

Re: Teenage decision-making in the context of the Jehovah's Witness faith (again)

To the Editor;

Dr Harrison's article (1) debates when paediatricians should accept a teenager's refusal of potentially life-saving or life-prolonging treatment. The article addresses only one of three necessary elements of consent: competence. Not discussed are the two other requirements – adequate information and voluntariness.

Full discussion of the three elements that are necessary for consent to medical treatment is particularly important when the adolescent patient is a member of a Jehovah's Witness (JW) family. This is a subject that can evoke strong emotions. Our paper (2) on this topic was published in the 2006 issue of *Paediatrics & Child Health*. Indeed, the governing body of JWs, the Watchtower Society (WTS), wrote to the *Journal* in protest over our then unpublished article, which had been accepted after two rounds of peer review. The editors of the *Journal* resisted the WTS's representations.

Our article presented details about three real cases of adolescents who refused blood transfusions. In each case, the information we offered came from publicly available sources, such as court transcripts or reports of court hearings. Our article, therefore, had rich grounding in actual cases and in reported alleged practices of JWs, the WTS and WTS lawyers. By contrast, the Harrison article presented and then discussed a hypothetical case. There is a place for theoretical cases and commentary thereon, but we suggest that the *Journal* follow the Hasting's Center report's example. A recent edition of the Hasting's Center report (3) presented a short hypothetical case of a JW teenager, followed by two commentaries from different perspectives. Two commentaries are preferable to one because it is unlikely that one person can fairly represent all views in this controversial bioethics matter.

We express concern also about the paucity of detail offered in Harrison's hypothetical case. When analyzing ethically fraught matters, it is customary to examine very carefully the context in which the situation arises. It is important to recognize that untold numbers of JWs, who are otherwise faithful to WTS teachings, in fact disagree with the WTS's biblical interpretations about the uses of blood. Some JWs, who have a different understanding of the relevant biblical passages, have created a Web site that we have found extremely useful (4). We suspect that the Web site will be similarly helpful to most paediatricians who may choose to offer it to families, thus permitting them to know that further information on the complexities of blood transfusion, and some alternative perspectives, are readily available.

In our article, we gave specific detail about possible problems in the quality of information an individual JW patient may have about the risks and benefits of blood. We also addressed problems of voluntariness in decision-making among teenagers. In other words, we described clearly that two of the three elements of informed consent may well have been absent – ie, adequate information and voluntariness. This discussion made it apparent that, even if an adolescent is assessed to be fully mature, the assessment does not, by itself, solve the problem of whether he or she can accept or refuse proposed medical treatment.

Indeed, cases of adolescent refusal of blood would be relatively easy if the only issue was maturity. But what is concerning are the issues that the recent article does not address: How does one establish that a young patient has good medical information when (among other problems) the religious authority's Web site contains misleading excerpts from dated medical journals (5), when medical personnel statements can be contradicted by religious people who visit hospitals (6), and when the credibility and good faith of medical personnel are constantly in question because they, like all other non-JWs, are said to be subjects of "Satan the Devil [who] really is the unseen ruler of the world! (7)"? How do physicians assure themselves that a patient is choosing without coercion when a particular medical choice will cause the loss of family and friends (8), when the patient's lawyer appears to also represent the religious authority (9,10) and when the WTS instructs individual JWs 'to squeal' – to breach medical confidentiality if, in their work as health care providers, they learn that a patient has accepted blood (11,12)? Finding answers to these questions ought to be the focus of bioethicists because these are not just difficult issues worthy of academic consideration, they are of vital practical importance to paediatricians and other physicians who must assess capacity to consent in a social context in which preventable death is a distinct possibility.

We agree that paediatricians are likely to suffer extreme moral distress if a teenage patient dies due to the lack of a blood transfusion. But we strongly disagree that it is "consistent with legal and professional standards (1)" to accept the teenager's 'decision' when the patient's quality of information and degree of voluntariness have not been considered, let alone assessed. In a supplement to our paper, we wrote:

Paediatricians must look for all elements of consent: competence, information and voluntariness. Most difficulties among physicians, parents and adolescents are resolved amicably. We support this. In some situations, reporting to Child Welfare is a statutory duty and legal help is required (13).

Refusal of life-saving or life-prolonging treatment clearly presents paediatricians with a difficult situation.

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LETTERS TO THE EDITOR

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Nevertheless, we agree with the conclusion regarding the JW case published in the Hasting's Center Report: "Physicians have a sacred charge to do no harm. If we err, I prefer it to be on the side of life" (3).

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The author responds;

Assessing decision-making capacity is context dependent. It involves determining the person's ability to understand their health condition, current health problems, the treatment that is being proposed and its potential harms and benefits, other treatment alternatives and potential harms and benefits, and potential consequences of accepting or refusing treatment. It also involves determining that the person is able to contextualize this information to his or her own circumstances.

