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POMH
PRESCRIBING OBSERVATORY FOR MENTAL HEALTH

The use of melatonin

QI programme 21a Baseline audit

Prepared by POMH for

East London NHS Foundation Trust

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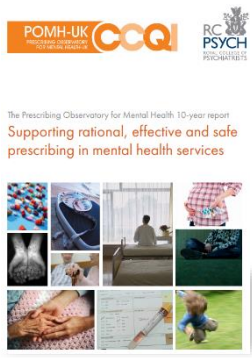
About POMH



The Prescribing Observatory for Mental Health (POMH) runs clinical audit-based quality improvement (QI) programmes that focus on discrete areas of prescribing practice. Membership of POMH is open to all NHS, private and not-for-profit providers of mental health services (NHS Trusts/healthcare organisations) in the UK.

The aim is to help mental health services improve prescribing practice by providing benchmarked information on their performance against evidence-based practice standards.

Those interested in learning more about the role of POMH should visit the website: http://www.rcpsych.ac.uk/pomh. A 10-year report (2016) on the work of POMH and a 15-year anniversary report (2020) are also available on the website.

There are also reviews of the POMH quality improvement methodology in the following publications:

Barnes TRE, Paton C. The role of the Prescribing Observatory for Mental Health (Editorial). British Journal of Psychiatry 2012; 201: 428-429

Barnes TRE, Paton C. Improving prescribing practice in psychiatry. International Review of Psychiatry 2011; 23: 328-335.

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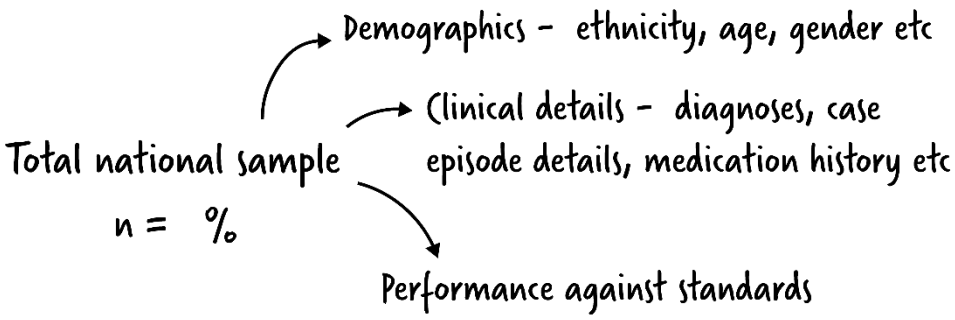

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The analyses presented in this section allow Trusts to compare the quality of their local practice, in absolute terms, with the practice standards and, in relative terms, with that of the other, anonymous, participating Trusts.

Each of the benchmarked graphs in this section provides evidence of performance on an aspect of prescribing practice across all Trusts individually and the TNS. In each figure, the Trust(s) on the left-hand side is closest to meeting the relevant standard while the Trusts on the right are further away from meeting the standard.

TEAM LEVEL RESULTS ----------p44

The figures in this section allow individual clinical teams in each Trust to compare their practice with each other and against the national data. For each figure, the team(s) on the left-hand side is closest to meeting the standard. The bar on the far right shows the TNS and the bar next to this shows the overall Trust performance.

The results presented in this report allow you to compare your team's/Trust's practice against:

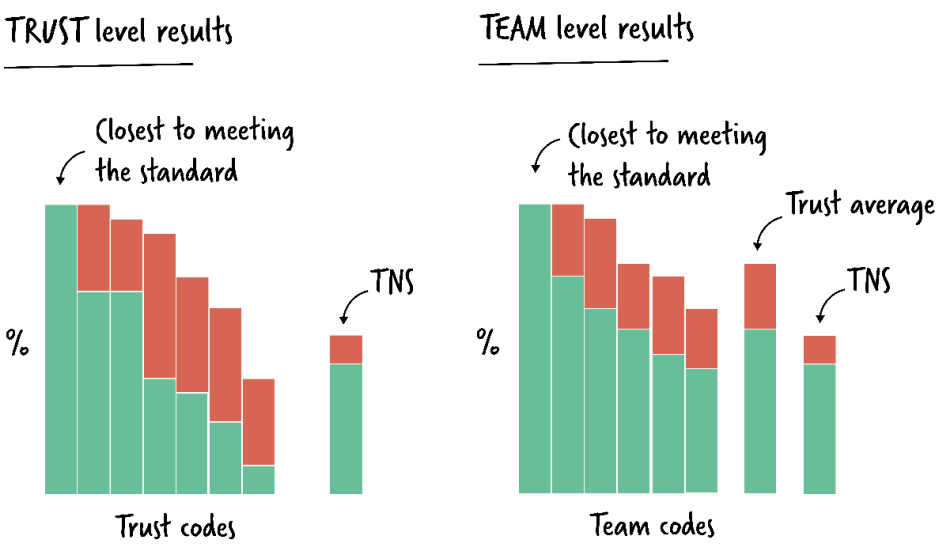
- Treatment recommendations in nationally recognised guidelines, including those published by the National Institute for Health and Care Excellence (NICE) and the British Association for Psychopharmacology (BAP).
- The practice of other participating Trusts.

Further analysis of your Trust's data

An Excel file containing the data submitted by your Trust has been made available to your Local POMH Lead. Please contact this person if you wish to conduct further analyses on your data.

Trust codes

Data from each clinical team or Trust are presented by code only. The POMH Project Team does not know the identity of individual teams. Only the Local POMH Lead for your Trust has the key to team codes for your Trust. You should contact the person if you need to identify data for your own particular team.



QI suggestion

These boxes appear throughout the report. They indicate suggested local QI activity that Trusts may wish to consider.

Executive summary

This report presents the results of the baseline audit for a quality improvement programme (QIP) addressing Topic 21a the use of melatonin.

During June and July, 61 NHS Trusts/healthcare organisations (See Appendix B) participated in this baseline audit, submitting data for 5097 patients under the care of 332 clinical teams. On this occasion, 6 community paediatric services that were not part of mental health Trusts, contributed 343 of these cases.

Practice standards

Number	Practice standards
	Evidence-based, non-pharmacological interventions should be tried before melatonin is prescribed
	The target symptoms for melatonin treatment should be documented (e.g. sleep onset, sleep duration, sleep quality)
	A licensed melatonin preparation should be prescribed where possible
	Where an unlicensed melatonin preparation is prescribed, an explanation should be given to the patient and/or parent and/or guardian and/or carer, as appropriate
	The efficacy and safety/tolerability of melatonin medication should be reviewed within 3 months of starting
	The need for continuing melatonin treatment should be reviewed annually, based on efficacy and side effects

The practice standards were derived from:

- General Medical Council (2021) Good Practice in Prescribing and Managing Medicines and Devices. GMC. https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices

- Anon. Melatonin for sleep problems in children with neurodevelopmental disorders. Drug and Therapeutics Bulletin2015,53;117-120

- Anon. Melatonin for primary insomnia? Drug and Therapeutics Bulletin2009;47:74-77.

- National Institute for Health and Care Excellence, 2013. Autism: The management and support of children and young people on the autism spectrum (CG 170). https://www.nice.org.uk/guidance/cg170

- Use of licensed medication for unlicensed applications in psychiatric practice (2nd edition). Royal College of Psychiatrists, CR210, 2017. https://www.rcpsych.ac.uk/improving-care/campaigning-for-better-mental-health-policy/college-reports/2017-college-reports/use-of-licensed-medicines-for-unlicensed-applications-in-psychiatric-practice-2nd-edition-cr210-dec-2017

- Wilson S, Anderson K, Baldwin D, et al. British Association for Psychopharmacology consensus statement on evidence-based treatment of insomnia, parasomnias and circadian rhythm disorders: An update. Journal of Psychopharmacology 2019;33:923–947.

Summary of key findings

This section focuses on the performance of your Trust against each of the practice standards, compared with the relevant national subsamples.

Performance against practice standard 1

Evidence-based, non-pharmacological interventions should be tried before melatonin is prescribed

Melatonin alone should not be considered a first-line treatment for sleep disturbance but may be considered alongside non-pharmacological interventions or after the latter have failed to adequately improve sleep.

Non-pharmacological interventions (primarily advice about sleep hygiene) were documented in the clinical records of just over two-thirds of the patients who had been started on melatonin in the past three months. Further details of these interventions may be found in Table 3 (page 21).

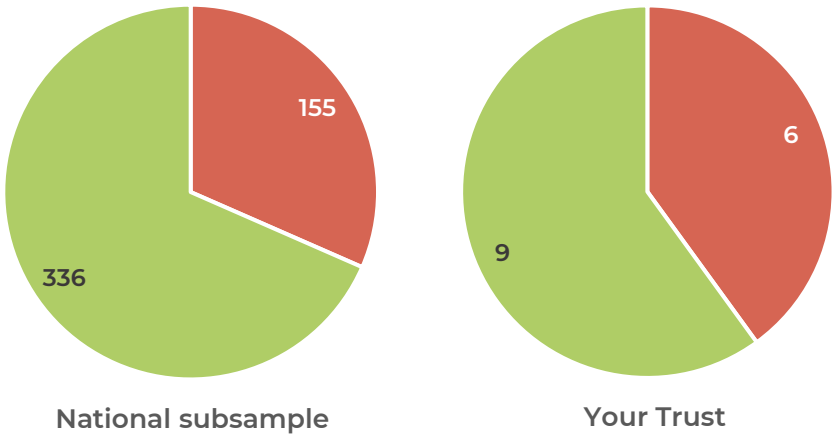


Figure 1: Documentation of non-pharmacological treatment interventions before melatonin was prescribed. Patients prescribed melatonin for less than three months: national subsample (n = 491) and your Trust subsample

Where local practice falls short of the standard, Trusts may wish to check whether prepared advice about sleep hygiene, suitable for clinicians to share with parents and carers, is readily available in settings where patients are seen; for example, written advice may be provided via a printed leaflet, by sharing a web-link, or in the form of an electronic document that can be e-mailed.

Performance against practice standard 2

The target symptoms for melatonin treatment should be documented (e.g. sleep onset, sleep duration, sleep quality)

In the total patient sample, the target symptoms/clinical reasons for prescribing melatonin were documented in the vast majority. However, for the one patient in seven for whom such documentation was missing, there may well be challenges to determining whether the medication has had any beneficial effects and whether or not it should be continued.

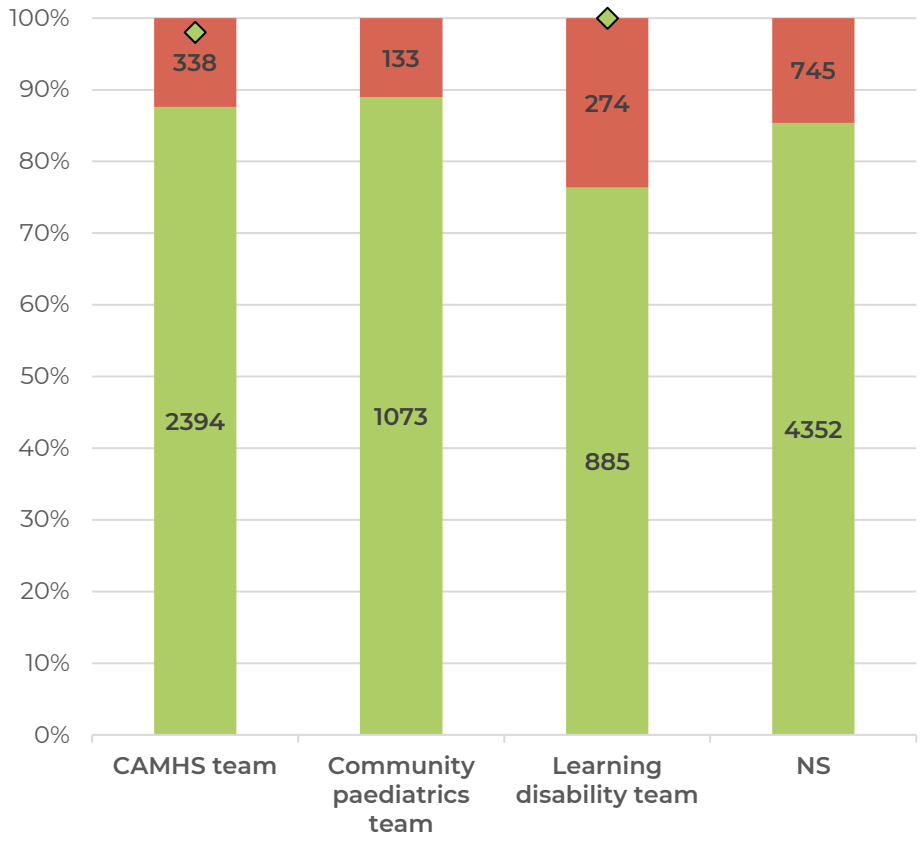


Figure 2: Documentation of the clinical reasons for prescribing melatonin. Total national sample (n = 5097), national service subsamples (CAMHS n = 2732, community paediatrics n = 1206, learning disability n = 1159) and your Trust service subsamples

Performance against the standard in CAMHS and community paediatric teams was better than in learning disability teams.

Further details of the clinical reasons for which melatonin was prescribed may be found in Table 6.

[a] Where there is no diamond in the bar, your Trust did not submit data for any patients in this clinical setting.

Performance against practice standard 3

A licensed melatonin preparation should be prescribed where possible

The Figure below shows that, in all three clinical service subsamples, a licensed preparation of melatonin was prescribed for the majority of patients but in only a small proportion were these for the licensed indication (i.e. most prescriptions were clearly for off-label indications).

Melatonin was prescribed generically for approximately three patients in ten; the licensed status of the products supplied against such prescriptions are unknown.

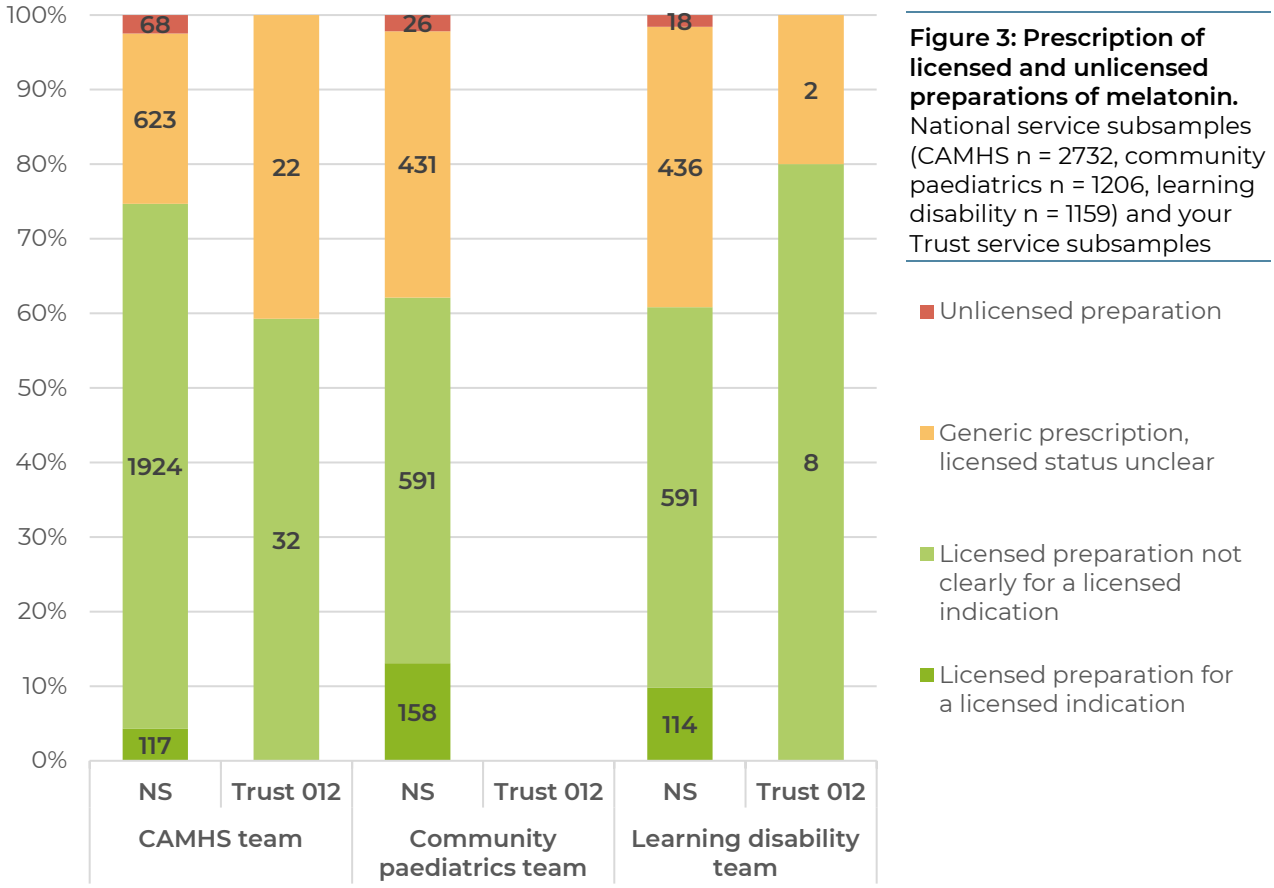


Figure 3: Prescription of licensed and unlicensed preparations of melatonin. National service subsamples (CAMHS n = 2732, community paediatrics n = 1206, learning disability n = 1159) and your Trust service subsamples

Where practice falls short of the standard, Trusts may wish to consider encouraging melatonin prescribing by brand. This removes the risk of unlicensed preparations of melatonin being supplied when this was not the specific intention of the prescriber.

Performance against practice standard 4

Where melatonin is prescribed off-label, an explanation should be given to the patient and/or parent and/or guardian and/or carer, as appropriate

When medication is prescribed off-label, professional bodies strongly recommend that this should be explained to the patient (Royal College of Psychiatrists, 2017; GMC, 2021). There are good clinical reasons for this recommendation. For example, the information leaflet packed with the medication will describe only the licensed indications, which will be conditions that the patient does not have. This may be confusing for parents/carers and cause them to lose trust in the prescriber.

Off-label use was not recognised for more than one patient in ten. Where off-label use was recognised, it was documented that this had been explained to the patient/parent/carer in only a small minority of cases.

