health services affiliated with medical schools engage in teaching of university students – not interns – without the informed consent of patients. These doctors assume that as the patients are attending a clinic or admitted to a ward

of a teaching hospital they are under an implicit obligation to comply. Patients may prefer not to be teaching subjects, particularly those with conditions they would rather keep private, such as infertility, mental illness or HIV and other infectious diseases.

Some patients may feel under pressure to agree to a request by their own doctor to become a teaching subject, particularly if students are already present in the clinician's room. Ideally, a patient should be given information about the hospital's teaching commitments by someone other than their doctor, possibly a nurse manager, at their first contact with the hospital or service. Patients should also be given time to reflect upon the proposition.

Prior notice and the opportunity to opt-out is common practice at many overseas facilities. For example:

Cumbria Partnership NHS Foundation Trust actively promotes teaching. Students or Senior Clinicians may be present at your appointment for teaching purposes and to ensure that we provide the best quality service possible. Should you prefer not to have a student sit in on your appointment, please inform the clinician prior to the appointment.⁴⁰

The AMA Code of Ethics provides guidance on the correct process to be followed in clinical teaching:

1.3 Clinical Teaching

- b. Before embarking on any clinical teaching involving patients, ensure that patients are fully informed and have consented to participate.⁴¹

Patient prompts

It has become common practice for health services and hospital units to send SMS prompts to patients to remind them of appointments. The prompts are often sent out regardless of a patient's excellent attendance record. Some health providers do not inform patients that the reminder will occur or provide an opt-in or opt-out of this system.

The Australian Charter of Healthcare Rights informs patients:

You have a right to privacy and confidentiality of your personal information.

SMS prompts may contain health information and potentially breach confidentiality or compromise patient privacy:

Reminder [PATIENT FULL NAME]: Your [NAME OF CLINIC] appointment at The Alfred on 27/4/10 at 03.00pm. Please reply NO if you CANNOT attend. Ref: [PATIENT FILE NUMBER] 20/4/10 07:51 0421269814⁴²

The wording of the prompt is the vital issue. Some are more discreet:

REMINDER: Your appointment with Dr Baker is on Tuesday 13 July 2010 at 2pm. Please let us know let us know asp if you are unable to attend.

The Child Support agency demonstrates best practice in dealing with personal information:

From time to time CSA may send you a SMS alert or an email reminder to, among other things, provide you with information about your child support or remind you of a payment due date.

No SMS or email reminder from CSA will contain your name or contact details, any reference numbers or direct links to any websites. You will not be required to respond via SMS or email to any CSA generated message.

If you do not wish to receive SMS alerts, please call us on 131 272 and ask to opt out of benefiting from this service.⁴³

Patients may change their phone numbers when they change provider and their numbers will be re-allocated to another customer. Or they may share or lose mobile phones. They should always be informed of the health provider's practice regarding patient prompts and preferably be permitted to opt-in, or at least to opt-out.

Recommendation 11

We endorse this recommendation.

Recommendation 12

We agree with the approach of linking architecture and physical space with healing. The usual style of mental health wards has a "goldfish bowl" as the nurses' station. This design creates frustration for the following reasons:

- it discourages communication between medical staff and patients
- it promotes a power imbalance

- it distances and unsettles patients because they are hesitant to knock on the door and risk being seen as troublesome
- it emphasizes the fact that they are under observation
- it impairs their privacy as the ward telephone is generally located close to the nurses' station and conversations are overheard

Privacy and safety are fundamental human rights⁴⁴ and should obviously be considered in healthcare service design. Ideally, single sex wards should always be an option for mental health patients. We acknowledge that violence can occur in single sex wards, but The Victorian Women and Mental Health Network claims harassment, physical and sexual assaults occur more often in mixed wards.⁴⁵ As well, wards tend to be locked. Patients in most facilities must then take visitors into their bedrooms or otherwise into communal lounges.

Having patients involved in the design of healthcare spaces can only improve the situation.

Recommendation 13

This recommendation is valuable. Communication skills, in particular, are relevant for the mental health sector. Websites and calendars for the three education and training clusters⁴⁶ funded by the Mental Health, Drugs and Regions Division make no reference to communication skills training.

Recommendation 14

We commend the promotion of patient-centred care as a method for increasing staff satisfaction and workforce surveys to improve staff retention rates. Mental health services have difficulty retaining staff. The Mental Health, Drugs and Regions Division acknowledges that: "The main challenges currently facing the Victorian specialist mental health sector regarding the supply of workers are shortages and turnover."⁴⁷

Staff shortages and high staff turnover undermine continuity in patient care.

Recommendation 15

It may be inappropriate to recommend integrating care experience into staff performance review processes in the mental health sector. For example, there may be a risk that criticism could undermine therapeutic relationships. At times, patients' perceptions may be affected by their state of health and the unequal relationship with staff.

