USER-LED MODIFICATION OF STANDARD MEDICAL CARE FOR CHILDREN: AN ANALYSIS OF PARENTS' AND HEALTHCARE PROFESSIONALS' LEGAL DUTIES OF CARE

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Increasingly, parents choose experimental treatment or modify existing treatment for their children where current therapies are ineffective or where the alternative seems to produce better health outcomes. The lack of knowledge of potential risks and benefits of non-standard treatment gives rise to concerns about the legal liability of healthcare professionals who support its use.[1] *This paper addresses the legal and ethical responsibilities of healthcare professionals and parents in respect of modified standard treatment in the healthcare of children. It analyses these duties using the example of user-led technology in children with type 1 diabetes where open source software links a continuous glucose monitor and insulin pump — a DIY looping system.*[2] *A research study carried out by an interdisciplinary team at the University of Melbourne has identified that parents are using DIY systems in preference to a commercial, regulated looping system which is available in Australia, and they report better management of their child's condition. This paper considers the parameters of ethically appropriate support by clinicians of use of a DIY system, which is a modification of standard treatment, and their potential legal liability in tort.*

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1 Healthcare professionals in paediatric medicine conventionally use off-label medications despite a lack of evidence: Madlen Gazarian et al, 'Off-Label Use of Medicines: Consensus Recommendations for Evaluating Appropriateness' (2006) 185(10) *Medical Journal of Australia* 544.

2 Alternate terminology includes 'open-source automated insulin delivery systems': Katarina Braune et al, 'Open-Source Automated Insulin Delivery: International Consensus Statement and Practical Guidance for Health-Care Professionals' (2022) 10(1) *Lancet Diabetes and Endocrinology* 58, and 'DIY artificial pancreas systems': Joseph TF Roberts, Victoria Moore and Muireann Quigley, 'Prescribing Unapproved Medical Devices: The Case of DIY Artificial Pancreas Systems' (2021) 21(1) *Medical Law International* 42.

I INTRODUCTION

An innovative treatment or therapy has been described as 'a newly introduced or modified therapy with unproven effect or side effect and is undertaken in the best interest of the patient'.[3] Innovations in healthcare push boundaries for improved treatment, and it is trite to note that any conventional medical treatment was conceived from an innovative idea. Moving innovative and untried therapies to an accepted or approved practice 'may be based on the results of activities ranging from anecdotal, uncontrolled "experiences" of numerous practitioners to highly organized, carefully conducted randomized clinical trials' published in peer reviewed journals.[4] Medical evidence in the form of credible studies published in peer reviewed literature provides an acknowledged standard for all healthcare professionals, regulatory and public health authorities. This 'evidence-based' medicine allows healthcare practitioners to make therapeutic decisions with some confidence[5] as to the effectiveness and known risks of a medical therapy and therefore the appropriateness of offering that treatment and obtaining informed consent for its use.

Families of patients for whom evidence-based therapies have proved ineffective may seek out innovative treatments as a last resort, and the internet provides a wealth of information to explore options. There have been many cases in England and Australia where parents have challenged the orthodox treatment proposed by the treating team. Sally Roberts shunned the proposed radiotherapy regime for her seven-year-old son, Neon, and favoured 'alternative treatments';[6] Ashya King's parents refused radiotherapy and sought proton beam therapy abroad to treat his brain tumour.[7] In the case of Charlie Gard, the English courts, and later the European Court of Human Rights, heard 'evidence' on the effectiveness of nucleoside therapy which Charlie's mother had come across during her research.[8] In Australia, Oshin Kiszko's parents actively rejected conventional chemotherapy and radiotherapy and wanted to try 'alternative therapies focussing on nutrition'.[9] These cases have highlighted the tensions that can arise between the treating team and parents when the standard treatment is rejected in favour of innovative or alternative treatment proposed by the parent(s). The courts have used the 'best

3 Ayman Al Eyadhy and Saleem Razack, 'The Ethics of Using Innovative Therapies in the Care of Children' (2008) 13(3) *Paediatrics and Child Health* 181, 181.

4 Dale H Cowan, 'Innovative Therapy versus Experimentation' (1986) 21(4) *Tort and Insurance Law Journal* 619, 621.

5 FM Hajjaj et al, 'Non-Clinical Influences on Clinical Decision-Making: A Major Challenge to Evidence-Based Practice' (2010) 103(5) *Journal of the Royal Society of Medicine* 178, 178.

6 *An NHS Trust v SR* [2012] EWHC 3842 (Fam), [14] (Bodey J). See also Jo Bridgeman, '"Leaving No Stone Unturned": Contesting the Medical Care of a Seriously Ill Child' (2017) 29(1) *Child and Family Law Quarterly* 63, 76–7.

7 *Re King* [2014] EWHC 2964 (Fam), [9]–[11] (Baker J).

8 *Great Ormond Street Hospital v Yates* [2017] EWHC 972 (Fam), [71] (Francis J); *Gard v United Kingdom* (European Court of Human Rights, Chamber, Application No 39793/17, 3 July 2017).

9 *Director of Clinical Services, Child and Adolescent Health Services v Kiszko* [2016] FCWA 19, [6]–[7], [28], [36] (Thackray CJ).

interests' approach in analysis of the parental wish to use non-conventional therapeutic regimes. These cases have the same themes in common — parental refusal of conventional therapy and a desire that the treating team supports or enables the child being treated with innovative, non-conventional treatment where there is a lack of medical evidence about its effectiveness.

In this paper, I consider legal duties of healthcare practitioners and parents where standard treatment is modified by technology, in contrast to an outright rejection of standard therapy. I use the example of DIY 'looping' technology to manage type 1 diabetes ('T1D') in children, where a standard therapy comprising a continuous glucose monitor ('CGM') and insulin pump is modified by adding a software algorithm which links the two devices to automate insulin delivery based on real time readings from the CGM.[10] The aim of DIY looping is the same as conventional management, control of glucose in the blood, and both require insulin. It is estimated that there is currently a global community of over 2,700 'loopers',[11] and in Australia a 2017 survey found that 20 individuals were actively looping, one under 10 years of age and two between 10–19 years of age,[12] despite the lack of regulatory approval from the Therapeutic Goods Administration ('TGA'). In addressing the question of legal liability of healthcare professionals who support DIY looping for their paediatric patients and parents who use this modified, unregulated treatment, I include findings from a research project, 'Personalised Closed Loop Systems for Childhood Diabetes' ('Closed Loop study'),[13] run by an interdisciplinary team at the University of Melbourne. One member of the project team uses a DIY looping system.

Part II of this paper considers the prevalence of T1D in children, and how DIY technologies are used to manage T1D. I describe the qualitative research project which evaluated key stakeholder perspectives on DIY looping in children under 18 in Australia. Part III outlines the regulatory regime for medical devices and software as a medical device in Australia. Part IV explores professional regulation and the impact on health practitioners who support DIY looping in paediatric patients. In Parts V–VII I address the legal duties of healthcare professionals in paediatric endocrinology (paediatric endocrinologists and diabetes educators) both to inform parents about the risks of DIY looping and to support parents' use of DIY systems and I then analyse the grounds for a claim in negligence against healthcare professionals who support parents using a DIY system. Parts VIII–IX discuss parents' protective duties towards their children and whether use of modified standard treatment aligns with acting in the best interests of their child. Contrasting

10 The International Consensus Statement refers to 'open-source automated insulin delivery system' but people in the community are more likely to refer to 'DIY looping' and those who use such systems as 'loopers', and I use these terms: Braune et al (n 2).

11 'OpenAPS Outcomes', *OpenAPS.org* (Web Page, 5 July 2022) <https://openaps.org/outcomes/>.

12 Tien-Ming Hng and David Burren, 'Appearance of Do-It-Yourself Closed-Loop Systems to Manage Type 1 Diabetes' (2018) 48(11) *Internal Medicine Journal* 1400, 1402.

13 Carolyn Johnston et al, 'Regulation of Personalised Digital Hybrid Closed Loop Systems to Manage Diabetes in Children', *University of Melbourne* (Web Page) <https://law.unimelb.edu.au/helex/research/research-projects/regulation-of-personalised-digital-hybrid-closed-loop-systems-to-manage-diabetes-in-children> ('Closed Loop study').

medical and anecdotal evidence challenges whether DIY looping technologies are the 'best' treatment, but I argue in Part X that, nevertheless, it is an appropriate choice for parents to make because the decision falls within the 'Zone of Parental Discretion' ('ZPD').[14] Part XI discusses child welfare as a justification for interference with parental decisions to use modifications to standard therapy for T1D. This paper concludes with recommendations for a way forward to ensure minimisation of risks where DIY technology is used, supporting a therapeutic relationship and the wellbeing of the child.

II DIY TECHNOLOGIES IN DIABETES MANAGEMENT

Type 1 diabetes is a chronic autoimmune disease usually with juvenile onset. According to the National (insulin-treated) Diabetes Register, in 2018, 'around 20,700 children and young adults aged 0–24 had type 1 diabetes' in Australia.[15] Standard management has utilised finger prick tests of blood glucose and insulin injections to control glucose levels but recently finger prick tests have been largely replaced by a CGM, 'a small wearable device that measures glucose levels throughout the day and night [which sets off] alarms … if glucose levels are getting too low or too high'.[16] Insulin pumps are devices that deliver insulin without the need for manual injections. 'Over the last decade, the use of insulin pump[s] … has markedly increased' in the paediatric age group[17] and trials have demonstrated that insulin pump therapy is superior for glycaemic control compared to multiple daily injections of insulin.[18]

Insulin pumps require manual adjustment in light of CGM readings, exercise and food intake.[19] This is burdensome on parents of children with T1D, especially overnight, and in addition to the pressures on family life and mental health impacts,

14 Lynn Gillam, 'The Zone of Parental Discretion: An Ethical Tool for Dealing with Disagreement between Parents and Doctors about Medical Treatment for a Child' (2016) 11(1) *Clinical Ethics* 1.

15 Australian Institute of Health and Welfare, *Diabetes* (Web Report No CVD 82, 15 July 2020) <https://www.aihw.gov.au/reports/diabetes/diabetes-snapshot/contents/how-many-australians-have-diabetes/type-1-diabetes>.

16 Diabetes Australia 'Continuous and Flash Glucose Monitoring', *National Diabetes Services Scheme* (Web Page) <https://www.ndss.com.au/living-with-diabetes/managing-diabetes/continuous-glucose-monitoring/>.