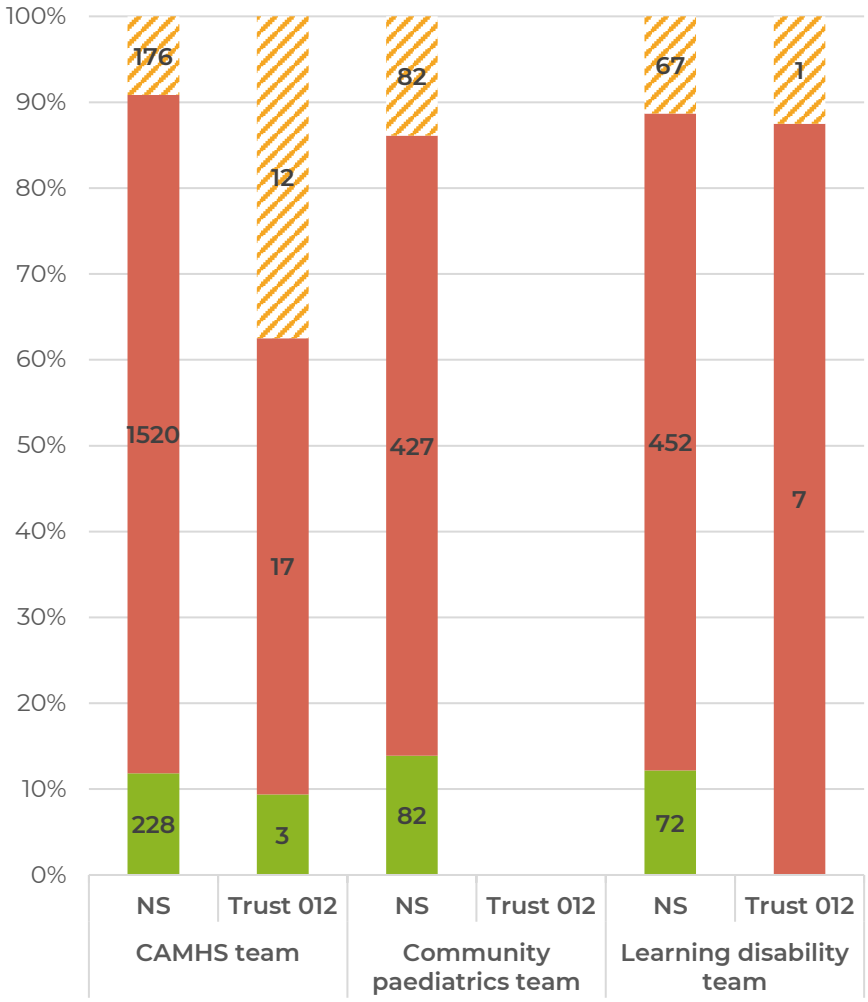


Figure 4: Documentation of an explanation to a patient/parent/guardian/carer that a melatonin prescription is 'off-label'. Patients with identified 'off-label' prescriptions for melatonin in the national service subsamples (CAMHS n = 1924 community paediatrics n = 591, learning disability n = 591) and your Trust service subsamples

- No information (off-label use not recognised)
- No documented evidence that the patient and/or parent/carer was informed that melatonin is being used off-label
- Documented in the clinical records that the patient and/or parent/carer was informed that melatonin is being used off-label

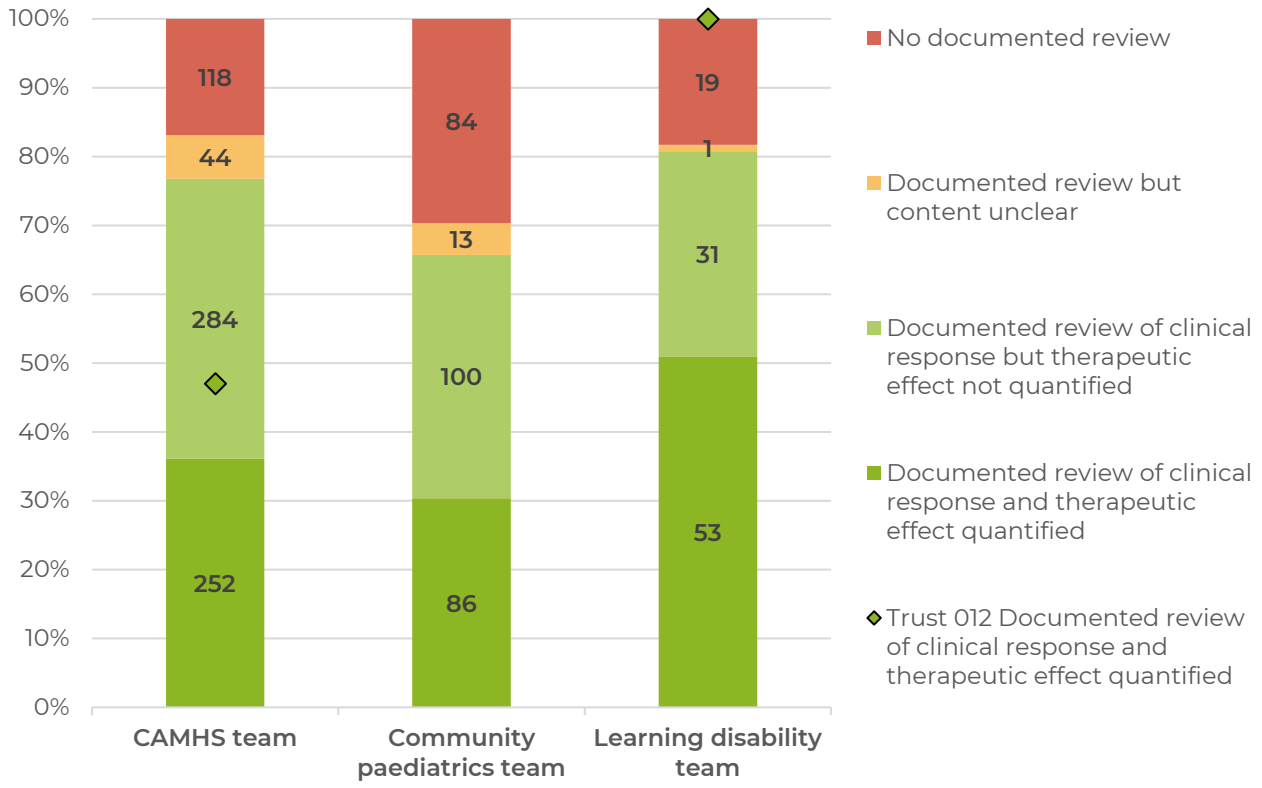
Where local practice falls short of the standard, appropriate committees within the ICS may like to consider reducing the burden of information-giving on clinicians by: (1) encouraging melatonin to be prescribed by brand within licence and/or: (2) making available standard information that explains why melatonin is being prescribed off-label so that clinicians can share this with patients/carers.

Performance against practice standard 5

The efficacy and safety/tolerability of melatonin medication should be reviewed within 3 months of starting

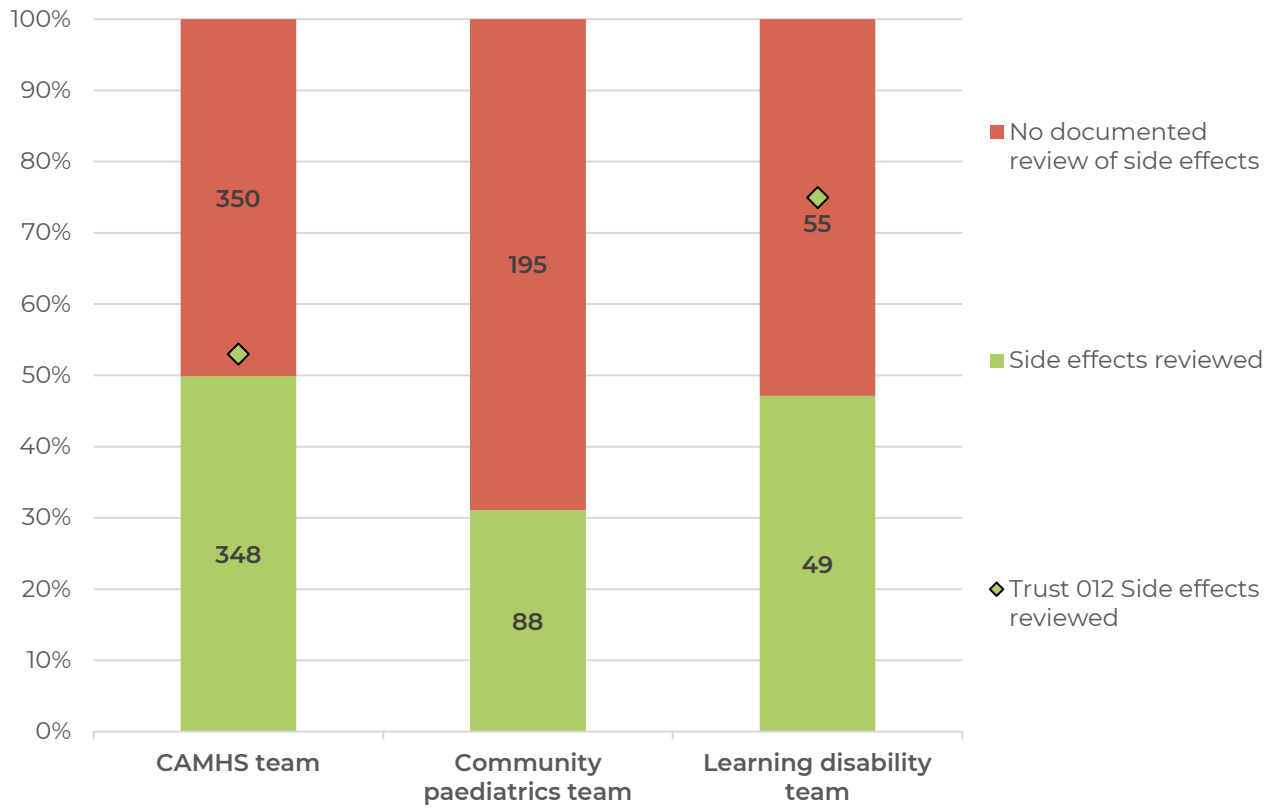
An early treatment review was documented for 4 patients out of every 5 overall. Such a review was more often documented for patients under the care of CAMHS or learning disability services than for those under the care of a community paediatrics team. Learning disability teams more often quantified the effect of melatonin on sleep, suggesting that these teams conducted more structured reviews on newly initiated melatonin.

Figure 5: Documented clinical review of the response to melatonin, within the first three months. Patients in the national service subsamples prescribed melatonin for between 3 months and a year (CAMHS n = 698, community paediatrics n = 283, learning disability n = 104) and your Trust subsamples



Where local practice falls short of the standard, the appropriate committee within the ICS may wish to review whether there is adequate resourcing in clinical teams, particularly community paediatric teams, to allow early follow up of patients for whom a new therapeutic intervention has been initiated.

Figure 6: Documented review of side effects within the first 3 months. Patients in the national service subsamples prescribed melatonin for between 3 months and a year (CAMHS n = 698, community paediatrics n = 283, learning disability n = 104) and your Trust subsamples



Where local practice falls short of the standard, Trusts may like to reflect on local protocols/systems for the systematic and structured review of the clinical benefits and side effects of newly initiated melatonin to ensure that this medication is discontinued if it is not helpful or is poorly tolerated.

Performance against practice standard 6

The need for continuing melatonin treatment should be reviewed annually, based on efficacy and side effects

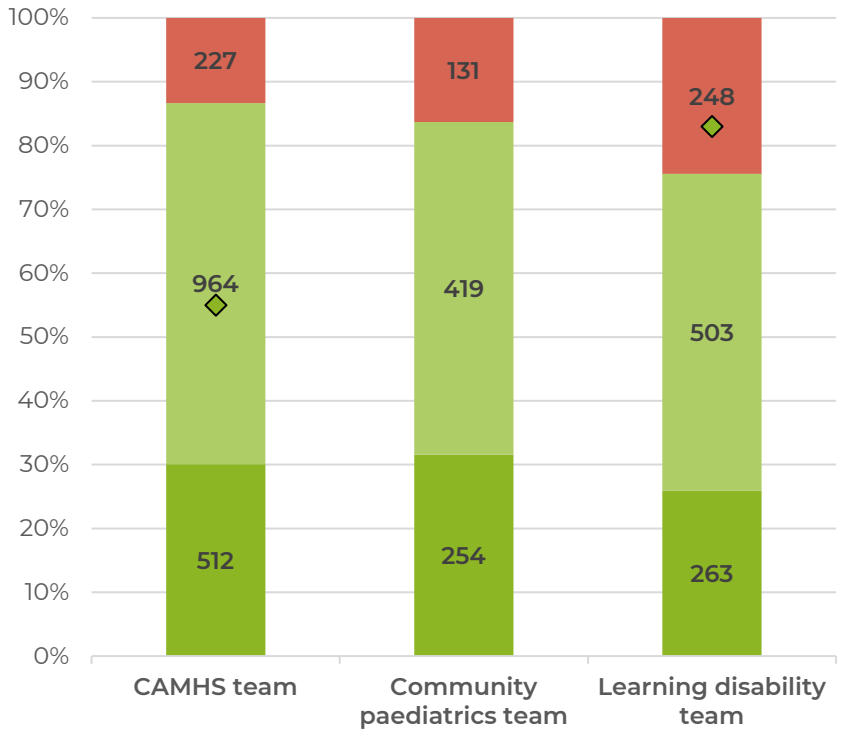


Figure 7: Documented review of the therapeutic effect of melatonin, in the past year. Patients in the national service subsamples prescribed melatonin for more than a year (CAMHS n = 1703, community paediatrics n = 804, learning disability n = 1014) and your Trust subsamples

- No documented review
- Documented review but therapeutic effect not quantified
- Documented review and therapeutic effect quantified
- Trust 012 Documented review and therapeutic effect quantified

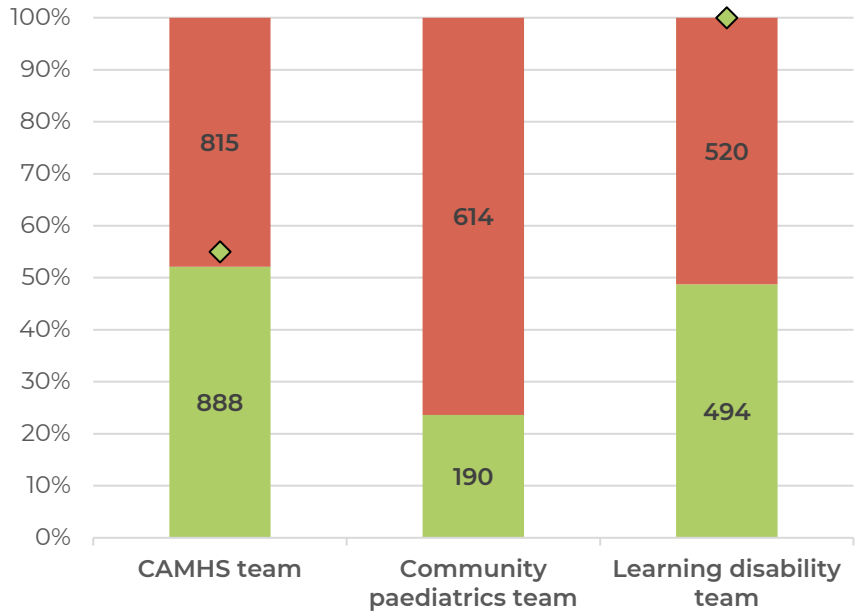


Figure 8: Documented review of side effects in the past year. Patients in the national service subsamples prescribed melatonin for more than a year (CAMHS n = 1703, community paediatrics n = 804, learning disability n = 1014) and your Trust subsamples

- No documented review of side effects
- Side effects reviewed
- Trust 012 Side effects reviewed

Where practice falls short of the standard, Trusts may like to reflect on local protocols/systems for systematically reviewing the clinical benefits and side effects of continuing prescriptions for melatonin to ensure that this medication is discontinued if it is not helpful or is poorly tolerated.

Introduction

Clinical background

Whilst around 20% of typically developing children and young people may experience disturbed sleep, the rates are nearer 70% for children with neurodevelopmental or psychiatric disorders. (Blader et al., 1997; Scottish Intercollegiate Guidelines Network, 2007; Bendz et al., 2010). There are a range of sleep problems commonly encountered in clinical practice including insomnia (problems falling or staying asleep), parasomnias (including night terrors and sleepwalking), circadian rhythm disorders (most commonly delayed sleep phase syndrome), obstructive sleep apnoea and restless leg syndrome. These disorders adversely affect the daytime functioning of a child and impact on family life (Hollway & Aman, 2011).

Current guidance on management of insomnia in children proposes that once physiological reasons for sleep disturbance are excluded, interventions that aim to change parents' management of their child's sleep should be the next step. This guidance is also applicable to children with neurodisability, although the evidence for the effectiveness of behavioural interventions alone is less strong. Pharmacological interventions (such as melatonin) are recommended where such interventions prove ineffective or alongside parent-directed approaches. A growing body of evidence indicates abnormal melatonin secretion and circadian rhythmicity in children with neurodevelopmental disorders, specifically autism, which may explain the abnormal development of sleep–wake cycles, present from the first year of life.

There is a limited number of relevant clinical trials in children and adolescents. Some have focused on sleep-onset insomnia (Armour & Paton, 2004) and have generally found that while melatonin can significantly reduce the time taken to fall asleep (sleep latency) there is no significant change in the total time asleep (Smits et al., 2001). However, in a larger RCT of sleep-onset insomnia in children with ADHD, melatonin treatment was associated with both a significant reduction in sleep latency and a significant increase in the mean total time spent asleep (Van der Heijden et al., 2007) and this finding has been replicated in a further RCT (Jalilolghadr et al., 2022).

Other studies have focused on children with neurodevelopmental conditions (Phillips & Appleton, 2004; Sajith & Clarke, 2007, Rossignol & Frye, 2014). A double-blind, placebo-controlled RCT of immediate-release melatonin found only a limited benefit for sleep problems in such children: while the participants fell asleep significantly faster, waking times became earlier (Gringras et al., 2012). However, a placebo-controlled crossover RCT of controlled-release melatonin treatment found improvement in both delayed sleep phase syndrome and total sleep time in children with neurodevelopmental difficulties who had delayed sleep phase/impaired sleep maintenance (Wasdell et al., 2008). A double-blind, placebo-controlled crossover RCT by Weiss et al. (2006) found that a combined sleep hygiene and melatonin intervention was a safe and effective treatment for initial insomnia in children with ADHD taking stimulant medication. Another double-blind, placebo-controlled RCT found prolonged-release melatonin to be an efficacious and safe treatment for insomnia in children with autism spectrum disorder, improving sleep latency, total sleep time and the longest sleep period (Gringras et al., 2017). The same study found that as the children's sleep improved, there was a reduction in daytime hyperactivity and an improvement in caregivers' quality of life (Schroder et al., 2019).

