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Two's company, is three a crowd? Ethical cognition in decision making and the role of industry third parties in pediatric diabetes care

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Abstract

Families of children with diabetes increasingly obtain health information from a variety of sources. Doctor patient relationships have accordingly become more fluid and dynamic with input from other parties. These outside parties include representatives from the diabetes health care industry- industry third parties (ITP's). This review is an exploration of the ethical principles and cognitive processes involved when doctors and patients negotiate around health care practices and the role of ITP's in that dialogue. Ethical principles of conflicts of interest, beneficence (act in the best interests of the patient), non-maleficence (act so as to do no harm) and justice (act so as to allocate resources fairly or justly) are relevant considerations. Reflexive and analytic thinking and various cognitive biases also play a significant part in clinical decision making. A complex case example is analysed to highlight a process of ethical cognition in decision-making to ensure high value care and optimal patient outcomes.

Key words: industry third parties, ethics, cognition

Introduction

The current renaissance period of modern science has provided a bewildering array of novel therapies and interventions. Many have proven to be highly effective in broad (eg cardiovascular drugs) and specific (eg oncology regimens) patients groups. However others have proved to be both expensive and non-transformative. Mis-directed use of some

interventions has proved to be counter-therapeutic leading to over-diagnosis, with unnecessary and potentially harmful subsequent clinical interactions (eg breast screening, prostate specific antigen testing [1]). In this milieu, the role of the clinician continues to be as a diagnostician, therapist and advocate who provides advice and guidance that should be in the best interests of their patient. The 'doctor-patient relationship' has been the cornerstone of health care since antiquity (2). This fiduciary relationship (3) has traditionally been seen as a sacrosanct dyad analogous to relationships between lawyers and clients or priests and parishioners. Increasingly though, the traditional doctor-patient relationship has been challenged by growing recognition of the need for patient health literacy (4), increasing patient empowerment (5), disruptive patterns of knowledge transfer and personalised medicine (6). Many would argue that these changes address an imbalance in power and control between therapist and client and are thus both inevitable and appropriate to current mores. The move away from a paternalistic paradigm has created a more dynamic nexus where roles and inputs are more fluid. This fluidity allows for third parties to influence the interaction – either directly or indirectly, be they family members, friends, members of social media communities or other parties with an interest in the outcomes of therapeutic decisions. This last group includes health care funders and health care industry providers (7, 8). The purpose of this analysis is to consider how clinical decision making within the doctor-patient relationship might be impacted upon by industry third parties (ITP's) in paediatric type 1 diabetes care. The emerging involvement of ITPs will be examined through a dispassionate prism of ethical and cognitive decision-making analysis.

Two's company in type 1 diabetes care – rationale for focusing on the doctor-patient relationship

Most type 1 diabetes care in paediatrics occurs in specialist multidisciplinary team settings that involve a number of specialist health care providers (9). In this context, much of the focus is upon fostering health literacy and self-efficacy by the allied health team with an attendant degree of patient contact. Given the myriad of team players in paediatric type 1

diabetes care, it can be easy to underestimate the role of the family's relationships with individual players, particularly their relationship with their doctor. The doctor-patient/parent relationship, however, remains a key element of care, for a number of reasons. A recent study from our group has shown that within the same multidisciplinary team, individual clinician attitudes and personality traits can significantly impact clinical outcomes such as metabolic targets (10). Specialist physicians often assume a leadership role in the setting of team structures, taking ultimate responsibility for key management decisions (11). Perhaps for this reason, patients and their families value continuity of care from the same physician (12). The best clinical outcomes ensue when there is clear communication and a confluence of goals between physician, patient and, in paediatrics, parent (13). The integrity of the doctor-patient relationship remains a strong determinant of health care and outcome. For these reasons, we focus in this paper on the doctor-patient relationship, and the impact of industry third parties on that relationship.

Who are the industry third parties?

For the purposes of this discussion, 'industry third parties' refers to any group participating in a dialogue around clinical decisions who is neither the patient or their guardian, nor the clinician, and who have a financial interest in the outcome of any clinical decision that is made. Specifically, this may include representatives from pharma or device companies or health insurance companies. In the context of paediatric diabetes care, these mainly include manufacturers of insulin and other glycaemic agents, insulin pumps, blood glucose meters and flash/continuous glucose meters. On the periphery, ITP's may also include unconventional groups such as purveyors of glycaemic detection companion animals and various alternative or complementary 'natural' therapies.

The regulations governing the amount of contact ITP's may have with clinicians and patients vary in local, national and international contexts. Such regulations may also vary between different industry types. Regulations may at one end of the spectrum stipulate no direct

marketing and no direct contact, and at the other extreme permit unfettered contact with patients and their families. Representatives from industry may have some clinical training (eg a clinical nurse specialist) or may have no clinical training at all. Products that are sold may be highly regulated through national accreditation bodies or, alternatively, have little to no specific regulatory framework governing their sale apart from generic consumer law.