17 Marie-Anne Burckhardt, 'Real-World Outcomes of Insulin Pump Compared to Injection Therapy in a Population-Based Sample of Children with Type 1 Diabetes' (2018) 19(8) *Pediatric Diabetes* 1459, 1459, citing SK McMahon et al, 'Insulin Pump Therapy in Children and Adolescents: Improvements in Key Parameters of Diabetes Management Including Quality of Life' (2005) 22(1) *Diabetic Medicine* 92 and Kiranjit K Joshi et al, 'Comparable Glycemic Outcomes for Pediatric Type 1 Diabetes Patients in Metropolitan and Non-Metropolitan Regions of Western Australia: A Population-Based Study' (2018) 19(3) *Pediatric Diabetes* 486.

18 Paolo Pozzilli et al, 'Continuous Subcutaneous Insulin Infusion in Diabetes: Patient Populations, Safety, Efficacy, and Pharmacoeconomics' (2016) 32(1) *Diabetes/Metabolism Research and Reviews* 21, 21–2, 26.

19 Frida Velcani and Karena Yan, 'Understanding Insulin Pump Settings', *DiaTribe Learn* (Web Page, 19 August 2019) <https://diatribe.org/understanding-insulin-pump-settings>.

there is a risk of over or underdosing.[20] 'T1D can be physiologically difficult to control, parenting stress can be elevated, and caregivers are strained by normal child caretaking routines'.[21] Maintaining good control of blood glucose is important to 'prevent the onset of acute and chronic T1D-related complications such as seizure, coma, diabetic ketoacidosis, cardiovascular disease' and damage to the retina and nerve endings as a result of impaired blood flow.[22] Well controlled blood glucose also avoids future health complications associated with damage to blood vessels.[23] A glycosylated haemoglobin ('HbA1c') check shows an average of blood glucose level over the previous 8–12 weeks[24] and is carried out every three to six months by a healthcare professional.

A developing technology for managing T1D is the closed loop system, known as an 'artificial pancreas'. This consists of a CGM that measures glucose levels every five minutes, an insulin pump, a sensor with transmitter attached and an algorithm within the pump that automatically works out how much insulin is needed.[25] Currently, there is no fully automated system, and users must still count carbohydrates and provide fast-acting insulin manually before meals, hence the term 'hybrid' closed loop system is used.

20 See Kimberly A Driscoll et al, 'Fear of Hypoglycemia in Children and Adolescents and Their Parents with Type 1 Diabetes' (2016) 16(8) *Current Diabetes Reports* 77.

21 Randi Streisand and Maureen Monaghan, 'Young Children with Type 1 Diabetes: Challenges, Research, and Future Directions' (2014) 14(9) *Current Diabetes Reports* 520:1–9, 1.

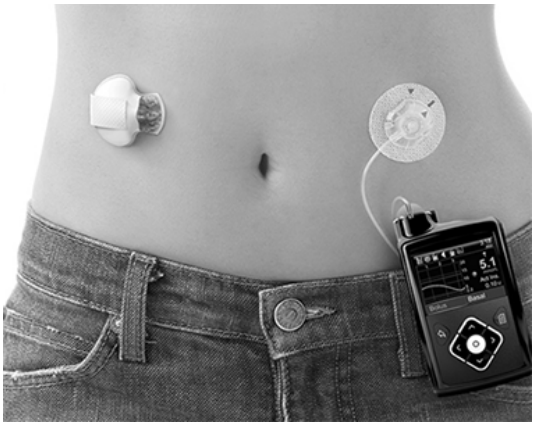
22 Ibid.

23 See Yang et al, 'New Perspective in Diabetic Neuropathy: From the Periphery to the Brain, a Call for Early Detection, and Precision Medicine' (2020) 10 *Frontiers in Endocrinology* 929:1–13.

24 World Health Organization, *Use of Glycated Haemoglobin (HbA1c) in the Diagnosis of Diabetes Mellitus: Abbreviated Report of a WHO Consultation* (Report, 2011) 6, citing DM Nathan, H Turgeon and S Regan, 'Relationship between Glycated Haemoglobin Levels and Mean Glucose Levels over Time' (2005) 50(1) *Diabetologia* 2239, 2239.

25 See Jane L Chiang et al, 'Type 1 Diabetes in Children and Adolescents: A Position Statement by the American Diabetes Association' (2018) 41(9) *Diabetes Care* 2026, 2031; Peter Jennings and Sufyan Hussain, 'Do-It-Yourself Artificial Pancreas Systems: A Review of the Emerging Evidence and Insights for Healthcare Professionals' (2020) 14(5) *Journal of Diabetes Science and Technology* 868, 868–9; Natalie Allen and Anshu Gupta, 'Current Diabetes Technology: Striving for the Artificial Pancreas' (2019) 9(1) *Diagnostics* 31:1–16, 3.

Figure 1: Medtronic Continuous Glucose Monitor



Source: 'About Continuous Glucose Monitoring', *Medtronic* (Web Page) <https://www.medtronic-diabetes.com/en-IL/about-diabetes/what-is-continuous-glucose-monitoring>.

In August 2018, the first commercial hybrid closed loop system, the Medtronic MiniMed 670G, was approved by the TGA for use in Australia.[26] Before this, those in the diabetic community, tired of waiting for progress to be made, came together under the hashtag #WeAreNotWaiting to share information and develop their own resources. The Open Artificial Pancreas System ('OpenAPS') was created in February 2015 by Dana Lewis and her partner who produced and then shared a predictive algorithm to manage insulin delivery through a pump. This is known as 'closing the loop' and users download the algorithm for free from sites such as OpenAPS and manage their blood glucose levels by 'looping'. Other DIY looping systems are AndroidAPS (based on the platform of the OpenAPS algorithm and adjusted for smartphones with the Android system) and Loop (adjusted for smartphones with the iOS system).

Clinical trials are taking place on commercial hybrid closed loop systems,[27] and the CREATE (Community deRivEd AutomaTEd insulin delivery) is the first randomised control trial on open-source automated insulin delivery.[28] In a news release from the American Diabetes Association the lead investigator of the study

26 Therapeutic Goods Administration, Department of Health, 'ARTG ID 308140: Public ARTG Summary', *Australian Register of Therapeutic Goods* (Web Document, 11 August 2018) < https://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs/PublicHTML/pdfStore.nsf&docid=A2596916D2121533CA25885500430F60&agid=(PrintDetailsPublic)&actionid=1>.

27 See, eg, 'Technology', *Children's Diabetes Centre* (Web Page) <https://diabetes.telethonkids.org.au/our-research/technology/>.

28 See M Burnside et al, 'CREATE (Community Derived Automated Insulin Delivery) Trial: Randomised Parallel Arm Open Label Clinical Trial Comparing Automated Insulin Delivery Using a Mobile Controller (AnyDANA-loop) with an Open-Source Algorithm with Sensor Augmented Pump Therapy in Type 1 Diabetes' (2020) 19 *Journal of Diabetes and Metabolic Disorders* 1615.

stated that the findings demonstrate that open-source automated insulin delivery is a 'safe and effective technology'.[29]

In 2018, Diabetes Australia issued a position statement which included the view that 'if a person with type 1 diabetes (or a parent or family member) chooses to build a DIY system, they must continue to receive support and care from their diabetes healthcare professional and the health system'.[30] Nevertheless, this creates legal and ethical challenges for healthcare professionals in respect of their support of their patients who wish to use DIY looping systems.

DIY looping is still in its infancy in Australia and its prevalence is unknown. The Closed Loop study, carried out at the University of Melbourne explored perspectives of key stakeholders on DIY looping in children under 18 in Australia.[31]

A *Stakeholder Attitudes and Experiences to DIY Looping: Reporting on a Qualitative Research Study*

There has been a lack of research on attitudes to, and experiences of, DIY looping in Australia.[32] The Closed Loop study sought to develop a detailed understanding of stakeholder experiences in respect of the use of DIY looping technology, the impact on the doctor–patient relationship and the ethical and legal obligations on paediatric endocrinologists and diabetes educators to provide care to patients using DIY systems.[33] The project was approved by the Melbourne School of Population and Global Health Human Ethics Advisory Group (ID 1953678.1) and was funded by the University of Melbourne Networked Society Institute. The interdisciplinary project team brought together expertise in law, ethics, medicine, information management and cultural communication, and included a consumer perspective (by partnering with the Manager for Type 1 Diabetes and Consumer Voice at Diabetes Australia).

B *Design*

The project comprised two stages of data collection and analysis, which began in October 2018 and ended in September 2019. An online survey was developed in REDCap and paediatric endocrinologists and diabetes educators in Australia were recruited (n = 20) through personal contacts and via the Australasian Paediatric Endocrine Group ('APEG') and Australian Diabetes Educators Association

29 'New Study Shows Open-Source Automated Insulin Delivery Is a Safe and Effective Treatment Option for People with Type 1 Diabetes', *American Diabetes Association* (Press Release, 6 June 2022) <https://www.diabetes.org/newsroom/press-releases/2022/new-study-shows-open-sourced-autmoated-insulin-delivery-safe-effective-treatment-option-type-1>.

30 Diabetes Australia, *People with Type 1 Diabetes and Do It Yourself (DIY) Technology Solutions* (Position Statement, August 2018) 1.

31 Closed Loop study (n 13).

32 See, eg, Hng and Burren (n 12) 1402, which had a limited sample size of only 19 participants providing valid data.

33 Closed Loop study (n 13).

('ADEA'). In the second phase semi-structured interviews were carried out with members of key stakeholder groups. In this paper I refer only to the findings from the second stage.

C *Recruitment*

Recruitment for interview was directed at key stakeholder groups: health practitioners involved in the care of children with T1D; parents of children with diabetes who have tried or were then looping; technical experts with experience in software development; legal professionals; and medical indemnity insurers. Participants in the online survey could nominate whether they would like to participate in an interview to further explore their views and experiences. Additionally, recruitment for interview was through invitation emails sent via networks of the research team and to individuals from stakeholder groups identified from an online search of publicly available information. Information about the project, with an invitation to be interviewed, was posted on identified social media groups specific to looping. As such, recruitment for interviews used a mix of targeted, convenience and snowball sampling.

D *Data Collection*

The final qualitative sample consisted of 25 participants across all of the stakeholder groups from three Australian states. There was no response to our invitations to participate from the TGA.

	Participants
Clinicians	• Diabetes Educators (n = 2) • Paediatric Endocrinologists (n = 3)
Other Professionals	• Medical Indemnity Insurers (n = 2) • Coroner (n = 1) • Lawyers (n = 3) • Social Workers (n = 3)
Technical Experts	• Software Developers (n = 3) • Digital Health Expert (n = 1)
Parents	• Children between 6–16 years old (n = 7)

Exploratory semi-structured interviews were conducted face-to-face, online via Zoom or over the phone in one-to-one or small groups (of two to three participants) and they ranged from 15 to 110 minutes in length. All interviews were audio recorded and interview notes taken. Third party transcription services were used to transcribe the audio tapes.

