


## Original Research

# Impact of a national audit on child and adolescent psychiatrists' prescribing practices

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### Abstract

**Background:** A look back review of South Kerry Child and Adolescent Mental Health Services (CAMHS) in Ireland, known as the 'Maskey report' (MR), highlighted substandard prescribing practices. The aim of this 'Maskey Impact Study' (MIS) was to explore changes to child and adolescent psychiatrists' prescribing practices following the MR.

**Method:** The study was cross-sectional and mixed method. A study specific questionnaire was distributed electronically to psychiatrists working in CAMHS ( $n = 160$ ).

**Results:** 102 psychiatrists participated in the study (response rate 63.8%). Perceived improvement in prescribing practices included improved medical record keeping (63.7%), consent documentation (53.9%), medication information provision (41.2%) and physical health monitoring (60.8%). However, 43.1% of psychiatrists reported a reluctance to prescribe medication even when clinically indicated and 50% were more likely to avoid off-label use. Most respondents reported increased stress levels (80.4%) with higher stress being significantly associated with reticence in prescribing ( $\chi^2 = 11.746, p < .001$ ) and avoiding off-label use ( $\chi^2 = 15.392, p < 0.001$ ). Thematic analysis highlighted increased medication hesitancy, enforced 'meaningless' bureaucracy and medication mistrust among families.

**Discussion:** Although improvements reported are welcomed, the increased hesitancy of medication use, avoidance of prescribing more than one medication, and avoidance of off-label use, is of concern with potential unintended adverse consequences. Reluctance in prescribing may deprive youth of access to evidence-based treatments and limit exposure of NCHDs to the safe practice of consultant-initiated psychopharmacology. Further research will be important to determine if this impacts clinical care. Continued education in psychopharmacology is essential along with increased public awareness of the evidence for medication, to help restore public confidence and trust in psychopharmacology.

**Keywords:** Child and Adolescent Mental Health Services; Maskey report; Maskey impact survey; prescribing practices; psychotropic medication

(Received 19 September 2023; revised 12 January 2024; accepted 26 February 2024; First Published online 13 May 2024)

### Introduction

Clinical concerns regarding misdiagnosis and unsafe use of psychotropic medication in youth attending a Child and Adolescent Mental Health Services (CAMHS) in South Kerry, Ireland precipitated a 'look back review' (LBR) of all open cases (over 1,300) between July 2016 and April 2021. The findings, published as the 'Maskey report' (MR) in January 2022, identified 240 children whose care 'did not meet acceptable standards' and 46 with 'clear evidence of significant harm' (Maskey 2022). Specific concerns were raised regarding a non-consultant hospital doctor (NCHD)'s prescription and monitoring of medications, diagnostic practice, and extent of clinical supervision offered/received and actioned.

The Health Service Executive (HSE), Ireland's publicly funded healthcare system, responded by commissioning an independent national prescribing audit (Health Service Executive 2023) and the establishment of a compensatory scheme for families (Health Service Executive 2022). The minister of state responsible for mental health in Ireland, Mary Butler, referred to the findings as 'shocking and disturbing', and requested the Mental Health Commission (MHC) to conduct an all-Ireland CAMHS review (Kelleher & Cullen 2022).

The MR was widely reported in the Irish media, referencing CAMHS as 'not fit for purpose' (Cosgrave 2022), adding to the sense of distress among families and public, and leading to urgent calls for CAMHS reform. Although some commentaries placed the failure at the hands of the HSE and Ministers within the Department of Health, other contributors referenced medical negligence and disciplinary action (O'Mahony 2022), proposing the view that 'mental health services must be prised from [the] grip of psychiatry' (MacLachlan 2023). Public anger, directed at both

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**Cite this article:** Bond L, Ong JZ, and McNicholas F. (2025) Impact of a national audit on child and adolescent psychiatrists' prescribing practices. *Irish Journal of Psychological Medicine* 42: 28–33, <https://doi.org/10.1017/ipm.2024.11>

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CAMHS and those delivering the service may have negatively impacted caregivers of youth attending CAMHS, however, to date, this has not been researched.

## Aim

The aim of this 'Maskey Impact Study' (MIS) was to explore changes to child and adolescent psychiatrists' prescribing practices following the MR.

