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Gender medicine and the Cass Review: why medicine and the law make poor bedfellows

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ABSTRACT

In April 2024, the final report of the Cass Review, an independent review chaired by Dr Hilary Cass, was published, offering recommendations to improve gender identity services for children and young people in the UK. The core purpose of the Review was to improve care for children and adolescents. Commissioned by National Health Service England, the Review identified a weak evidence base for medical endocrine interventions and recommended that these treatments be provided within a structured research framework. The Review received widespread support from the clinical community. However, in July, the British Medical Association Council, without consulting its own members, unexpectedly passed a motion calling for a public critique of the Review, citing concerns over methodological weaknesses - a position it then softened following public criticism from members, concluding that their review would come instead from a position of neutrality. The original motion was based on two non-peer-reviewed online papers, prominently the work of McNamara *et al*—a paper which was written for a primarily litigious, rather than academic, purpose. We critically examine these sources and analyse the wider legal context in which they have been applied. We conclude that these sources misrepresent the Cass Review's role and process (specifically, by mistakenly comparing the Review to clinical practice guideline development), while many of the methodological criticisms directed at the Cass Review, including its use of evidence appraisal and systematic reviews conducted by University of York (UK), are unfounded. These misunderstandings, based on flawed and non-peer-reviewed analyses intended for legal (rather than clinical) purposes, jeopardise the implementation of crucial reforms in the care of gender dysphoric youth. The UK clinical community should move beyond these critiques and focus on the Cass Review's recommendations to establish a safer, more holistic and evidence-based service model for children and young people experiencing gender identity issues.

INTRODUCTION

April 2024 saw the publication of the final report of the Independent Review of Gender Identity Services for Children and Young People, chaired by Dr Hilary Cass (Cass Review, or the Review).¹ The purpose of the Cass Review was to make recommendations to the National Health Service (NHS) in England (NHSE) on how to improve services for people under 18 experiencing issues with gender identity. It was underpinned by a robust research

programme, engaged over 1000 stakeholders and took 4 years to complete. The results of the Review were embraced by the UK clinical community,² as well as a number of other professional and third sector organisations and both main political parties. The editor-in-chief of the *BMJ* aptly observed, 'The Cass Review is an opportunity to pause, recalibrate, and place evidence informed care at the heart of gender medicine. It is an opportunity not to be missed for the sake of the health of children and young people.'³ NHSE accepted the Review's recommendations in full and has initiated a 3-year implementation plan.⁴

In an action at odds with this widespread support, however, the British Medical Association (BMA) Council, without consultation with its wider membership, passed a motion in July to 'publicly critique' the Review and called for its implementation to be paused pending this critique.⁵ This unexpected announcement was founded on 'concern about weaknesses in methodologies', referencing two papers: one, a preprint of a paper by Noone *et al* yet to undergo peer review,⁶ and another, a non-peer-reviewed online-only paper by McNamara *et al*, which continues to undergo multiple silent changes.⁷ Of the two online papers, the paper by McNamara *et al*, titled 'An Evidence-Based Critique of 'The Cass Review'' and hosted on the Yale Law School's web page named The Integrity Project,⁸ is the more extensive, as it incorporates the arguments by Noone *et al* while adding additional claims of its own. The apparent imprimatur of Yale University on one of the sources may perhaps have imbued it with a status not normally attributed to a web-based publication that had not been peer reviewed. It should be noted, though, that a disclaimer clarifying it had no official endorsement from Yale University was eventually added.

The BMA Council did not specify the basis of its concerns beyond these online sources, nor identify which of the Review's 32 recommendations it objected to, nor how the impact of a potential pause in the implementation might be mitigated for patients. Following some negative reaction from its membership and the wider clinical community, the BMA subsequently announced that it has changed its position from 'public critique' to a 'position of neutrality' while it conducts its own review.⁹

Gender medicine is a complex and highly sensitive topic, with the shadow of social and political influence looming large over the scientific process. Child health professionals may understandably be

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confused by these conflicting positions and anxious about the implications for their clinical practice.

