Contemporary Challenges regarding Informed Consent & Vaccination in Australia

This paper examines the contemporary challenges with the doctrine of informed consent '*Doctrine*' and its application in the vaccination program of the Australian Government[1]. In order to understand the challenges, we must first understand the background of the development of the *Doctrine.*

The *Doctrine* commenced with the seminal *Schloendorff*[2] decision, where it was held the need for Informed Consent is a prerequisite to the Doctor-Patient Relationship.

With Justice Cordozo stating "In the case at hand, the wrong complained of is not merely negligence. It is trespass….and a surgeon who performs an operation without his patient's consent, commits an assault, for which he is liable in damages.[3]"

In determining what information should be given to clients doctors traditionally used the "Physician-Based Standard[4]", this was the idea that a physician isn't liable for negligence or malpractice if they followed the consensus of opinion in medical practice. It was accepted by the English Courts in *Bolam v Friern Hospital Management Committee*[5] this became known in law as the *Bolam Principle*[6]

The Australian Experience

In F v. R[7] a woman who wasn't warned of a 1% failure rate in a medical procedure sued for negligence. The Doctors argued that the consensus of medical opinion was it wasn't necessary to warn when failure rate was so low, the Court refused to apply the *Bolam principle.*

> King C.J. said: The ultimate question, however, is not whether the defendant's conduct accords with the practices of his profession or some part of it, but whether it conforms to the **standard of reasonable care demanded by the law**. That is a question for the court and the duty of deciding it cannot be delegated to any profession or group in the community.
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> King C.J. agreed with the Supreme Court of Canada in Reibl v. Hughes (1980): The issue under consideration is a different issue from that involved where the question is whether the doctor carried out his professional activities by applicable professional standards. What is under consideration here is the patient's right to know what risks are involved in undergoing or foregoing certain surgery or other treatment[8].

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[1] Immunise Australia Program, Department of Health, accessed here 5/02/2017 at 11.18am http://immunise.health.gov.au/internet/immunise/publishing.nsf/Content/about-the-program.

[2] Mary E. Schloendorff v The Society of the New York Hospital, 05 N.E. 92, 211 N.Y. 125, New York Court of Appeals.

[3] Ibid.

[4] Barry Furrow et al., ed., Health Law, 2015, p. 123

[5] Bolam v Friern Hospital Management Committee [1957] 1 WLR 582.

[6] Ibid.

[7] F v. R.(1983) 33 S.A.S.R. 189.

[8] Ibid.

Since F v R, the High Court of Australia '*HCA*' was called upon to answer once and for all whether the *Bolam principal* applies in Australia in the case of *Rogers v Whitaker*[9]. In reference to the standard of care the *HCA* stated it is "not determined solely or even primarily by reference to the practice followed or supported by a responsible body of opinion in the relevant profession or trade"[10].

The *HCA* in rejecting the *Bolam principle* provided new guidelines:

> "while evidence of acceptable medical practice is a useful guide for the
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> courts, it is for the courts to adjudicate on what is the appropriate
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> standard of care after giving weight to 'the paramount consideration
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> that a person is entitled to make his own decisions about his life' "[11].

In *Rogers v Whitaker* there was a consensus of opinion in the medical profession that held disclosure to the patient of the possibility of rare but known risks would only be disclosed to the patient if there was a specific inquiry, since the patient did not ask, the risk was not disclosed.

The *HCA* Held :

> "While the opinion that the respondent should have been told of the dangers of sympathetic ophthalmia only if she had been sufficiently learned to ask the precise question seems curious, it is unnecessary for us to examine it further, save to say that it demonstrates vividly the dangers of applying the *Bolam principle* in the area of advice and information.
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> The respondent may not have asked the right question, yet she made clear her great concern that no injury should befall her one good eye. The trial judge was not satisfied that, if the respondent had expressed no desire for information, proper practice required that the respondent be warned of the relevant risk.
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> But it could be argued, within the terms of the relevant principle as we have stated it, that **the risk was material**, in the sense that a reasonable person in the patient's position would be likely to attach significance to the risk, and thus required a warning. It would be reasonable for a person with one good eye to be concerned about the possibility of injury to it from a procedure which was elective.[12]"

The *Rogers v Whitaker* decision saw a move in Australia away from the physician based standard towards a Patient-Oriented Standard: set by what a reasonable patient would want to know.