## Methods

The study was cross-sectional and mixed methods in design. Following ethical approval, a study specific questionnaire was distributed electronically via Google Forms by the College of Psychiatrists of Ireland to all consultants, clinical fellows and senior registrars working in Child and Adolescent Psychiatry ( $n = 160$ ), with a reminder email sent four weeks later (April–May 2023). All responses were anonymised. The strengthening the reporting of observational studies in epidemiology cross-sectional checklist (von Elm et al. 2007) has shaped the reporting of the data.

Demographic details collected included position, work setting, public or private commitment and contract type. Participants were asked to rate any changes to their actual prescribing practices and stress levels at work post-MR. They reported on engagement in continuous professional development (CPD) access and psychiatry training opportunities for NCHDs, and public and patient/caregiver perceptions of CAMHS. All responses used a seven-point Likert scale with the option for free text responses for qualitative data.

Statistical analysis was carried out using Statistical Package for the Social Sciences version 22.0. Descriptive data were calculated for each variable. Associations between psychiatrists' changes in prescribing practices with demographic factors, views on public, patient/caregiver perceptions of CAMHS, stress levels since the MR and perceptions of CPD access and psychotropic medication training opportunities for NCHDs were analysed using Pearson's chi-squared test. Fisher's exact test statistic was used when expected frequencies were observed to be less than 5. The  $p$ -value was set at 0.05. Thematic analysis was conducted to capture frequently cited and meaningful information from free text relevant to prescribing practices (Braun & Clarke, 2006).

## Results

A total of 102 psychiatrists responded (63.8% response rate). The majority of child and adolescent psychiatrists were from the public sector (91.2%), the majority identifying as consultants ( $n = 70$ , 68.6%) with the remaining 32 as NCHDs (31.4%). Most psychiatrists worked in community CAMHS (88.2%) with a small number working as liaison child and adolescent psychiatrists (7.8%) or in inpatient units (4.0%). More than half ( $n = 56$ , 54.9%) were on a permanent contract. Demographics are summarised in Table 1.

### Changes in prescribing practices since the Maskey report

Since the MR, psychiatrists reported several changes to their prescribing practices in terms of documentation, communication, monitoring, and prescribing practices (Table 2). Prior to commencing medication, most psychiatrists ( $n = 62$ , 60.8%) stated they were more vigilant of medical monitoring for patients on psychotropic medication with most ( $n = 59$ , 57.8%) being more likely to align their prescribing and monitoring practice to

**Table 1.** Demographics of respondents ( $n = 102$ )

Demographics	$n$ (%)
Public/private setting	
Public	93 (91.2%)
Private	9 (8.8%)
Role	
Consultants	70 (68.6%)
NCHDs	32 (31.4%)
Work setting	
Community CAMHS	90 (88.2%)
Liaison	8 (7.8%)
Inpatient	4 (4.0%)
Contract type	
Permanent	56 (54.9%)
Fixed	39 (38.2%)
Locum	7 (6.9%)

international, national, or organisational guidelines. Most psychiatrists ( $n = 58$ , 56.9%) reported being more likely to refer to the literature for updated prescribing information.

Most psychiatrists reported an increased tendency to document clinical indications ( $n = 65$ , 63.7%) and caregiver consent ( $n = 55$ , 53.9%) prior to prescribing, with some ( $n = 42$ , 41.2%) more likely than before to provide parents with medication information leaflets. Whilst most psychiatrists ( $n = 63$ , 61.8%) reported no change in informing the general practitioner (GP) when psychotropic medication was commenced or the dose altered, more than a third ( $n = 39$ , 38.2%) felt this behaviour had increased post-MR.

Half of psychiatrists ( $n = 51$ , 50%) were more likely to avoid off-label use when prescribing and half ( $n = 51$ , 50%) were more likely to prescribe in accordance with regulatory bodies such as Food and Drug Administration (FDA), United Kingdom (UK) or the Medicines and Healthcare products Regulatory Agency (MHRA) in Republic of Ireland (ROI). Rates of polypharmacy were also perceived to have reduced post-MR, with almost half of psychiatrists ( $n = 43$ , 42.2%) reporting that they were less likely to consider prescribing more than one medication at the same time. Whilst half of psychiatrists ( $n = 57$ , 55.9%) reported no change to their prescribing post-MR, a significant proportion ( $n = 44$ , 43.1%) felt they were less likely to prescribe psychotropic medication even when clinically indicated, with no significant difference by seniority.

