

**LETTER**

# NICE DKA guidelines are not just a discretionary or optional advice in the United Kingdom

Management of diabetic ketoacidosis (DKA) in children has been widely debated over the past decades. Previously, the National Institute for Health and Care Excellence (NICE) in the United Kingdom published guidelines related to DKA in 2015 and advocated the use of more restricted fluid regimen in children. In 2020, national interim DKA guidelines published by the British Society of Paediatric Endocrinology and Diabetes (BSPED) recommended a more liberal approach to fluid replacement therapy for DKA in childhood.<sup>1</sup> Following the publication of the BSPED national guidance, a letter from the South Thames Retrieval Service (STRS) was published in the Archives of Diseases in Childhood, which publicly argued against the introduction of the BSPED guideline 2020 and declared that STRS would choose to use the old BSPED DKA guidelines from 2015 for the most severe DKA cases.<sup>2</sup> At the heart of the debate was concern that the liberal approach to fluid replacement therapy would increase the risk of developing cerebral oedema, a serious complication of DKA and a condition in which the pathogenesis remains unknown today. In December 2020, NICE updated its DKA guidelines for children and young people in the light of recent evidence related to the benchmark study (The PECARN FLUID trial) of 1255 children, comparing fast versus slow rehydration in DKA management of children.<sup>3,4</sup> The PECARN study reported no significant difference in the incidence of clinically apparent cerebral injury or neurological outcomes between the fast and slow rehydration trial groups ( $p = 0.24$ , CI 0.15–1.64). A further sub-analysis of 372 patients who presented with severe DKA ( $\text{pH} < 7.1$ ) did not show any significant difference in incidence of clinically apparent cerebral oedema or rates of decline of GCS below 14. The study, however, reported that some neurological tests including digit span recall test scores were found to be significantly better in children in the fast rehydration group trial arm.<sup>3</sup>

In the light of the NICE 2020 publication, there remains a concern among the paediatric community that some groups will regard NICE guidance as an optional or discretionary advice. This commentary discusses recent jurisprudence which suggests that NICE guidelines are being increasingly viewed as mandatory by the courts;

however, there may be other factors that could result in a more discretionary interpretation of their status.

## 1 | MEDICOLEGAL ASPECTS

In the case law *Re v North Derbyshire Health Authority, ex parte Fisher* 1997, the court ruled that a decision made to not adhere to national policy from the Secretary of State, as published guidance was only lawful if there was a justifiable reason that was exceptional to depart from the national guidance.<sup>5</sup> It is noted that the standard of reasonable practice was set before NICE guidelines came into existence such as in *Bolam v Friern Hospital Management Committee* [1957] which ruled that a professional duty of care is not breached if a clinician acted ‘in accordance with a practice that was accepted as proper by a responsible body of opinion’. In 2014, the court applied a similar judgement to the case *Re (on the application of Elizabeth Rose) v Thanet Clinical Commissioning Group (CCG)*, where the court ruled that Thanet CCG was obligated in public law to follow NICE guidelines and therefore fund a NICE-recommended guideline on oocyte cryopreservation.<sup>7</sup> It further stated that there was no basis or reasons given by the CCG to refuse to follow NICE guidance. These case laws outlined highlight that mere disagreement with national guidelines is not enough to free clinicians or organisations from liability. However, the question is whether it is acceptable to disregard a national guideline such as the example given by the dissenting view of the NICE DKA guidance by the STRS. In *Glass v UK* [2004]<sup>10</sup> and *Portsmouth Council v King* [2014],<sup>8</sup> the court stressed the importance of consent procedures and clear information provided to parents so that parents understood the clinician’s reasoning for pursuing particular different treatment options. In the example of the DKA guideline, the dissenting views to the NICE guideline by the South Thames group needs to be justified in its decision to depart from the NICE guideline. These precise issues need to be made clearer and there would be contingencies to weigh up. The evidence as to their dissent would be a crucial factor.