E *Data Analysis*

Interviews were checked for accuracy against the audio file and de-identified. Transcripts were uploaded, coded and managed in Nvivo 12 and independent co-coding was conducted by two to three members of the research team. Findings were discussed and refined several times including receiving input from the entire team. The data was analysed using grounded theory and the main themes emerging from the data were benefits and risks of DIY systems and the autonomy of parents to choose DIY looping. In this paper I use key quotations from participant interviews to illustrate and give context to the themes addressed.

DIY looping differs in some respects from parental *refusal* of conventional therapy in favour of innovative treatment, considered in the cases mentioned in the Introduction. Firstly, DIY looping is not an outright rejection of standard therapy for T1D. The looping algorithm links the CGM and pump, which may be standard or have been modified to accommodate the software (although some devices used are old and no longer in warranty).[34] Secondly, parents and healthcare professionals are working towards the same outcome, that is, best management of the child's blood glucose. There is anecdotal evidence that DIY looping manages T1D better than conventional therapy and parents in our study reported improved blood glucose levels in their children. Online communities such as OpenAPS are positive about improved outcomes.[35] Finally, insulin is needed for management of T1D and so, if parents use DIY systems, they need to engage with healthcare professionals to obtain an ongoing supply. This raises the issue of whether healthcare professionals are endorsing the use of an unregulated system if they provide insulin knowing that it will be used in a DIY system, and if this is preferable to ending the therapeutic relationship.

III REGULATION OF MEDICAL DEVICES AND SOFTWARE AS A MEDICAL DEVICE UNDER THE *THERAPEUTIC GOODS ACT 1989*

The *Therapeutic Goods Act 1989* (Cth) ('*Therapeutic Goods Act*') provides a framework to ensure the safety of therapeutic goods, including medical devices, used in Australia, whether produced in Australia or elsewhere. The TGA administers the implementation of its provisions. Chapter 4 of the Act deals with the 'safety and satisfactory performance of medical devices'.[36] Section 41BD of the Act defines a 'medical device' as including any instrument, apparatus, appliance, including the software necessary for its proper application, intended to be used for the purpose of monitoring, treatment or alleviation of a disease.[37]

34 Rachel Freeman and Louise Ginnivan, 'DIY Looping Technologies' (2019) 22(1) *Australian Diabetes Educator*.

35 Dana Lewis and Scott Leibrand, 'Real-World Use of Open Source Artificial Pancreas Systems' (2016) 10(6) *Journal of Diabetes Science and Technology* 1411.

36 *Therapeutic Goods Act 1989* (Cth) s 41B ('*Therapeutic Goods Act*').

37 Ibid s 41BD.

The TGA recognises that '[s]oftware is becoming increasingly important in medical devices and … as a medical device in its own right'.[38] It provides examples of software which meets the definition of 'medical device': smart phone apps that calculate insulin doses based on a patient's blood glucose levels, X-ray image processing software and software that uses information about a patient to make a diagnosis.[39] This type of software as a medical device requires regulation, in contrast to health software apps as sources of information, or tools to manage a healthy lifestyle, which are not medical devices and are not regulated.

'[E]nhancement of traditional medical software used in or as medical devices has increased its complexity and usage'.[40] In its rapid literature review of safety and performance issues of medical software published in July 2020, the TGA identifies potential risks and harms of software.[41] It notes, in respect of diabetes management software, 'that there are few randomized control trials, case-control studies and cohort studies' due to the 'constant feature evolution and improvement, the inability to devise placebo effect, and the financial cost and resources required to conduct studies relative to commercial value of products during its short life cycle'.[42]

Open source software is used in many commercial devices. In August 2018, the first commercial hybrid closed loop system for managing T1D, the Medtronic MiniMed 670G, received approval from the TGA.[43] In a DIY system, the CGM and insulin pump are medical devices, as is the software (algorithm) used in a DIY system because it is used for therapeutic purposes in the monitoring and treatment of T1D and alleviating the symptoms of the disease.

In order to be lawfully *supplied* in Australia a medical device must undergo conformity assessment procedures with regard to its quality, safety and efficacy, and be registered on the Australian Register of Therapeutic Goods ('ARTG'),[44] thus the regulatory framework operates as a barrier to accessing those items on the

38 'Regulation of Software Based Medical Devices', *Therapeutic Goods Administration* (Web Page, 3 May 2022) <https://www.tga.gov.au/regulation-software-medical-device> ('Regulation of Software Based Medical Devices').

39 Therapeutic Goods Administration, Department of Health, *Examples of Regulated and Unregulated Software (Excluded) Software Based Medical Devices* (Guidance, 11 October 2021) 8, 10, 19.

40 Therapeutic Goods Administration, Department of Health, *Actual and Potential Harm Caused by Medical Software: A Rapid Literature Review of Safety and Performance Issues* (Report, 16 July 2020) 4 ('*Actual and Potential Harm Caused by Medical Software*').

41 Ibid.

42 Ibid 8, citing G Alexander Fleming et al, 'Diabetes Digital App Technology: Benefits, Challenges, and Recommendations' (2020) 43(1) *Diabetes Care* 250, 254.

43 Therapeutic Goods Administration, Department of Health, 'ARTG ID 308140: Public ARTG Summary', *Australian Register of Therapeutic Goods* (Web Document, 11 August 2018) < https://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs/PublicHTML/pdfStore.nsf&docid=A2596916D2121533CA25885500430F60&agid=(PrintDetailsPublic)&actionid=1>.

44 Failure to do so is an offence: *Therapeutic Goods Act* (n 36) ss 41ME, 41MI.

open market. An Australian entity could take on accountability and sponsor the product, however, to date, no application has been made by an Australian sponsor for such open source software to be listed on the ARTG. Anyone from the open-source community could apply as a sponsor for the software to be assessed for efficacy and safety by medical and technical experts, but the cost of the product evaluation at around $100,000 is prohibitive and the process for application is complex for a community of users to negotiate.[45]

But open source software for a DIY system can be downloaded free of charge and it is not advertised or marketed for profit, so listing on the ARTG is not actually required for it to be available for use. The *Therapeutic Goods Act* does not address the *use* of medical devices and software, and it is not illegal for parents to use a DIY system to manage their child's T1D. Lack of regulation may be an issue for healthcare professionals who support use of a DIY system through ongoing monitoring and provision of insulin prescriptions. Although regulatory approval may support a finding of reasonableness, this does not necessarily mean that supporting a medical device which does not have regulatory approval is unreasonable in all cases.

The software developers we interviewed for the Closed Loop study noted the proactive approach of the Food and Drug Administration ('FDA') in the United States working with Tidepool to develop an app designed for DIY automated insulin delivery devices ('Tidepool Loop').[46] Comments from these participants included: '[I]t sounds like the FDA has been a lot more flexible and looking to progress rather than what the TGA is doing', and 'I don't think the TGA has the growth mindset'. One participant identified the role of a regulator in assessing the safety of a DIY system: 'Personally, I would actually trust 30 of the developers using these systems on themselves and saying, "Yes, I think it's good", rather than the TGA telling me, "Yes, we approve this system". I know which one I'd trust more'.

Section 41MI of the *Therapeutic Goods Act* provides an offence of 'supplying' a medical device, including software as a medical device, which is not listed on the ARTG. Supply includes application in the treatment of a person.[47] This seems to prohibit healthcare practitioners recommending or providing a DIY system and perhaps suggesting changes to settings. There are stiff civil and criminal penalties for healthcare professionals who breach the requirements of the Act.[48]

Separately from potential statutory civil and criminal penalties, a clinician could be liable to a claim in negligence for foreseeable harm arising from use of a DIY system in the management of their patient's T1D. In its recent literature review,

45 Conversation with former employee of the Therapeutic Goods Administration.

46 Christopher Snider, 'Tidepool Loop Development Update', *Tidepool* (Blog Post, 12 February 2020) <https://www.tidepool.org/blog/tidepool-loop-development-update>.

47 *Therapeutic Goods Act* (n 36) s 3 (definition of 'supply' para (d)).

48 Ibid 41MI: 'Imprisonment for 5 years or 4,000 penalty units, or both'; s 41MIB: maximum civil penalty of 5,000 penalty units for an individual and 50,000 penalty units for a body corporate.

noted above, the TGA identified safety concerns where medical professionals directly use or guide use of the software in direct-to-consumers apps.[49] It states that 'where regulation does not currently apply, the responsibility of adverse consequences from apps falls on individual clinicians'.[50] So, clinicians are put on notice about potential legal liability if they support the use of DIY systems.

IV PROFESSIONAL REGULATION RELEVANT TO PRACTITIONERS SUPPORTING USE OF DIY LOOPING FOR PAEDIATRIC PATIENTS

Children who have been diagnosed with T1D attend regular (three-monthly) outpatient appointments at a specialist paediatric endocrinology unit for check-ups and their care will usually be managed by a team comprising a paediatric endocrinologist and a diabetes educator. Some parents seek the support of a private diabetes educator. Healthcare practitioners in Australia are required to be registered with the Australian Health Practitioner Regulation Agency which implements the *Health Practitioner Regulation National Law Act* ('*National Law*')[51] to maintain standards through registration of health practitioners who are 'suitably trained and qualified to practise in a competent and ethical manner'.[52]

The APEG is the premier professional body representing paediatric endocrinology in Australasia. Endocrinologists diagnose and treat conditions such as thyroid diseases and metabolic disorders, and they provide expert advice on the management of diabetes. APEG states that it is 'committed to high standards of clinical care, advocacy, education, stakeholder relationships and research in paediatric endocrinology'.[53] The ADEA is the leading organisation for healthcare professionals providing diabetes education and care. A credentialled diabetes educator is a healthcare professional, including a nurse, dietician, pharmacist, medical practitioner, with expertise and training in diabetes education. Their role is to '[assist] those with diabetes by empowering them to effectively self-manage the care and treatment of their diabetes'.[54]

The ADEA sought 'advice regarding the legal implications for their members when consulting with a person … who ha[s] chosen to use DIY looping',[55] which provided that '[h]ealth practitioners treating or advising an individual using DIY

49 *Actual and Potential Harm Caused by Medical Software* (n 40) 10.

50 Ibid.

51 See *Health Practitioner Regulation National Law Act 2009* (Qld) sch ('*National Law*').

52 Ibid s 3(2)(a). Registration as a medical specialist is available to practitioners who have successfully completed an approved program of study leading to fellowship of an accredited specialist college: at ss 57, 58.