Melatonin appears to be well tolerated and, for children with neurodevelopmental disorders (van der Heijden et al., 2007; Hoebert et al., 2009), only mild transient adverse effects, such as headache, hyperactivity, dizziness, and abdominal pain, have been reported in the short to medium-term (Garstang & Wallis, 2006; Gringras et al., 2012; Buckley et al., 2020).

In the UK, melatonin is a prescription only medicine. Melatonin has a more extensive evidence base than any other drug used for paediatric sleep disorder and there are licenced preparations for children with ASD and ADHD. Although melatonin may also be an appropriate treatment for typically developing children with insomnia refractory to behavioural interventions, there are no preparations licensed for this indication (Janjua & Goldman, 2016; Rolling et al., 2022).

Unlicensed melatonin products are also available, but there is no standard formulation, raising the possibility of variability in both product quality and clinical effect. If a prescription is not for a licensed indication or for an unlicensed product, the prescriber should provide the patient and/or carers with sufficient information to allow them to make an informed decision about this 'off-label' use of melatonin (Drug and Therapeutics Bulletin, 2015).

There also seems to be an emerging consensus that for children with circadian rhythm disorders, particularly delayed sleep phase syndrome, melatonin, with regular follow-up and assessment, can be a useful treatment (Drug and Therapeutics Bulletin, 2015, Abdelgadir et al., 2018), particularly in those with neurodevelopmental disorders (Bruni et al., 2019).

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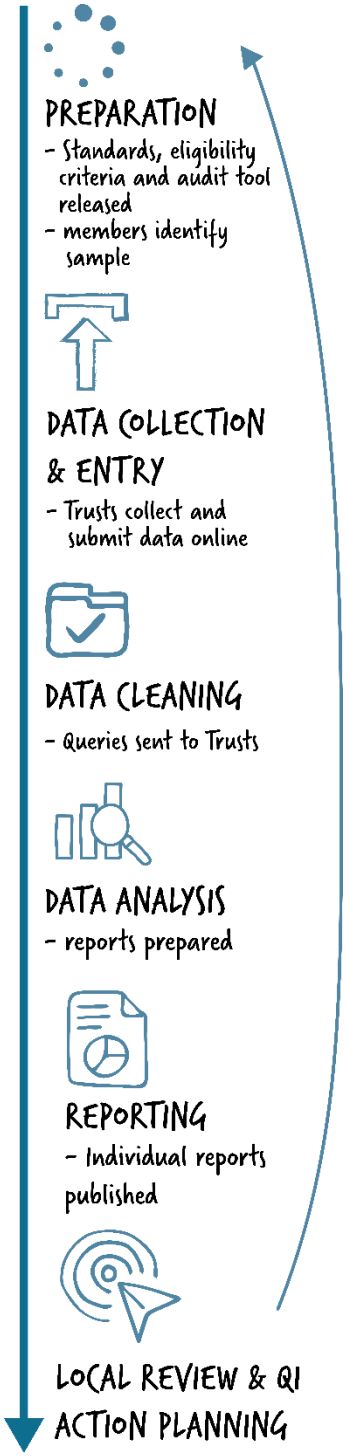
Method

A clinical records audit was conducted for patients prescribed melatonin under the care of CAMHS, community paediatrics or learning disability services. A questionnaire/audit tool was sent out to all Trusts/healthcare organisations with instructions that copies should be made available to allow clinical teams to audit prescribing practice for a sample of patients who were currently being treated with melatonin medication (See Appendix D).



Submission of data

Each Trust was allocated a code number that was known only to the Trust and POMH. Trusts were asked to allocate codes to participating services and eligible patients and, if they wished to, individual consultants. The key to these codes is held by the Trust and is not known to POMH. Data coded in this way were entered onto an internet-based form and submitted to POMH via a secure website.

Ownership of data submitted to POMH is retained by the Trust that provided it. See Appendix A for further information on data ownership.

Data collection

A copy of the data collection tool used for this audit can be found in Appendix D.

All Trusts and clinical teams were self-selected in that they chose to participate. All the participating Trusts/healthcare organisations are listed alphabetically in Appendix B.

Data cleaning

Data were collected using FORMIC (electronic survey software).

Data were cleaned to correct instances of obvious data entry error. Details of corrections are held on file by POMH; please contact pomh-uk@rcpsych.ac.uk if you wish to examine these.

Data analysis

As in previous reports, the data were analysed at three levels:

1) **National level.** This section describes the demographic and clinical characteristics of patients in the total national sample. The data relating to prescribing practice were analysed in a variety of ways to facilitate understanding of the national picture and stimulate discussion in participating clinical teams.
2) **Trust level.** The analyses conducted on the national data were repeated for each Trust/healthcare organisation that submitted audit data. This allows Trusts to compare their performance against the practice standards with the performance of the other, anonymous, participating Trusts.
3) **Clinical service level.** This analysis allows Trusts and individual clinical teams to compare their practice with each other and against the national data.

All the figures presented are rounded up (no decimal places) for simplicity, so in some of the tables and figures in the report the total percentages may add up to 99% or 101%.

The POMH Lead for each participating Trust will be sent an Excel dataset containing their Trust's data. This allows Trusts to analyse their local data further, should they wish to do so.

National level results

This section includes the demographic and clinical characteristics of the total national sample.

The findings of the data analyses are presented in graphs and tables, primarily to show the extent to which clinical prescribing across the participating services is meeting the practice standards.

61 Trusts/healthcare organisations submitted data on the treatment of 5097 patients who were prescribed melatonin. 2732 (54%) of these patients were under the care of a CAMHS team, 1206 (24%) a community paediatrics team and 1159 (23%) a learning disability team. The demographic and clinical characteristics of the total national sample and each of the three clinical subsamples are shown in Tables X and Y below.

Demographic and clinical characteristics

Table 1: Demographic characteristics. Total national sample (n = 5097) and three service subsamples

As might be expected, almost all patients under the care of CAMHS and community paediatric services were 18 years of age or younger and one patient in eight in the latter clinical subsample was 5 years of age or younger. The learning disability subsample was also relatively young, with a median age of 24 years. Almost two-thirds of patients in the total national sample were male.

Key demographic variables			CAMHS team	Community paediatrics team	Learning disability team	TNS
n(%)			n = 2732	n = 1206	n = 1159	n = 5097
Sex	Male		1592 (58)	856 (71)	761 (66)	3209 (63)
	Female		1140 (42)	350 (29)	398 (34)	1888 (37)
Ethnicity	White/White British		1964 (72)	903 (75)	909 (78)	3776 (74)
	Black/Black British		39 (1)	24 (2)	20 (2)	83 (2)
	Asian/Asian British		65 (2)	41 (3)	81 (7)	187 (4)
	Mixed or other		187 (7)	72 (6)	38 (3)	297 (6)
	Not collected/stated/refused		477 (17)	166 (14)	111 (10)	754 (15)
Age in years	Median age		15	10	24	15
	Age range		3 - 21	1 - 19	1 - 82	1 - 82
	Age bands	5 years or younger	5 (<1)	149 (12)	3 (<1)	157 (3)
		6 to 12 years	613 (22)	681 (56)	87 (8)	1381 (27)
		13 to 18 years	2093 (77)	372 (31)	148 (13)	2613 (51)
		19 to 25 years	21 (1)	4 (<1)	414 (36)	439 (9)
		26 to 30 years	-	-	169 (15)	169 (3)
		31 to 40 years	-	-	116 (10)	116 (2)
		Over 40 years	-	-	222 (19)	222 (4)

Table 2: Clinical diagnoses. Total national sample (n = 5097) and three service subsamples

Just over half of the total national sample had a diagnosis of an autistic spectrum disorder and over a third ADHD. As might be expected, a diagnosis of learning disability was much more common in the subsample under the care of learning disability services, affective and anxiety spectrum disorders more common in the CAMHS subsample and primary sleep disorders more common in the community paediatrics subsample.

Almost one in ten in the total national sample had a diagnosis of epilepsy. There were only a small number of patients with specific genetic diagnoses known to be associated with disordered sleep.

Clinical diagnoses n(%)	CAMHS team n = 2732	Community paediatrics team n = 1206	Learning disability team n = 1159	TNS n = 5097
Psychiatric diagnoses				
Autism/autistic spectrum disorder (F84)	1273 (47)	685 (57)	771 (67)	2729 (54)
Hyperkinetic disorders including ADHD (F90)	1268 (46)	393 (33)	242 (21)	1903 (37)
Anxiety, dissociative, stress-related, somatoform and other nonpsychotic mental disorders (F40-F48)	905 (33)	78 (6)	219 (19)	1202 (24)
Mood (affective) disorders (F30-F39)	448 (16)	9 (1)	124 (11)	581 (11)
Tic disorders (F95)	136 (5)	25 (2)	16 (1)	177 (3)
Other behavioural and emotional disorders with onset usually occurring in childhood and adolescence (F91, F92, F93, F94, F98, F99)	261 (10)	77 (6)	44 (4)	382 (7)
Other behavioural syndrome (F50, F52-59)	73 (3)	12 (1)	14 (1)	99 (2)
Intellectual disability				
Mild intellectual disability (F70)	101 (4)	28 (2)	266 (23)	395 (8)
Moderate intellectual disability (F71)	76 (3)	71 (6)	323 (28)	470 (9)
Severe/profound intellectual disability (F72,F73)	64 (2)	97 (8)	449 (39)	610 (12)
Other or unspecified intellectual disability (F78, F79)	78 (3)	154 (13)	76 (7)	308 (6)
Sleep related disorders				
Circadian rhythm sleep disorders, including delayed sleep phase syndrome (G47.2)	181 (7)	198 (16)	89 (8)	468 (9)
Other insomnia (Other F51)	161 (6)	184 (15)	92 (8)	437 (9)
Parasomnias, including night terrors and sleep walking (G47/G51/F51.4)	18 (1)	30 (2)	8 (1)	56 (1)
Sleep related breathing disorders, including sleep apnoea (G47.3)	8 (<1)	21 (2)	16 (1)	45 (1)
Hypersomnias, including narcolepsy (G47.1)	11 (<1)	1 (<1)	-	12 (<1)
Sleep-related movement disorders, including restless legs syndrome (G25.81)	3 (<1)	5 (<1)	2 (<1)	10 (<1)
Chromosomal abnormalities				
Down syndrome (Q90)	5 (<1)	9 (1)	72 (6)	86 (2)
Smith-Magenis syndrome (Q93.88)	1 (<1)	-	13 (1)	14 (<1)
Tuberous sclerosis (Q85.1)	2 (<1)	1 (<1)	10 (1)	13 (<1)
Angelman's syndrome (Q93.51)	-	1 (<1)	10 (1)	11 (<1)
Rett's syndrome (F84.2)	2 (<1)	1 (<1)	4 (<1)	7 (<1)
Williams syndrome (Q93.82)	2 (<1)	1 (<1)	1 (<1)	4 (<1)
Other congenital malformations, deformations and chromosomal abnormalities	71 (3)	118 (10)	139 (12)	328 (6)
Epilepsy				
Diagnosis of epilepsy	54 (2)	93 (8)	334 (29)	481 (9)
Diagnosis of epilepsy being considered	19 (1)	16 (1)	26 (2)	61 (1)

Performance against practice standard 1

Evidence-based, non-pharmacological interventions should be tried before melatonin is prescribed

In the total national sample, 491 patients had been treated with melatonin for less than three months. It was documented in the clinical records that non-pharmacological interventions had been tried prior to prescribing melatonin in just over two-thirds of cases, most commonly that advice was given about sleep hygiene. Although not shown in the Figure, performance against this standard was similar across the three clinical subsamples.

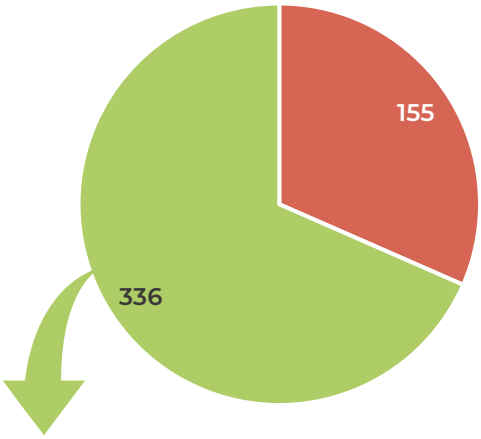


Figure 9: Documentation of non-pharmacological treatment interventions before melatonin was prescribed. National subsample of patients prescribed melatonin for less than three months (n = 491)

Non-pharmacological interventions documented n(%)	TNS n = 336
Advice given about establishing a standard bed-time regimen	264 (79)
Advice given about the bedroom environment	256 (76)
Advice given to keep a sleep diary	124 (37)
Advice given about limiting caffeine	90 (27)
General sleep hygiene advice	50 (15)
Advice given about limiting alcohol	33 (10)
Other patient specific intervention	17 (5)
CBTi cognitive behavioural therapy for insomnia	10 (3)
Replace previous sedative medication	8 (2)
A trial of analgesic medication to exclude pain	3 (1)

Table 3: The non-pharmacological interventions documented before melatonin was prescribed. National subsample of patients prescribed melatonin for less than three months who had a documented non-pharmacological intervention (n = 336)

Prior to prescribing melatonin, discretionary clinical investigations/tests such as an ECG (4 cases), actigraphy (1 case) and polysomnography (1 case) had rarely been documented.

Very few patients had received CBTi despite some promising evidence for efficacy in school-age children and adolescents (Dewald-Kaufman et al., 2019).

Trusts may wish to check whether prepared advice about sleep hygiene, suitable for clinicians to share with parents and carers, is readily available in settings where patients are seen; for example, written advice may be provided via a printed leaflet, by sharing a web-link, or in the form of an electronic document that can be e-mailed.

Melatonin medication regimen and reasons for use

Melatonin was prescribed to be administered on a regular basis in the vast majority of cases. Around one patient in ten was prescribed melatonin on a PRN (as required) basis only.

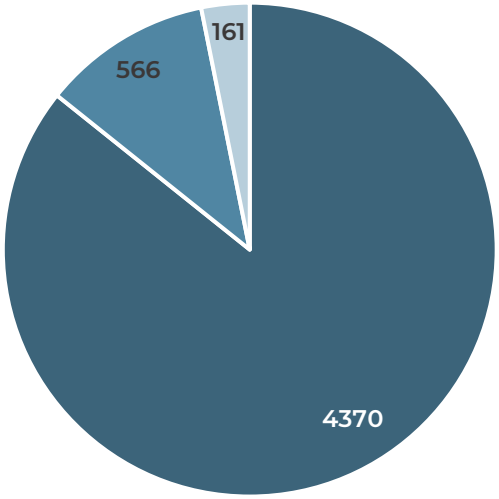


Figure 10: Regular and PRN prescriptions of melatonin. Total national sample (n = 5097)

- For regular use/administration only
- For PRN administration only
- For both regular and PRN administration

As might be expected, melatonin was prescribed to be taken at bedtime in the vast majority of cases.

The most commonly prescribed brand of melatonin was Circadin (n = 2683; 53%). Melatonin was prescribed generically in 1490 (29%) of cases; the exact preparation supplied against these prescriptions being determined by the supplying pharmacist.

Melatonin brand	n(%)
Circadin	2683 (53)
Generic prescription (brand not specified)	1490 (29)
Slenyto	373 (7)
Melatonin Colonis	356 (7)
Other licensed preparation	83 (2)
Unlicensed preparation	112 (2)

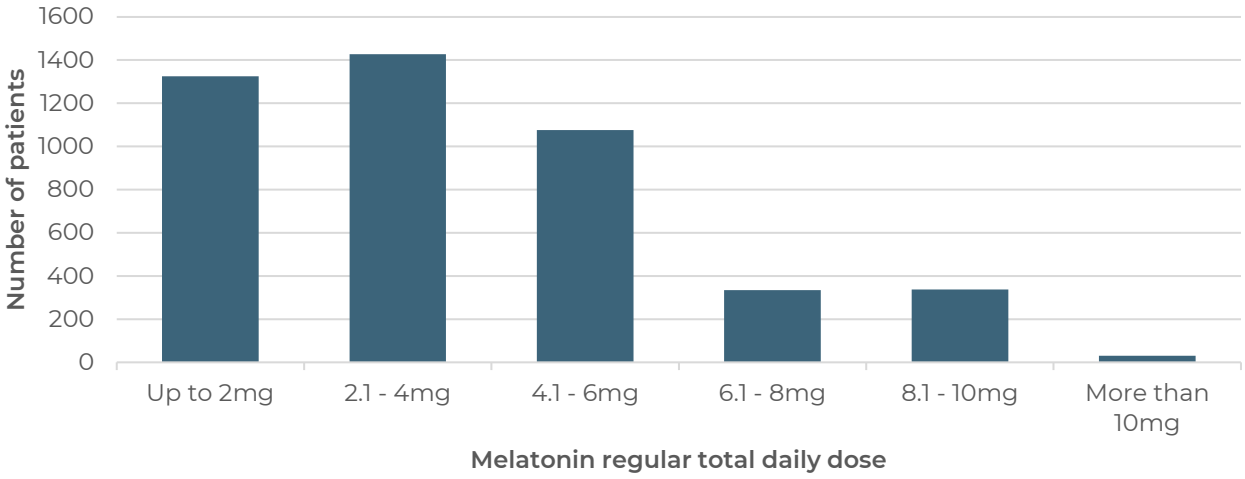
Table 4: Brands of melatonin prescribed. Total national sample (n = 5097)

In the vast majority of cases (n = 4555, 89%), a controlled release preparation (branded or generic, regular or PRN prescription) was prescribed.

The licensed daily maximum dose of melatonin varies widely between brands; for example for Circadin (licensed for insomnia in adults over the age of 55 years) the maximum daily dose is 2mg while for Slenyto (licensed for children/adolescents with a diagnosis of an autistic spectrum disorder or Smith-Magenis syndrome) it is 10mg. Doses higher than the licensed maximum may be used in some cases: a randomised controlled trial of melatonin in children and adolescents with a range of neurological and developmental disorders found that a third of participants required a dose of 12mg (Gringras et al., 2012).