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[9] Rogers v Whitaker (1993) 67 ALJR 47.
[10] Rogers v Whitaker (1993) 67 ALJR 47 at 48-49.
[11] Ibid at 51.
[12] Ibid at 53.

With this the Medical Board of Australia has developed a code of conduct for medical practitioners to follow Good medical practice: a code of conduct for doctors in Australia[13]

The code covers working with patients[14], treating each patient as an individual[15], encouraging patients to be well informed and to use this information wisely when they are making decisions[16] and ensuring patients are informed of the **material risks** associated with the vaccine[17].

The Australian Immunisation Handbook *'AIH'*[18] is more than a mere guideline that medical practitioners use when providing vaccination services. According to the operative section of the No Jab, No Pay policy in *A New Tax System* (Family Assistance) Act 1999, S.6

> Medical contraindication, natural immunity
>
> (3) The child meets the immunisation requirements if:
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> (a) a general practitioner has certified in writing that the immunisation of the child would be medically contraindicated under the specifications set out in the Australian Immunisation Handbook;

The *AIH* defines valid consent as:

> the voluntary agreement by an individual to a proposed procedure, given after sufficient, appropriate and reliable information about the procedure, including the potential risks and benefits, has been conveyed to that individual.
>
> Persons should be given sufficient information (preferably written) on the risks and benefits of each vaccine, including what adverse events are possible, how common they are and what they should do about them (the table inside the front cover of this Handbook, Side effects following immunisation for vaccines used in the National Immunisation Program (NIP) schedule, can be used for this purpose). [19]

It continues with, "For consent to be legally valid, the following elements must be present:

> It must be given **voluntarily in the absence of undue pressure, coercion or manipulation.**
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> It can only be given after the potential risks and benefits of the relevant vaccine, risks of not having it and any alternative options have been explained to the individual.

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[13] Good medical practice: a code of conduct for doctors in Australia, accessed 03/02/2017 at 5.05pm http://www.medicalboard.gov.au/Codes-Guidelines-Policies/Code-of-conduct.aspx
[14] Ibid at S.3.
[15] Ibid at S.3.2.2.
[16] Ibid at S.3.2.5.
[17] Ibid at S.3.3.6.
[18] The Australian Immunisation Handbook 10th Edition, accessed 03/02/2017 at 7.58pm http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook10-home
[19] Ibid at S.2.1.3

> The individual must have sufficient opportunity to seek further details or explanations about the vaccine(s).

Consent should be obtained before each vaccination, once it has been established that there are no medical condition(s) that contraindicate vaccination."

We see that the doctrine of informed consent is well developed in Australia, to the point it is codified in codes of conduct of the medical profession and even in the *AIH*, so why all the controversy around vaccines?

It is beyond the scope of this paper to go into the efficacies and the Government stance that vaccines are "safe and effective[20]", instead the issues are examined from a health law perspective. In contrast to the Australian Government position, the United States Supreme Court case of Bruesewitz Et al. v Wyeth LLC, FKA Wyeth, Inc., Et al[21] stated :

> "Indeed, Congress' principal aim in enacting §22(b)(1) was not to preserve manufacturing and labeling claims (those, too, were already preserved by §22(a)), but rather, to federalize comment k-type protection for "**unavoidably unsafe**" vaccines."[22]

Another distinguishing factor they have the The National Childhood Vaccine Injury Act of 1986 [which] created a no-fault compensation program to stabilize a vaccine market adversely affected by increased vaccine-related tort litigation and to facilitate compensation to claimants who found pursuing legitimate vaccine-inflicted injuries too costly and difficult[23].