On occasion staff has to intervene in ways that may not be popular. Data might still be collated for organisational improvement but individual staff financial penalties could be inappropriate. There are other more appropriate complaints mechanisms eg: Australian Health Practitioner Regulation Agency.

We agree with other suggestions in the discussion paper, such as incorporating responsibility for improving patient-centred care in job descriptions; explaining the responsibility at orientation; linking staff promotions or rewards to patient-centred care; linking quality metrics to performance reviews of governance bodies and chief executives, and putting quality issues on the agenda for board or governance committee meetings.

Recommendation 16

We endorse this recommendation.

Conclusion

As ACSQHC acknowledges in the discussion paper, active change in health delivery can be difficult to implement. In general, the public health sector, including the mental health sector, is underfunded and overly busy and the associated stresses impact upon the best intentions of practitioners. Noble notions get lost in everyday practicalities. Many healthcare professionals we encounter claim never to have heard of the Australian Charter of Healthcare Rights, and are unfamiliar with the Victorian Charter of Human Rights and Responsibilities and the mission statements of their own services.

We believe patient-centred care will improve quality and safety throughout Australian health services.

Endnotes

¹ Topp V, Thomas M, Ingvarson M, Lacking Insight, Mental Health Legal Centre, 2008, p. 42.

² s 33 - Document affecting personal privacy.

³ s 25 - Deletion of exempt matter or irrelevant material.

⁴ Topp V, Thomas M, Ingvarson M, Lacking Insight, Mental Health Legal Centre, 2008, p. 42.

⁵ Topp V, Thomas M, Ingvarson M, Lacking Insight, Mental Health Legal Centre, 2008, p. 42.

⁶ Mental Health Review Board 2010 Annual Report, p. 5.

⁷ <http://www.health.vic.gov.au/mentalhealth/>, (viewed 23 December, 2010).

⁸ The “ghost wards” scandal in Victoria saw many public hospitals submitting manipulated or erroneous data to the Department of Human Services. The hospitals presented patients on waiting lists as admitted to wards that did not exist in order to obtain performance-based bonuses for meeting admission targets. Government records obtained under freedom of information in 2009 by the then State Opposition named the Austin, Royal Melbourne, Angliss, Royal Children’s, Mercy, Sunshine, Dandenong and Western hospitals. The Royal Women’s Hospital admitted data manipulation for a period of almost 10 years, but apparently did not receive any bonus payments as a consequence: Barr R, *Director of Hospital Data Integrity Status Report* (Melbourne) (July 2009); Wallace R, “Scandal Nets Second Hospital”, *The Australian* (Sydney) (2 April July 2009); Baker R and McKenzie N, “Hospital Called in to Explain Lists”, *The Age* (Melbourne) (19 March 2009). Some hospitals denied engaging in data manipulation while others admitted “clerical errors”, the term originally used by The Royal Women’s to describe its data manipulation: Miller N and Rood D, “Hospital Waiting Lists Scandal Grows”, *The Age* (Melbourne) (1 April 2009). Several months later, a parliamentary inquiry was told that The Alfred and The Royal Victorian Eye and Eye Hospital had allegedly created ghost wards: Medew J, “State’s ‘Ghost Ward’ Scandal Spreads”, *The Age* (Melbourne) (20 August 2009): referred to in Taylor V, Another hospital saga: The chronicles of Professor Kossmann and Bayside Health, (2010) 18, pp 1-200 *Journal of Law and Medicine*, p. 96.

⁹ Hickie I, The patient needs urgent attention, *The Australian*, 6-7 February 2010; McGorry P., Mental health needs early care, *The Australian*, 6-7 February 2010.

¹⁰ Groene O, Skau J K H, and Frolich A, An international review of projects on hospital performance assessment, *International Journal for Quality in Healthcare*, 2008, Volume 20, Number 3, p 169.

¹¹ <http://www.health.vic.gov.au/mentalhealth/pmc/catchment.htm> (viewed 12 December 2010).

¹² <http://www.health.vic.gov.au/mentalhealth/>. The website is managed by the Mental Health, Drugs & Regions Division of the Victorian Department of Health.

¹³ https://fac.dhs.vic.gov.au/home.aspx?TabID=9&active_tab=1 (viewed 12 December 2010).

¹⁴ <http://www.myhospitals.gov.au/about-the-data> (last viewed 12 December 2010); Viellaris R, Hospital website opens with big holes, 11 December 2010, <http://www.couriermail.com.au/news/hospital-website-opens-with-big-holes/story-e6freomx-1225969513649> (viewed 12 December 2010); <http://www.couriermail.com.au/news/hospital-website-opens-with-big-holes/story-e6freomx-1225969513649> (last viewed 12 December 2010).