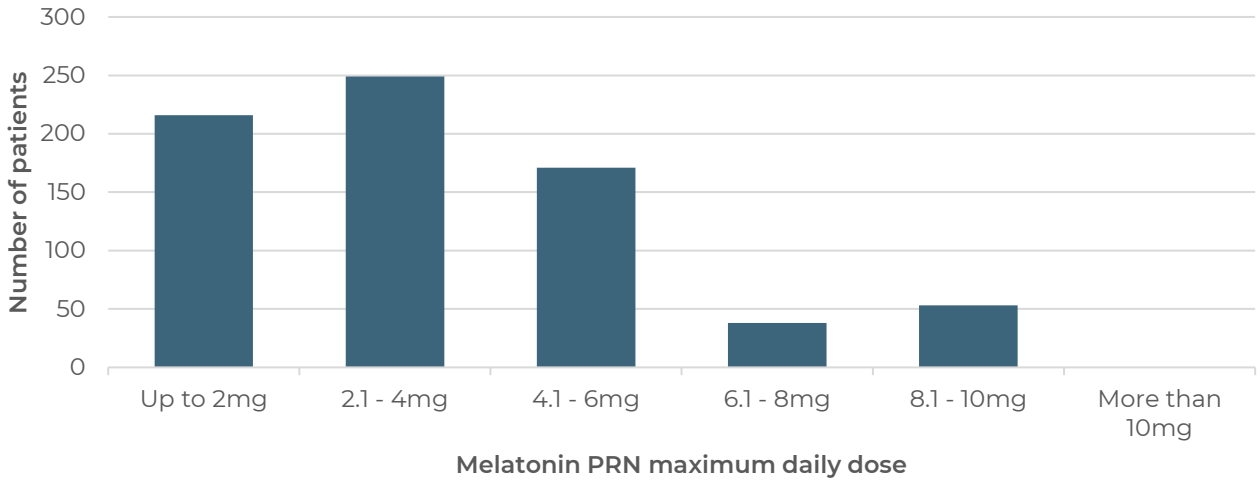
The Figure below shows that where melatonin was prescribed to be administered on a regular basis, 1325 (29%) of prescriptions were for a daily dose of 2mg or less and only 31 (1%) were for a daily dose greater than 10mg.

Figure 11: Total daily dosages of regular prescriptions for melatonin. National subsample of patients with such prescriptions (n = 4531)



Where melatonin was prescribed on a PRN basis, the dosage distribution was very similar to that shown above for regular use.

Figure 12: Maximum daily dosages of PRN prescriptions for melatonin. National subsample of patients with such prescriptions (n = 727)



Other medications prescribed for sleep problems

Another psychotropic medication targeting sleep disturbance was co-prescribed with melatonin for only one patient in ten. Promethazine, a sedative antihistamine, was prescribed in over half of these cases.

Medications currently co-prescribed for sleep disturbance	n(%)
Promethazine	299 (6)
A benzodiazepine	71 (1)
A Z-hypnotic	36 (1)
Guanfacine	33 (1)
Clonidine	29 (1)
Sedative antihistamine other than promethazine	27 (1)
Sedative antidepressant	19 (<1)
Antipsychotic medication	17 (<1)
Chloral	14 (<1)
Trazodone	6 (<1)
Other medication	3 (<1)
Gabapentin	1 (<1)
No medication other than melatonin prescribed for sleep disturbance	4570 (90)

Table 5: Medications currently co-prescribed with melatonin for sleep disturbance. Total national sample (n = 5097)

Promethazine is an antihistamine that is licensed for the treatment of certain allergic conditions, as an anti-emetic, and for short-term use as a sedative in adults and children from the age of 2 years, although what is meant by 'short-term' is not clearly defined in the Summary of Product Characteristics.

Performance against practice standard 2

The target symptoms for melatonin treatment should be documented (e.g. sleep onset, sleep duration, sleep quality

Overall, the target symptoms/clinical reasons for melatonin were not documented for one patient in seven. This makes it difficult to review whether such treatment has had any beneficial effects and should be continued or not.

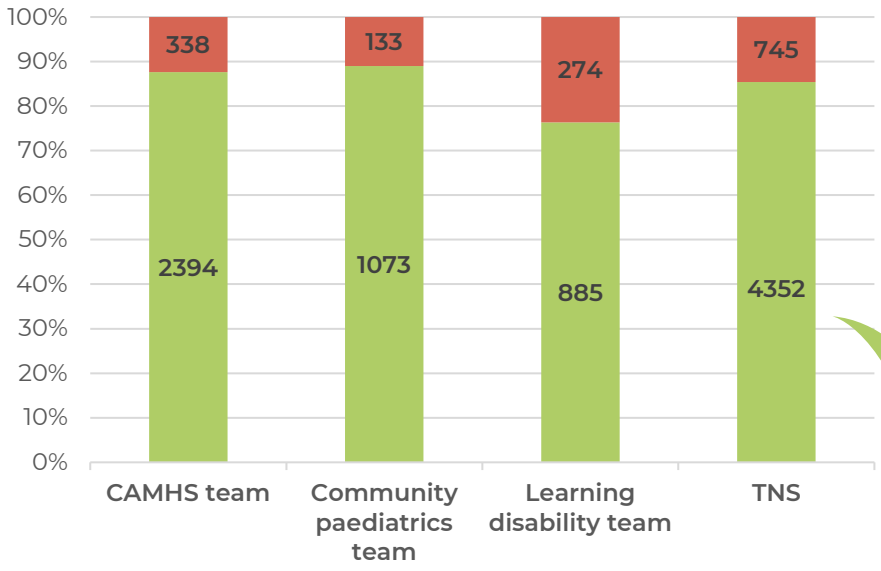


Figure 13: Documented clinical reasons for prescribing melatonin. National service subsamples: CAMHS (n = 2732), community paediatrics (n = 1206), and learning disability (n = 1159)

Overall, where the clinical rationale for prescribing melatonin was documented, this was to reduce sleep latency in four out of every five cases, reduce night-time awakenings in two out of every five, and increase the total duration of sleep in one in three.

Table 6: Documented clinical reasons for regular and PRN prescriptions of melatonin. National subsample of patents for whom such reasons were documented (n = 4352)

Documented clinical reasons for prescribing melatonin* n(%)	For regular use/ administration only n = 3721	For PRN use/ administration only n = 485	For both regular and PRN use/ administration n = 146
To reduce sleep latency (get to sleep quicker)	2878 (77)	393 (81)	118 (81)
To reduce night-time awakenings (improve sleep quality)	1541 (41)	164 (34)	84 (58)
To increase the total duration of sleep (sleep longer)	1258 (34)	137 (28)	59 (40)
To improve day-time behaviour	440 (12)	42 (9)	30 (21)
To improve day-time mood and concentration	416 (11)	61 (13)	25 (17)
As part of the management of ADHD symptoms	347 (9)	39 (8)	24 (16)
To reduce care giver burden improve care giver quality	246 (7)	24 (5)	15 (10)
Non-specific sleep disturbance	135 (4)	27 (6)	1 (1)
As part of the management of delayed sleep phase disorder	138 (4)	13 (3)	3 (2)
Other specific sleep disturbance	25 (1)	1 (<1)	2 (1)

**More than one reason could be documented for each patient.*

Licensed/'off-label' use

The indications for use differ across the licensed melatonin brands with respect to age, dose, diagnosis and duration of use.

The Table below shows the use of such brands within the audit sample for the population for whom each is licensed. The most commonly prescribed brand was Circadin, a controlled release (CR) preparation for which the vast majority of prescriptions were off-label.

Table 7: Licensed melatonin brands and their use. National subsample of patients prescribed licensed brands of melatonin (n = 3495)

Brand (n)	Population for whom the preparation is licensed	n (%)		
		Prescriptions for the licensed population	Off-label use	
			Recognised by Trust	NOT recognised by Trust
Circadin (2683)	Adults aged 55 years or older (CR)	91 (3)	2284 (85)	308 (11)
Slenyto (373)	Children/adolescents aged 2 - 18 years, with a diagnosis of an autism spectrum disorder or Smith-Magenis syndrome (CR)	278 (75)	81 (22)	14(4)
Melatonin Colonis (356)	Licensed only for jet lag	None	356 (100)	None
Syncrodin (49)	Licensed only for jet lag	None	49 (100)	None
Adaflex (23)	Children/adolescents aged 6 - 17 years, with a diagnosis of ADHD	20 (87)	1 (4)	2 (9)
Melatonin Mylan (9)	Adults aged 55 years or older (CR)	None	8 (89)	1 (11)
Melatonin Teva (2)	Adults aged 55 years or older (CR)	None	2 (100)	None

Performance against practice standard 3

A licensed melatonin preparation should be prescribed where possible

The Figure below shows that in all three clinical subsamples, a licensed preparation of melatonin was prescribed for the majority of patients but in only a small proportion were these for the licensed indication. In other words, the vast majority of prescriptions were clearly for off-label indications.

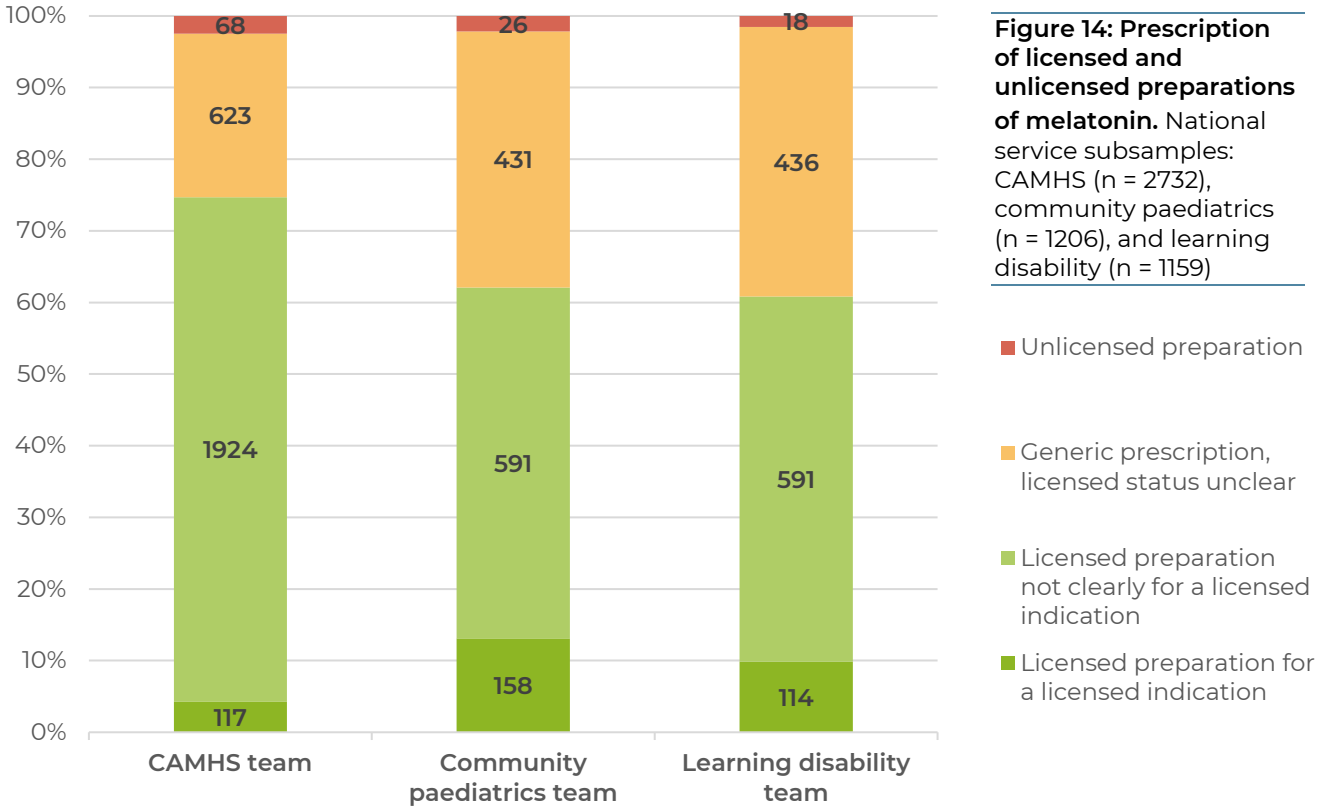


Figure 14: Prescription of licensed and unlicensed preparations of melatonin. National service subsamples: CAMHS (n = 2732), community paediatrics (n = 1206), and learning disability (n = 1159)

Melatonin was prescribed generically in over a quarter of cases. When a medication is prescribed generically, the pharmacy that supplies the medication makes the decision about which preparation to supply. A licensed preparation should be supplied if one is available. Where no licensed preparation exists, an unlicensed preparation may be supplied. The prescriber is therefore unaware of the preparation supplied to the patient against the prescription they have written and there is no guarantee that the same preparation will be supplied each time.

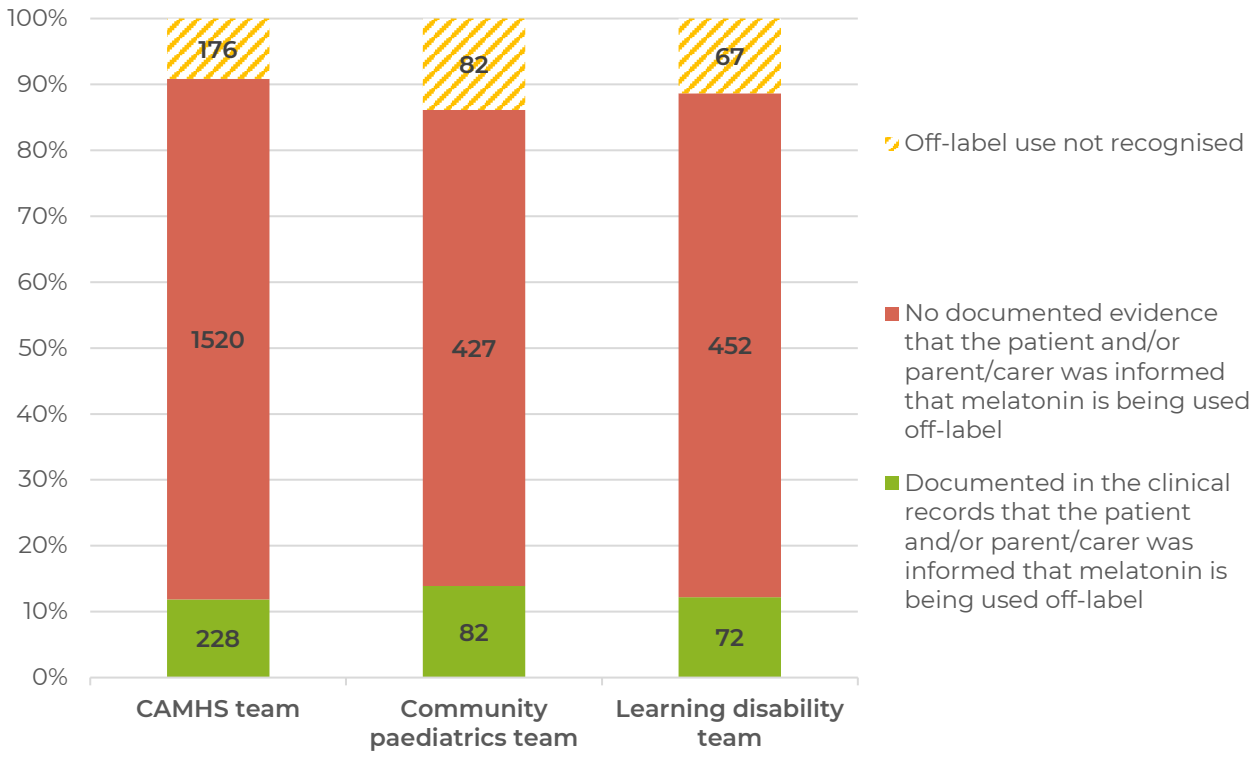
Given the recent increase in the number of licensed preparations of melatonin that are available (including preparations that are specifically licensed for the management of insomnia associated with autism and ADHD in children and adolescents), Trusts may wish to consider encouraging melatonin prescribing by brand. This removes the risk of unlicensed preparations of melatonin being supplied when this was not the specific intention of the prescriber.

Performance against practice standard 4.

If medication is prescribed off-label, there is no legal requirement to tell the patient, but it is generally recommended that a patient/carer should be provided with sufficient information to enable them to give informed consent to any treatment (GMC, 2021; Sharma et al., 2016; Royal College of Psychiatrists, 2017). There are good clinical reasons for such a recommendation. Patients and their carers may well become aware over time that medication is being prescribed outside the licensed indications. For example, the information in the package insert will refer only to the use of the medication for its licensed indications, which will be conditions that the patient does not have (the package insert for Circadin refers only to its use for the treatment of insomnia in adults age 55 years or older). This may be, at best, confusing for patients/carers and, at worst, cause them to lose trust and confidence in their prescriber.

Where melatonin is prescribed off-label, an explanation should be given to the patient and/or parent and/or guardian and/or carer, as appropriate

Figure 15: Documentation of an explanation to a patient/parent/guardian/carer that a melatonin prescription is 'off-label'. Patients with 'off-label' prescriptions for melatonin in the national service subsamples: CAMHS (n = 1924), community paediatrics (n = 591), and learning disability (n = 591)



Given the increasing number of licensed preparations of melatonin that are available (including preparations that are specifically licensed for the management of insomnia associated with autism and ADHD in children and adolescents), appropriate committees within ICSs may like to consider reducing the burden of information-giving on clinicians by: (1) encouraging melatonin to be prescribed by brand within licence and/or: (2) making available standard information that explains why melatonin is being prescribed off-label so that clinicians can share this with patients/carers.

Who prescribes melatonin?

As might be expected, melatonin was most often prescribed by a clinician in the team providing care: a CAMHS doctor in patients under the care of CAMHS, a community paediatrician in patients under the care of community paediatrics, etc.

Table 8: Clinicians with current responsibility for prescribing melatonin. Total national sample (n = 5097)

Current prescriber*	CAMHS team n = 2732	Community paediatrics team n = 1206	Learning disability team n = 1159	TNS n = 5097
GP	845 (31)	478 (40)	566 (49)	1889 (37)
GP as sole prescriber	774 (28)	454 (38)	524 (45)	1752 (34)
Doctor from a CAMHS team	1669 (61)	10 (1)	20 (2)	1699 (33)
Doctor from a community paediatrics team	32 (1)	672 (56)	28 (2)	732 (14)
Doctor from a learning disability team	3 (<1)	3 (<1)	549 (47)	555 (11)
Non-medical prescriber	238 (9)	57 (5)	14 (1)	309 (6)
Paediatrician or other specialist	7 (<1)	5 (<1)	6 (1)	18 (<1)
Not sure or unclear	47 (2)	8 (1)	16 (1)	71 (1)

** More than one clinician was involved in prescribing melatonin in a small number of cases*

A GP was the sole prescriber for more than a third of patients overall.