When examining the Australian policy and legislation in the search for answers as to why Australia has no such system here. The first question is if a Doctor follows the procedure in the *AIH*, is consent "valid"? Secondly if a patient after considering all available information, isn't sufficiently satisfied that vaccines are "safe and effective" as claimed by the Government, can they get an exemption for a medical contraindication?

The search for answers starts with the Victorian No-Jab No-Play legislation '*PHW*'[24] (which leads back to and relies upon Commonwealth Legislation for its implementation[25]) before a child can be confirmed as enrolled in "early childhood service" '*care*', an "immunisation status certificate" is required showing the child is up-to-date.

Interestingly S.147 of *PHW* points to sections 46A and 46B of the *Health Insurance* Act (Cth) 1973, however, there are no such section(s) in that Act, which can be confusing, that said, assuming a child hasn't been fully vaccinated according to the Victorian Immunisation

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[20] Immunise Australia Program, Department of Health, accessed here 5/02/2017 at 11.18am http://immunise.health.gov.au/internet/immunise/publishing.nsf/Content/about-the-program.
[21] BRUESEWITZ ET AL. v. WYETH LLC, FKA WYETH, INC., ET AL. CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT.
[22] Ibid at pg.18.
[23] Ibid at pg.1 para 1.
[24] *Public Health and Wellbeing Act* 2008 (Vic).
[25] *A New Tax System* (Family Assistance) Act 1999, S.6.

Schedule[26] then the only way a child can enter *care* is either be vaccinated or obtain an exemption.

There is only one provision to obtain a permanent exemption before entering *care* to one or more vaccines, that is section 143B(1)(b) of the *PHW*[27], which states :

(b) immunisation of the child with one or more vaccines so that the child is age appropriately immunised would be **medically contraindicated under the specifications set out in the Australian Immunisation Handbook** within the meaning of section 3(1) of the A New Tax (Family Assistance) Act 1999 of the Commonwealth.

The difficulty with this provision is that the *AIH*, insofar as contraindications go, provides a narrower scope than the manufacturers provide as contraindications and gives the *AIH* force of law, suddenly what the manufacturer warns of is no longer relevant.

The *AIH* Section 2.1.4[28] on pre-vaccination screening titled "Contraindications to vaccination" provides a child only one possible contraindication, that is an adverse event to a previous vaccination of anaphylaxis.

Short of a parent already vaccinating a child, who then had an immediate life threatening reaction, as far as the *AIH* is concerned there is no valid exemption. This is in stark contrast to the manufacturers own recommendations that are included with the vaccines.

The information leaflets have far broader guidelines regarding contraindications, it appears that the *AIH* over-rides vaccine manufacturers own advice.

For instance, MMR[29] contraindications include **hypersensitivity to any component** of the vaccine, including **gelatin**, Anaphylactoid reactions to neomycin[30] and individuals with a family history of congenital or hereditary immunodeficiency, a doctor relying on the *AIH* would not even need to consider these.

Merck continues with additional warnings that persons with history of cerebral injury, convulsions, live vaccine risks and persons with hypersensitivity to chick embryo cultures may see adverse reactions, they go on to say:

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[26] Immunisation schedule Victoria 2016, accessed here on 3/2/2017 at 9.29pm https://www2.health.vic.gov.au/public-health/immunisation/immunisation-schedule-vaccine-eligibility-criteria/immunisation-schedule-victoria

[27] Public Health and Wellbeing Act 2008 (Vic), S.143B(1)(b).

[28] The Australian Immunisation Handbook, accessed here on 3/2/2017 at 10.09pm http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook10-home~handbook10part2~handbook10-2-1#2-1-4

[29] M-M-R® II (MEASLES, MUMPS, and RUBELLA VIRUS VACCINE LIVE), Manufactured by Merck, Product leaflet accessed here on 3/2/2017 http://www.merck.com/product/usa/pi_circulars/m/mmr_ii/mmr_ii_pi.pdf

[30] Wikipedia, Neomycin is an aminoglycoside antibiotic found in many topical medications such as creams, ointments, and eyedrops. https://en.wikipedia.org/wiki/Neomycin

> **The potential risk to benefit ratio should be carefully evaluated before considering vaccination in such cases. Such individuals may be vaccinated with extreme caution…**
>
> Persons who have experienced anaphylactic reactions to **neomycin** should not receive measles vaccine. Neomycin allergy often manifests as a **contact dermatitis**, which is a **delayed-type** immune response rather than anaphylaxis, this is a perfect example of where there may be long term side effects that parents are not warned of.