53 Louise Conwell, 'Welcome', *Australasian Paediatric Endocrine Group* (Web Page) <https://apeg.org.au/>.

54 'What is Credentialling?', *Australian Diabetes Educators Association* (Web Page) <https://www.adea.com.au/credentialling/what-is-credentialling/>.

55 Freeman and Ginnivan (n 34).

looping need to discuss these issues with the person, and how it affects the advice they can provide'.[56] The ADEA aimed to have a position statement finalised in 2019, but to date this has not been published, nor are there clinical guidelines on DIY looping. Guidelines and consensus statements assist clinicians in making treatment decisions and may provide some 'extrinsic evidence of what constitutes reasonable care'.[57] Without a position statement and/or clinical guidelines on DIY looping, members of APEG and ADEA lack certainty and clarity about how they respond to requests from their patients to support them, and this may give rise to concerns about their legal liability.

Reporting on the position in the UK, Roberts, Moore and Quigley note that there are currently no clinical guidelines or statements from authoritative bodies, such as the National Institute for Health and Care Excellence or the Royal Colleges on DIY systems.[58] Nevertheless, from their evaluation of the General Medical Council's *Good Practice in Prescribing and Managing Medicines and Devices* and *Good Medical Practice* guidance they conclude that although clinicians should 'exercise caution before recommending or advising patients use DIY [systems]', this guidance 'does not completely preclude them from doing so'.[59] Healthcare practitioners must exercise their clinical judgement to decide whether a DIY system is necessary to meet the needs of their patient. The authors of the International Consensus Statement on Open-Source Automated Insulin Delivery encourage healthcare professional organisations to apply evidence to update legal frameworks.[60]

V THE NATURE AND SCOPE OF LEGAL DUTIES

A clear healthcare practitioner–patient relationship is established when a child is seen by a healthcare practitioner[61] in respect of management of their T1D. This sets up various duties including the duty to treat competently and to provide adequate ongoing management of the condition. The Medical Board of Australia in its document, *Good Medical Practice: A Code of Conduct for Doctors in Australia*, states that '[d]octors have a duty to make the care of patients their first concern and to practise medicine safely and effectively'.[62] Could it be successfully alleged that a doctor breaches their duty of care in supporting the use of a DIY system in the care of a child? I consider below the elements of a claim in negligence against a paediatric endocrinologist who supports parental use of a DIY system for

56 Ibid.

57 Ash Samanta et al, 'The Role of Clinical Guidelines in Medical Negligence Litigation: A Shift from the *Bolam* Standard?' (2006) 14(3) *Medical Law Review* 321, 321, 334.

58 Roberts, Moore and Quigley (n 2) 51, 63.

59 Ibid 64, discussing General Medical Council, *Good Practice in Prescribing and Managing Medicines and Devices* (Guidance, 18 February 2021) and General Medical Council, *Good Medical Practice* (Guidance, 29 April 2019).

60 Braune et al (n 2) 70.

61 *Lowns v Woods* (1996) Aust Torts Reports 81–376, 63,160 (Mahoney JA).

62 Medical Board of Australia, *Good Medical Practice: A Code of Conduct for Doctors in Australia* (at 1 October 2020) cl 2.1.

their child and conclude that it is unlikely to be successful if the parents are properly counselled about the risks.[63]

There are two potential breaches of the paediatric endocrinologist's duty of care that parents could allege:

1. Failure to adequately provide information to parents about the risks of using a DIY system to manage their child's T1D; and

2. Continuing to support the use of a DIY system through provision of prescriptions for insulin and using data from the system to monitor the child. Support is used here in the context of implicit support (knows and does not say anything) rather than explicit support (knows and encourages use of a DIY system).

A *Disclosure of Information*

For patients who are young children, who themselves are not competent to make healthcare choices, their parents are decision-makers and so healthcare providers owe them a duty to provide up-to-date information about treatment options and their relative risks and benefits. Healthcare professionals working in paediatric endocrinology will discuss with parents the standard management of T1D, the way CGM and insulin pumps work, how to manage the hardware, read the data and make minor adjustments to titration of insulin. The UK case of *Al Hamwi v Johnston* found that in providing information a clinician must 'take reasonable care to give a warning which is adequate in scope, content and presentation, and take steps to see that the warning is understood'.[64] In *Rogers v Whitaker*,[65] the High Court of Australia set out the standard of disclosure. A doctor must inform patients of risks which are material to them. A risk is a material risk if 'a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it'.[66]

Where there is more than one treatment option the patient needs to be informed of their comparative benefits and risks to make an informed choice. In the English case of *Birch v University College London Hospital NHS Foundation Trust*, Cranston J said that where there are two procedures that 'were open' for the patient, they 'needed to have explained to [them] the comparative risks' of the alternate

63 It seems unlikely that parents who instigate the support of the clinician in respect of a DIY technology they have set up would bring a claim in negligence if the child suffers harm as a result. An alternative means of recourse is a complaint made to the Australian Health Practitioner Regulation Agency.

64 [2005] Lloyd's Rep Med 309, [43] (Simon J).

65 (1992) 175 CLR 479 ('*Rogers*').

66 Ibid 490 (Mason CJ, Brennan, Dawson, Toohey and McHugh JJ).

procedures.[67] Healthcare is traditionally predicated on the basis that professionals offer treatment options to patients and patients choose whether to accept them. DIY looping is a patient-led modification of the standard therapy and it is unregulated so it could not be considered an 'alternate' treatment for children with T1D which the healthcare professionals should *propose* to parents.[68] Is there however a duty on healthcare professionals to discuss risks of alternate treatment options that they would not propose but are aware that the patient is or might be using? Does a paediatric endocrinologist have a duty to discuss with parents the risks of a DIY system if they are aware that the parents are using such a system and, if so, to what extent should they become informed in order to meaningfully discuss those risks? This modification of standard treatment demonstrates a disparity of knowledge between parents and healthcare professionals about the way a DIY hybrid closed loop system works and the risks and benefits of using it.

B *Patient/Parents as 'Experts' in DIY Management of T1D*

Diabetes self-management education is an important component of diabetes care, but rather than healthcare professionals providing the information, parents are the 'experts' in this new technology, and this changes the traditional paradigm of care. In the Closed Loop study, it was clear that parents developed expertise in setting up the DIY system. They acquired information, not through discussion with their healthcare team, but rather through social media groups such as 'Aussie, Aussie, Aussie, Loop, Loop, LOOP!'.[69] This community is knowledgeable, supportive and accessible.

As it is the parents who are setting up the DIY system, they are the experts and perhaps know more about the potential pitfalls than the healthcare professionals:

> [T]he group who are essentially supporting or promoting or starting this whole idea of you can loop yourself, I think are quite knowledgeable … they're very tech-savvy, I think they probably understand the equipment far better than any educator or health professional at this point, because that's not our forte, we rely on companies to provide us with that equipment. I think the people who have actually essentially started up this movement are … very clever, very dedicated to what they're doing and I think brainstorm and think through and have an ability to see what the devices are doing and what they need to understand, so they're like scientists. (*Diabetes Educator 2*)

The parents in our study identified the lack of knowledge of healthcare professionals about looping and their seeming unwillingness to engage in discussion about it:

> Not that I was open about it, but if I ever mention it to general doctors, like saying, 'Have you heard about looping?', I think the majority have never even heard of it (*Parent 5*).

67 (2008) 104 BMLR 168, 197 [78].

68 If DIY looping becomes more common and benefits are clearly demonstrated, this may then become a reasonable alternative treatment.

69 'Aussie, Aussie, Aussie, Loop, Loop, LOOP!' (Facebook) <https://www.facebook.com/groups/AussieLooping>.

In providing patients with a balanced account of the advantages, drawbacks and capabilities of DIY looping,[70,] healthcare practitioners could enable them to make the best use of these technologies and foster realistic expectations.[71] Nevertheless, the healthcare professionals we interviewed commented about their level of understanding of DIY looping systems:

> I would say first off that I didn't know much about [the technical aspect]. I would probably do a bit of asking around to see. I'd want to point them in the right direction in terms of where you would get the information that you would need' (*Diabetes Educator 1*).

Another had sought out information because they were asked to supervise a paediatric patient using a DIY system:

> [B]ecause of the clinical necessity of needing to know what my obligation[s] and the legal ramifications were I therefore had to approach various agencies and that is the only reason why I had such particular knowledge in the area. If I didn't have a patient asking me specifically, it's not something that I would have been particularly researching. (*Paediatric Endocrinologist 3*)

As Roberts, Moore and Quigley note, 'the safety of these systems relies heavily upon the individual being competent in managing their own insulin' and system settings.[72] Of concern to healthcare professionals is the possibility that parents with limited technical knowledge will build DIY looping systems incorrectly, with untoward consequences. More extensive and deeper knowledge of DIY looping systems amongst this specialised group of healthcare practitioners would support parents and their families with T1D using these new technology systems within safe parameters. Until the ethical and legal issues for healthcare practitioners are resolved, they 'still need to stay abreast of this rapidly developing area'.[73]

C *Clinicians' Duties to Inform about Risks of Unregulated Treatments*

Disclosure of information about a medical procedure or treatment is made in the context of obtaining informed consent from the patient prior to a decision on whether or not to undergo it, as noted in *Rogers v Whitaker*, '*whether* the patient has been given all the relevant information to choose between undergoing and not undergoing the treatment'.[74] A DIY system is not an 'alternative' treatment option

70 See Wu et al, 'Use of a Do-It-Yourself Artificial Pancreas System Is Associated with Better Glucose Management and Higher Quality of Life among Adults with Type 1 Diabetes' (2020) 11 *Therapeutic Advances in Endocrinology and Metabolism* 1–11.

71 Jennings and Hussain (n 25) 874.

72 Roberts, Moore and Quigley (n 2) 51, 63.

73 Jennings and Hussain (n 25) 875.

74 *Rogers* (n 65) 489 (Mason CJ and Brennan, Dawson, Toohey and McHugh JJ) (emphasis in original).

that clinicians should propose to parents of children with T1D. But could it be argued that there is a duty on clinicians to discuss risks of this unregulated treatment with parents when they are aware that they are using such a DIY system? If there is such a duty, then healthcare professionals would be required to inform themselves about how a DIY system works and the likely risks and potential benefits. A comparison could be made with the discussion of risks of complementary therapies when the healthcare professional is aware their patients are using them.