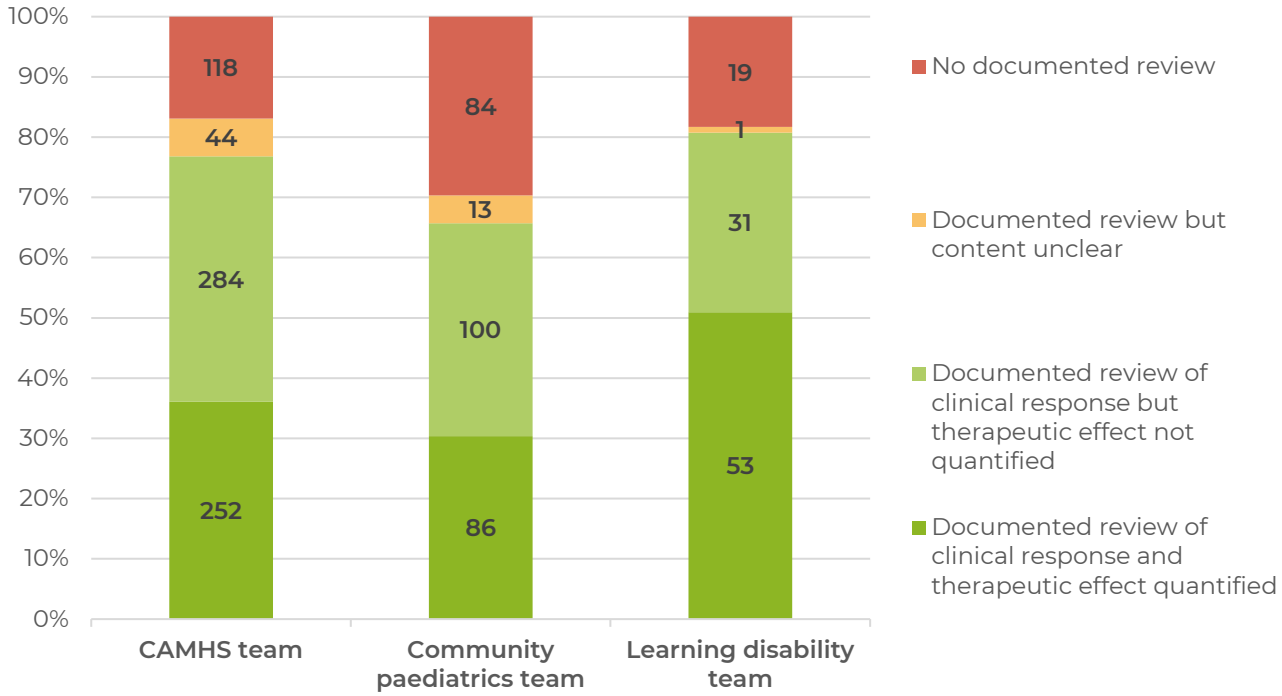
Given that the GP often has sole responsibility for prescribing melatonin, Trusts may wish to review the content of their shared-care guidelines, specifically focusing on who is responsible for monitoring and review and whether the systems they have for communicating patient-specific clinical information between secondary and primary care are effective.

Performance against practice standard 5

The efficacy and safety/tolerability of melatonin medication should be reviewed within 3 months of starting

An early treatment review was documented for 4 patients out of every 5 overall. Such a review was more often documented for patients under the care of CAMHS or learning disability services than for those under the care of a community paediatrics team. Learning disability teams more often quantified the effect of melatonin on sleep, suggesting that these teams conducted more structured reviews of newly initiated melatonin.

Figure 16: Documented clinical review of the therapeutic response to melatonin, within the first three months. Patients in the national service subsamples prescribed melatonin for between 3 months and a year: CAMHS (n = 698), community paediatrics (n = 283), and learning disability (n = 104)



Trusts may like to reflect on local protocols/systems for the systematic and structured review of the clinical benefits and side effects of newly initiated melatonin to ensure that this medication is discontinued if it is not helpful or is poorly tolerated.

Where the clinical effect of melatonin treatment has not been quantified (e.g. gets to sleep 30 minutes earlier, longest period of unbroken sleep increased from 2 to 4 hours), there may not be a shared understanding of the benefits of melatonin amongst the multi-disciplinary team. If the initial benefits are unclear, this makes it more challenging to develop and review a logical treatment plan, potentially resulting in unnecessary long-term treatment for some patients.

The appropriate committees within ICSs may wish to review whether there is adequate resourcing in clinical teams, particularly community paediatric teams, to allow early follow-up of patients for whom a new therapeutic intervention has been initiated.

The Figure below shows that an assessment of the need for continuing treatment was documented in between a quarter and a third of cases suggesting that melatonin treatment may be continued in some cases in the absence of any assessment of the risk-benefit balance for the patient.

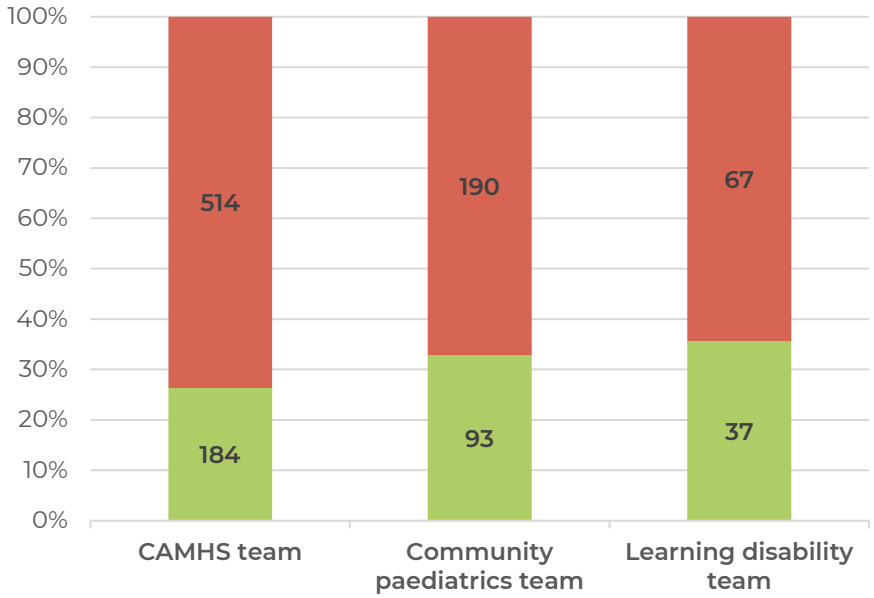


Figure 17: Documented review of the need to continue melatonin, within the first three months. Patients in the national service subsamples prescribed melatonin for between 3 months and a year: CAMHS (n = 698), community paediatrics (n = 283), and learning disability (n = 104)

The Figure below shows that a review of side effects was conducted in between a third and a half of cases depending on the clinical service providing care.

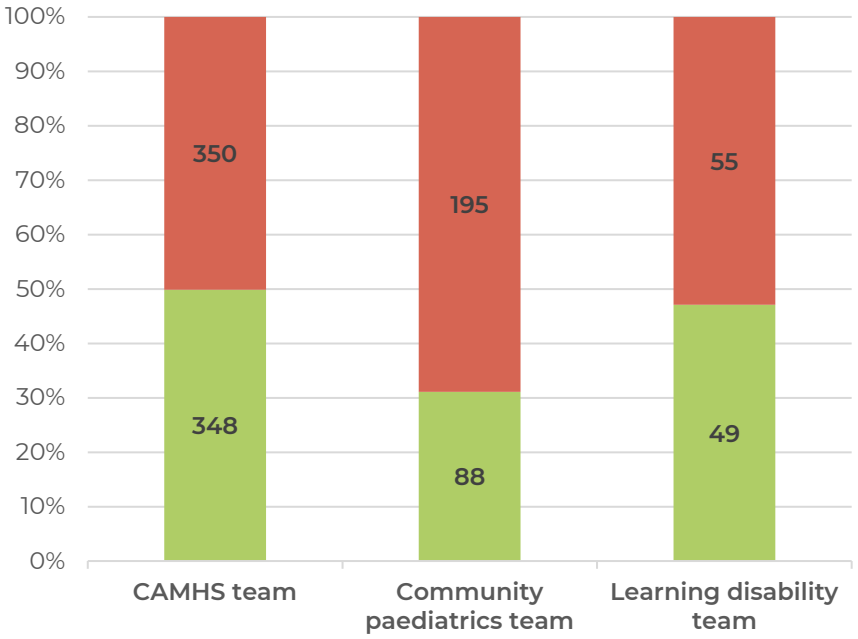


Figure 18: Documented assessment of melatonin side effects, within the first three months. Patients in the national service subsamples prescribed melatonin for between 3 months and a year: CAMHS (n = 698), community paediatrics (n = 283), and learning disability (n = 104)

Where side effects had been reviewed, they were identified very infrequently (for only one patient in twenty) with residual morning sedation, GI symptoms and headache being most common.

Given the high level of off-label use of melatonin and the low level of early on-treatment reviews of side effects, Trusts may like to consider how the identification and management of treatment-emergent side effects can be ensured.

Performance against practice standard 6

The need for continuing melatonin treatment should be reviewed annually, based on efficacy and side effects

For those patients receiving continuing treatment with melatonin, a treatment review had been documented in the last year for just over 4 patients out of every 5 overall.

However, for 1 patient in 5 there was no documented review and therefore no possibility that a treatment break was considered or tried, to determine whether continuing treatment with melatonin was indicated.

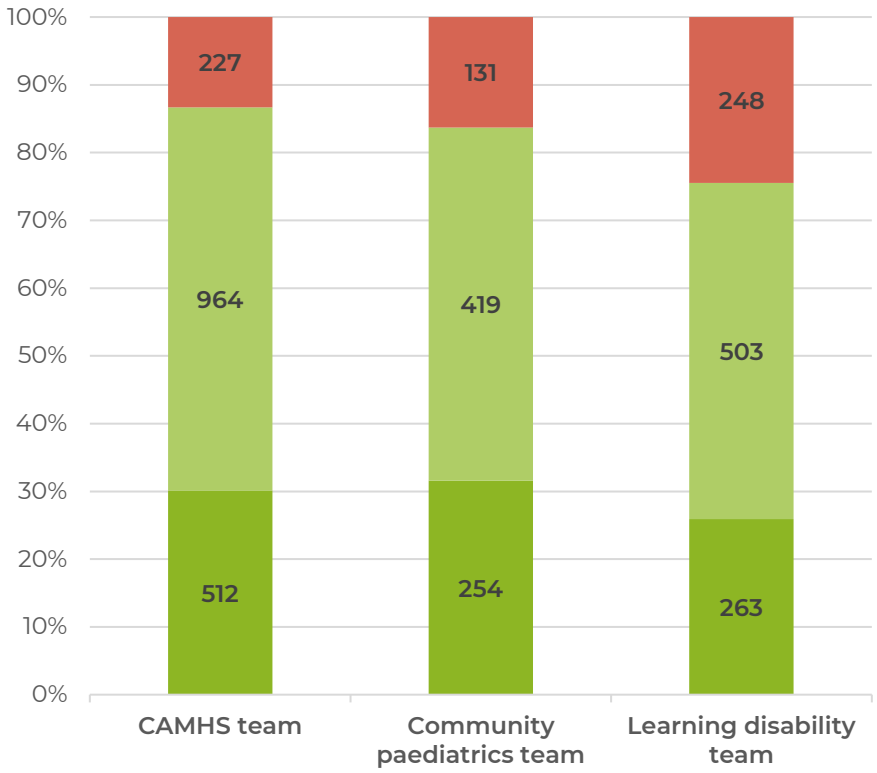


Figure 19: Documented review of the therapeutic effect of melatonin, in the past year. Patients in the national service subsamples prescribed melatonin for more than a year: CAMHS (n = 1703), community paediatrics (n = 804), and learning disability (n = 1014)

Trusts may like to reflect on local protocols/systems for systematically reviewing the clinical benefits and side effects of continuing prescriptions for melatonin to ensure that this medication is discontinued if it is not helpful or is poorly tolerated.

Consistent with early on-treatment reviews, an assessment of the need for continuing treatment was documented in between a third and a half of cases receiving continuing treatment with melatonin.

It should be acknowledged that an audit of clinical records has limitations with regard to assessing whether the need for continuing treatment has actually been assessed. Nevertheless the data shown in the Figure below suggest that clinical documentation of this issue is limited which may have implications for communicating the risk-benefit balance of continuing medication to other clinicians who are or may become involved in the patient's care.

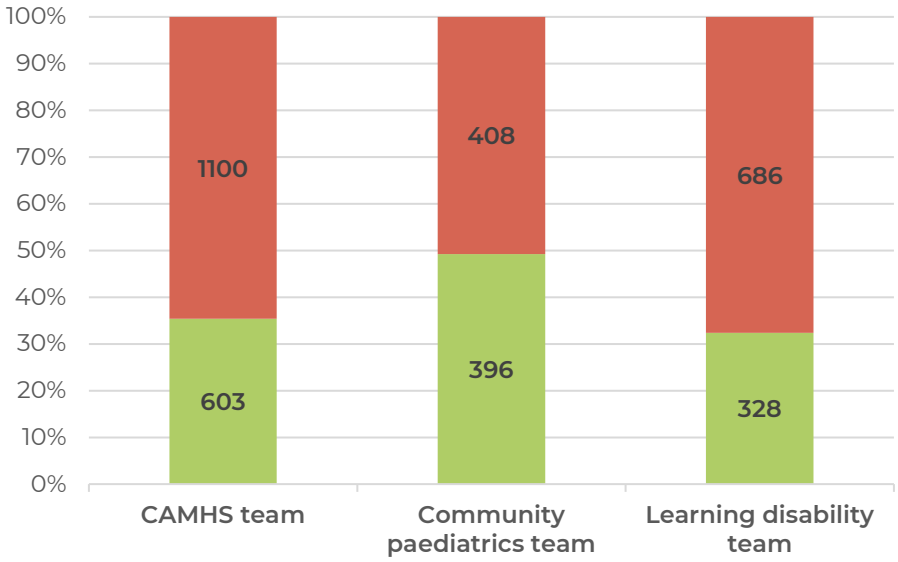


Figure 20: Documented review of the need to continue melatonin, in the past year. Patients in the national service subsamples prescribed melatonin for more than a year: CAMHS (n = 1703), community paediatrics (n = 804), and learning disability (n = 1014)

The Figure below shows that a review of side effects was conducted in the last year in between a quarter and a half of cases depending on the clinical service providing care.

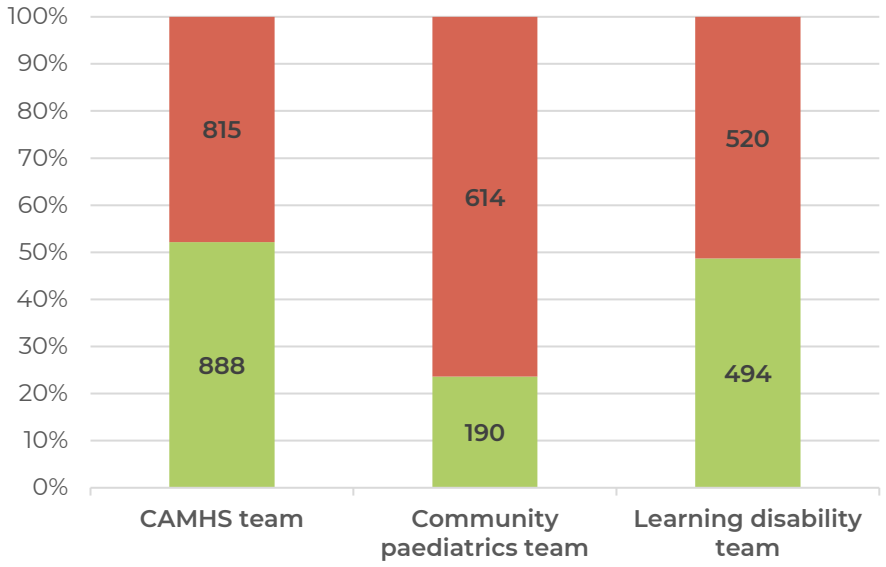


Figure 21: Documented assessment of melatonin side effects, in the past year. Patients in the national service subsamples prescribed melatonin for more than a year: CAMHS (n = 1703), community paediatrics (n = 804), and learning disability (n = 1014)

Where side effects had been reviewed, they were identified very infrequently (for only one patient in thirty) with residual morning sedation, GI symptoms and headache being most common.

Given the long-term off-label use of melatonin, Trusts may like to consider whether the care planning component of their electronic patient record system has a specific field that prompts regular medication review.

Trust level results

Analyses presented in this section were conducted for each Trust individually and for the total sample to allow benchmarking.

Data from each Trust are presented by code.

Your Trust code is: 012

Charts in this section are ordered by performance against the practice standards so the position of your Trust will vary in each figure relative to other Trusts.