There are many more warnings listed but it's beyond the scope of this paper to examine all the contradictions, the above demonstrates clearly the dangers of a Doctor merely following the *AIH* as commanded by Legislation.

Not only does the *AIH* not cover issues Merck covers, it goes one step further and dictates to doctors what is or is not a valid contraindication[31]. The contraindications excluded include **family history** of adverse events following immunisation, history of **convulsions**, **asthma**, **eczema**, atopy, previous infection with the same pathogen (**natural immunity**) and neurological conditions among other things are not considered valid contraindications.

What is significant about this is the very things that Merck lists as contraindications and warnings are the things that Doctors are told to ignore in the *AIH*.

What should a doctor follow? The *AIH* or Merck's own contraindications?

The additional warnings and precautions in the Merck document could lead to a medical practitioner making in their own judgment a valid contraindication based on an individual patient's needs.

This would be in line with the Australian Medical Boards Code of Conduct[32] for doctors in Australia. Examining content of Section 3[33], includes issues of treating the patient as an individual and the requirement of valid informed consent, it appears the legislation and *AIH* are inconsistent at best and incompatible at worst with the requirements for valid informed consent.

The Government would be asking the doctor to breach their own code of conduct if they are to ignore the manufacturers product information leaflets in lieu of the narrow guidelines in the *AIH*.

Most significantly looking at the Medical Board of Australia's Code of Conduct, specifically Section 41.3.6 Children and young people

> a. Caring for children and young people brings additional responsibilities for doctors. Good medical practice involves:
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> i. Placing the interests and wellbeing of the child or young person first.

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[31] The Australian Immunisation Handbook, Table 2.1.4: False contraindications to vaccination.
[32] Australian Medical Boards Code of Conduct, accessed here on 3/2/2017 at 11.01pm http://www.medicalboard.gov.au/Codes-Guidelines-Policies/Code-of-conduct.aspx .
[33] Ibid.

In the case of actions and decisions affecting an individual child, it is the best interests of that individual child which must be taken into account[34]. Parents have primary decision-making responsibility on behalf of their children (articles 5 and 18.1).

To satisfy the question of what is in the best interests of the child, what first must be examined is what is the risk involved that the vaccine seeks to prevent, take Infanrix hexa[35], a vaccine used to prevent six diseases: diphtheria, tetanus, whooping cough, hepatitis B, polio and Haemophilus influenzae type b.

According to the World Health Organisation[36] there have been 9 Cases of Diptheria in Australia **since 2007**, there have been **Zero** cases of Tetanus (Neonatal) and **Zero** cases of Polio. Hepatitis B is a blood-borne virus. There's an insignificant statistical risk of Hep B transmission in a community setting, especially among children who are unlikely to engage in high-risk behaviours, such as needle sharing or sex[37], so is not a relevant or foreseeable risk to an infant unless one of the parents have Hep B themselves as held in Re H [2011] QSC 42711 and Director-General, Department of Community Services; Re Jules [2008] NSWSC 1193 (2 September 2008), Hib does not cover the prevalent strains so can't be considered a significant benefit and finally pertussis is an interesting anomaly in that the more we have vaccinated against it the more it occurs[38] with cases peaking last year at 22,508.

Against this back drop of seemingly little statistical basis to arouse a parent to fear that their child is at risk, the adverse events associated with Infanrix ought to be considered.

Infanrix Hexa according to the product leaflet published by the TGA[39] states it **should not** be administered to subjects with known hypersensitivity to the active substances or to any of the excipients or residues[40], this is in conflict with the *AIH* guidelines.