Complementary medicines may pose risks on their own or if they are used with prescribed medicine. St John's Wort, for example, may affect drug metabolism or levels of neurotransmitters and should not be used by people who use anticoagulant medications such as Warfarin, and it is regulated by the TGA. As Kerridge and McPhee point out, there are difficulties in identifying the content of the duty to inform in relation to complementary and alternative medicine ('CAM').[75] They note: 'The issue of how much medical practitioners should know about CAM is made more complex because of real questions about the availability, quality and accessibility of evidence on its efficacy, risks and benefits'.[76]

Whether a novel duty extends to a healthcare professional disclosing risks of treatment that they are aware the parents are using, but which is not proposed by the healthcare practitioner, could be considered with reference to salient features of that relationship.[77] Salient features include consideration of the parents' vulnerability (inability to protect themselves),[78] the doctor's assumption of responsibility,[79] knowledge or awareness of the likelihood of harm to the child,[80] and the doctor's control over the situation. A novel duty is more likely to be established where the doctor is in a position of knowledge and control relative to the parents. This does not seem to be the situation where parents instigate the modification to standard treatment, download software from sites such as OpenAPS and seek out knowledge and support through social media. The paediatric endocrinologist may not have much power to control the use of a DIY system. The management of the devices and software is supported outside a medical context and it is the parents who understand the potential risks of a DIY system and how to manage them, so they are not relying on the healthcare professional for advice. In *Pyrenees Shire Council v Day*, Kirby J noted that '[r]easonable assumptions of self-reliance make it appropriate to withhold the

75 Ian H Kerridge and John R McPhee, 'Ethical and Legal Issues at the Interface of Complementary and Conventional Medicine' (2004) 181(3) *Medical Journal of Australia* 164.

76 Ibid 165.

77 *Perre v Apand Pty Ltd* (1999) 198 CLR 180, 253 [198] (Gummow J); *Caltex Refineries (Qld) Pty Ltd v Stavar* (2009) 75 NSWLR 649, 676 [102] (Allsop P, Simpson J agreeing at 705 [241]).

78 *New South Wales v Bujdoso* (2005) 227 CLR 1, 14 [45] (Gleeson CJ, Gummow, Kirby, Hayne, Callinan and Heydon JJ).

79 *New South Wales v Godfrey* (2004) Aust Torts Reports 81–741, [15], [47] (Spigelman CJ), quoting *Godfrey v New South Wales (No 2)* (2003) Aust Torts Reports 81–700, [62] (Shaw J).

80 *Crimmins v Stevedoring Industry Finance Committee* (1999) 200 CLR 1, 39 [92]–[93] (McHugh J).

imposition of a duty of care where the party suffering loss had reasonable opportunities to inspect a danger or otherwise to protect itself'.[81]

The healthcare practitioner may refuse to provide a prescription for insulin, but the parents can source that from others, including their general practitioner. We have seen from our interviews with parents their wish to have more control over their child's condition:

> [I]n my opinion, it becomes the job of the endos and whatnot to check outcomes, rather than try and dictate how you should treat your disease. It's not their disease, it's the patient's disease. And, really I don't quite know the answer, but their job needs to be less about treating diabetes and more about empowering patients. (*Parent 1*)

Thus, the disparity of knowledge, control, and autonomy of the parties points away from extending a duty of care on healthcare practitioners to disclose risks of DIY systems. Although there may be no legal duty to disclose, I argue that healthcare professionals need to know enough in order to be able to maintain a therapeutic relationship with the parents and to fulfil their duty to act in the child's best interests. In the context of CAM, Kerridge and McPhee state that medical practitioners 'no longer have any choice but to gain some knowledge about CAM and the interface between conventional and complementary medicine. In so doing, the profession will be better able to provide care that accords with patients' values and needs [and] satisfy the ethical dimensions of healthcare decision-making'.[82]

Perhaps it is enough for the doctor to say, 'I don't know much about DIY systems, but you need to be aware that they are unregulated and the responsibility for managing them is yours, not mine'.

As long ago as 1985, Teff proposed a 'therapeutic alliance' as a counterbalance to the supremacy of the medical profession, where the patient's voice is integrated in decision-making.[83] Hanna later commented that therapeutic alliance 'is primarily concerned with welfare … protected through the duty of the doctor'.[84] In *Montgomery v Lanarkshire Health Board*, the UK Supreme Court noted the social and legal developments in the law about disclosure of information.[85] Now there is a focus on patients 'accepting responsibility for the taking of risks affecting their own lives, and living with the consequences of their choices'.[86]

81 (1998) 192 CLR 330, 427 [253].

82 Kerridge and McPhee (n 75) 166.

83 Harvey Teff, 'Consent to Medical Procedures: Paternalism, Self-Determination or Therapeutic Alliance?' (1985) 101(3) *Law Quarterly Review* 432, 450. See also Harvey Teff, *Reasonable Care: Legal Perspectives on the Doctor-Patient Relationship* (Clarendon Press, 1994) ch 6.

84 NJ Hanna, 'Challenging Medical Decision-Making: Professional Dominance, Patient Rights or Collaborative Autonomy?' (1998) 18(1) *Oxford Journal of Legal Studies* 143, 148.

85 [2015] AC 1430, 1461 [81] (Lords Kerr and Reed JJSC).

86 Ibid.

An exchange of information and expertise between healthcare professionals in paediatric endocrinology and parents who are setting up looping systems for their children can create a dialogue necessary for a productive therapeutic relationship, rather than closing the opportunity for understanding because of mistrust. Gaining information about the nature and likelihood of the risk of malfunction of a DIY looping system alongside the short and long-term benefits in management of T1D will enable healthcare professionals to consider whether supporting the use of DIY systems is in the best interests of the child. Promoting a therapeutic alliance may remove the threat of being sued and could empower parents to make good choices, rather than displacing their control.

D *Healthcare Professionals' Support of a DIY System*

A DIY looping system is a patient-driven innovation which nevertheless requires the 'support' of clinicians through the provision of insulin, which is a prescription-only drug, and ongoing monitoring of blood glucose readings from the CGM. The healthcare professionals we interviewed for the study were concerned about their legal liability and indemnity insurance if they supported DIY looping systems:

> I don't know that I can legally support you to make decisions to change therapy because it's not a TGA approved device. (*Diabetes Educator 1*)

> I would certainly be concerned about the legalities and the indemnity side of things. (*Paediatric Endocrinologist 1*)

> And my medical defence insurance said no, they won't cover me. I'm not medically or legally covered in any way to [support DIY looping]. (*Paediatric Endocrinologist 3*)

> [W]e can certainly support the kids in terms of advice around blood glucose targets and how to manage hypos and stick to their management and complication screen, that sort of thing. But we're not, at the moment, because they're not legal, it's not, not authorized here, that we're not permitted I guess to be directly involved in the actual management with any setting adjustment so we can't do anything like that with the pumps … (*Paediatric Endocrinologist 2*)

The indemnity insurers we interviewed took a conservative approach:

> If I was giving advice to an endocrinologist, I would tell them straight out we wouldn't cover them. Is the short answer. The risks to the endocrinologist are just too high. Effectively, you're aggregating your responsibility for a patient to not just the patient, but to a parent without having any real control. (*Indemnity Insurer*)

The reality is that it is the child's parents who bear day-to-day responsibility to achieve optimal glycaemic outcomes and they should be trusted to take on the care of their child's T1D.

In Australia, a healthcare practitioner is liable to a claim in negligence if they have breached their duty of care which results in foreseeable harm. If parents, on behalf of their child, wish to bring a claim, they would be required to show that the healthcare practitioner did something which a prudent and reasonable

endocrinologist or diabetes educator would not do, thus failing to meet the expected standard of care.

Statutory provisions in Australia — the *Wrongs Act 1958* (Vic) ('*Wrongs Act*') and similar provisions in other states — set out the framework for the tort of negligence.[87] Section 48 of the *Wrongs Act* identifies preconditions for liability in negligence to exist[88] — the risk must satisfy the threshold of being 'not insignificant' and reasonably foreseeable.

It is reasonably foreseeable that some kind of harm might arise from the use of a modified hybrid closed loop system; it is a risk that a healthcare professional working in the field of paediatric endocrinology either knows or ought to know about. It is not illogical nor 'far-fetched'[89] to conceive that there may be an issue with the software or the hardware itself which leads to a miscalculation of insulin.[90] The risk of harm is not insignificant — an excess of insulin in the bloodstream results in hypoglycaemia. The symptoms of mild hypoglycaemia include sweating, dizziness, mild confusion and rapid heartbeat; more severe symptoms, sometimes referred to as diabetic shock, include seizures, unconsciousness and can lead to death. 'Hypoglycemia is a frequent occurrence in children and adolescents with type 1 diabetes.'[91] In the United States, a news story published in May 2019 with the title 'Patient Hurt by Do-It-Yourself Artificial Pancreas Prompts FDA Warning' reported an adult experiencing an accidental overdose when using a DIY looping system and the patient required medical help.[92] So, it can be concluded that the provision of insulin for use in a DIY system creates a reasonably foreseeable risk of not insignificant harm.

However, it is problematic to see how the parents might frame the breach of duty. They might allege that the healthcare professional failed to take reasonable care to ensure the safety of their child and that, because of the risk of serious (possibly fatal) health implications as a result of a miscalculation of insulin by the DIY system, the doctor should have taken a number of precautions, including taking reasonable steps to ensure parents are warned of the risks of use of a DIY system and refusing to provide insulin for use in the DIY system. The first proposal appears self-defeating. As noted in Part C above, I have argued that there is no duty to disclose risks of a non-standard treatment that has not been proposed by, and

87 *Civil Liability Act 2002* (NSW) ('*Civil Liability Act (NSW)*'); *Civil Liability Act 2002* (WA); *Civil Liability Act 2002* (Tas); *Civil Law (Wrongs) Act 2002* (ACT); *Personal Injuries (Liabilities and Damages) Act 2003* (NT); *Civil Liability Act 2003* (Qld); *Civil Liability Act 1936* (SA).

88 The same applies under the New South Wales legislation: see *Roads and Traffic Authority (NSW) v Refrigerated Roadways Pty Ltd* (2009) 77 NSWLR 360, 397 [173] (Campbell JA), discussing *Civil Liability Act (NSW)* (n 87) s 5B.

89 *Wyong Shire Council v Shirt* (1980) 146 CLR 40, 48 (Mason J) ('*Wyong Shire Council*').

90 Hng and Burren (n 12) 1401.

91 Driscoll et al (n 20) 77:1–9, 1.

92 Michelle Fay Cortez, 'Patient Hurt by Do-It-Yourself Artificial Pancreas Prompts FDA Warning', *Bloomberg* (online, 17 May 2019) <https://www.bloomberg.com/news/articles/2019-05-17/patient-hurt-by-do-it-yourself-pancreas-prompting-fda-warning>.

even advocated against, by the doctor. The doctor would have done enough by discussing with parents the general risks.