As part of the assessment process, the health care provider doing the assessment should provide the person with the information about the matters detailed in the previous paragraph, and ensure that he or she appreciates that there are options.

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Deaths

Across the clinical studies, 17 deaths were reported in 21,464 male and female subjects. The events reported were consistent with events expected in healthy adolescent and adult populations. The most common cause of death was motor vehicle accident (4 subjects who received GARDASIL[®] and 3 placebo subjects), followed by overdose/suicide (1 subject who received GARDASIL[®] and 2 subjects who received placebo), and pulmonary embolism/deep vein thrombosis (1 subject who received GARDASIL[®] and 1 placebo subject). In addition, there were 2 cases of sepsis, 1 case of pancreatic cancer, and 1 case of arrhythmia in the group that received GARDASIL[®], and 1 case of asphyxia in the placebo group.

All-cause Common Systemic Adverse Experiences

All-cause systemic adverse experiences for female and male subjects that were observed at a frequency of greater than or equal to 1% where the incidence in the vaccine group was greater than or equal to the incidence in the placebo group are shown in ADVERSE REACTIONS, Table 3 of the product monograph.

Systemic Autoimmune Disorders

In the clinical studies, subjects were evaluated for new medical conditions that occurred over the course of up to 4 years of follow up. The number of subjects who received both GARDASIL[®] and placebo and developed a new medical condition potentially indicative of a systemic immune disorder is shown in ADVERSE REACTIONS, Table 4 of the product monograph.

Post-Market Adverse Drug Reactions

The following adverse experiences have been spontaneously reported during post-approval use of GARDASIL[®]. Because these experiences were reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or to establish a causal relationship to vaccine exposure.

Nervous system disorders: dizziness, syncope.

Gastrointestinal disorders: nausea, vomiting.

Immune system disorders: Hypersensitivity reactions including anaphylactic/anaphylactoid reactions, bronchospasm, and urticaria.

DRUG INTERACTIONS**Drug-Drug Interactions**

Use with Other Vaccines: Results from clinical studies indicate that GARDASIL[®] may be administered concomitantly (at a separate injection site) with hepatitis B vaccine (recombinant).

The safety of GARDASIL[®], when administered concomitantly with hepatitis B vaccine (recombinant), was evaluated in a placebo-controlled study. The frequency of adverse experiences observed with concomitant administration was similar to the frequency when GARDASIL[®] was administered alone.

Use with Common Medications: In clinical studies, 11.9%, 9.5%, 6.9%, and 4.3% of individuals used analgesics, anti-inflammatory drugs, antibiotics, and vitamin preparations, respectively. The efficacy, immunogenicity, and safety of the vaccine were not impacted by the use of these medications.

Use with Hormonal Contraceptives: In clinical studies, 57.5% of women (aged 16 to 26 years) who received GARDASIL[®] used hormonal contraceptives. Use of hormonal contraceptives did not appear to affect the immune responses to GARDASIL[®].

Use with Steroids: In clinical studies, 1.7% (n=158), 0.6% (n=56), and 1.0% (n=89) of individuals used inhaled, topical, and parenteral immunosuppressants, respectively, administered close to the time of administration of a dose of GARDASIL[®]. These medicines did not appear to affect the immune responses to GARDASIL[®]. Very few subjects in the clinical studies were taking steroids, and the amount of immunosuppression is presumed to have been low.

Use with Systemic Immunosuppressive Medications: There are no data on the concomitant use of potent immunosuppressants with GARDASIL[®]. Individuals receiving therapy with immunosuppressive agents (systemic doses of corticosteroids, antimetabolites, alkylating agents, cytotoxic agents) may not respond optimally to active immunization (See WARNINGS AND PRECAUTIONS, General).

Drug-Food Interactions: Interactions with food have not been established.

Drug-Herb Interactions: Interactions with herbal products have not been established.

Drug-Laboratory Interactions: Interactions with laboratory tests have not been established. There was no evidence from the clinical studies database of impact of GARDASIL[®] administration on the performance characteristics of the Pap test and some commercially available HPV tests.

OVERDOSAGE

There have been occasional reports of administration of higher than recommended doses of GARDASIL[®].

In general, the adverse event profile reported with overdose was comparable to recommended single doses of GARDASIL[®].

DOSAGE FORMS, COMPOSITION AND PACKAGING

Vials: GARDASIL[®] is supplied as a carton of one 0.5 mL single-dose vial

Syringes: GARDASIL[®] is supplied as a carton of one 0.5 mL single-dose prefilled Luer Lock syringe, preassembled with an UltraSafe Passive[®] delivery system. One needle is provided separately in the package.