This paper aims to demystify the debate by evaluating the context and content of the sources which underpinned the original BMA Council motion. As our analysis reveals, the concerns raised in the referenced online sources suffer from a significant number of errors and misrepresentations. The central criticism is based on a fundamental misunderstanding of the role and process of *independent reviews* in the UK's healthcare regulatory systems, while the specific methodological criticisms levelled at the research that underpinned the Review (including the National Institute for Health and Care Excellence (NICE)^{10 11} and University of York (UK) systematic reviews¹²) are largely unfounded.

In order to explore these in detail, we will:

1. Summarise the process and outputs of the Cass Review.
2. Explain the unique role and process of independent reviews and inquiries in the UK healthcare regulatory system, which are distinctly different from clinical practice guidelines (CPGs).
3. Outline the premise of the McNamara *et al*'s paper which forms the primary basis for the BMA's concerns, and set it in the context of the US legal landscape for which it was written.
4. Review the most substantive arguments in the methodological critique of the Cass Review, analysing them for veracity and coherence to evaluate the basis of the BMA's misgivings.

THE CASS REVIEW'S APPROACH AND KEY FINDINGS

The Cass Review,¹ commissioned in 2020, was an independent review commissioned on behalf of the UK government by NHSE to make recommendations on how to improve NHS gender identity services, and ensure that children and young people who are questioning their gender identity or experiencing gender dysphoria receive the highest possible standard of care, that meets their needs and is safe, holistic and effective. The Review was triggered by two significant issues. First, NICE had been commissioned to carry out systematic reviews of the evidence on use of puberty blockers and masculinising/feminising hormones in gender dysphoric youth as part of NHSE's policy development process.^{10 11} These reviews identified a remarkably weak evidence base, such that it was not possible for NHSE to develop clinical policies for their use for this indication. Second, the challenge of a weak evidence base was set in the context of well-documented concerns¹³ about clinical practice at the Gender Identity Development Service at Tavistock and Portman NHS Trust, the only specialist service providing gender services for children and young people in England, Wales and Northern Ireland.

Following an open national procurement process, the Review commissioned the University of York (UK) to deliver an independent mixed-methods research programme to build on the evidence appraisal by NICE. The aim was to provide the best available collation of published evidence relevant to epidemiology, clinical management, models of care and outcomes. In addition to the commissioned research, the Review undertook a multipronged engagement approach which prioritised two categories of stakeholders: people with relevant lived experience, and clinical staff and other professionals providing care or treatment to children and young people.

The Review issued 32 recommendations addressing care delivery and commissioning of treatments. Because one of the key findings of the Review was that not enough is known about

who might benefit from medical endocrine interventions as part of their care, it was recommended that these treatments should be delivered as part of a carefully constructed research programme to provide a better evidence base for future generations.⁴ The recommendations were accepted in full by both the previous and current UK governments.

THE ROLE OF INDEPENDENT REVIEWS AND INQUIRIES

Independent reviews such as the Cass Review serve an invaluable function in the UK healthcare regulatory landscape. When clinical practice begins to operate in ways that threaten care quality and patient safety, NHS bodies and/or the UK government have a responsibility to intervene. The intervention can be any combination of commissioned independent reviews and/or public inquiries, which examine the root causes of the problems and provide recommendations about how to solve them.¹⁴ Findings often include lessons learnt from past mistakes and recommendations can range from restructuring service delivery, changes to the clinical workforce or decommissioning services or interventions due to insufficient evidence of benefit or significant risk of harm.

The utility of independent, comprehensive investigations such as the Cass Review was notably demonstrated by the 2001 Bristol Royal Infirmary Inquiry into the higher than expected mortality rates in paediatric cardiac surgery.¹⁵ While NICE was created 2 years before the Bristol Inquiry, the Inquiry's findings were instrumental in elevating the role of NICE and its mandate for improving clinical standards across the NHS.

Reviews and inquiries have key characteristics that differentiate them from other healthcare regulatory processes. The appointed chair is a respected public figure with no ties to the area under review. The process engages multiple and diverse stakeholders with the goal of improving understanding of the issues, but the chair makes the final recommendations. They are guided not by the rules for creating CPGs, but by specific 'Terms of Reference' which outline the objectives, scope and other parameters which serve as a foundational document that guides the process.