Eighty-two (80.4%) of respondents perceived their stress level to have increased post-MR. Higher stress levels were significantly associated with increased reticence in prescribing ( $\chi^2$  ( $n = 102$ ; 1) = 11.746,  $p < .001$ ), in that those who reported increased stress were more reluctant to prescribe. Psychiatrists who were more stressed were also more likely to restrict their prescribing practice to recognised clinical guidelines ( $\chi^2$  = ( $n = 102$ ; 1) = 7.909,  $p = 0.005$ ), FDA, UK MHRA and/or ROI regulations, ( $\chi^2$  = ( $n = 102$ ; 1) = 8.956,  $p = 0.003$ ) and more likely to avoid off-label use ( $\chi^2$  = ( $n = 100$ ; 1) = 15.392,  $p < 0.001$ ).

An overwhelming majority of respondents believed that there was a worsening of public ( $n = 94$ , 92.2%) or parent ( $n = 71$ , 69.6%) perception of CAMHS following the publication of the MR

**Table 2.** Changes in prescribing practices since the Maskey report

Please rate if/how your following prescribing practices have changed since the South Kerry CAMHS review and Maskey report:	Decreased (% within role)	No change (% within role)	Increased (% within role)
Likelihood to prescribe psychotropic medication when clinically indicated			
Total ( <i>n</i> = 102)	44 (43.1%)	57 (55.9%)	1 (1.0%)
Consultants ( <i>n</i> = 70)	33 (47.1%)	37 (52.9%)	0 (0.0%)
NCHDs ( <i>n</i> = 32)	11 (34.4%)	20 (62.5%)	1 (3.1%)
Likelihood to consider polypharmacy			
Total ( <i>n</i> = 102)	43 (42.2%)	54 (52.9%)	5 (4.9%)
Consultants ( <i>n</i> = 70)	29 (41.4%)	41 (58.6%)	0 (0.0%)
NCHDs ( <i>n</i> = 32)	14 (43.8%)	13 (40.6%)	5 (15.6%)
Avoiding off-label use when prescribing psychotropic medication			
Total ( <i>n</i> = 102)	7 (6.9%)	44 (43.1%)	51 (50.0%)
Consultants ( <i>n</i> = 70)	5 (7.1%)	35 (50.0%)	30 (42.9%)
NCHDs ( <i>n</i> = 32)	2 (6.3%)	9 (28.1%)	21 (65.6%)
Aligning practice to international/national/organisational guidelines when prescribing/monitoring psychotropic medication			
Total ( <i>n</i> = 102)	0 (0.0%)	43 (42.2%)	59 (57.8%)
Consultants ( <i>n</i> = 70)	0 (0.0%)	30 (42.9%)	40 (57.1%)
NCHDs ( <i>n</i> = 32)	0 (0.0%)	13 (40.6%)	19 (59.4%)
Restricting practices to FDA, UK MHRA or ROI medication use when prescribing psychotropic medication			
Total ( <i>n</i> = 102)	0 (0.0%)	51 (50.0)	51 (50.0)
Consultants ( <i>n</i> = 70)	0 (0.0%)	40 (57.1%)	30 (42.9%)
NCHDs ( <i>n</i> = 32)	0 (0.0%)	11 (34.4%)	21 (65.6%)
Referring to the literature when prescribing psychotropic medication			
Total ( <i>n</i> = 102)	0 (0.0%)	44 (43.1%)	58 (56.9%)
Consultants ( <i>n</i> = 70)	0 (0.0%)	34 (48.6%)	36 (51.4%)
NCHDs ( <i>n</i> = 32)	0 (0.0%)	10 (31.3%)	22 (68.8%)
Documenting clinical indication when prescribing psychotropic medication			
Total ( <i>n</i> = 102)	0 (0.0%)	37 (36.3%)	65 (63.7%)
Consultants ( <i>n</i> = 70)	0 (0.0%)	27 (38.6%)	43 (61.4%)
NCHDs ( <i>n</i> = 32)	0 (0.0%)	10 (31.3%)	22 (68.8%)
Documenting caregiver consent on commencement of psychotropic medication			
Total ( <i>n</i> = 102)	0 (0.0%)	47 (46.1%)	55 (53.9%)
Consultants ( <i>n</i> = 70)	0 (0.0%)	36 (51.4%)	34 (48.6%)
NCHDs ( <i>n</i> = 32)	0 (0.0%)	11 (34.4%)	21 (65.6%)
Providing information leaflets to patients and caregivers of the psychotropic medication being commenced			
Total ( <i>n</i> = 102)	0 (0.0%)	60 (58.8%)	42 (41.2%)
Consultants ( <i>n</i> = 70)	0 (0.0%)	47 (67.1%)	23 (32.9%)
NCHDs ( <i>n</i> = 32)	0 (0.0%)	13 (40.6%)	19 (59.4%)
Informing the general practitioner (GP) when psychotropic medication is commenced/dose altered			
Total ( <i>n</i> = 102)	0 (0.0%)	63 (61.8%)	39 (38.2%)
Consultants ( <i>n</i> = 70)	0 (0.0%)	48 (68.6%)	22 (31.4%)
NCHDs ( <i>n</i> = 32)	0 (0.0%)	15 (46.9%)	17 (53.1%)
<b>Please rate if/how the following have changed since the South Kerry CAMHS review and Maskey report:</b>	<b>Decreased (% within role)</b>	<b>No change (% within role)</b>	<b>Increased (% within role)</b>
Your stress levels at work			
Total ( <i>n</i> = 102)	0 (0.0%)	20 (19.6%)	82 (80.4%)
Consultants ( <i>n</i> = 70)	0 (0.0%)	12 (17.1%)	