Summary of national participation

Trust code	Number of participating teams	Number of cases
002	4	79
003	12	86
005	10	36
006	12	102
008	6	133
009	5	34
012	6	64
013	2	102
015	5	24
016	4	158
018	6	88
020	1	80
021	17	150
025	3	58
027	5	78
029	11	98
031	2	10
034	8	91
040	8	99
042	16	49
050	11	74
054	11	82
056	4	179
059	19	242
062	2	56
063	2	17
064	5	19
065	6	47

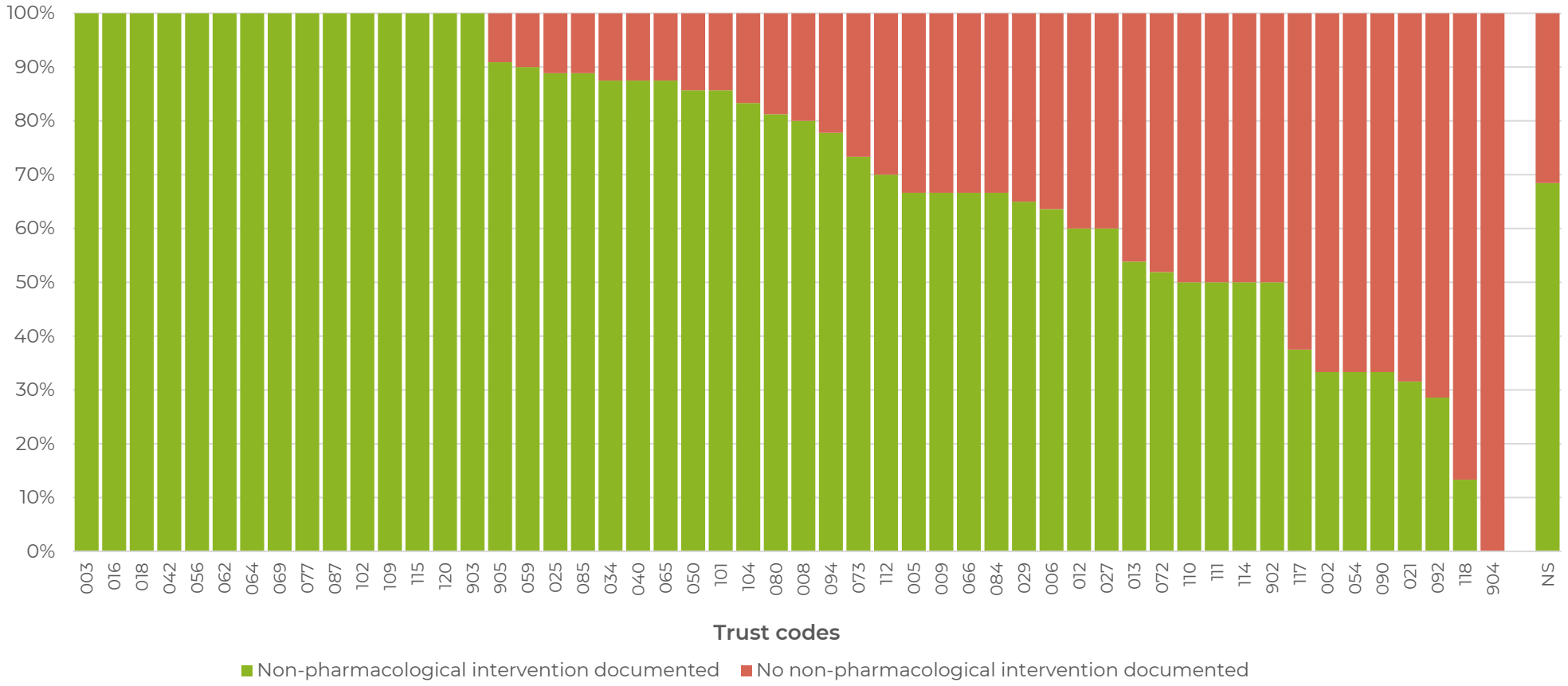
Table 9: The number of participating clinical teams and data submissions for each participating Trust (n = 61)

066	3	66
069	16	93
072	6	342
073	3	168
077	8	127
079	7	48
080	5	115
083	2	5
084	2	67
085	2	111
087	5	70
090	5	67
092	4	227
094	8	70
100	1	7
101	7	109
102	2	14
104	1	73
109	5	91
110	7	17
111	2	26
112	2	44
114	4	75
115	2	16
117	8	147
118	1	212
120	1	12
Community paediatric services not part of mental health Trusts		
902	3	6
903	2	46
904	1	53
905	1	145
906	2	89
907	1	4
61	**332**	**5097**

Performance against practice 1

Evidence-based, non-pharmacological interventions should be tried before melatonin is prescribed

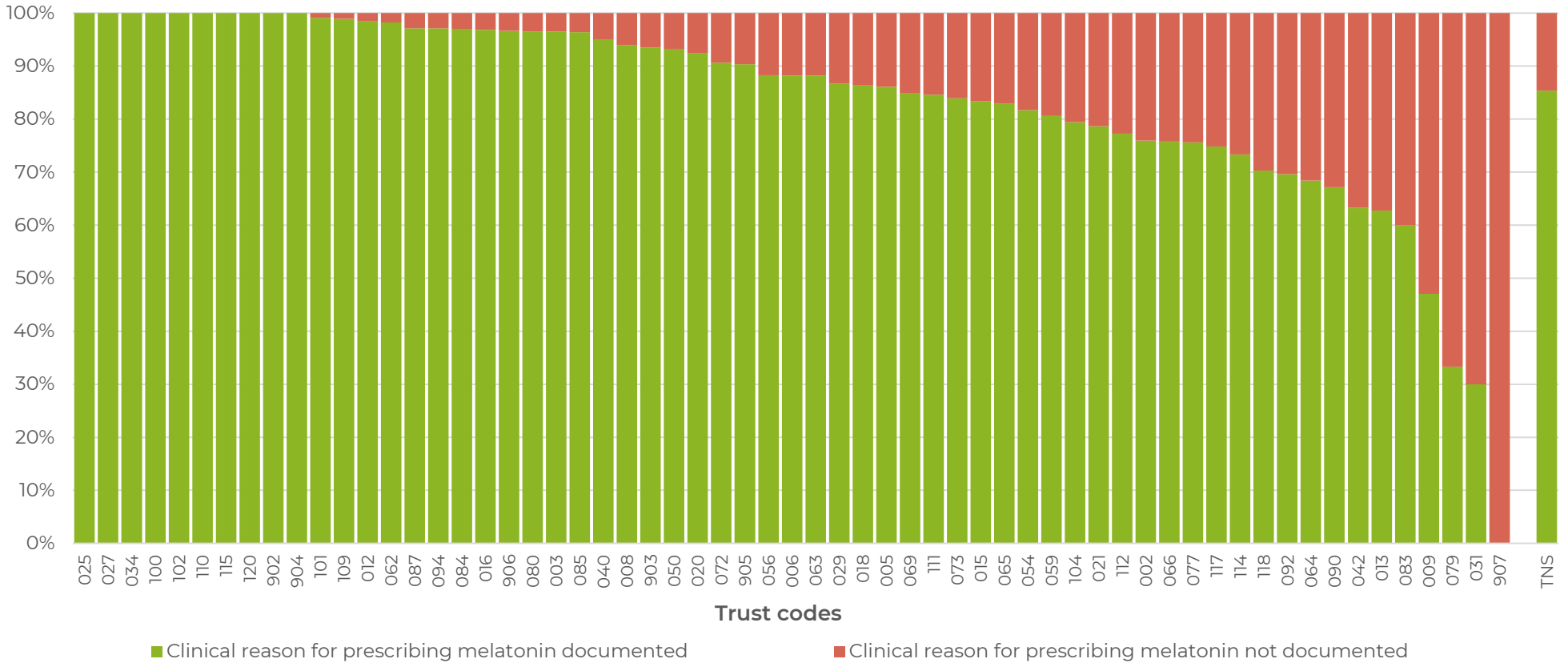
Figure 22: Documentation of non-pharmacological intervention before melatonin was prescribed. National subsample (n = 491) and each participating Trust's subsample



Performance against practice 2

The target symptoms for melatonin treatment should be documented (e.g. sleep onset, sleep duration, sleep quality)

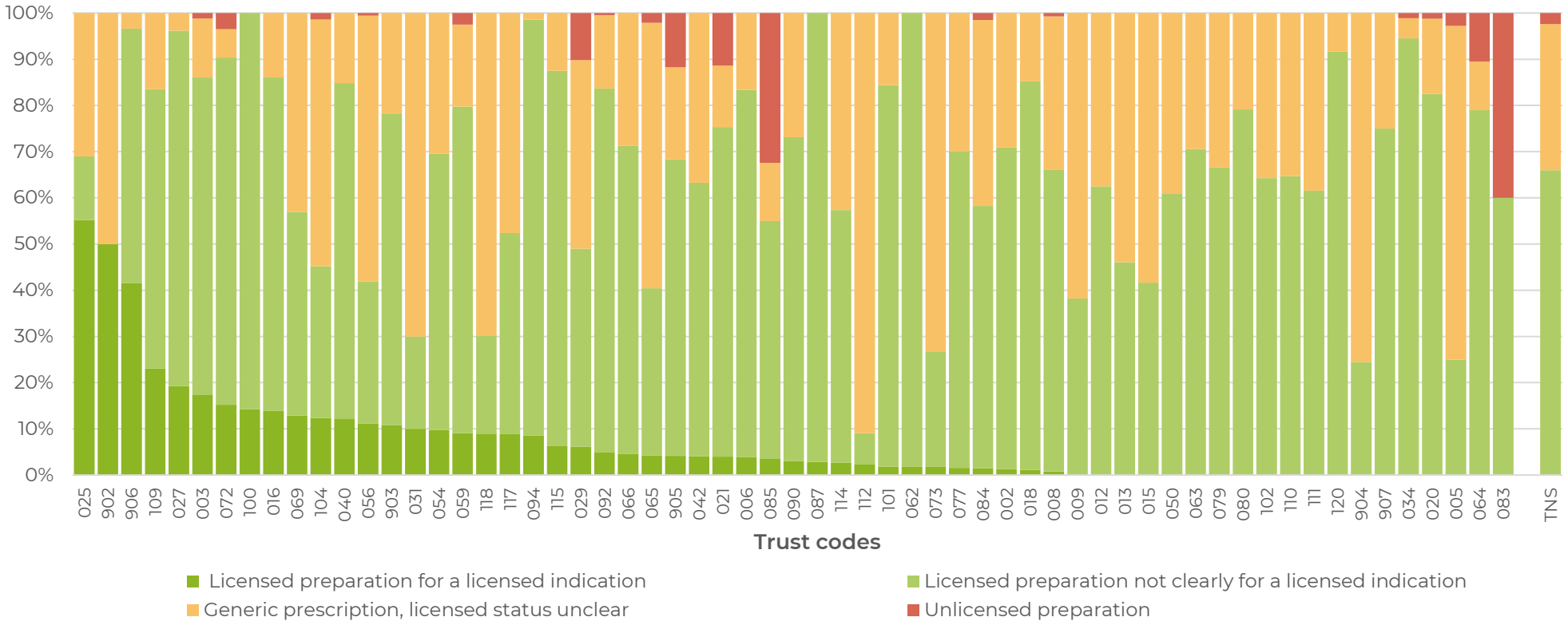
Figure 23: Documentation of the clinical reasons for prescribing melatonin. Total national sample (n = 5097), and each Trust's sample



Performance against practice 3

A licensed melatonin preparation should be prescribed where possible

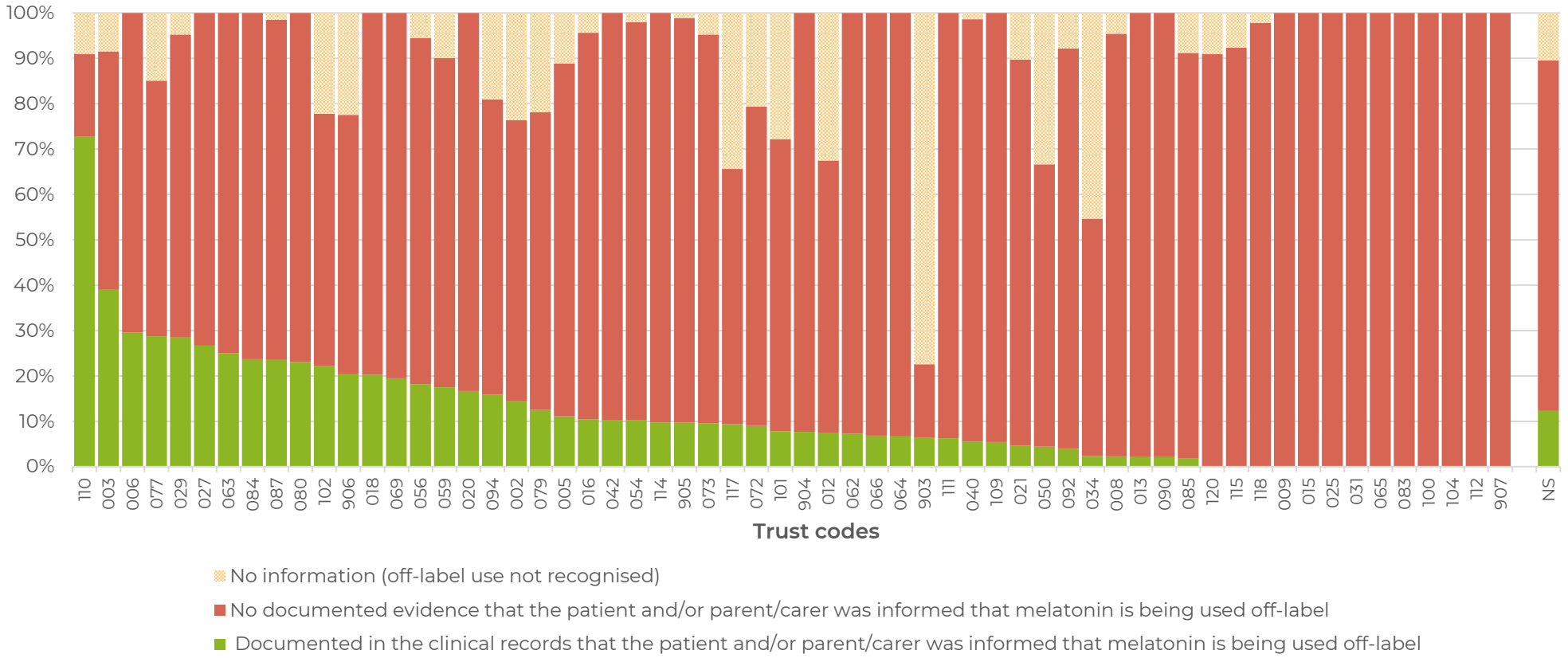
Figure 24: Prescription of licensed and unlicensed preparations of melatonin. Total national sample (n = 5097), and each Trust's sample.



Performance against practice 4

Where melatonin is prescribed off-label, an explanation should be given to the patient and/or parent and/or guardian and/or carer, as appropriate

Figure 25: Documentation of an explanation to a patient/parent/guardian/carer that a melatonin prescription is 'off-label'. National subsample (n = 3106) and each Trust's subsample



Performance against practice 5

The efficacy and safety/tolerability of melatonin medication should be reviewed within 3 months of starting

Figure 26: Documented clinical review of the response to melatonin, within the first three months. National subsample of patients prescribed melatonin for between 3 months and a year (n = 1085), and each Trust's subsample

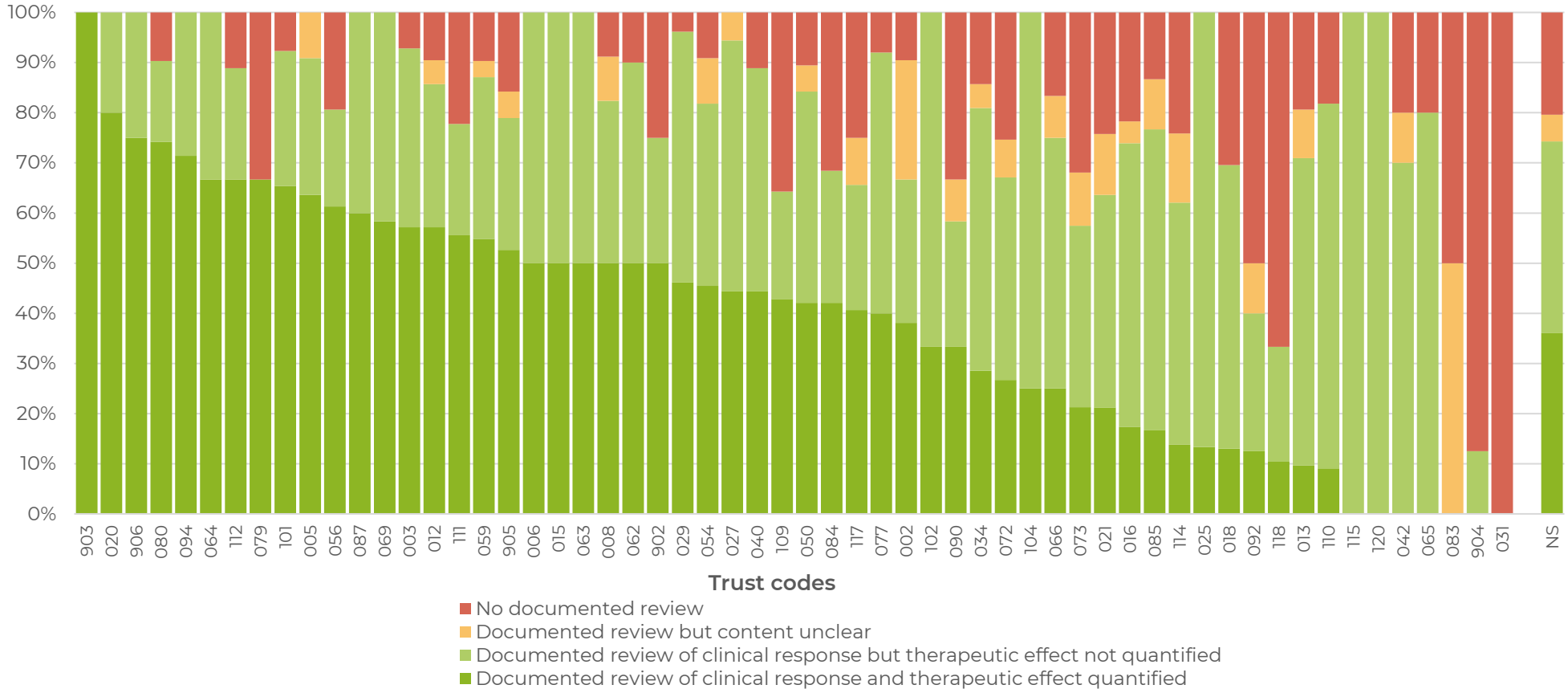


Figure 27: Documented review of side effects within the first 3 months. National subsample of patients prescribed melatonin for between 3 months and a year (n = 1085) and each Trust's subsample

Performance against practice 6

The need for continuing melatonin treatment should be reviewed annually, based on efficacy and side effects

Figure 28: Documented review of the therapeutic effect of melatonin, in the past year. National subsample of patients prescribed melatonin for more than a year (n = 3521), and each Trust's subsample