The Cass Review is among the most comprehensive, evidence-based reviews of a medical service from the long history of such independent investigations. Online supplemental appendix 1 provides a more detailed comparison of the Cass Review with three other well-known inquiries and reviews, from dozens conducted to date, which reflect the UK's commitment to accountability and learning from past failures.

MEDICINE, LAW AND THE INTEGRITY PROJECT

Given the BMA motion's prominent reference to the paper by McNamara *et al*, it is informative to understand the context and purpose for which it was written. Although McNamara *et al* resembles an academic critique, its primary purpose is to support litigation. On the same day the paper was published on The Integrity Project website which is hosted by Yale Law School, a version of it was introduced into evidence in a landmark US legal case in which the lead author served as an expert witness.¹⁶ Another iteration has been submitted by the same author group to a Supreme Court case in the USA.¹⁷

The Integrity Project is led by an attorney and a paediatrician, and both are coauthors of the McNamara *et al*'s paper. The Integrity Project's litigious purpose is explicit: 'We write reports that summarize peer-reviewed scientific knowledge for a legal audience, and we directly participate in processes that shape health policy to assist public agencies and judges in evaluating the scientific record.'¹⁸ Several of the McNamara *et al* coauthors

have served and continue to serve as paid expert witnesses, so far in more than a dozen ongoing court cases over the practice of regulation of youth gender medicine, where they oppose the state bans on medical and surgical gender transition treatments. Various versions of McNamara *et al* have already been introduced into evidence in at least two high-profile court cases.^{16 17}

Legal settings are, generally, an unsuitable vehicle for settling medical debates. However, unlike the UK, the USA lacks a centralised medical policy-making body, resulting in what has been described as a ‘bewildering regulatory maze’.¹⁹ While drugs and medical devices are regulated at the federal level, the practice of medicine itself is regulated at the state level.²⁰ Currently, 26 US states have enacted laws that restrict or ban gender transition treatments for young people. These laws have led to numerous legal challenges from transgender advocacy groups, who assert they are discriminatory. The state of ‘lawfare’ in which the USA finds itself is escalating: one advocacy organisation recently announced the receipt for a \$180 million grant to fund its litigation efforts.²¹

Ultimately, these cases hinge on judges deciding between two conflicting perspectives. One side, argued by transgender advocacy groups and supported by the World Professional Association for Transgender Health (WPATH)²² and the Endocrine Society,²³ asserts that medical transition for minors is backed by sufficient evidence, making restrictions unnecessary and discriminatory. On the other side, some states claim the practice is experimental, harmful to youth and that the constitution allows them to protect citizens from unsafe medical treatments. The Cass Report’s findings, highlighting the weak evidence base for youth transitions, and written with children as the key focus of the report, have thus become important in the US debate.

That McNamara *et al*’s paper was written for litigation purposes explains and contextualises the approach it takes to critical appraisal of the Cass Review. McNamara *et al*’s arguments and language are tailored for the courtroom. Viewed through this lens, the way in which the authors highlight their perceived authority, with an emphasis on their ‘86 years collectively caring for 4800 transgender youth’—which would be an unusual addition in a purely academic context—makes more sense. Similarly, a ‘shotgun’ argumentation approach, where an argument is made to seem more persuasive not by the quality but volume of arguments (fallacious or otherwise), is an approach which is well suited to litigious, adversarial settings.

The following section will scrutinise in detail the many and varied arguments which McNamara *et al* lay at the door of the Cass Review and the evidence appraisal underpinning it.

METHODOLOGICAL CRITICISMS OF THE CASS REVIEW

Some of this methodological section may appear somewhat technical. However, given the potential impact that both McNamara *et al* and the Cass Review may have on current and future generations of gender dysphoric children and young people, it is crucial to delve into this in detail: outlining errors of fact and interpretation, couched within the legal context described above, will better inform policymakers and clinicians to make child-centred and evidence-based decisions as objectively as possible.