*(Continued)*

Table 2. (Continued)

Please rate if/how your following prescribing practices have changed since the South Kerry CAMHS review and Maskey report:	Decreased (% within role)	No change (% within role)	Increased (% within role)
NCHDs (n = 32)	0 (0.0%)	8 (25.0%)	58 (82.9%) 24 (75.0%)
Frequency at which you have engaged in CPD activities			
Total (n = 102)	0 (0.0%)	87 (85.3%)	15 (14.7%)
Consultants (n = 70)	0 (0.0%)	62 (88.6%)	8 (11.4%)
NCHDs (n = 32)	0 (0.0%)	25 (78.1%)	7 (21.9%)
Please rate if/how perceptions of CAMHS have changed since the MR:	Worse (% within role)	No change (% within role)	Improved (% within role)
Wider public perception of CAMHS			
Total (n = 102)	94 (92.2%)	3 (2.9%)	5 (4.9%)
Consultants (n = 70)	67 (95.7%)	1 (1.4%)	2 (2.9%)
NCHDs (n = 32)	27 (84.4%)	2 (6.3%)	3 (9.4%)
Patient/caregiver perception of CAMHS where you work			
Total (n = 102)	71 (69.6%)	24 (23.5%)	7 (6.9%)
Consultants (n = 70)	50 (71.4%)	15 (21.4%)	5 (7.1%)
NCHDs (n = 32)	21 (65.6%)	9 (28.1%)	2 (6.3%)
Please rate the following:	Below adequate (% within role)	Adequate (% within role)	Above adequate (% within role)
Psychotropic medication training for NCHDs			
Total (n = 102)	52 (51.0%)	36 (35.3%)	14 (13.7%)
Consultants (n = 70)	28 (40.0%)	32 (45.7%)	10 (14.3%)
NCHDs (n = 32)	24 (75.0%)	4 (12.5%)	4 (12.5%)

(see Table 2). Those who perceived the MR was linked with a worsening of public perception of CAMHS were also less likely to prescribe, even when clinically indicated. ( $\chi^2 = (n = 102, 1) = 20.22$ ,  $p < 0.001$ ) and were more likely to avoid off-label use ( $\chi^2 = (n = 102, 1) = 10.074$ ,  $p = 0.039$ ).

Over half, (52, 51.0%) felt that there was inadequate psychotropic medication training for NCHDs and a minority (15, 14.7%) increased their own engagement with CPD activities post-MR. Referring to the literature when prescribing psychotropic medication was significantly positively associated with lower engagement with CPD activities ( $\chi^2 = 6.364$ ,  $p = 0.042$ ) and poorer perceptions of psychotropic medication NCHD training ( $\chi^2 = 12.579$ ,  $p = 0.002$ ). Increased reference to the literature was also more likely to have had increased in psychiatrists who were working in public settings ( $\chi^2 = 4.829$ ,  $p = 0.028$ ) and having a locum contract ( $\chi^2 = 10.209$ ,  $p = 0.017$ ).