When faced with a request by parents to support their use of a DIY system, what would be reasonable and practicable for a healthcare professional to do, and could it be argued that a reasonable doctor would not provide insulin for use in a DIY system? This requires consideration of the precautions a reasonable healthcare professional would have taken to avoid risks of harm from a DIY system.[93] The 'negligence calculus' requires consideration of the precautions a reasonable paediatric endocrinologist would take in response to the seriousness of the harm and likelihood of the risk, weighing the cost and burdens of taking those precautions and the social utility of the activity that creates the risk of harm.[94]

It is difficult to assess the likelihood of harm arising to a child from a miscalculation of insulin in a DIY system given the low numbers of people anticipated to be using them and the lack of data on reported incidents.[95] It is to be expected that parents using a DIY system would be fearful of reporting a malfunction because of concerns about negative judgments of their ability to parent the child and a risk that child protection measures would be instigated.

Interviews we conducted with parents who were looping considered the likelihood of harm to their child to be low — they had backup arrangements and would revert to the management that the clinician recommended:

> We're very conscious that we're doing that and we're watching very closely. And, all of the key safety litigations in the algorithm are still active, we still have our remote alarms which are an independent system, so, there's still all of those safeguards (*Parent 4*).

The safety of DIY systems was noted by the software developers:

> [W]hen I hear you talk about medical professionals worry that there's not a backup insulin pump within 24 hours. To me it's like — it's ridiculous. They can go back to pens or syringe, right (*Software Developers*).

Although the evaluation of risk has been undertaken in the process of listing a commercial system such as the Medtronic MiniMed 670G on the ARTG, the comparative risk between DIY systems and commercial systems is not known. One parent participant commented that DIY looping is 'not possibly any more risky than current practice' and a legal professional raised the issue of the unknown inherent risk of commercial systems.

93 *Wrongs Act 1958* (Vic) s 48(2) ('*Wrongs Act*').

94 Ibid; *Vairy v Wyong Shire Council* (2005) 223 CLR 422, 446–7 [72] (Gummow J) ('*Vairy*'), citing *Wyong Shire Council* (n 89) 47 (Mason J).

95 See Braune et al (n 2).

There are inbuilt alarms and safeguards in a DIY system, 'designed to accept multiple failure points [including] loss of connectivity',[96] and the potential for harms arising from malfunction of a DIY system appear to be mitigated by backup systems used by committed parents. The first wave of users of DIY systems are highly motivated and competent and engage well with their diabetes care. For these groups who engage with regular monitoring, rather than being 'a risk with a high probability of occurrence',[97] the likelihood of risk of harm to a child using a DIY system is very low. Indeed, there is a likely reduction in harm because the automated system can avoid the human errors associated with manual calculation.

The seriousness of harm[98] from use of a DIY system seems to be the main concern of the paediatricians and diabetes educators that we interviewed:

> With open-source software, the people who are encouraging it are effectively encouraging people who have no training in coding to effectively start coding a medical device giving highly risky, high risk by definition, life-threatening drug, with no coding training whatsoever. (*Paediatric Endocrinologist 3*)

The serious outcomes from miscalculation of insulin are described above, but given the arguably low probability of them arising, what are the burdens of taking precautions to avoid those risks, and would a reasonable paediatric endocrinologist refuse to provide prescriptions for insulin and to monitor the child as a response to the risk?

Section 48(2) of the *Wrongs Act* necessitates consideration of the burdens required of a reasonable practitioner to avoid the risk of harm and 'the expense, difficulty and inconvenience of taking alleviating action'.[99] A risk of harm from any system providing insulin to a child, commercial or DIY, cannot be avoided completely. The risk of harm of a DIY system could be avoided by a healthcare practitioner stating that they will not support its use, monitor the child nor provide prescriptions for insulin. Thus, the burden to avoid the risk of harm, at first blush, seems light — a discussion by the paediatrician with the parents that they will not support their management of the DIY system and will only continue to monitor the child if they revert to standard therapy. Parents might find another more accommodating doctor, or an alternative supplier of insulin; both options would be harmful to the therapeutic relationship with the parents and may deter them from engaging with the clinician team thus undermining the ongoing care and support of familiar faces who know the child well.

Avoiding the (low) risks from use of DIY looping by engaged parents through not providing ongoing care, including the provision of insulin prescriptions, appears to be a high burden. Use of a DIY looping system in children does carry an intrinsic

96 Dana Lewis, 'Why the DIY Part of OpenAPS Is Important', *DIYPS.org* (Blog Post, 31 March 2015) <https://diyps.org/2015/03/31/why-the-diy-part-of-openaps-is-important>.

97 *Roads and Traffic Authority (NSW) v Dederer* (2007) 234 CLR 330, 351 [61] (Gummow J).

98 See *Paris v Stepney Borough Council* [1951] AC 367.

99 *Wyong Shire Council* (n 89) 47 (Mason J).

risk but nevertheless arguably has some social utility.[100] Parents who are motivated to set up the system show real engagement with the care and wellbeing of their child, and a refusal of a healthcare practitioner to support the use of DIY looping could be harmful to the ongoing relationship with the parents and the care of the child:

> They weren't very open-minded or supportive. I didn't feel they were very interested, so we just stopped seeing them. (*Parent 2*)

Indeed, it could be argued that there is social utility in the doctor supporting the use of a DIY system for their paediatric patient (the activity that creates the risk of harm)[101] because it ensures that risks are monitored, and the therapeutic relationship continues. The harm of disengagement with parents using a DIY system was acknowledged by two of the three lawyers interviewed for the Closed Loop study:

> [T]he usual reaction from the medical profession and insurers: 'We're damned because everyone's going to sue us'. When you actually work through it, on what basis are they going to sue you, and would I feel better as a doctor if I said to that person, 'Well, look, I'm not going to help you at all'? (*Lawyer 1*)

> I don't think it's appropriate to just advise them to stop using it and then stick your head in the sand. Because I think that they know that's not going to happen. (*Lawyer 2*)

As the probability of a risk of harm from proper use of a DIY system is low and there is social utility in maintaining a therapeutic relationship with the family, I consider that healthcare practitioners who provide support of a DIY system through provision of insulin and ongoing monitoring will have taken reasonable precautions if they ensure that the parents: are knowledgeable and confident in setting up and running the system; have alternate ways to provide insulin if the automated system malfunctions; monitor the child; provide readings from the system and attend outpatient appointments.[102]

VI STANDARD OF CARE FOR PROFESSIONALS

In order to establish negligence, there must have been a breach of the standard of care. Whether a person meets the standard of care is determined by civil liability legislation mirroring the common law.[103] Section 58 of the *Wrongs Act* provides that the standard of care is determined by reference to 'what could reasonably be expected of a person possessing that skill' at the time. Where a person is exercising a profession, as paediatric endocrinologists and diabetes educators do, responsible professional opinion has a role to play in setting the standard of care. Guidelines

100 *Wrongs Act* (n 93) s 48(2)(d). See generally *Adeels Palace Pty Ltd v Moubarak* (2009) 239 CLR 420.

101 *Wrongs Act* (n 93) s 48(2)(d).

102 See Braune et al (n 2) 67.

103 See generally *Vairy* (n 94).

and policy statements from professional bodies can be used in court to establish responsible professional practice. Whilst no policy statements have been provided by APEG and ADEA to date, they have noted that as some of the apparatus used in DIY looping is not TGA approved it may be 'outside the evidence base for [their] legal scope of practice'.[104] The views of ADEA and APEG are likely to be influential in establishing what reasonable professionals would do but they are not determinative.

A paediatric endocrinologist would not incur liability in negligence if they can demonstrate that they acted in a manner that at the time was widely accepted in Australia as competent professional practice by a significant number of respected practitioners in the field ('peer professional opinion').[105] Section 59 of the *Wrongs Act* provides a defence for the professional, although there has been a tendency for courts to conflate it with the inquiry of breach of duty,[106] so that the standard of care is set by reference to 'professional practice widely accepted by rational peer professional opinion'.[107] As noted in *Dobler v Halverson*, '[t]he plaintiff will usually call his expert evidence to the effect that the defendant's conduct fell short of acceptable professional practice, and will invite the Court to determine the standard of care in accordance with that evidence'.[108]

Supporting a DIY system is not yet a part of accepted professional practice for healthcare professionals in the specialty of paediatric endocrinology.[109] Online forums show that although Australian adults and children are engaged in DIY looping, the total number is likely to be very small.[110] Even though '[p]eer professional opinion does not have to be universally accepted to be considered widely accepted',[111] a healthcare professional who supports use of DIY looping may find it difficult to provide expert evidence to establish that they acted according to professional practice widely accepted by peer professional opinion. Additionally, a court would have the final determination on whether peer professional opinion is unreasonable.[112] In *Tanah Merah Vic Pty Ltd v Owners*

104 Freeman and Ginnivan (n 34).

105 *Wrongs Act* (n 93) s 59(1).

106 For a discussion of the New South Wales equivalent: see *Dobler v Halverson* (2007) 70 NSWLR 151, 166–8 [54]–[64] (Giles JA) ('*Dobler*'), discussing *Civil Liability Act (NSW)* (n 87) s 5O.

107 Catherine Mah, 'A Critical Evaluation of the Professional Practice Defence in the Civil Liability Acts' (2014) 37(2) *University of Western Australia Law Review* 74, 81.

108 *Dobler* (n 106) 167 [60] (Giles JA), discussing *Civil Liability Act (NSW)* (n 87) s 5O.

109 If there were peer professional opinion widely accepted in Australia by a significant number of respected practitioners that endorsed the use of DIY looping, this could demonstrate that the practice is reasonable: *Wrongs Act* (n 93) s 59(3).

110 See Roberts, Moore and Quigley (n 2) 51 n 41; Hng and Burren (n 12) 1401.

111 *Wrongs Act* (n 93) s 59(4).

112 Ibid s 59(2). See above n 107 for explanations of the differing state formulations of the professional practice defence.

Corporation No 1 of PS613436T,[113] the Victorian Court of Appeal noted that an opinion can be unreasonable if it lacks a logical basis, in the sense of 'a rationally defensible basis', and the 'ultimate question is simply whether in all the circumstances of the case the opinion was unreasonable'.[114] In *Bolitho v City and Hackney Health Authority*, Lord Browne-Wilkinson said that 'the judge before accepting a body of opinion as being responsible, reasonable or respectable, will need to be satisfied that, in forming their views, the experts have directed their minds to the question of comparative risks and benefits and have reached a defensible conclusion on the matter'.[115]

As Sappideen notes, 'the court makes a judgment based on expert evidence whether the practices are "responsible" thus excluding fringe, unsubstantiated practices'.[116] Although professional support of DIY looping may not be widely practised, it may be going too far to suggest that it is unsubstantiated. Parents in our study articulated the comparative benefits over risks of looping, and the #WeAreNotWaiting movement provides user-led evidence as to the effectiveness of DIY looping in managing T1D. The defence of peer professional opinion may become increasingly important if more healthcare professionals support its use and where evidence of the benefits of DIY looping is established.