The criticisms levelled at the Cass Review fall into four main groups, which we present in detail below.

Criticism of the Cass Review process

The central criticism of McNamara *et al* is that the Cass Review ‘violate[s] standard processes’ for creating a CPG. However, in the UK, development of CPGs is the responsibility of NICE or

approved bodies such as medical royal colleges. By confusing an independent review with a CPG, the authors commit a category error that invalidates many of the paper’s arguments and leads to the following mistaken assertions:

1. **Misunderstanding the key requirement of the Review’s independence.** McNamara *et al* claim that the Review lacks credibility due to its leadership’s lack of experience in transgender healthcare. However, the independence of the Review chair from the specific medical field is a key safeguarding measure to prevent bias inherent to working within the field, and to protect patients and the public from the undue influence of these vested interests in the process.
2. **Confusing the Review’s contributors for CPG development groups.** McNamara *et al* state that the Review is not trustworthy because ‘many of the Review’s authors’ identities are unknown’. This reflects a misunderstanding of the Review process. The sole author of the Review is Dr Cass, and the over 1000 individuals the Review met with did not function as a guideline development group. Disclosure of the identities of individuals providing evidence or input to the Review is neither an expectation of independent reviews, nor would it be appropriate in this case, given the extreme politicisation of the topic and not infrequent threats to personal safety.²⁴
3. **Misunderstanding the role of Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) framework in the Review’s recommendation process.** Critiques surrounding GRADE, the most commonly used tool for grading the quality of evidence in systematic reviews as they apply to clinical recommendations, appear as a central theme. McNamara *et al* assert that the Review contravenes standard practice in scientific evaluations by not using GRADE in its recommendations. This is inaccurate: first, the NICE systematic reviews did indeed deploy GRADE in its assessment of the evidence (which it assigned as ‘very low quality’); nothing in the York additional systematic reviews challenged this finding. Second, GRADE is indeed (appropriately) absent from the Cass Review recommendations: but this is because GRADE is a tool for CPGs and not designed for Reviews which make recommendations regarding system changes such as restructuring of clinical services, establishment of a research programme, workforce development and training.

Criticism of the York evidence appraisal

Both of the online sources quoted by the BMA Council outline concerns over the systematic reviews from the University of York’s Centre for Reviews and Dissemination, one of three bodies funded by the National Institute for Health and Care Research to provide systematic reviews for the NHS.

The criticisms range from assertions that York should not have adapted its evidence appraisal methods after the protocol registration, even when the evidence called for this (although such adaptations are in fact common in research^{25 26}); to inaccurate claims that York’s ‘single search’ methodology was not inclusive enough (in fact, the search was the most comprehensive of any systematic reviews to date, yielding the highest number of studies). See online supplemental appendix 2 for more detailed explanations.

Both Noone *et al*⁶ and McNamara *et al* also claim that important studies that ‘demonstrate’ effectiveness of medical treatment were ignored by the York reviews. McNamara *et al* specify in particular two US studies: Chen *et al* and Tordoff *et al*.^{27 28} We assessed these two studies using the Risk of Bias in Non-Randomised Studies – of Interventions (ROBINS-I) tool, which

Noone *et al* and McNamara *et al* state as their preferred tool for evaluation of risk of bias: both studies received a ROBINS-I rating of 'critical risk of bias' (see online supplemental appendix 3). Notably, the appraisal scale used by York (Newcastle-Ottawa Scale) is actually more forgiving than ROBINS-I. Chen *et al*, in fact, reported two completed suicides among 315 hormonally treated youth, raising additional safety concerns.