COMPOSITION

Active Ingredients: GARDASIL[®] is a sterile preparation for intramuscular administration. Each 0.5 mL dose contains approximately 20 µg of HPV 6L1 protein, 40 µg of HPV 11 L1 protein, 40 µg of HPV 16 L1 protein, and 20 µg of HPV 18 L1 protein.

Inactive Ingredients: Each 0.5 mL dose of the vaccine contains approximately 225 µg of aluminum (as amorphous aluminum hydroxyphosphate sulphate adjuvant), 9.56 mg of sodium chloride, 0.78 mg of L-histidine, 50 µg of polysorbate 80, 35 µg of sodium borate, and water for injection. The product does not contain a preservative or antibiotics.

PACKAGING

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If he or she is not able to understand the information and appreciate that there are options, then the health care provider would not likely deem him or her capable to give or withhold consent.

I concluded in my article that "If the patient is capable, and freely choosing to forgo treatment, you should honour his or her wishes, or transfer care to someone who will." Because having decision-making capacity entails being fully informed and having the ability to understand the information that has been provided, and appreciating that one has options, when a person is found to be both capable and making a free choice, I would be interested in the ethical argument that would justify overriding this person's wishes.

*Christine Harrison PhD
The Hospital for Sick Children,
Toronto, Ontario*

Re: Faith held by Jehovah's Witnesses does not always forbid blood transfusions

To the Editor;

It appears that Dr Harrison confuses official church doctrine with 'family values and religious beliefs' (1). This mistake presents a false and perilous premise for medical ethical deliberations.

Families among Jehovah's Witnesses (JW) do not form and maintain a doctrine forbidding themselves from conscientiously accepting transfusion of blood or else they are "choosing not to be members of the church and its community" (1). Rather, it is an elite religious hierarchy ('governing body') that makes and enforces this doctrine, including the caveat that to accept blood is an act of disassociation (2). Contrarily, there is evidence demonstrating that a considerable number of JWs do not fully accept this doctrine (3,4). Drs Gyamfi and Berkowitz state that, "it is naïve to assume that all people in any religious group share the exact same beliefs, regardless of doctrine... Why should that not also be true for Jehovah's Witnesses?" (5). Official church doctrine should never be confused with personal belief.

Before 1945, there was no evidence suggesting that the general population of JWs held a taboo against blood transfusion and, in fact, the governing body at the time expressed praise when relating experiences in which allogeneic blood was used to save lives (6). In 1945, the governing body then taught that it was morally wrong to accept blood transfusions. In 1961, this doctrine began to be enforced under the pain of organized shunning (7). Speaking retrospectively and specifically about its blood taboo, in 1966, the governing body put it bluntly to the JW community by reminding them of the "placing of additional obligations on each [Jehovah's Witness] individually" (8). The governing body placed these obligations. No measurable, prevailing, communal view of JWs asked for it. This shunning imposes a duty to conform so extreme that JWs are required to refrain from even private spiritual socializing with a family member who has conscientiously accepted a forbidden blood product (9). Extreme pressure to conform in the face of such a threat to social and family support is unavoidable, and should be realized by judges, clinicians, social workers and ethicists.

Members of the Associated Jehovah's Witnesses for Reform on Blood encourage doctors to treat patients as those patients want to be treated, rather than treating them as a religion would want them treated.

*Lee Elder, Director
Associated Jehovah's Witnesses for Reform on Blood*

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hypersensitivity (including skin rash, urticaria, fever, arthralgia, exfoliative dermatitis, erythema multiforme with histopathological findings of necrotizing vasculitis, and thrombocytopenic purpura); anorexia; nausea; dizziness; headache; dyskinesia; drowsiness; blood pressure and pulse changes, both up and down; tachycardia; angina; abdominal pain; weight loss during prolonged therapy. There have been rare reports of Tourette's syndrome. Toxic psychosis has been reported. Although a definite causal relationship has not been established, the following have been reported in patients taking this drug: instances of abnormal liver function, e.g., hepatic coma; isolated cases of cerebral arteritis and/or occlusion; leukopenia and/or anaemia; transient depressed mood; a few instances of scalp hair loss. Very rare reports of neuroleptic malignant syndrome (NMS) have been received, and in most of these, patients were concurrently receiving therapies associated with NMS. In a single report, a ten-year-old boy who had been taking methylphenidate for approximately 18 months experienced an NMS-like event within 45 minutes of ingesting his first dose of venlafaxine. It is uncertain whether this case represented a drug-drug interaction, a response to either drug alone, or some other cause.