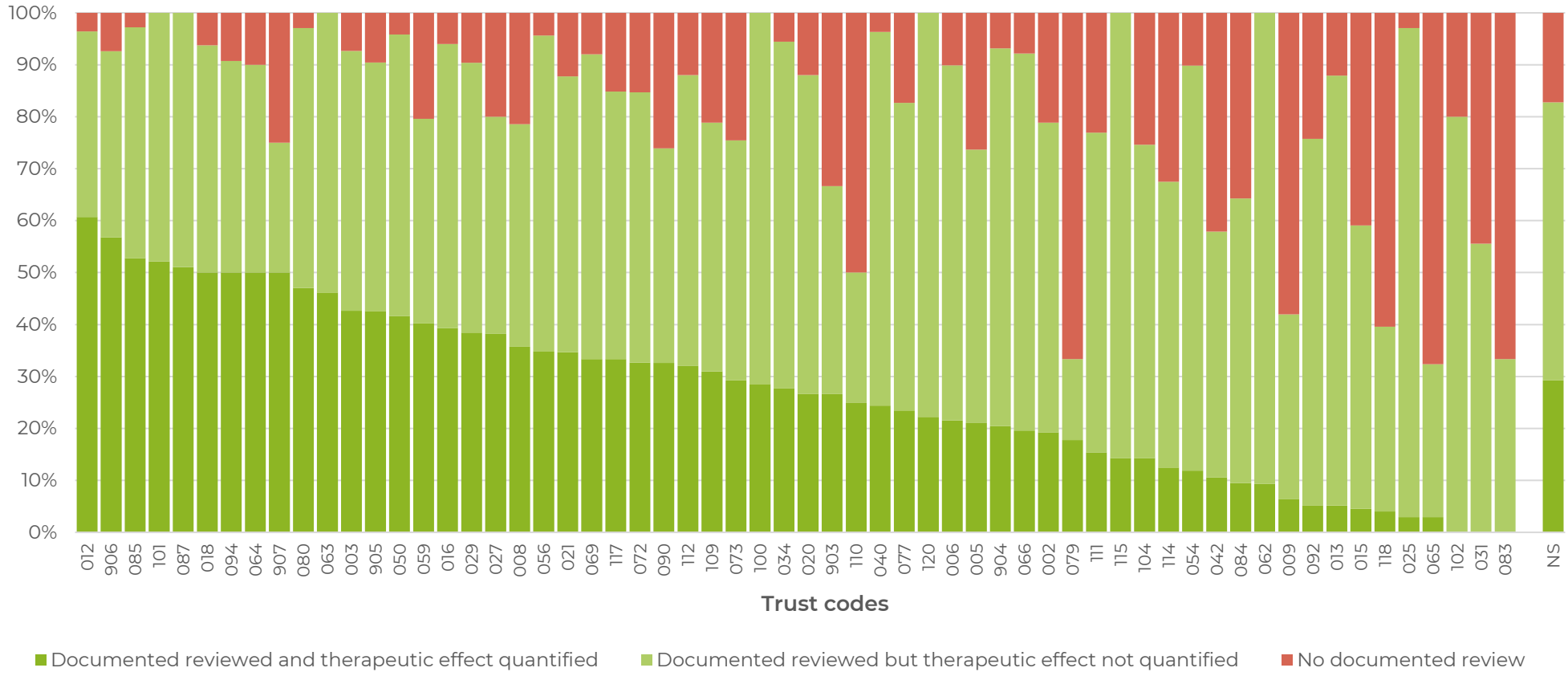
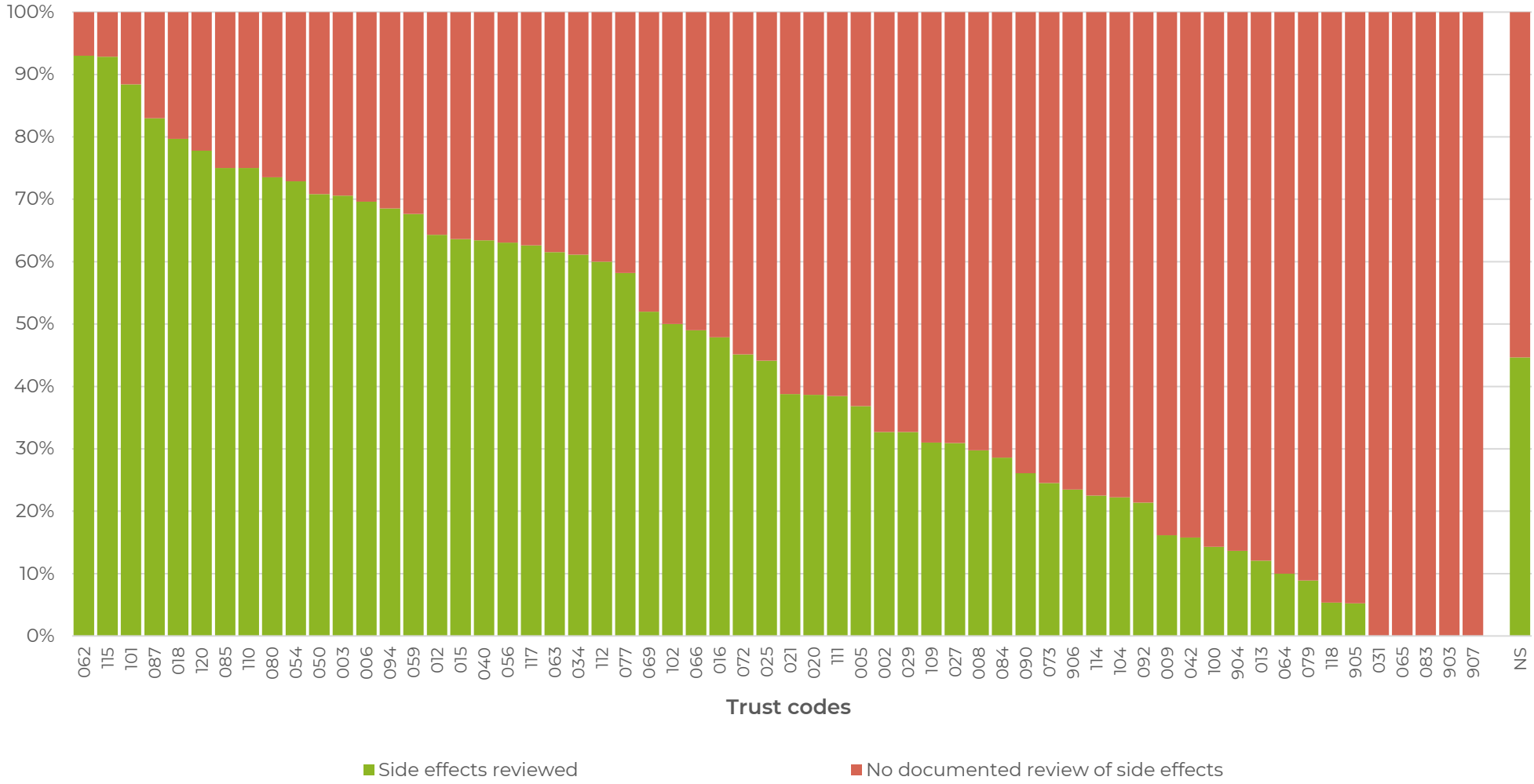


Figure 29: Documented review of side effects in the past year. National subsample of patients prescribed melatonin for more than a year (n = 3521) and each Trust's subsample



Clinical team level results

Analyses presented in this section were conducted for each clinical team from your Trust individually, for your total Trust sample and for the total national sample to allow benchmarking.

Data from each Trust clinical team are presented by code only.

The POMH Central Project Team does not know the identity of individual clinical teams.

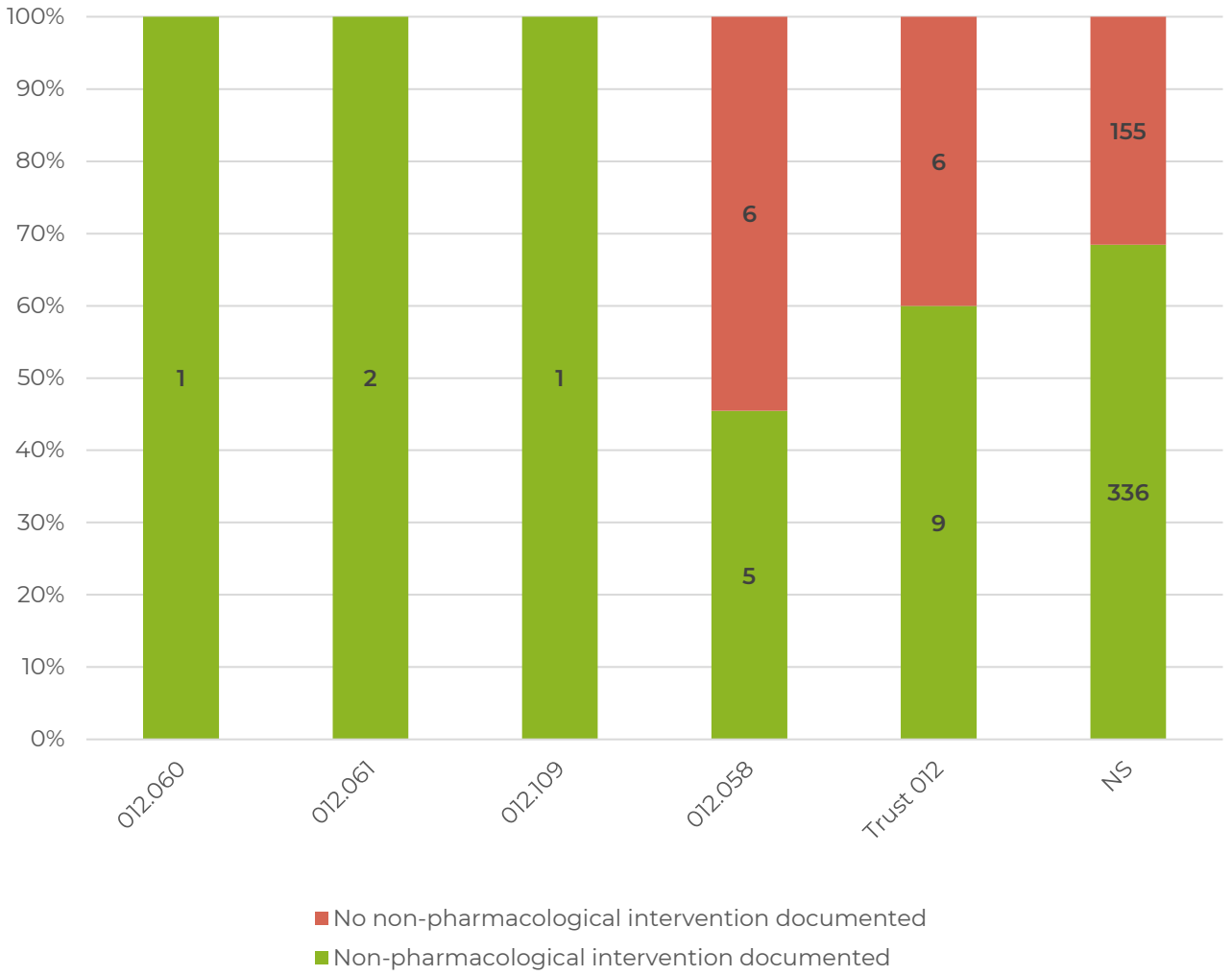
Only the Local POMH lead for your Trust or organisation has the key to clinical team codes. You should contact this person if you need to identify data for your own clinical team.

Charts in this section are ordered by frequency of key results and so the position of teams in each figure will vary.

Performance against practice standard 1

Evidence-based, non-pharmacological interventions should be tried before melatonin is prescribed

Figure 30: Documentation of non-pharmacological interventions before melatonin was prescribed. National subsample of patients prescribed melatonin for less than three months (n = 491) and your Trust's clinical team subsamples



Performance against practice standard 2

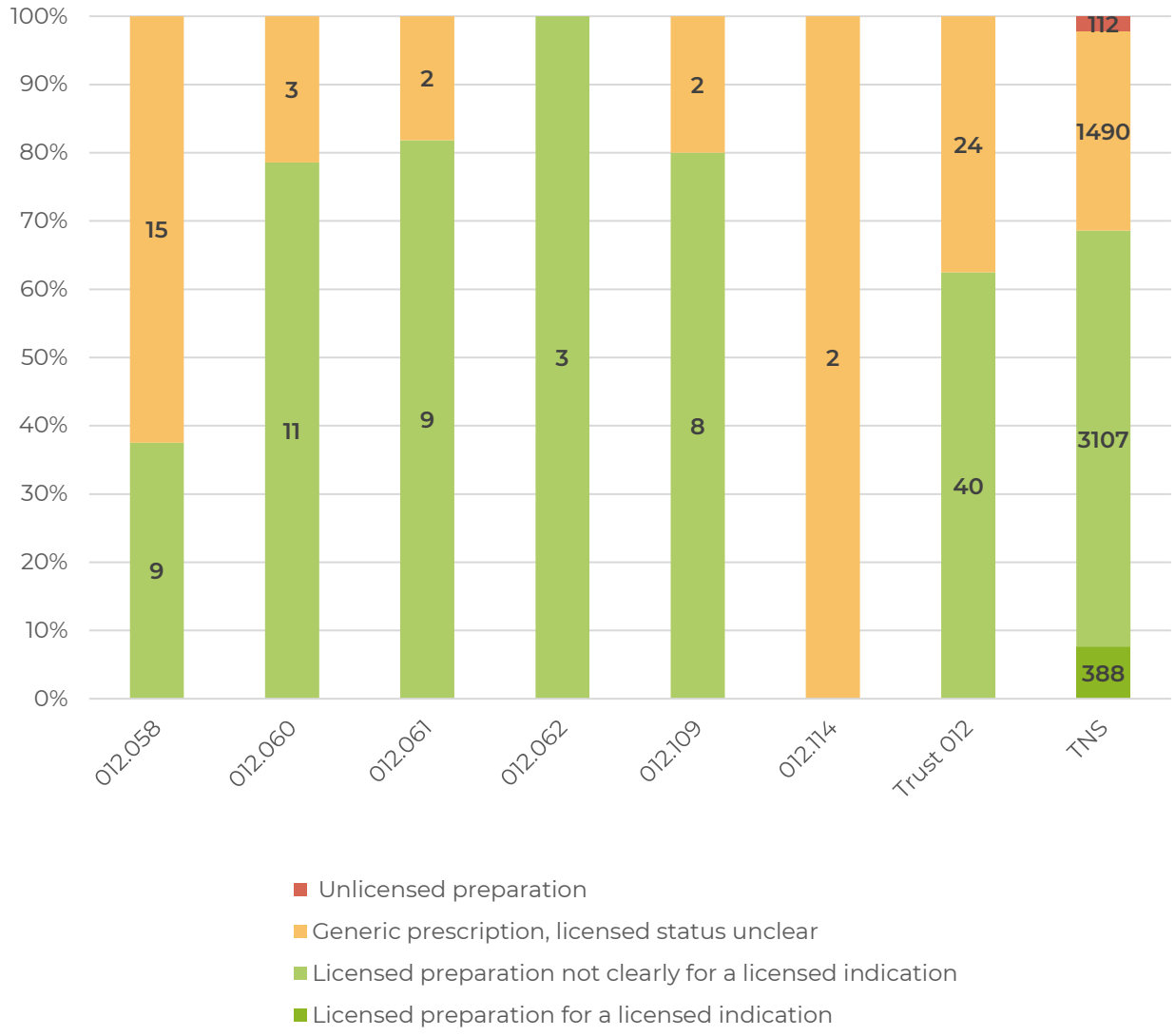
The target symptoms for melatonin treatment should be documented (e.g. sleep onset, sleep duration, sleep quality

Figure 31: Documentation of the clinical reasons for prescribing melatonin. Total national sample (n = 5097), and your Trust's clinical team subsamples

Performance against practice standard 3

A licensed melatonin preparation should be prescribed where possible

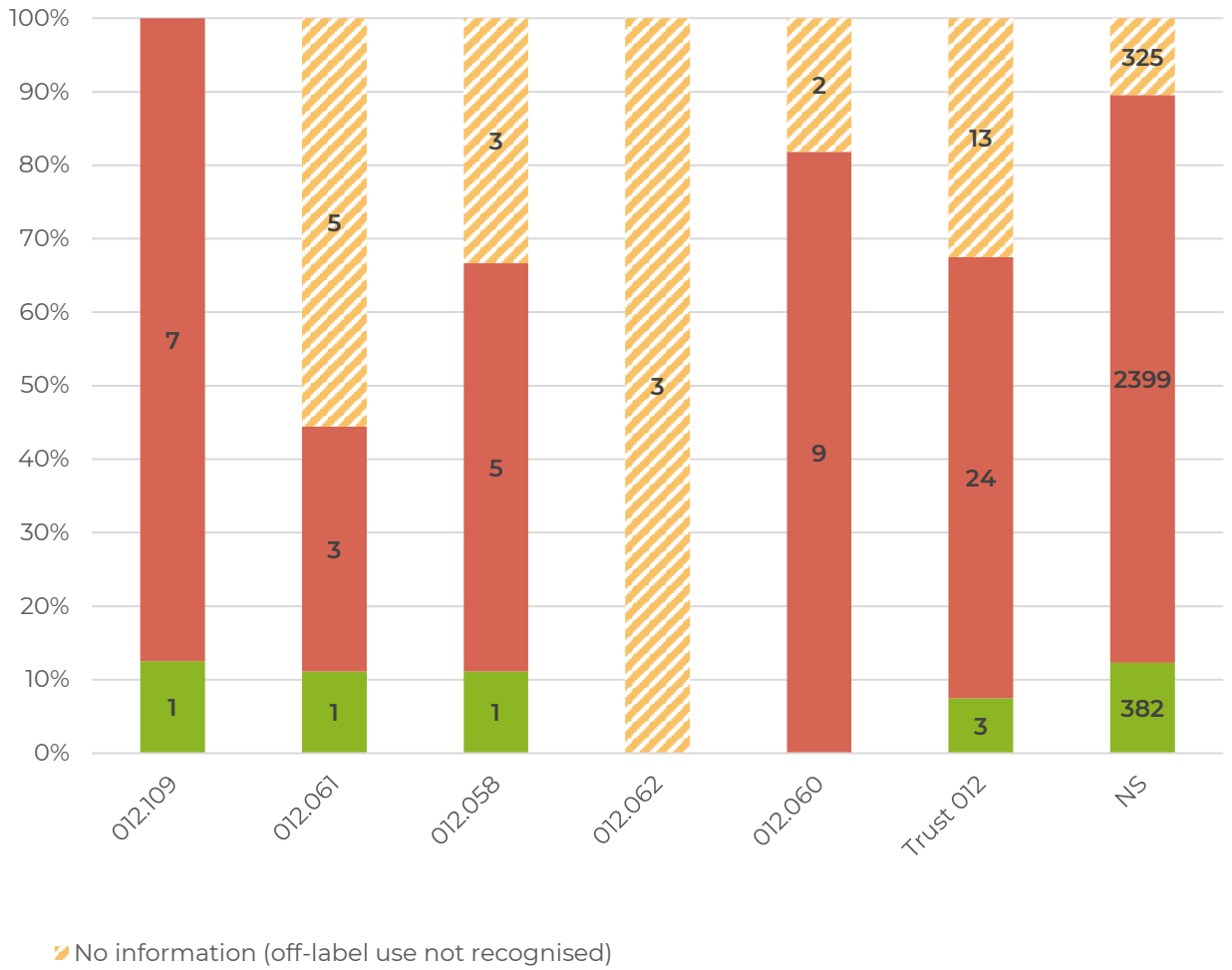
Figure 32: Prescription of licensed and unlicensed preparations of melatonin. Total national sample (n = 5097), and your Trust's clinical team subsamples