Industry third parties may have broad relationships with clinician societies, research institutions, hospitals and advocacy groups. They may involve themselves in presentations to government funding bodies utilizing either a direct submission or an advocacy-aligned interest approach. Industry third parties may have relationships with health care insurers. Industry third parties may support research, patient information materials, peer-support groups and clinician meetings. There may or may not be a robust scientific literature that acts as a marketing base for an ITP's product. Indeed adherence to scientific or epistemological norms can be affected by money and funding from ITP's (14).

Who has the moral high ground?

Conflicts of interest are rightly a 'cause du jour' in the clinical and scientific worlds. All credible research writings and presentations have to be accompanied by a conflict of interest statement from the originator. Clinicians are readily familiar with the concept. Hence conflict of interest is one obvious lens through which to view the involvement of ITPs in the clinical setting.

The traditional doctor-patient relationship was conceptualized as a closed, private relationship between these two players only. In this worldview, any outsider, or third party, is readily perceived an interloper, all the more so if they are hawking some sort of product. If sale of that product generates a profit that rewards the third party, then the third party interloper is readily recognised as a having conflict of interest, with all of the negative value

connotations of that term (15). This is especially so if the rewards generated by sale of the product are not necessarily linked to improvements in patient outcomes or in some cases if the product is perceived to cause harm (16). On this approach, the involvement or influence of ITP's in a decision about use of a medical device for a patient is, *prima facie*, ethically problematic.

But is this just lazy thinking? Conflict of interest is neither simple nor uni-dimensional. Some have argued that the malign influence of pharmaceutical and device companies is overplayed, with notable lack of evidence of any harm to patients that is directly traceable to financial conflict of interest (17). Financial gain by these companies may feel self-serving, even corrupt, but more is needed than just an uncomfortable feeling to show that it is necessarily ethically problematic. Even if this so-called 'defensive discourse' is not ultimately supported by the facts, it sounds a warning against jumping too quickly to conclusions (18). What's more, clinicians themselves are not immune from conflict of interests. Clinicians too financially benefit by doctor-patient relationships. Clinician remuneration might be directly linked to a clinical encounter or linked to providing a series of clinical encounters (or a clinical service) to a health care institution (19). Clinicians may have incentives to act in certain ways to retain their employment, advance in their career, along the way cultivating the good opinion of their colleagues and fitting in with institutional culture (ie a herd effect). Clinicians get paid whether patients recover or deteriorate, in a manner not dissimilar to ITP's. Finally, clinicians may benefit directly from ITP's themselves, either from research support, service support, sponsorships to attend meetings, honoraria, clinical advisory payments or rarely a direct fee-for-service arrangement. One might argue that the profit motive of industry is a more egregious underpinning of conflict of interest, but given doctors and industry operate in the same financial societal context (ie doctors, ITP's and health care in general all benefit from patient care in a successful economy), the distinction between the two can begin to blur.

Attempting to adjudicate on the degree of conflictedness of the various players in a clinical encounter in order to resolve the issue of ITP involvement is thus a fraught endeavour. It would seem reasonable to assume that almost all participants enter a doctor-patient relationship with intent of beneficence, with the end goal being the improvement in the patient's condition. Even ITPs with a profit motive may be assumed to have, at the very least, a non-maleficent attitude to patient well-being, since harm to patients will not promote the interests of ITPs in the long run. Given this broad commonality of purpose, an examination of the motivations of the various players is unlikely to be either discriminating or enlightening.

What are the ethical considerations?

Autonomy and choice

Going to the ethical heart of the matter might be a more fruitful approach. The principle of respect for autonomy is central to medical ethics. It requires that medical professionals respect patients' right to self-determination and to make informed choices about their own health and care in accordance with their personal values and wishes (3). In medical ethics, it is generally accepted that autonomy should be balanced alongside the principles of beneficence (act in the best interests of the patient), non-maleficence (act so as to do no harm) and justice (act so as to allocate resources fairly or justly) (20). For adults of sound mind, autonomy is generally accorded greater ethical weight than beneficence and non-maleficence. In the process of adult clinical decision-making, patient autonomy is realised through provision of information and obtaining informed consent. In paediatric medicine, parents or guardians undertake clinical decision-making on the child's behalf. In this context, parental autonomy is respected by providing them with information and seeking their informed consent on behalf of their child.

Information is crucial to informed consent, but there is no compelling reason as to why doctors should have a monopoly on the provision of information about medicines and

treatments (21). Industry third parties can and will be sought out as a source of information and support by patients and their parents or guardians. How ITP's deal with patient-initiated contact will depend upon local regulations, but in many instances responses will be forthcoming. Contact between ITP's and patients frequently occur when there is a service vacuum or in remote and regional contexts when tertiary services are unable to be accessed. Alternatively, patients or guardians may source drugs and medical devices from other regulatory jurisdictions over the Internet or by travelling friends and family members. Recently and increasingly, patients have been accessing cloud-based openware "Do It Yourself Pancreas System" for closed loop insulin delivery (#WeAreNotWaiting-<https://openaps.org/>) from 'non-industry' third parties that are unregulated and not approved by any governmental authority. All of these initiatives seemingly play strongly into the principle of autonomy and patient self-determination. Patients and their guardians are making health care choices that are unconstrained by the doctor-patient relationship and the particular biases of their clinician. However, the gain in autonomy may be somewhat illusory. Patients and their guardians will usually seek out information and advice. The advice proffered by an ITP will be impacted by the ITP's need to represent their particular commercial interest. Hence patients and guardians may simply be swapping one set of perceived limiting biases for another - those of the doctor for those of the ITP. Only now, patients are increasingly prone to the cognitive biases typical of the consumer in a commercial relationship, rather than a patient in a fiduciary relationship (22). Their ability to make independent decisions may be impacted upon by their emotional investment in the communication process (ie they have gone outside usual channels to seek out advice, so they are likely to give it more weight). This could be potentially exacerbated by contextual vulnerability of being recipients of a sole service ITP-provider in areas where traditional health care resources are scarce. All of this occurs in the inevitable context of sophisticated consumer marketing (23). This raises the question of whether engagement with ITP's that is motivated by a perception of limited options within the doctor-patient relationship really