Themes that emerged using the free text responses were 'anxiety related to prescribing', 'public mistrust', and 'administrative burden'. Regarding anxiety relating to prescribing, respondents reported that they were now 'very reluctant to prescribe medications and have adopted a defensive approach to clinical practice' with 'doctors (especially) more on edge when trying to do the right thing with medication use'. Some perceived this to be linked to 'increased fear of complaint, litigation, or poor clinical outcomes due to non-adherence to prescribed medication'.

Respondents reported that mistrust in medications use had increased among patients and families, stating that 'it was already difficult to get the trust of families, particularly when it comes to necessary medication, but this has undermined it further' and

reports that some 'people immediately stopped their child's ADHD medication'. Hesitancy in prescribing off-license medication was evident in open ended comments, such as '[Post MR] made me more defensive and less willing to prescribe off-license even when such practice would be reasonable' and a complete avoidance in some cases; 'frankly I will avoid at all costs prescribing risperidone to children with ASD and behavioural difficulties!'. The added administrative duties, describes as 'a farce of paperwork due to fearing nonadherence to the Standard Operating Procedure and MHC' created an onerous burden adding additional work pressures, at the expense of 'time which could have been better spent clinically'. Such additional duties left some psychiatrists feeling 'burnt out and fed up with being audited'.

## Discussion

This is the first study to explore changes in the practice and attitudes of child and adolescent psychiatrists psychotropic prescribing following on from the HSE LBR and MR (Maskey 2022). This study identified many improved prescribing practices among CAMHS psychiatrists including the extent to which psychiatrists documented clinical indications for medication, gathered informed consent and shared prescribing changes with GPs. Psychiatrists also reported they were more likely to refer to the literature, prescribe within accepted clinical or regulatory parameters, avoid polypharmacy, and share psychoeducational material with families. They were also more likely to report higher vigilance with respect to physical health monitoring. These practices are welcome, consistent with safe and judicious use of



medication, and recognised as an area in need of improvement in the recent national audit on prescribing practices of CAMHS (Health Service Executive 2023). Whether these self-reported perceived improved practices will translate into improvements in subsequent audits remains to be seen.

However, this study also highlighted some areas of concern, most notably, an increase in psychiatrists' anxiety around prescribing psychotropic medications with almost half (43.1%) hesitant to prescribe even when clinically indicated. Respondents spoke of 'fear' and adopting 'a defensive attitude to prescribing'. This is despite growing evidence from controlled trials of psychotropic medication efficacy in youth for most psychiatric disorders (Correll et al. 2021). The practice of polypharmacy, prescription of two or more psychiatric medications, was perceived to have reduced post Maskey Report. Given the paucity of research in paediatric polypharmacy, despite the significant increase over the past 25 years (Zito et al. 2021), it is prudent to be mindful of the need to limit concomitant use of drugs, reducing the risk of additional and interactive adverse effects. Rates of polypharmacy in psychiatry range from 13% to 90%, (Kukreja et al. 2013), and notwithstanding the need to adopt a conservative and 'n of 1' trial approach especially in paediatric polypharmacy (Jureidini et al. 2013), a blanket avoidance of combination therapy is also not without negative results. Using more than one medication at any one time may be necessary, advantageous, and supported by various clinical guidelines, especially for hard to treat or comorbid cases. This is the case especially for ADHD, one of the most common reasons for attendance in CAMHS and a disorder with the largest amount of evidence for effective medication use (Baker et al. 2021).

In this study, half of the psychiatrists reported that they were more likely to avoid off-label prescribing. This is despite much of the prescribing in child and adolescent psychiatry being off label (Meng et al. 2022; Sharma et al. 2016) and most of hospital and primary care paediatric prescribing also being off label (Kimland & Odling 2012). Off-label use is driven by the high costs of conducting paediatric research and low returns to pharmaceutical companies, and is in and of itself, not synonymous with adverse effects or low efficacy. Some researchers believe that depriving patients of medications based on off-label status may be more disadvantageous than any potential adverse effects experienced (van der Zanden et al. 2022).

The highlighting of unsafe prescribing practices identified in the MR may have increased psychiatrists' awareness and concern with off-label prescribing due to misconceptions of safety and medico-legal issues, and 'increased fear of complaint, [and] litigation'. A potential and unintended consequence of this is that effective and safe drug treatments may be withheld or underused. With respect to product license use, Sharma and colleagues (2016) caution us that restricting prescribing to product license use does not guarantee safety and in some cases an off-label alternative may be more appropriate and safer. Additionally, when off-label prescribing is supported by an evidence base and/or a clinical guideline, such practice is easily defensible (Sharma et al. 2016). Prudence would suggest that when faced with low levels of evidence, off-label prescribing should be accompanied by a second opinion to support such decisions (Sharma et al. 2016).