The United Nation Conventions on the Rights of the Child states ‘that everyone has the right to have the highest

attainable standard of health and treatment to illness'.<sup>9</sup> In the United Kingdom, the NHS Service Act began in 1977 and provided a legal framework which imposes on the Secretary of State, the duty and role to support a nation's health service in the delivery of prevention, diagnosis and treatment of illness. The NHS Patients Charter 2014 sets out patients' rights in the NHS and the standards of service they can expect to receive in healthcare.<sup>10</sup> Current GMC guidance for treatment of children 0–18 years<sup>11</sup> states 'that doctors should always act in the best interests of children', and this is the guiding principle in all decisions which affect them. However, it recognises that determining what is their best interests is not always clear, especially in cases related to treatment options that do not always have a proven health benefit. The GMC further states that 'the law relating to children is complex and doctors need some understanding of the law as it applies to how they practise'.<sup>11</sup> Existing legislations are constructed to provide protection to patients receiving healthcare. In today's climate, litigation is often viewed as an indispensable form of monetary compensation against medical error. It has become mandatory for clinicians working today to ensure they are fully protected against litigation, and insurance coverage has been seen to be skyrocketing each year.

National Institute for Health and Care Excellence remains a part of the Government's agenda for delivery of high-quality patient care. NICE clinical guidelines are established by robust methodology based on evidence-based medicine from the highest levels of evidence. In 1999, NICE guidelines were developed with the aim to provide 'evidence-based guidance' for healthcare professionals and were seen to be discretionary and used as an optional advice. At the time, NICE guidelines were not intended to be legally binding. However, recent case laws on NICE clinical guidelines have set a precedent that are likely to make NICE guidelines legally binding. In the landmark case of *Montgomery v Lanarkshire* [2015],<sup>12</sup> the court ruled that healthcare practitioners are required to obtain consent from patients and provide relevant information in a comprehensible way, while ensuring the information given is properly understood. These factors have become important for the courts to determine liability. The case law on NICE guidelines has set a precedent to have the same effect, particularly when healthcare professionals are making clinical decisions about how to treat a patient. Failure to adhere to NICE guidelines without exceptional reasons is likely to lead to legal consequences. While non-adherence to established national guidelines does not necessarily bode an adverse outcome for the defendant when faced with a litigious claim, NICE states that 'organisations commissioning and delivering services are expected to take the recommendations contained within NICE clinical guidelines into account

when planning and delivering services'. There are no fixed timescales for implementation of NICE guidelines because of the different ways services are delivered in very different organisations. The recent court judgement does, however, mean that if organisations refuse to put NICE clinical guidelines in place because they disagree with them, this could leave them open to challenge.<sup>7</sup> The key point is that legal principles established here are binding on the courts and thus applicable to questions over adherence to NICE guidelines.

Recent court cases have ruled that national guidelines are important and relevant in determining the legal standards of healthcare. Such cases further illustrate that the courts are determining that NICE guidelines are likely to be accorded a greater weight, as NICE is developed with the highest levels of evidence and are strongly supported by government policy. While there is an argument that there should not be a legal expectation for healthcare professionals to rigidly follow and adhere to guidelines as this could diminish clinical judgment, clinicians should still be acutely aware that they can be open to legal challenge if they choose not to adhere to national guidance because they simply disagree with the recommendations in the guideline without strong evidence backing such a decision.

## CONFLICT OF INTERESTS

Associate Professor Sze May Ng is a committee member in the NICE Diabetes Update Guideline Development Group 2020-2022 and is Chair of the Association of Children's Diabetes Clinicians UK. She is also the Chair of the UK Diabetes Research Steering Group for Children and is the Guideline Officer for the British Society of Paediatric Endocrinology. She has received no financial payments for work from a body with a commercial interest in the condition. She has a MSc, PhD, MBA and a Master's in Law with over 15 years' experience in medicolegal work related to the field of paediatric endocrinology and diabetes.

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