empowers patients and makes them more autonomous in their decision-making. The considerations just cited suggest not.

Non-maleficence, beneficence, justice and health care value

What of the need to balance autonomy with non-maleficence, beneficence, and justice? Is the treatment or intervention being promoted by an ITP potentially harmful? Does it work? Does investment in it re-direct resources away from other health care priorities? Whilst concepts such as personalised medicine and disciplines such as pharmaco-genomics promise much in highly individualised and tailored therapies, they can raise concerns regarding non-maleficence, beneficence, and justice. Indeed, the underbelly of personalised medicine is that highly specialised and effective therapies designed for patients with particular characteristics may be extremely expensive and 'budget-busting' to health care systems. Examples of these include combined immunotherapy regimens used in oncology (24) and so-called 'orphan drugs' for rare diseases (25). Alternatively there may more conventional therapies that are designed for a broader patient group that are of only marginal benefit, have significant risk profiles and with marginal to negative cost benefit or financial hardship (26, 27). Finally, some unregulated therapies may be either harmful or low value, either causing direct patient harm or anguish due to unmet expectations (28). When issues of distributive justice are not addressed, inequities can be created where, within one health care system, some patients can access expensive, non-transformative therapies, whilst others cannot access basic, proven, life-saving therapies (29).

When a therapy has minimal benefit, or the potential harm outweighs potential benefits, it is deemed low value health care. Low value health care places significant burdens on health care costs and is currently the target of international health care professional campaigns such as 'Choosing Wisely' (<http://www.choosingwisely.org/>). Traditionally, it has been the role of health care regulators and treating clinicians within the public health care system to try and balance these imperatives of individual autonomy and benefit to the individual

patient with distributive justice. This is arguably the most highly contested area of medical ethics.

This ethical analysis has not produced a clear resolution to balancing these considerations. Seeking information and services from ITPs may not dramatically enhance parent and patient autonomy, but this does not show that patient contact with ITPs should therefore be banned. ITPs may promote low value health interventions in some instances, but they are not alone in this. The distributive justice problems of low value health care extend right across the health care system.

Additional scrutiny of the cognitive processes of decision-making within a clinical encounter further illuminates the ethical complexity of ITP involvement in clinical encounters.

Why do people make the decisions they do?

Motivated reasoning

Not all clinicians assess evidence in the same way. Two clinicians can see the same dataset yet arrive at varying conclusions. How is this possible? Analyses of cognitive processes have highlighted two, key processes. Motivated reasoning, the process whereby individuals confronted by the same evidence can arrive at opposite conclusions, has been long recognised in psychological literature (30). Motivated reasoning describes how reasoning and cognition is profoundly affected by emotion. In essence, motivated reasoning is a prejudicial phenomenon of pre-existing beliefs outweighing new facts when evidence is being considered and synthesized. It has been described in many fora, including debates around evolution, vaccination and climate change (31). Clinicians, in particular paediatric diabetologists, are not immune from this form of cognitive bias. This was evidenced in a debate about diabetes technology at the 2014 Annual Scientific Meeting of the International Society for Pediatric and Adolescent Diabetes (“Is new technology improving diabetes care in children and adolescents?”[32]). In response to a comment that the Cochrane Reviews

had shown limited benefits of insulin pump therapy, the refrain “We should ignore the Cochrane reviews and randomized control trial data when we *know* they are wrong” was received with applause. In its extreme form, motivated reasoning can be associated with what the Nobel Laureate Richard Feynman called ‘Cargo-cult science’ -practices that have the semblance of being scientific, but do not in fact follow the scientific method (33). Feynman emphasized the need to look at all of the evidence and “not just the information that leads to judgment in one particular direction or another” (33). In the field of clinical diabetes care, Edwin Gale summarized the same phenomenon: “One needs to consider the facts before generating a theory or run the risk of prematurely generating a theory to which the facts are made to fit” (34).