In examining data reports of adverse events released by the TGA[41], since January 1st 2014 there have been 2,575 adverse reactions associated with Infanrix, **which include death in two reported cases**.

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[34] Australian Human Rights Commission, Human Rights Brief No. 1, The Best Interests of Child http://www.humanrights.gov.au/publications/human-rights-brief-no-1 accessed 29.11.2016 at [4.54pm]

[35] Department of Health, Therapeutic Goods Administration, Infanrix Hexa, https://www.tga.gov.au/alert/infanrix-hexa-vaccine accessed 29/11/2016 at [4.55pm].

[36] World Health Organisation, Global Summary, Australia http://apps.who.int/immunization_monitoring/globalsummary/incidences?c=AUS accessed 29.11.2016 at [4.56pm].

[37] Tetyana Obukhanych, An open letter to legislators http://thinkingmomsrevolution.com/an-open-letter-to-legislators-currently-considering-vaccine-legislation-from-tetyana-obukhanych-phd-in-immunology/ accessed 29.11.2016 at [4.57pm]

[38] World Health Organisation, Global Summary, Australia, http://apps.who.int/immunization_monitoring/globalsummary/incidences?c=AUS accessed 29.11.2016 at [4.58pm].

[39] Infanrix Hexa Product leaflet, Therapeutic Goods Administration accessed at 05/02/2017 https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2010-PI-06624-3&d=20161129161146224 83&d=2017020516114622483

[40] Childrens Medical Saftety Research Institute, Dirty Vaccines: New Study Reveals Prevalence of Contaminants, http://info.cmsri.org/the-driven-researcher-blog/dirty-vaccines-new-study-reveals-prevalence-of-contaminants accessed 10/02/2017 at 12.04am.

[41] Department of Health, Therapeutic Goods Administration, INFANRIX Database search from 1/1/2014 to 17.8.2016 accessed at [5.04pm] here http://apps.tga.gov.au/PROD/DAEN/daen-report.aspx

The TGA admits there's no data or studies comparing vaccinated vs unvaccinated children to see if there are any trends in health outcomes of those vaccinated against children who are not[42].

CONCLUSION.

A risk at common law is one that's real and foreseeable, but not "far-fetched or fanciful"[43], here it's clear there are real and foreseeable risks that an adverse reaction to a vaccine may occur, it is neither farfetched nor fanciful and a parent ought to consider the manufacturers warnings and the **potential risk to benefit ratio should be carefully evaluated before considering vaccination in cases where a child is suspected to be hypersensitive to adjuvants in the vaccines or potentially affected by one or more of the contraindications and warnings.**

If a Doctor merely follows the *AIH* guidelines it is questionable whether there is sufficient information provided to constitute valid informed consent. On the other hand, if according to guidelines a parent sought an exemption, the legislative provisions are not reasonable for the patient to seek what is defined as a valid exemption. It would appear vaccination policy places a parent seeking an exemption into a position where they, even if uncomfortable with the decision are coerced to vaccinate to get child *care*, which may invalidate informed consent.

Whether the consent is granted under the *AIH* guidelines or coerced under Government policy, unfortunately it falls under the normal rules of negligence, which means no harm no foul, even with invalid informed consent there is no medical malpractice unless there is harm done, short of anaphylaxis, where the adverse reaction is severe and immediate, a parent will not know for some time if there are any long term negative impacts on the child's health.

This gives Doctors confidence in vaccines even if they know that it's not really valid informed consent, if the adverse reaction is minor (not permanent or long lasting) then there is no claim for malpractice[44] if the adverse event sets on gradually over time, then causation is impossible to prove, it would appear the Government along with the Medical Profession is sidestepping informed consent in favour of the *Bolam Principle* that the High Court Rejected.

[42] Email from TGA – Marked as Annex "A"

[43] Wyong Shire Council v. Shirt [1980] HCA 12; (1980) 146 CLR 40, per Mason J. at p 47. See also Gala v. Preston [1991] HCA 18; (1991) 172 CLR 243, at p 253)

[44] Wrongs Act 1958 (Vic) s.48(l).