Despite the York team's appointment being an open procurement process, and the documented scientific distance it maintained in its academic process and outputs, McNamara *et al* have also cast doubt on their independence. Even more surprising is the decision to juxtapose this relationship with that between WPATH and Johns Hopkins University (JHU) which had been commissioned to carry out systematic reviews to inform WPATH's latest revision (Standards of Care Version 8, SOC8), a relationship which the authors uphold as an example of appropriate 'separation between evidence appraisals and the expert panel'. Recently unsealed court documents in a US lawsuit²⁹ suggest otherwise: WPATH policy stated that all JHU manuscripts had to have input from WPATH's own expert panel members, and all conclusions and final manuscripts had to be approved by WPATH leadership. Following the policy's implementation, only one systematic review met WPATH's strict criteria,³⁰ leaving much of the evidence unpublished.³¹ Despite this extensive and intrusive publication approval process, WPATH additionally mandated that any published JHU research must contain a public disclaimer of authorial independence.

York's systematic reviews, like all research, have its limitations. However, the limitations do not threaten the validity of the conclusions, which corroborate the findings of the previously commissioned NICE reviews, as well as a number of other independent systematic reviews to date.^{32 33}

Errors of fact

There are a number of factual errors in the paper by McNamara *et al*. The unusually high prevalence of error has already been noted in various extensive online critiques, although, as with McNamara *et al*, these also lack peer review.³⁴⁻³⁷ Two particularly salient examples are included here:

1. An assertion that the Cass Review highly ranked the quality of WPATH guidelines.

McNamara *et al* state the Cass Review ranked WPATH guidelines among the top five of 23 guidelines, particularly for rigour of development and editorial independence. This is incorrect. The Appraisal of Guidelines, Research and Evaluation II assessment of WPATH's SOC8 placed it among the lowest, scoring 35% for rigour of development, 39% for editorial independence and an overall score of 3/7, with a majority view that it could not be recommended for clinical use.³⁸

2. A claim that the audit data reported by the Review demonstrate a detransition rate of 0.3%.

The audit included in the Review was of treatment at point of discharge from the Gender Identity Service, so did not include any follow-up data. Hence, no conclusions about detransition rates can be drawn.

Claims that the Review holds gender medicine to a higher standard than other paediatric practices

McNamara *et al* also argue that the Cass Review is holding gender medicine to an 'unfairly high standard' in terms of evidence, that 'no other area of paediatrics is held to'. They attribute the 'very low quality' evidence rating primarily to the

absence of randomised controlled trials. This is incorrect: well-conducted cohort studies could also raise the certainty level of the evidence. The very low quality of evidence in gender medicine stems not from a lack of randomised controlled trials, but from poor study design, inappropriate comparison groups, high attrition and inadequate follow-up.

This argument has the potential to cause considerable harm to children and young people, and is worth specific consideration. McNamara *et al*'s cited comparisons to other paediatric practices, which they assert are based on similarly low-quality evidence, are flawed. Their example of GLP-1 drugs for childhood obesity is wholly inaccurate, as these drugs have been extensively tested in under-18s through randomised, double-blind, placebo-controlled trials.³⁹ By contrast, no comparable trials exist for GnRHAs (puberty blockers) in children entering normally timed puberty. While it is common in paediatric care for drugs to be used 'off-label' because they have been tested for an identical indication in adults but not in children, the use of a drug for an entirely novel indication without appropriate trials is entirely different and cannot be justified.

The authors also cite neonatal critical care as an area where treatments are given with a 'less than high-quality evidence base'.⁷ In fact, the history of neonatology provides a salutary lesson in the consequences of providing treatment that appears to be biologically plausible outside a research framework: namely, the provision of oxygen therapy to extremely premature babies which, despite clinicians' best intentions, resulted in thousands of children being rendered blind from retinopathy of prematurity. This has led modern neonatal care to operate to very high research standards, with multicentre follow-up studies continuing into adulthood to assess outcomes of treatment.

CONCLUSION

The Cass Review is not an end in itself, but establishes the basis from which better clinical care can evolve through collaboration between young people, their families, and clinicians and researchers. We believe this is both a crucial and exciting opportunity to advance the holistic care of gender questioning children and young people. The opportunity for unity among concerned clinicians, afforded by the findings and recommendations of the Cass Review, should not be missed. It is time for the UK clinical community to move forward and focus its attention on the Cass Review recommendations to develop a new service model for gender dysphoric children and young people, which is, above all, safe, holistic and robustly underpinned by the evolving evidence base.

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