Cognitive biases, System 1 and System 2 thinking

More recently, another Nobel Laureate, Daniel Kahneman, described two systems of cognition in his well-known book ‘Thinking, fast, and slow’ (35). In this treatise, Kahneman describes System 1 thinking, which is intuitive, automatic, fast and effortless, and System 2 thinking which is analytic, conscious, slow and requires more work. People usually prefer to rely on System 1 thinking for obvious reasons. System 1 thinking is generally useful in routine problem solving though it can lead to significant and systematic errors (36). System 1 thinking is limited by an individual’s heuristics (experiential mindlines or mental short cuts), which in turn are sensitive to a variety of biases. Clinicians appear to be subject to their own heuristics and cognitive bias in medical decision-making (37, 38). In a clinical context, biases that result in the persistence of low value care outcomes include: omission regret (wanting to avoid regret at *not* administering an intervention which may have benefited at least a few recipients); attribution bias (over confidence, illusion of control); impact bias (over-estimation of benefits and under-estimation of harms of interventions); affect bias (initially favorable impressions of an intervention result in lasting attitude of benefits despite subsequent evidence to the contrary); availability bias (testimonial recall of noteworthy though unrepresentative cases); extrapolation bias (indication creep); and

uncertainty bias (over-investigation or treatment to reduce anxiety) (39). Such biases may also lead researchers to fall prey to framing effects (presenting data in a favourable manner, eg changes in relative risk rather than absolute risk [40, 41]) or surrogate marker effects (pathophysiologic sophistry with a surrogate outcome measure that does not necessarily equate to a biologically relevant outcome). Marketing and advertising campaigns are generally designed to appeal to System 1 thinking. The novelty, attribution and extrapolation biases in particular are central to most ITP marketing campaigns ('It's new, it's brilliant and it will work for you!') or company sponsored post-marketing studies (42). When ITP marketing campaigns are directed at experienced clinicians and patients, there is the potential for a very powerful synergy between motivated reasoning and System 1 thinking (43), appealing to bias, belief and an 'eminence-base' in any subsequent decision process.

System 2 thinking, on the other hand, is underscored by the notion that "data is not the plural of anecdote" (44). Whilst it is usually considered as a form of mental processing for an individual, System 2 thinking can also be considered a description of collective decision-making. Rigorous evidence-based reviews undertaken by science professionals without bias (ie non-clinicians) are arguably the acme of collective System 2 thinking. Such deliberative and dispassionate endeavors are blind to pre-existing biases or beliefs and adhere to a strict scientific and pre-defined method. There is an emphasis on the quality, context and generalisability of evidence. In many respects, such an approach is the antithesis or antidote to marketing or advertising campaigns. System 2 thinking reviews are most readily evident in the Cochrane Library and Campbell Collaboration for medical and social sciences respectively (45). Such reviews can be used to form clinical decision support tools that can be utilized by clinicians to assist in their clinical deliberations. They can be used to highlight any benefit versus harm trade-offs in clinical interventions and act as a basis of shared decision-making between clinician and patient (46).

Balancing cognitive biases and competing ethical imperatives- a juxtaposition of System 1 and System 2 thinking in a clinical dilemma.

Billy is 12 years old and has had type 1 diabetes for 4 years. He has chronically poor control- his HbA1C's are all over 9.0%. He performs blood glucose testing erratically, not checking his levels at all on many days. He is on a MDI insulin regimen but frequently misses breakfast and lunchtime insulin injections. His parents run a coffee shop and work early morning shifts. His 15-year-old sister is the only person at home with Billy at breakfast time. Despite ongoing support from the allied health team, multiple attempts at increasing parental supervision and involvement of social work, Billy's situation has not improved since diagnosis. Recently, Billy was admitted with DKA after a holiday with friends, falsely stating that he had given all of his injections when, in reality, he had had no insulin for 24 hours.

Billy's parents occasionally participate in a social media diabetes support group. This group strongly advocates for insulin pump therapy for children with diabetes. Billy's parents have been directed to a device company representative who states that she is a clinical nurse specialist and that in her opinion an insulin pump would be a good idea for Billy. Billy's parents lobby their local community Rotary group to raise funds for a pump for his 'life-threatening' diabetes. The pump is purchased and at the next clinic visit the treating team are shown the pump and 'told' by his parents that Billy must start on the pump immediately.

The treating team does not wish to start Billy on pump therapy. They have serious reservations about his ability to adhere to self-care tasks involved in pump therapy, particularly given ongoing poor levels of parental supervision. They think that pump therapy will potentially put Billy at a greater risk of an adverse clinical outcome. Billy's parents react angrily, stating that they have been told that the pump will sort everything out and asking what right do the hospital staff have to deny Billy what is clearly the best therapy.

In this situation, a System 1 thinking approach may consider patient autonomy as ethically paramount. Billy and his parents have been made aware by an ITP of an apparently superior therapy that they have chosen to adopt. This is the newest therapy available and on the basis of what they have been told, this is the best therapy for Billy. Billy's parents made their own free choice to mobilize local community philanthropic resources to pay for the insulin pump, which they are entirely within their rights to do. The online support group, ITP, community philanthropic group and Billy's family all think that Billy should have access to pump therapy and the treating team have no right to deny him this. The treating team does not know for certain that Billy will not succeed on pump therapy. The evidence they have seen shows that many young people have good outcomes with insulin pump therapy, so why not Billy? Billy appears to be motivated and energized by this potential change in therapy paradigm. Furthermore it may negatively impact upon the family's standing within their community if the Rotary-funded pump were not utilized. So parental autonomy should be respected and Billy should be put on the pump. While this line of reasoning appears logical, it is potentially influenced by novelty bias ('it's new so it must be good'), attribution bias ('it's the pump that will improve things'), anecdotal bias ('my online support friends' child did really well on a pump') and extrapolation bias ('it works for some so it must work for everybody'). A System 1 heuristic approach to the ethical issues in this context and decisions affected by various cognitive biases may conclude that Billy should receive pump therapy.