VII SUPPORT OF DIY TECHNOLOGY CAUSATIVE OF HARM

Could it be argued that the healthcare professional *causes* harm to a child using a DIY system through provision of insulin and continuing clinical management of the child? Factual causation could perhaps be made out — the breach of care by the doctor (supporting the use of DIY technology) is a necessary condition of the occurrence of the harm. *But for* the supply of insulin by the doctor, the parents would not have used the DIY system and the child would not have had, for example, a hypoglycaemic shock due to malfunction of the system. But, for policy reasons it seems unlikely that a court would impose liability on the doctor if he or she has provided information to the parents and monitored the child.

One of the lawyers interviewed for the project commented:

> How could I sue the doctor? The doctor has acted reasonably. He can't say that the machine's going to be in perfect working order every day of its life. He's done nothing that's caused the machine to break down, so that claim would lie against the manufacturer, assuming that there was a fault in the machine; it wasn't just wear and tear and it hadn't been replaced. But, it'd be different if the doctor was encouraging the use of it and not disclosing the risks. (*Lawyer 1*)

113 [2021] VSCA 72.

114 Ibid [244] (Beach and Osborn JJA and Stynes AJA).

115 [1998] AC 232, 242.

116 Carolyn Sappideen, 'Medical Professionals and the Erosion of the "Ordinary" Practitioner Standard' (2019) 27(1) *Tort Law Review* 37, 41.

In its document, 'DIY Looping Technologies', a working group from the ADEA and APEG recognise the tension between care of the patient and legal obligations:

> As care of the person with diabetes is our concern and focus, we are mindful of the conflict that may occur when balancing our advice/assistance to the individual with our legal and professional obligations in these circumstances, especially as the glycaemic management of the person is often markedly improved with this self-care.[117]

Keren-Paz, Cockburn and El Haj note the common claim that the threat of malpractice liability stifles use of practitioner-led innovations in treatment, although they also note the need for empirical research to assess this perception.[118] Certainly use of an innovative treatment is 'less likely to accord with *accepted* practice'[119] and as I have argued above, a diabetes educator or endocrinologist who supports the use of DIY looping is departing from the standard practice in Australia. Nevertheless, I consider that a healthcare professional working in paediatric endocrinology would fulfil their duty of care if they have discussed with parents the calibration of the device, safety issues, including when to take the child to hospital, and have authenticated the blood glucose readings from the device.[120] Concerns about legal liability should not stifle innovations which improve treatment for patients where the parents are informed, accept the risks and have themselves evaluated that DIY looping is in the best interests of their child. Real world experience from the DIY community itself indicates that use of DIY hybrid closed loop systems 'may offer considerable advantages and benefits … over conventional methods of diabetes management and even commercially approved' systems.[121]

VIII PARENTS' PROTECTIVE DUTIES: MODIFIED STANDARD TREATMENT AND BEST INTERESTS OF THE CHILD

'Best interests' is an overarching principle in decision-making concerning children. The *United Nations Convention on the Rights of the Child* ('*Convention*') provides, at art 3.1, that in all actions concerning children 'the best interests of the child shall be a primary consideration'.[122] Parents have parental responsibility to make

117 Freeman and Ginnivan (n 34).

118 Tsachi Keren-Paz, Tina Cockburn and Alicia El Haj, 'Regulating Innovative Treatments: Information, Risk Allocation and Redress' (2019) 11(1) *Law, Innovation and Technology* 1, 1, 3.

119 Ibid 1 (emphasis in original).

120 Although parents may be considered to take on the risks of using a DIY system, a doctor could not rely on this as a defence to a claim in negligence: *Wrongs Act* (n 93) s 54.

121 Jennings and Hussain (n 25) 873.

122 *United Nations Convention on the Rights of the Child*, opened for signature 20 November 1989, 1577 UTS 3 (entered into force 2 September 1990) art 3.1 ('*Convention*'). In 2010, the *Convention* was reviewed by key stakeholders as it related to children in hospital and in 2017, the *Charter on the Rights of Children and Young People in Healthcare Services in Australia* was published: Children's Hospitals Australasia, *Charter on the Rights of Children and Young People in Healthcare Services in Australia* (31 May 2017).

healthcare decisions for their children under the age of 18 years. The *Family Law Act 1975* (Cth) states that they have 'all the duties, powers, responsibilities and authority which, by law, parents have in relation to children'.[123] The *Child Youth and Families Act 2005* (Vic) makes it clear that parents, exercising their parental responsibility can make treatment decisions for their child and that the best interests of the child must always be paramount.[124] However, the concept of best interests is a 'notoriously subjective and grey concept'[125] and there are practical, legal and ethical challenges where parents' views about the best interests of their child differs from that of the clinical team. Where the clinical team considers that a child's parents are not exercising their parental responsibility appropriately, they may seek an order from the court in exercise of its inherent *parens patriae* jurisdiction.[126] Parents would provide their anecdotal evidence that a DIY system promotes their child's best interest in better management of T1D, and testimony of medical experts would be sought.

IX FACTORS THAT ARE DETERMINATIVE OF BEST INTERESTS

Common law indicates a range of factors that are included in evaluating the best interests of the child in healthcare decision-making, encompassing medical, emotional and welfare issues. In the case of *An NHS Trust v MB*,[127] Holman J said 'the task of the court is to balance all the factors'.[128] The English courts have adopted a balance sheet approach which requires a consideration of the benefits and the burdens of the options for treatment. In *Re Baby A*, Dessau J noted that deciding what is in a child's best interests is 'an exquisitely difficult task'.[129] The parents in our research study identified a range of benefits of DIY looping over the conventional therapy in control of blood glucose levels:

> Our child's HbA1c is five-point-eight. The recommendation is seven-point-five or below. Eighty-three percent of Australian children are not even meeting that. They're above ten points. (*Parent 2*)

> So, through another bit of trial, a lot of research, we've worked out how to maintain a very, very, very accurate calibration. (*Parent 1*)

Another benefit reported by parents was the increased independence for the child, which had a positive impact on the wellbeing of the family overall:

123 *Family Law Act 1975* (Cth) s 61B. Both parents will exercise parental authority unless a court order changes this presumption: at s 61C.

124 *Child Youth and Families Act 2005* (Vic) ss 10(1), 3 (definition of 'parental responsibility'). See also *Medical Treatment Planning and Decisions Act 2016* (Vic) s 55(4).

125 Gillam (n 14) 1.

126 See, eg, *Re Kara* [2020] NSWSC 1083.

127 [2006] EWHC 507 (Fam).

128 Ibid [58].

129 [2008] FamCA 417, [35].

> So, I think it's given him vastly more independence than he might have had otherwise, and I think it's got mental health benefits for him in that sense … and, that's important and it helps him have as much normalcy as possible when he's living 24 hours a day with something that's so abnormal. It helps him be able to eat more freely, less restrictions around the timing of food and things like that. (*Parent 4*)

> So, sleep, which has enormous flow-ons to, like, our relationship, to our relationship with our kids to our ability to engage professionally and to work productively. It gives him — I think for him it gives him in a lifestyle sense, a lot of independence. [Son] went on his year six camp without any parents and he spent a week on an island … and I honestly don't know that that would have been possible without him looping. (*Parent 4*)

> Imagine going from you being the sole person keeping your child alive, because that is really what it's like to be a type 1 parent, and if your involvement isn't there every hour of every day for the next 15 years, the child will die. Simple as that. And, the looping is a lot like having a nurse 24/7 checking and correcting every five minutes. (*Parent 1*)

The wellbeing of the entire family unit can support the child's best interests. Herring has argued that a child's best interests can be countenanced within the framework of the members of that family.[130] His welfare approach recognises that 'children are raised in relationships and that the best way of promoting a child's welfare is to ensure that the child is brought up in healthy relationships'.[131] Through supporting the caregiver the child's interests are promoted. Indeed, the *Convention* requires the best interests of the child to be *a* primary consideration, leaving space for parents (or other decision-makers) to balance the best interests of the child against equally weighty primary considerations of their own.[132] As Woodhouse has explained, a 'truly child-centered perspective would also expose the fallacy that children can thrive while their care givers struggle, or that the care giver's needs can be severed from the child's'.[133]

There may be a risk of optimism bias[134] in parents who resort to the innovative technology of DIY looping — a tendency to overestimate the probability of positive results and events and underestimate the probability of risks. Parents interviewed in the study did identify risks of looping but considered they had sufficient systems in place to deal with issues as they arose,

130 Jonathan Herring, 'Farewell Welfare?' (2005) 27(2) *Journal of Social Welfare and Family Law* 159, 166.

131 Ibid, citing Selma Sevenhuijsen, 'A Third Way: Moralities, Ethics and Families' in Alan Carling, Simon Duncan and Rosalind Edwards (eds), *Analysing Families: Morality and Rationality in Policy and Practice* (Routledge, rev ed, 2005) 129 and Karen Czapanskiy, 'Interdependencies, Families, and Children' (1999) 39(4) *Santa Clara Law Review* 957.

132 *Convention* (n 99) art 3.1.

133 Barbara Bennett Woodhouse, 'Hatching the Egg: A Child-Centered Perspective on Parents' Rights' (1993) 14(6) *Cardozo Law Review* 1747, 1824.

134 Denise Meyerson, 'Innovative Surgery and the Precautionary Principle' (2013) 38(6) *Journal of Medicine and Philosophy* 605, 620–1.

> because there are very, very strong protections in the software and in the pump hardware (*Parent 2*)
>
> If this whole system fails, I've got a backup. (*Parent 1*)

The parents interviewed in the Closed Loop study considered that their child's best interests are promoted through use of this DIY technology. T1D is a chronic condition requiring ongoing self-management, indeed '[i]ndividuals with diabetes have been shown to make a dramatic impact on the progression and development of their disease by participating in their own care'.[135] One healthcare professional interviewed identified this as a benefit of looping: 'I think it's fantastic. I think it's good, because there is a lot more of a community out there and from a clinician point of view, I guess it means that there, they have an interest in self-management'.