¹⁵ Cresswell A, Roxon defends data as MyHospitals website opens, *The Australian*, 10 December 2010, <http://www.theaustralian.com.au/national-affairs/myhospitals-wesbite-opens-for-checkups/story-fn59niix-1225968930384> (viewed 11 December 2010). Minister Roxon said data was double-checked by the Australian Institute for Health and Welfare. But the Institute would not be in the position of checking the accuracy of the original data; Betts, Marianne and McArthur, Grant, Dodgy data taints hospital rating, *Herald Sun*, 11 December 2010, <http://www.heraldsun.com.au/ipad/dodgy-data-taints-hospital-rating/story-fn6bfm6w-1225969203780> (viewed 12 December 2010); AAP, Questions raised over My Hospital, December 10, 2010, <http://www.theaustralian.com.au/news/breaking-news/questions-raised-over-my-hospital/story-fn3dxity-1225968761103> (viewed 11 December 2010). Inaccuracies re waiting list lengths and differences in how the term “adverse event” was defined has made Victorian hospital data unreliable in recent years. At one time, there were over 250 definitions of “adverse event” in use in use in the State: Taylor V, Another hospital saga: The chronicles of Professor Kossmann and Bayside Health, (2010) 18, pp 1-200 *Journal of Law and Medicine*, p. 82.

¹⁶ Jeffs S, Be loyal to wellness, *Mental Illness Fellowship*, <http://www.mifellowship.org/documents/Beloyaltowellness.pdf> (viewed 23 December 2010)

¹⁷ Taylor K, Integrating Conflicting Professional Roles: Physician Participation in Randomized Clinical Trials, *Social Science & Medicine*, Vol, 35, No. 2, 1992, p. 220; Hales G, Beveridge A & Smith D, (2001), The Conflicting roles of clinicians versus investigators in HIV randomised clinical trials, *Culture, Health & Sexuality*, 3:1, p. 77.

¹⁸ Kodish E, Lantos J & Siegler M, Opinion: The ethics of Randomization, *CA-A Cancer Journal for Clinicians*, p. 181.

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- ¹⁹ National Statement on Ethical Conduct in Human Research, National Health and Medical Research Council, Australian Research Council, Australian Vice-Chancellors' Committee, March 2007, p. 36.
- ²⁰ Australian Medical Association Code of Ethics 2004, Editorially Revised 2006, Preamble, p 1.
- ²¹ Arnold Mann v Australian Capital Territory, John Anthony Bissett, Leonard Edward Withers, Anthony Charles Clarke, John James O'Donnell, Brian Peter Hurley and Noel Tait [1997] ACTSC 43 (19 June 1997); Lewis and Comcare [2002] AATA 197 (25 March 2002); Arrow Pharmaceuticals Limited v Merck Co Inc [2004] FCA 129 (23 February 2004); The Western Australian Branch of the Australian Medical Association Incorporated v RFDS (Western Operations) [2004] WAIRComm 13041 (27 September 2004); SAJ, re [2007] QGAAT 62 (11 September 2007); The Western Australian Branch of the Australian Medical Association Incorporated v St John of God Health Care Inc [2003] WAIRComm 7445 (24 January 2003); Wilks v Medical Practitioners Board of Victoria (Occupational and Business Regulation) [2007] VCAT 2439 (17 December 2007). *See also*: Royal Flying Doctor Services Of Australia, Rfds Western Operations, Medical Practitioners Industrial Agreement 2003; St John Of God Health Care Murdoch AMA Medical Practitioners Industrial Agreement 2002.
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- ²³ The Altair Study Participant Information & Consent Form, The Alfred Hospital, Version 1.0., Dated 16th April 2007, p. 2.
- ²⁴ The CORAL Study Participant Information & Consent Form, The Alfred Hospital, Version 2, Dated 23th (sic) February 2009, p. 2.
- ²⁵ The Altair Study Participant Information & Consent Form, The Alfred Hospital, Version 1.0., Dated 16th April 2007, pp. 5-6.
- ²⁶ Taylor K, Integrating Conflicting Professional Roles: Physician Participation in Randomized Clinical Trials, *Social Science & Medicine*, Vol, 35, No. 2, 1992, p. 223.
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⁴¹ Australian Medical Association Code of Ethics 2004, Editorially Revised 2006, Preamble, p 2.

⁴² SMS patient prompt sent without consultation by the Infectious Diseases Unit of the Alfred Hospital.

⁴³ <http://www.csa.gov.au/privacy.aspx>

⁴⁴ Articles 3 & 12 of the Universal Declaration of Human Rights; Article 17 of the International Covenant on Civil and Political Rights; Article 8 of the European Convention for the Protection of Human Rights and Fundamental Freedoms; Article 13 of the Victorian Charter of Human Rights and Responsibilities; The Australian Charter of Healthcare Rights.

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