A System 2 thinking approach would, amongst other things, recognize the conflict of interest for the device company representative and the advice proffered. However, rather than simply decry this, a System 2 thinking approach might instead focus on the many ethical and cognitive nuances at play in this situation). While parental autonomy is important, it does not necessarily carry the same ethical weight as the autonomy of the adult patient of sound mind. Parental autonomy is limited by consideration of a child's interests and well-being (47). Will pump therapy *definitely* improve things? Consideration of

the randomized control trial and observational data suggests not (48-50). Moreover, past behavior is a strong predictor of future behavior (51), so Billy's lack of parental supervision and his own poor self-care would seem to make him an unlikely candidate to improve on pump therapy (52). Could the pump in fact be harmful to Billy? This is the crucial ethical question, because respect for parental autonomy does not justify acquiescing to parental requests that put a child at risk of significant harm (53). Insulin pumps can malfunction or be misused resulting in serious life-threatening adverse consequences such as diabetic ketoacidosis (54-60). Those at highest risk of an adverse event are those who are unaware of their changing clinical status until it is too late for them to remedy the situation themselves. The European Association for the Study of Diabetes and the American Diabetes Association Diabetes Technology Working Group consensus statement emphasizes the need for patient selection in order to reduce the likelihood of an adverse event (61). The US Manufacturer and User Facility Device Experience (MAUDE) database indicates that unsupervised adolescents who do not test their blood glucose regularly are most at risk of adverse outcomes (62). Billy fits such an unfavorable profile. Well-managed diabetes is not an ever-present Damoclean sword of imminent catastrophe - the vast majority of patients never have serious acute complications. But if Billy and his parent's behavior remains unchanged, his risk profile may worsen after commencing pump therapy.

It is also important to consider distributive justice. Commencing a young person on insulin pump therapy requires resources be allocated to structured education and follow-up in the period after initiation. In the zero sum game of a resource-constrained clinical environment, those resources are not available to another patient who might be a better candidate for successful pump therapy. Who has the right to determine where resources are allocated? Properly understood, patient autonomy supports only the right to refuse treatment, not the right to demand treatment that doctors have decided is not appropriate (63). In public healthcare systems, allocation of health care resources should be done in a way that acknowledges each person's equal right to a fair share of those resources. Fair shares are

not determined on the basis of individual desires, but on need and capacity to benefit. A clinical team can do this using an evidence base or clinical decision support tool to decide which patients will receive the greatest benefit and least harm from the therapeutic option in question (64). One could make a strong case that a pump would be an example of low value care in Billy's case. Acquiescing to the family's demands would be both abrogating the moral responsibility of stewardship over clinical resources and antithetical to a clinical decision support approach. It is not inconceivable that Billy might have some sort of clinical epiphanic moment after commencing pump therapy, and dramatically improve his adherence and glucose control. However, such an outcome would appear to be so highly unlikely that a reasonable case could not be made for pump therapy being high-value care for him.

What of the potential for cognitive bias to affect this clinical decision? A System 2 thinking approach recognises that cognitive bias is implicit in all human decision-making. For example, there is a potential bias (or motivated reasoning) generated by the frustration and irritation that Billy's doctors are highly likely to be feeling towards this family (65). Billy's parents have ignored medical advice, failed to recognize their own contribution to Billy's poor diabetic control, and manipulated money out of the Rotary club that could arguably have been better used for other purposes. Deciding a particular point of view is wrong, because one does not like the person putting it forward ('shooting the messenger'), is a known type of bias. Interpretation of data is also subject to bias. Whilst the potential for bias can be minimised through an evidence-based approach, one has to be cognizant of how that evidence is assessed, the potential for framing effects, surrogate marker effects and availability bias, and be wary of being drawn to an intellectual echo chamber. The use of high quality meta-analyses underpinning clinical decision support tools should minimise these biases. On a more layered System 2 ethical analysis with an emphasis on high value care, the clinical evidence, balancing the probability of outcomes, and deeper reflection on

the relevant ethical considerations, the conclusion is that Billy should *not* commence pump therapy.

So, where to from here? Interpersonally, patients and their families exist in communities and interact with support groups and ITP's in addition to their health care teams. This is the reality of clinical situations. Another reality that needs to be acknowledged is that System 1 thinking, with its inherent biases, is a normal cognitive process for both parents and clinicians. A step back is required when competing views and priorities come into play. A model of 'ethical cognition' – a System 2, ethically appropriate and minimally-biased approach to clinical decision making - can incorporate all of these competing priorities in an appropriately weighted manner. In the event that a decision not favourable to the family is made, as in Billy's case, this approach to decision-making can then guide communication with the family. The clinical decision should be explained to the family in a manner that is clear and transparent (66), with the reasoning behind the decision made overt. While such conversations may not be easy, communicating openly with parents shows respect for their concerns and the sense of obligation they have to their child. Moreover, such a process would allow for clarity about a future possible pathway for Billy where a pump could be an appropriate option, if he could meet specified criteria.