The other healthcare professionals we interviewed did not articulate benefits of looping. They were concerned about risks — of 'hacking', malfunction and errors made by parents:

> [T]here's a risk of making mistakes … I guess the counter argument is that there's risks of making mistakes anyway with the current technology and our role is to support them to minimize those risks. (*Diabetes Educator 1*)
>
> I think there's great risk that people will go on these devices and get it wrong. (*Diabetes Educator 2*)
>
> I think the safety is the big issue. I understand that the algorithms are found to be very good and very safe and there haven't been any issues so far, but the safety in terms of bolus, the advice that they're given would be of concern and also the security of the cloud-based data. You know anything in the cloud has the potential to be hacked into and therefore manipulated, that's the concern. (*Paediatric Endocrinologist 2*)

A parental request for novel or non-standard treatment represents a challenge to the treatment offered by the healthcare provider and what is conventionally 'best' for the child. Whether looping could be in the best interests of a child requires a balancing of different factors. The weighting given to these factors by the various stakeholders may legitimately differ, but the parent's views should be respected unless they do not promote the child's welfare. In the case of *Re King*, Baker J recognised a divergence of views between parents and the treating team:

> The course of treatment proposed by Mr and Mrs King is entirely reasonable. Ashya has a serious medical condition. Any parents in the position of Mr and Mrs King would do whatever they could to explore all options. Some parents would follow the advice of the local doctors to use conventional radiotherapy, others would prefer the relatively untested option of proton therapy … in the hope that the toxic effects of radiation will be reduced. Both courses are reasonable and it is the parents who bear

135 Saurabh RamBihariLal Shrivastava, Prateek Saurabh Shrivastava and Jegadeesh Ramasamy, 'Role of Self-Care in Management of Diabetes Mellitus' (2013) 12(1) *Journal of Diabetes and Metabolic Disorders* 14: 1–5, 2.

> the heavy responsibility of making the decision. It is no business of this court, or any other public authority, to interfere with their decision.[136]

X ZONE OF PARENTAL DISCRETION AND SIGNIFICANT HARM

Diekema acknowledges that parents are best placed to make decisions on behalf of their children as they know their child's needs and bear the burden of the impact of their healthcare decisions.[137] Their legal authority to make treatment decisions for their child is only restricted where the decision they make is not in the child's best interests.[138] Auckland and Goold consider that '[w]here there is room for reasonable disagreement, there is essentially no right or "best" answer, and so the question of "best interests" cannot be properly answered'.[139]

Indeed, Diekema argues that the 'best interest standard provides insufficient guidance for decision-making regarding children and does not reflect the actual standard used by medical providers and courts'.[140] He proposes the 'harm principle' is a more appropriate threshold to justify interference with parental decisions, one where the decision would put their child at significant risk of serious harm.[141]

In the Court of Appeal, Charlie Gard's parents argued, relying on *Re King*,[142] that a parent's preferred treatment option should only be overridden if it is established that the option would likely cause the child 'significant harm'.[143] This approach was rejected by McFarlane LJ in the Court of Appeal,[144] and subsequently, by the European Court of Human Rights, which did not find it necessary to decide on whether it was the appropriate test because the earlier decisions had already concluded that there existed a risk of significant harm.[145]

However, as a tool for ethical deliberation, Gillam proposes the Zone of Parental Discretion ('ZPD') to be used in clinical practice where there is disagreement

136 [2014] 2 FLR 855, 864 [34] ('*Re King*').

137 Douglas S Diekema, 'Parental Refusals of Medical Treatment: The Harm Principle as Threshold for State Intervention' (2004) 25(4) *Theoretical Medicine and Bioethics* 243, 244.

138 Ibid.

139 Cressida Auckland and Imogen Goold, 'Parental Rights, Best Interests and Significant Harms: Who Should Have the Final Say over a Child's Medical Care?' (2019) 78(2) *Cambridge Law Journal* 287, 307.

140 Diekema (n 137) 245.

141 Ibid 245, 250–2.

142 *Re King* (n 136).

143 *Great Ormond Street Hospital for Children NHS Foundation Trust v Yates* [2018] 1 All ER 569, 605–6 [54] (McFarlane LJ) ('*Yates*').

144 Ibid [105].

145 *Gard v United Kingdom* (European Court of Human Rights, Chamber, Application No 39793/17, 3 July 2017) 26 [118]–[119].

between parents and doctors about medical treatment for a child.[146] Rather than getting stuck on the question of what treatment is 'best' for the child, the ZPD is a method of clinicians putting into practice the harm principle articulated by Diekema. In this process of ethical deliberation, harm occurs when 'one course of action causes a *serious* set-back to interests *overall*, when compared to the other possible courses of action'.[147] What treatment option is best for a child should be evaluated on the health outcomes for the child, rather than whether the treatment is standard, a modification of standard treatment, or experimental. As Francis J stated, 'experimentation cannot be in Charlie's best interests unless there is a prospect of benefit for him'.[148]

Measuring health outcomes should not exclude parental accounts of improvements achieved through looping. The data they provide is useful evidence if it can be authenticated and the calibration of the DIY system checked. The small number of parents interviewed in the Closed Loop study certainly thought that DIY looping was the best option to manage their child's T1D. From an ethical perspective it could be argued that the use of DIY looping does not present significant harm to the child which justifies overriding the parent's decision to use it. In the English case of *Re Wyatt*, Hedley J stated that healthcare professionals have a 'responsibility to work in partnership with the parents' and they are under a duty to act in the best interests of the child, accommodating parental wishes as far as 'professional judgment and conscience' allows.[149]

The use of looping could be considered a reasonable course of action, and one which should not be interfered with by the court.

XI INTERFERENCE WITH PARENTAL DECISION-MAKING: CHILD WELFARE

Some parents interviewed for the Closed Loop study volunteered concerns about child protection:

> [O]ne of the main reasons that I go and continue to see the same doctor is so there's a written record in the public system that says that [X's] diabetes care is above average. (*Parent 1*)

> [D]on't think we told them before we started, I think I was very nervous about what they would say. I was very nervous that they might say you can't do this, take it off your child or we'll call DOCS [now called Child Protection Helpline]. Some people have experienced that overseas. Not in Australia, that I'm aware of, but they've had this terrible dilemma where they've said we have to — this has been the best thing for my child's clinical outcomes and I have to stop because otherwise I won't have a child anymore. (*Parent 4*)

146 Gillam (n 14) 2.

147 Ibid 3 (emphasis in original).

148 *Yates* (n 143) 575 [21].

149 [2005] 4 All ER 1325, 1332 [29], 1334 [41].

Whether use of DIY looping reaches a level of harm to justify child protection measures was explored with clinical professionals we interviewed. In Victoria, the *Children Youth and Families Act 2005* (Vic) ('*Children Youth and Families Act*') states when a child needs protection through state-based services.[150] Section 162 of the *Children Youth and Families Act* provides that a child is in need of protection if:

> [T]he child's physical development or health has been, or is likely to be, significantly harmed and the child's parents have not provided, arranged or allowed the provision of, or are unlikely to provide, arrange or allow the provision of, basic care or effective medical, surgical or other remedial care.

In the *Child Protection Manual*, examples of actions leading to harm include 'failure to ensure appropriate access to medical care or treatment', 'failure to ensure safety', and 'poor understanding of infant or child physical or health needs'.[151]

The social workers that we interviewed for the Closed Loop study were genuinely conflicted on whether use of looping in children could trigger child protection measures. One considered that cumulative information is important in painting a picture of the risk — 'it's a movie, not a snapshot'.

Another social worker commented on the importance of the engagement of parents in monitoring their child:

> [B]ut the fact that they can be bothered to even go and research and invest the time into this new technology, they obviously want what's best for their son, so they spend time, they've modified the monitor, they're talking — engaging with other parents who [are] living this experience, which is quite different than medical professionals providing care, somebody living this day to day, I think that's really important. (*Social Worker 3*)

Taking this into account I conclude that where parents continue to engage with healthcare professionals by attending appointments, reporting on the child's Hb1Ac readings and having backup plans if the device fails, then the child is not at risk of significant harm justifying referral to social services for using DIY looping.

XII WAY FORWARD

Parents turn to new technologies, or modifications of standard treatment, to promote their child's best interests as they perceive them to be. Internet of Things

150 Equivalent Acts in other states and territories: *Children and Young Persons (Care and Protection) Act 1998* (NSW); *Child Protection Act 1999* (Qld); *Children and Community Services Act 2004* (WA); *Children and Young People (Safety) Act 2017* (SA); *Children, Young Persons and Their Families Act 1997* (Tas); *Children and Young People Act 2008* (ACT); *Care and Protection of Children Act 2007* (NT).

151 Department of Health and Human Services (Vic), 'Areas of Concern', *Child Protection Manual* (Web Document, 3 July 2017) < https://www.cpmanual.vic.gov.au/advice-and-protocols/tools-and-checklists/areas-concern>.

technologies in the provision of healthcare are advancing rapidly, testing the adequacy of regulation and highlighting concerns of healthcare professionals. In this paper I have considered DIY looping using unregulated open source software to manage childhood T1D as a paradigm case study, to illustrate the legal and ethical duties of healthcare professionals and parents. I argue that, although healthcare professionals may justifiably be concerned about their indemnity insurance if they support parents who use modifications to standard diabetes treatment for their children, liability in negligence would not likely be established if the healthcare professional engages in discussion with the parents about the risks and how they may be managed. The decision to use the modified therapy is one the parents chose, exercising their parental responsibility. Where parents carefully monitor their child, engage with healthcare professionals and have backup strategies if there is a failure of the software, then the use of DIY looping does not put the child at significant risk to justify child protection measures. It would fall within the ZPD and is a decision that can justifiably be made by the parents. It is crucial then that the perceived risks of DIY looping can be identified and managed. This occurs through ongoing dialogue between parents and healthcare professionals. Proactive measures could be taken, such as software or IT experts at the tertiary hospital where the child is receiving care checking the software and calibration of the device. Thus, the risks could be identified and clarified for the purpose of an effective balancing exercise of benefits and burdens of the DIY system.

If the child's blood glucose levels improve with the use of the modified therapy, then the increased wellbeing of the child, the beneficial impact on the family and future health outcomes point towards it being taken seriously as potentially the *best* treatment option. If regulation is the key to enabling a new treatment to be supported, then some resolution of the gap between regulation and practice needs to occur. This might take the form of crowdfunding to fund an application for the software to be registered on the ARTG and use of patient-led data and patient experiences to provide evidence of the benefit of DIY looping. Ongoing constructive dialogue with key stakeholders — parents, healthcare professionals, regulators, software developers and indemnity insurers — can ensure that the potential of emerging technologies to radically improve healthcare is achieved.