Respondents in this survey also reported a perception of increased patient and family reluctance to consider psychotropic medication and this is not surprising given the widespread media reporting of 'risky' or 'unsafe' medication practice (BreakingNews, 2022), and significant elaboration on the myriad of adverse

side effects linked to medications, often given without any prevalence data. Parental challenges surrounding medication use in children with ADHD in Ireland have already been reported. (Flood et al. 2019). High levels of parental guilt at initiation of medication, uncertainty, and doubt regarding medication short- and longer-term effects, and lack of confidence in risk/benefit decisions exist alongside recognition of positive medication response, growing agency, and acceptability with medication use. The 'abrupt' discontinuation of medication reported by this survey, especially in youth with ADHD, when coupled with the already low prescription rates and low adherence among youth in general is a cause for concern (Edgcomb & Zima 2018). Non-adherence can significantly disrupt a young person's life and development through untreated mental illness and associated social, education and occupational impairments (Emilsson et al. 2017; Nagae et al. 2015). Furthermore, given difficulties in accessing other non-pharmaceutical treatment, and the post-code lottery with an "unacceptable variation" across CAMHS in Ireland (Mental Health Commission 2023), other effective treatment may also be beyond the reach of youth, leaving a child vulnerable to no effective treatment and services just "handholding". Whilst the reported increased hesitancy in families and reluctance to take medication was somewhat counterbalanced by the psychiatrist's admission of increased information sharing and increased discussion of the clinical indications for medication, it is likely that focused work will be needed to increase both service users and public trust in effective use of medication. Previous research in Ireland highlighted that public opinion regarding psychotropic prescribing along with a lack of psychiatrists' confidence represents a major barrier to effective prescribing (McNicholas et al. 2014).

Safe psychotropic prescribing for some medications requires regular physical monitoring of vital signs, anthropometrics, blood tests and ECGs. The lack of availability of such services requires CAMHS to rely on service users' GPs or general hospitals. The national audit of CAMHS carried out by the Mental Health Commission identified less than accepted standards for physical monitoring and attributed the reliance on others, and the lack of electronic health records, to be contributory. (Health Service Executive 2023; Mental Health Commission 2023). Many psychiatrists in this survey suggested the establishment of dedicated CAMHS physical health monitoring clinics. The advantages of a standardised physical monitoring approach have already been within CAMHS eating disorder (Walsh & McNicholas 2020) and ADHD (Rice et al. 2023) services.

### Strengths and limitations

The study's strengths include a high response rate, with respondents drawn from public and private sector across various CAMHS settings. The mixed methods design allowed the personal impact following the look back review to be captured, providing a context for the quantitative data. The cross-sectional design limits any inference on causality and the retrospective and self-report methods used carry a risk of responder recall bias.

### Conclusion

The look back review conducted by Dr Sean Maskey triggered a national review of CAMHS across Ireland, with the intention of examining and ensuring safe clinical practice. Research of attendee's experiences in CAMHS has also been promised, along with the establishment of a compensation scheme for those adversely affected by unsafe care. However, the experiences of

those providing CAMHS and doctors at whom such 'unsafe' and 'risky' prescribing practices are being levelled, also need to be heard. This 'Maskey Impact Study' has addressed this gap. The MIS revealed a welcome improvement in prescribing practices among respondents with increased vigilance in monitoring and reference to existing guidelines. However, the MIS also uncovered a hesitant and cautious approach to medication use with potential unintended consequences. A reduction in appropriate prescribing deprives CAMHS patients of effective treatments and trainees from exposure to effective consultant-led prescribing practice. National clinical prescribing guidelines, regular high-quality training in psychopharmacology and increasing public awareness of the evidence base are all urgently needed to redress the lack of trust in both CAMHS and medication regimes.

**Financial support.** None.

**Competing interests.** None.

**Ethical standards.** Ethical approval was granted by University College Dublin on the 7<sup>th</sup> of March 2023 [LS-LR-23-54-BOND-MCNICHOLAS].

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committee on human experimentation with the Helsinki Declaration of 1975, as revised in 2008.

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