Conclusion

There is an inevitability of ITP's joining the dialogue that normally occurs between doctors and their patients. This can occur at many levels including the lobbying of regulatory bodies, use of social media by patients and parents, traditional marketing campaigns, and direct financial support of physicians, research programs and patient groups. Whilst some would argue that these activities are harmful to patients (16), they appear unlikely to dissipate. Accordingly, clinicians may feel that their role has been diminished. But the literature appears to indicate that this is not the case (10). A recent meta-analysis of factors that influence medication adherence showed that the doctor is still the primary source of

reinforcement when it comes to health related behavior (67). Given this continuing influence, clinicians have an added fiduciary responsibility to consider the ethical imperatives and cognitive processes that form a backdrop to these ITP interactions, in order to avoid low value health care outcomes. In the context of an evolving dynamic of doctor-patient relationships with ITP's, the 'ethical cognition' approach discussed in this paper can offset the motivated reasoning and System 1 thinking of both parents and doctors that is generated by the marketing campaigns of ITPs. System 2 thinking offers a pathway to maintaining the integrity of effective communication between health care teams and their patients. A nuanced awareness of 'ethical cognition' can provide guidance in a complex, challenging and potentially fraught clinical decision-making context.

References

1. Baxi SS, Kale M, Keyhani S, Roman BR, Yang A, Derosa AP, Korenstein D. Overuse of Health Care Services in the Management of Cancer: A Systematic Review. *Med Care* 2017; 55:723-733.
2. Rodwin MA. Conflicts of Interest and the Future of Medicine. The United States, France and Japan. Oxford University Press, 2011, New York.
3. Beauchamp T, Childress JF. Principles of Biomedical Ethics (7th ed.). 2013. Oxford University Press, New York.
4. Palumbo R. Examining the impacts of health literacy on healthcare costs. An evidence synthesis. *Health Serv Manage Res* 2017; 30:197-212.
5. Palumbo R. The bright side and the dark side of patient empowerment: Co-creation and co-destruction of value in the healthcare environment Springer International Publishing, 2017.
6. Antolovich G. So, do we really need doctors anyway? Information, expertise and the changing dynamic between doctors and families. In *When Doctors and Parents Disagree: Ethics, Paediatrics and the Zone of Parental Discretion*, 2016. Sydney: Federation Press, p. 42-56.
7. Burns LR, Nash DB, Wholey DR. The evolving role of third parties in the hospital physician relationship. *Am J Med Qual* 2007; 22:402-9.
8. Fralick M. Putting patients first in the age of pharma. *CMAJ* 2014; 186:253.

9. Pihoker C, Forsander G, Fantahun B, Virmani A, Corathers S, Benitez-Aguirre P, Fu J, Maahs DM. The delivery of ambulatory diabetes care to children and adolescents with diabetes. *Pediatr Diabetes* 2018 (in press)
10. Cameron FJ, Russell E, McCombe J, O'Connell MA, Skinner T. The clinician factor: Personality characteristics of clinicians and their impact upon clinical outcomes in the management of children and adolescents with type 1 diabetes. *Pediatr Diabetes* 2018; 19: 832-839.
11. Cameron FJ, de Beaufort C, Aanstoot H-J, Hoey H, Lange K, Castano L, Mortensen HB on behalf of past and present members of the Hvidoere International Study Group on Childhood Diabetes. Lessons from the Hvidoere International Study Group on Childhood Diabetes: be dogmatic about outcome and flexible in approach. *Pediatr Diabetes* 2013; 14:473-80.
12. Hanberger L, Ludvigsson J, Nordfeldt S. Quality of care from the patient's perspective in pediatric diabetes care. *Diabetes Res Clin Pract* 2006; 72:197-205.
13. Swift PG, Skinner TC, de Beaufort CE, Cameron FJ, Aman J, Aanstoot HJ, Castaño L, Chiarelli F, Daneman D, Danne T, Dorchy H, Hoey H, Kaprio EA, Kaufman F, Kocova M, Mortensen HB, Njølstad PR, Phillip M, Robertson KJ, Schoenle EJ, Urakami T, Vanelli M, Ackermann RW, Skovlund SE; Hvidoere Study Group on Childhood Diabetes. Target setting in intensive insulin management is associated with metabolic control: the Hvidoere childhood diabetes study group centre differences study 2005. *Pediatr Diabetes* 2010; 11: 271-8.
14. Resnik DB. *The Price of Truth. How Money Affects the Norms of Science*. Oxford

University Press, 2007, New York.

15. Winch S, Sinnott M. Toward a sociology of conflict of interest in medical research. *J Bioeth Inq* 2001; 8:389-391.

16. Lurie P. DTC advertising harms patients and should be tightly regulated. *J Law Med Ethics* 2009; 37:444-50, 396.

17. Barton D, Stossel T, Stell L. After 20 years, industry critics bury skeptics, despite empirical vacuum. *Int J Clin Pract* 2014; 68:666-73.