Table 1.3: Adverse Events Occurring in Long-Term Safety Trials

Frequency	Very Frequent	Frequent	Frequent	Less Frequent
Body System	>10% - <50%	5-10%	<5% and ≥1%	<1%
Body as a Whole	headache	accidental injury, abdominal pain, fever	flu syndrome, allergic reaction, infection, aggravation reaction, pain, extremity pain, back pain	surgery procedure, accidental overdose, chest pain, cyst, infection fungal, photosensitivity reaction, malaise, asthenia, neck pain
Cardiovascular System			hypertension	cardiovascular disorder, tachycardia, migraine
Digestive System		anorexia, vomiting	gastroenteritis, diarrhea, nausea, dyspepsia	rectal disorder, gastritis, increased appetite, nausea and vomiting, periodontal abscess, tongue disorder, tooth disorder, constipation
Endocrine System				diabetes mellitus
Hemic and Lymphatic System				ecchymosis, petechia, lymphadenopathy
Metabolic and Nutritional System			weight loss	dehydration
Musculoskeletal System			myalgia	arthralgia, leg cramps
Nervous System	insomnia		twitching, nervousness, emotional lability, anxiety, depression, somnolence, hostility, dizziness	apathy, neurosis, hallucinations, speech disorder, sleep disorder, tremor, thinking abnormal, abnormal dreams
Respiratory System	upper respiratory tract infection	pharyngitis, cough increased, rhinitis	sinusitis, respiratory disorder, asthma, bronchitis, epistaxis	dyspnea, pneumonia, voice alterations, laryngitis
Skin System			rash, contact dermatitis	pustular rash, urticaria, eczema, pruritus, skin benign neoplasm, acne, alopecia, nail disorder, psoriasis, herpes simplex
Special Senses		otitis media	conjunctivitis	ear disorder, diplopia, ear pain
Urogenital System				albuminuria, urinary frequency, urinary tract infection, urinary urgency

OVERDOSAGE

Signs and Symptoms Signs and symptoms of acute methylphenidate overdose, resulting principally from overstimulation of the CNS and from excessive sympathomimetic effects, may include the following: vomiting, agitation, tremors, hyperreflexia, muscle twitching, convulsions (may be followed by coma), euphoria, confusion, hallucinations, delirium, sweating, flushing, headache, hyperpyrexia, tachycardia, palpitations, cardiac arrhythmias, hypertension, mydriasis and dryness of mucous membranes. **Recommended Treatment** Treatment consists of appropriate supportive measures. The patient must be protected against self-injury and against external stimuli that would aggravate the overstimulation already present. Gastric contents may be evacuated by gastric lavage as indicated. Before performing gastric lavage, control agitation and seizures (if present) and protect the airway. Other measures to detoxify the gut include administration of activated charcoal and a cathartic. Intensive care must be provided to maintain adequate circulation and respiratory exchange; external cooling procedures may be required for hyperpyrexia. Efficacy of peritoneal dialysis or extracorporeal hemodialysis for CONCERTA overdose has not been established. The prolonged release of methylphenidate from CONCERTA tablets should be considered when treating patients with overdose. Alcohol may induce the production of ethylphenidate. The amount of ethylphenidate production is proportional to the blood alcohol concentration (see DRUG INTERACTIONS; Overview). As with the management of all overdosage, the possibility of multiple drug ingestion, including alcohol, should be considered. Product Monograph available at www.janssen-ortho.com or from Janssen-Ortho Inc. Medical Information Services (800) 567-3331.



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The author responds,

My understanding is that although Jehovah's Witnesses (JWs) seek medical care and accept most medical treatments, their religious beliefs preclude transfusion of whole blood and its major components. JWs regard donor-derived blood transfusion (whole blood, red cells, white cells, platelets and plasma) as contrary to scriptural commands. They request medical management using alternatives to blood transfusion, eg, blood conservation and 'bloodless' surgery (ie, surgery performed without the use of transfused blood).

The sources of my understanding include materials from the Jehovah's Witnesses – Office of Public Information Web site:

- <<http://www.jw-media.org/region/global/english/releases/health/000615.htm>>
- <<http://www.jw-media.org/beliefs/beliefsfaq.htm>>

A JW Liaison Committee Chair member stated that:

If a baptized member of the faith willfully and without regret accepts a blood transfusion, he indicates by his actions that he no longer wishes to be one of Jehovah's Witnesses. The individual revokes his own membership by his actions – Chuck Goodvin, Hospital Liaison Committee for Jehovah's Witnesses (personal communication).

JWs do not necessarily reject the use of some blood fractions that may have been processed or derived from plasma or blood cells (eg, albumin, clotting factors, immunoglobulins, fibrin glue, cryoprecipitate, oxygen-carrying red-cell substitutes and interferons). Because JW patients make their own individual personal decisions on these matters, it is essential to discuss the acceptability of blood and specific blood products with each individual patient or family.

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