18. Purdy S, Little M, Mayes C, Lipworth W. Debates about Conflict of Interest in Medicine: Deconstructing a Divided Discourse. *J Bioeth Inq* 2017; 14:135-149.

19. Kane GM. Influences on the Patient-Physician Relationship: No Quick Fix. *J Contin Educ Health Prof* 2016; 36:138-9.

20. Selgelid MJ. Promoting justice, trust, compliance, and health: the case for compensation. *Am J Bioeth* 2009; 9:22-4.

21. Coutts G. Relationships with the drug industry: Collaboration to improve care. *BMJ* 2009; 338:b232.

22. Biegler P, Kennett J, Oakley J, Vargas P. "Ethics of implicit persuasion in pharmaceutical advertising." 1647-1667. *Handbook of neuroethics*. Clausen J, Levi N (eds). Springer, 2015, New York.

23. Biegler P, Vargas P. Feeling Is Believing: Evaluative Conditioning and the Ethics of Pharmaceutical Advertising. *J Bioeth Inq* 2016; 13:271-9.
24. Ramsey S. Drug pricing should depend on shared values. *Nature* 2017; 552:S78.
25. Burns J. Orphan Drugs: Way Too Many, Way Too Expensive. *Manag Care* 2017; 26:12-17.
26. Davis C, Naci H, Gurpinar E, Poplavska E, Pinto A, Aggarwal A. Availability of evidence of benefits on overall survival and quality of life of cancer drugs approved by European Medicines Agency: retrospective cohort study of drug approvals 2009-13. *BMJ* 2017; 359:j4530.
27. Rosenthal E. Even Small Medical Advances Can Mean Big Jumps in Bills. *The New York Times*, April 5, 2014.
28. Brown AC. An overview of herb and dietary supplement efficacy, safety and government regulations in the United States with suggested improvements. Part 1 of 5 series. *Food Chem Toxicol* 2017; 107:449-471.
29. Fralick M, Avorn J, Kesselheim AS. The Price of Crossing the Border for Medications. *N Engl J Med* 2017; 377:1699-1700.
30. Kunda Z. The case for motivated reasoning. *Psychol Bull* 1990; 108:480-98.
31. Mooney C. The Science of Why We Don't Believe Science. How our brains fool us on climate, creationism, and the vaccine-autism link. *Mother Jones* 2011.
<https://www.motherjones.com/politics/2011/04/denial-science-chris-mooney/>.
Accessed 9th July 2018.

32.

http://medialibrary.ispad.cyim.com/mediatheque/results.aspx?channel=9857&search=%7B%22Text%22%3A%22Is%20new%20technology%20improving%20diabetes%20care%20in%20children%20and%20adolescents%3F%22%7D&search_expr=Is%20new%20technology%20improving%20diabetes%20care%20in%20children%20and%20adolescents%3F

Accessed 9th July 2018.

33. Feynman RP. 1974. Cargo Cult Science. Some remarks on science, pseudoscience, and learning how to not fool yourself. Caltech's 1974 commencement address.

<http://calteches.library.caltech.edu/51/2/CargoCult.htm>

Accessed 9th July 2018.

34. Gale EA. Personal communication 13th April 2018.

35. Kahneman D. Thinking, fast and slow. Farrar, Straus and Giroux. 2011

36. Tversky A, Kahneman D. Judgement under uncertainty: heuristics and biases. Science 1974 185: 1124-31.

37. Blumenthal-Barby JS, Krieger H. Cognitive biases and heuristics in medical decision making: a critical review using a systematic search strategy. Med Decis Making 2015; 35:539-57.

38. Seshia SS, Makhinson M, Young GB. 'Cognitive biases plus': covert subverters of healthcare evidence. Evid Based Med 2016; 21:41-5.

39. Scott IA. Cognitive challenges to minimising low value care. *Intern Med J* 2017a; 47:1079-1083.
40. Bui TC, Krieger HA, Blumenthal-Barby JS. Framing effects on physicians' judgment and decision making. *Psychol Rep* 2015; 117:508-22.
41. Scott IA. Statistical and clinical significance. *Med J Aust* 2017; 207:187-189.
42. Gale E. Post-marketing studies of new insulins: sales or science? *BMJ* 2012; 344:e3974.
43. Avorn J. The Psychology of Clinical Decision Making - Implications for Medication Use. *N Engl J Med* 2018; 378:689-691.
44. Bernstein IS. Metaphor, cognitive belief, and science. *Behavioral and Brain Sciences*, 1988; 11: 247-248.
45. Leigh A. *Randomistas: How Radical Researchers Changed Our World*. Latrobe University Press, 2018.
46. Kaplan RS, Haas DA, Warsh J. Adding Value by Talking More. *N Engl J Med* 2016; 375:1918-1920.
47. Gillam L. The zone of parental discretion: An ethical tool for dealing with disagreement between parents and doctors about medical treatment for a child. *Clinical Ethics* 2015; 11:1-8

48. Yeh HC, Brown TT, Maruthur N, Ranasinghe P, Berger Z, Suh YD, Wilson LM, Haberl EB, Brick J, Bass EB, Golden SH. Comparative effectiveness and safety of methods of insulin delivery and glucose monitoring for diabetes mellitus: a systematic review and meta-analysis. *Ann Intern Med* 2012; 157:336-47.
49. de Beaufort CE, Swift PG, Skinner CT, Aanstoot HJ, Aman J, Cameron F, Martul P, Chiarelli F, Daneman D, Danne T, Dorchy H, Hoey H, Kaprio EA, Kaufman F, Kocova M, Mortensen HB, Njølstad PR, Phillip M, Robertson KJ, Schoenle EJ, Urakami T, Vanelli M; Hvidoere Study Group on Childhood Diabetes 2005. Continuing stability of center differences in pediatric diabetes care: do advances in diabetes treatment improve outcome? The Hvidoere Study Group on Childhood Diabetes. *Diabetes Care* 2007; 30:2245-50.
50. de Beaufort CE, Lange K, Swift PG, Aman J, Cameron F, Castano L, Dorchy H, Fisher LK, Hoey H, Kaprio E, Kocova M, Neu A, Njølstad PR, Phillip M, Schoenle E, Robert JJ, Urukami T, Vanelli M, Danne T, Barrett T, Chiarelli F, Aanstoot HJ, Mortensen HB; Hvidoere Study Group. Metabolic outcomes in young children with type 1 diabetes differ between treatment centers: the Hvidoere Study in Young Children 2009. *Pediatr Diabetes* 2013; 14:422-8.
51. Neylon OM, O'Connell MA, Skinner TC, Cameron FJ. Demographic and personal factors associated with metabolic control and self-care in youth with type 1 diabetes: a systematic review. *Diabetes Metab Res Rev* 2013; 29:257-72.
52. Neylon OM, Skinner TC, O'Connell MA, Cameron FJ. A novel tool to predict youth who will show recommended usage of diabetes technologies. *Pediatr Diabetes* 2016; 17:174-83.

53. Diekema, DS. Parental refusals of medical treatment: The harm principle as threshold for state intervention. *Theor Med* 2004; 25:243-264.
54. Hanas R, Lindgren F, Lindblad B. A 2-yr national population study of pediatric ketoacidosis in Sweden: predisposing conditions and insulin pump use. *Pediatr Diabetes* 2009; 10:33-7.
55. Cope JU, Samuels-Reid JH, Morrison AE. Pediatric use of insulin pump technology: a retrospective study of adverse events in children ages 1-12 years. *J Diabetes Sci Technol* 2012; 6:1053-9.
56. Wheeler BJ, Donaghue KC, Heels K, Ambler GR. Family perceptions of insulin pump adverse events in children and adolescents. *Diabetes Technol Ther* 2014; 16:204-7.
57. Wheeler BJ, Heels K, Donaghue KC, Reith DM, Ambler GR. Insulin pump-associated adverse events in children and adolescents--a prospective study. *Diabetes Technol Ther* 2014; 16:558-62.
58. Brorsson AL, Viklund G, Örtqvist E, Lindholm Olinder A. Does treatment with an insulin pump improve glycaemic control in children and adolescents with type 1 diabetes? A retrospective case-control study. *Pediatr Diabetes* 2015;16:546-53.
59. Hommel E, Olsen B, Battelino T, Conget I, Schütz-Fuhrmann I, Hoogma R, Schierloh U, Sulli N, Gough H, Castañeda J, de Portu S, Bolinder J; SWITCH Study Group. Impact of continuous glucose monitoring on quality of life, treatment satisfaction, and use of medical care resources: analyses from the SWITCH study. *Acta Diabetol* 2014; 51:845-51.

60. Guenego A, Bouzillé G, Breitel S, Esvant A, Poirier JY, Bonnet F, Guilhem I. Insulin Pump Failures: Has There Been an Improvement? Update of a Prospective Observational Study. *Diabetes Technol Ther* 2016; 18:820-824.
61. Heinemann L, Fleming GA, Petrie JR, Holl RW, Bergenstal RM, Peters AL. Insulin pump risks and benefits: a clinical appraisal of pump safety standards, adverse event reporting and research needs. A joint statement of the European Association for the Study of Diabetes and the American Diabetes Association Diabetes Technology Working Group. *Diabetologia* 2015; 58:862-70.
62. Cope JU, Morrison AE, Samuels-Reid J. Adolescent use of insulin and patient-controlled analgesia pump technology: a 10-year Food and Drug Administration retrospective study of adverse events. *Pediatrics* 2008; 121:e1133-8.
63. Graber MA, Tansey JF. Autonomy, consent, and limiting healthcare costs. *J Med Ethics*. 2005; 31:424-6
64. Graham MM, James MT, Spertus JA. Decision Support Tools: Realizing the Potential to Improve Quality of Care. *Can J Cardiol* 2018. [Epub ahead of print].
65. Danis M, Solomon M. Providers, payers, the community, and patients are all obliged to get patient activation and engagement ethically right. *Health Aff (Millwood)* 2013; 32:401-7.
66. Brody H. Transparency: informed consent in primary care. *Hastings Cent Rep* 1989; 19:5-9.

67. Náfrádi L, Nakamoto K, Schulz PJ. Is patient empowerment the key to promote adherence? A systematic review of the relationship between self-efficacy, health locus of control and medication adherence. PLoS One 2017; 12:e0186458.

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