Performance against practice standard 4

Where melatonin is prescribed off-label, an explanation should be given to the patient and/or parent and/or guardian and/or carer, as appropriate

Figure 33: Documentation of an explanation to a patient/parent/guardian/carer that a melatonin prescription is 'off-label'. National subsample (n = 3106) and your Trust's clinical team subsamples



Performance against practice standard 5

The efficacy and safety/tolerability of melatonin medication should be reviewed within 3 months of starting

Figure 34: Documented clinical review of the response to melatonin, within the first three months. National subsample of patients prescribed melatonin for between 3 months and a year (n = 1085) and your Trust's clinical team subsamples

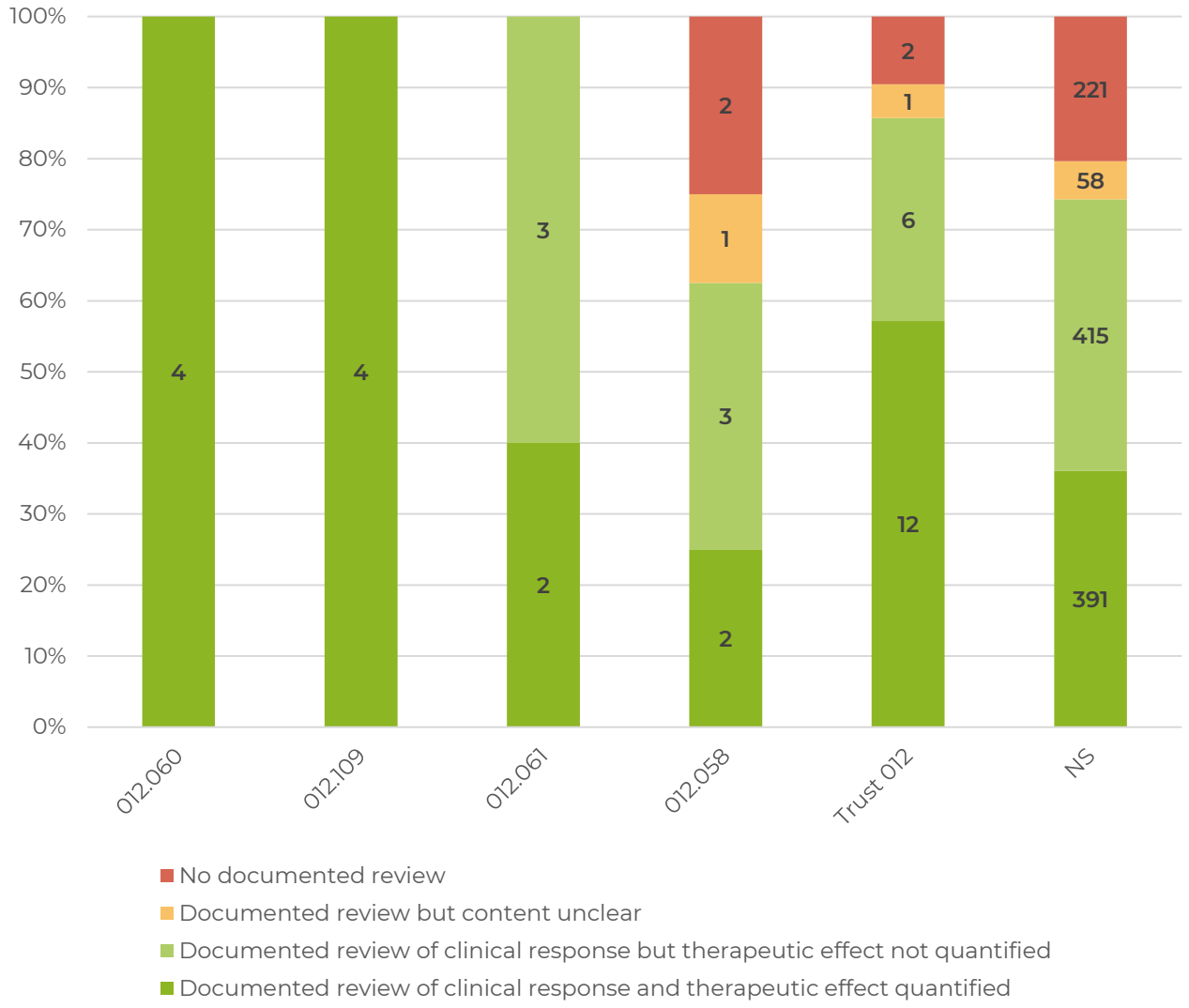
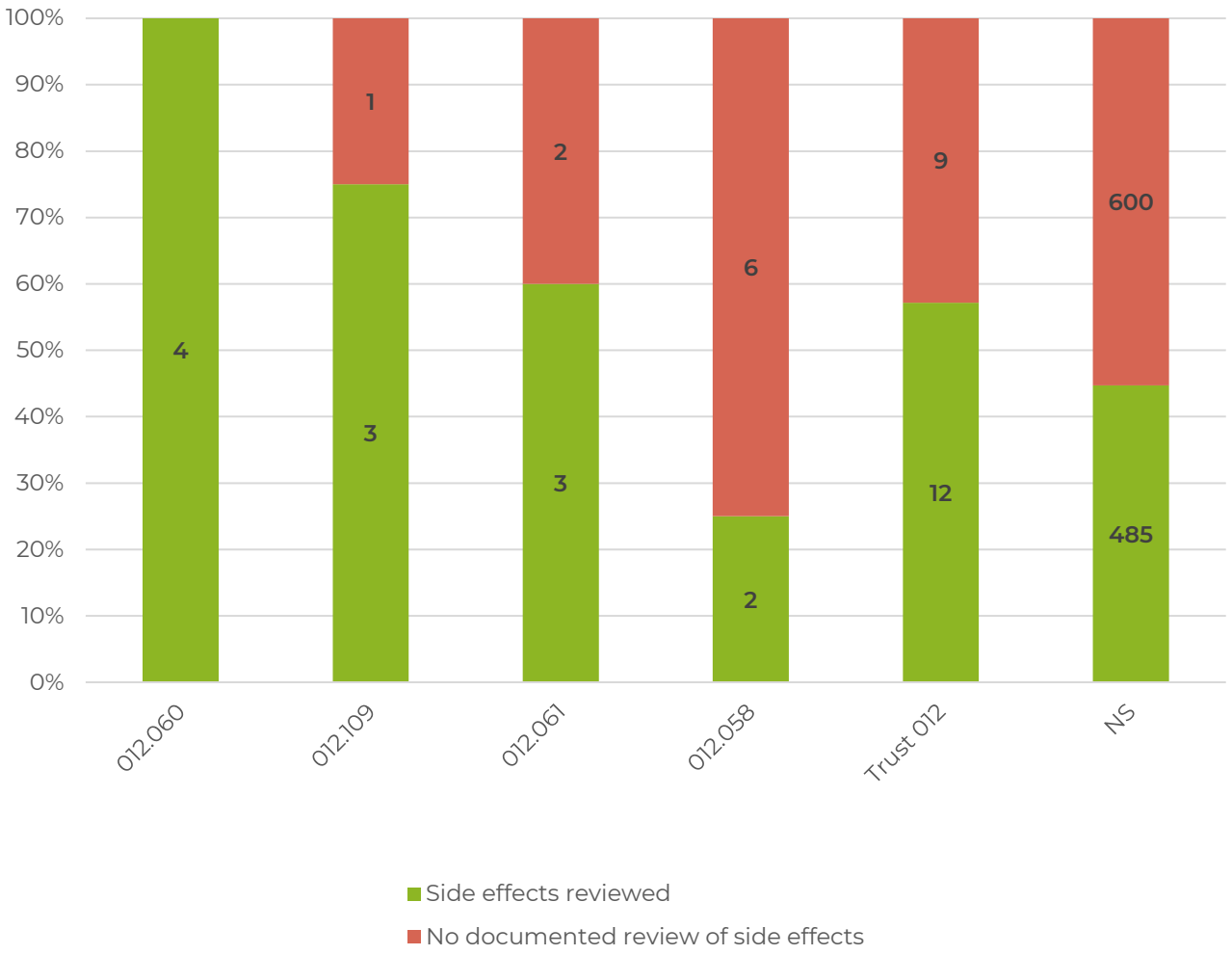


Figure 35: Documented review of side effects within the first 3 months. National subsample of patients prescribed melatonin for between 3 months and a year (n = 1085) and your Trust's clinical team subsamples



Performance against practice standard 6

The need for continuing melatonin treatment should be reviewed annually, based on efficacy and side effects

Figure 36: Documented review of the therapeutic effect of melatonin, in the past year. National subsample of patients prescribed melatonin for more than a year (n = 3521) and your Trust's clinical team subsamples

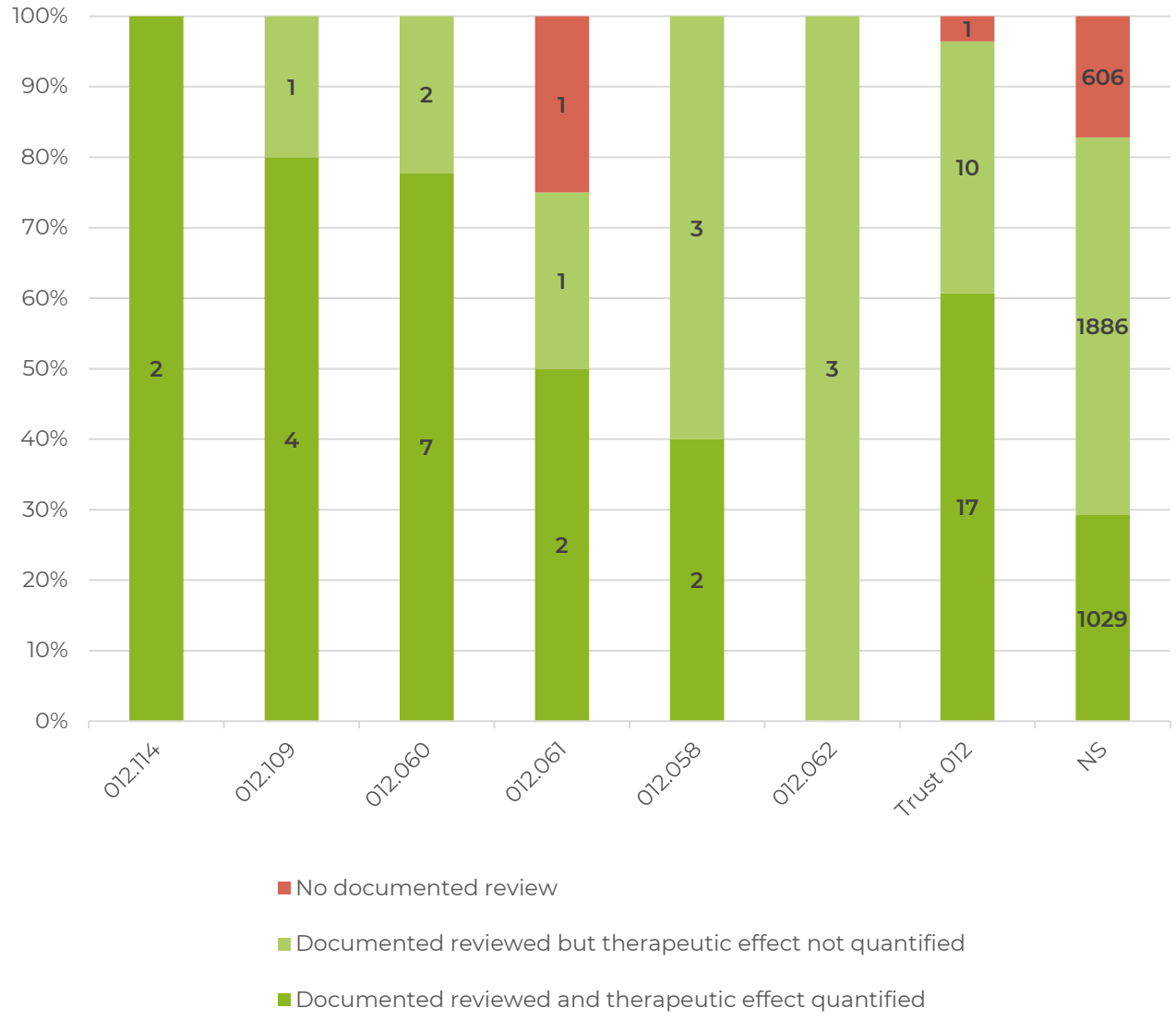
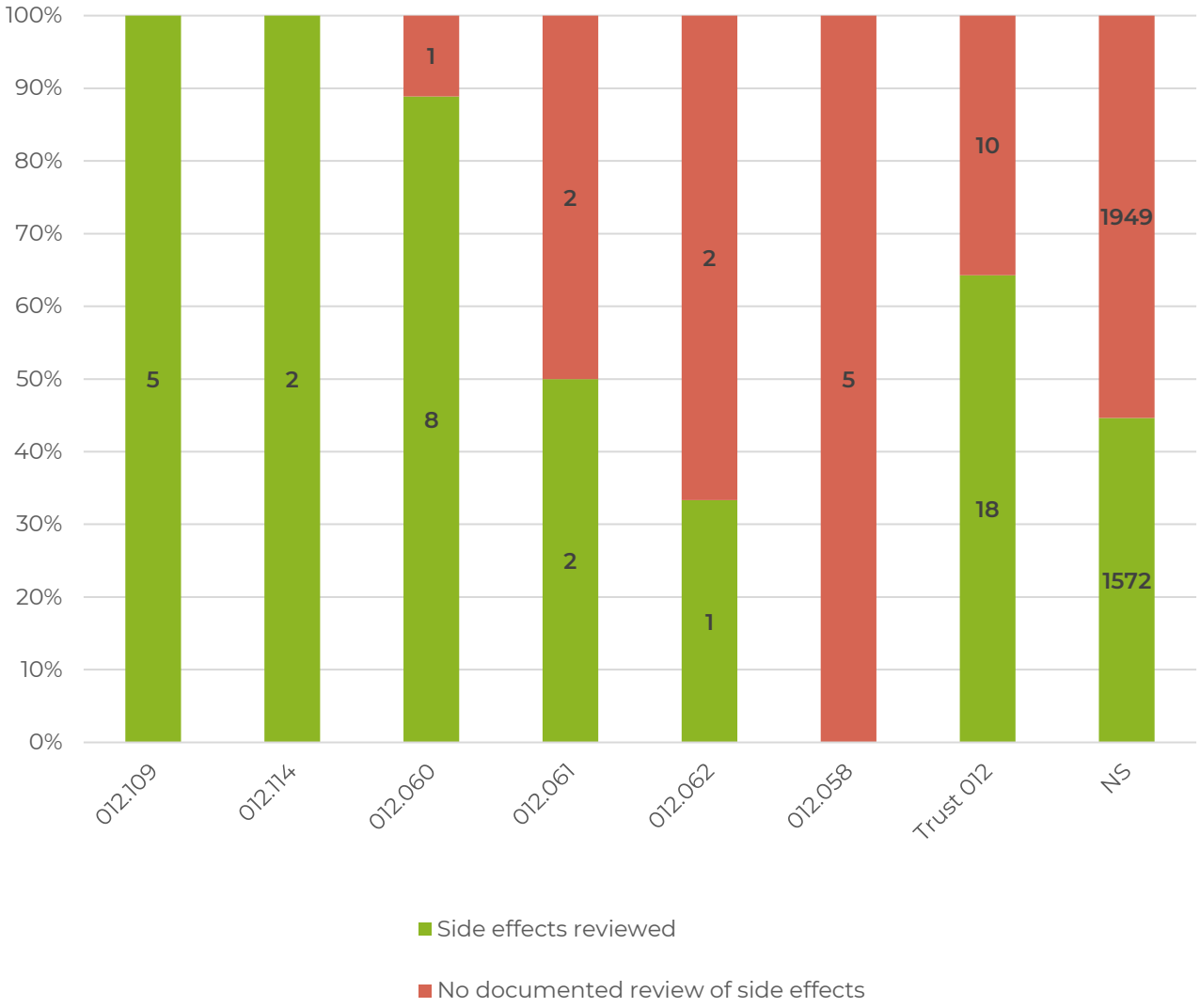


Figure 37: Documented review of side effects in the past year. National subsample of patients prescribed melatonin for more than a year (n = 3521) and your Trust's clinical team subsamples



Appendices

Appendix A: Data use and management

Data control statement for POMH quality improvement programme 21a: The use of melatonin

Data ownership and control

Control of the local data submitted to POMH is retained by the healthcare organisation that submitted them. These data have been made available to POMH in a way that is pseudonymous, with the exception of the identity of the source organisation. The aggregate data from all participating organisations are analysed by POMH to produce our customised reports. These reports summarise the national results and local results at organisation and clinical team level, benchmarked anonymously against the other organisations taking part.

Data Sharing

There is a publication strategy allowing POMH to publish the aggregated data on its web site and/or in appropriate scientific journals. Any organisations requesting these audit data will be referred to the POMH reports appearing in the public domain or provided with a list of member healthcare organisations and asked to approach them individually. It is each organisation's decision whether, and with whom, to share their data.

Data for Quality Improvement

Given that the data are collected for the purpose of quality improvement they are not necessarily representative of performance across the Trust. The use of data for ranking or judgement at an organisational level may therefore not be appropriate. Participation in POMH QIPs can be considered to indicate engagement in quality improvement. Relative and absolute performance against the practice standards should always be considered with the above caveats in mind.

Reflection by clinical teams on their benchmarked performance is perhaps the most potent element of POMH programmes. In addition to performance against the clinical standards, the audit data include demographic, diagnostic and other relevant clinical information that provide a context for interpretation and understanding of practice, which can inform local strategies and systems to achieve improvement. The data collected are designed to be suitable for this clinical purpose, and not for objective ranking of healthcare organisations, for which they are untested and would not necessarily be appropriate.

Privacy Notice

In accordance with the General Data Protection Regulation (GDPR) we have updated our privacy notice, which provides full details on how we use your data and the data submitted as part of a national clinical audit, along with our legal basis for doing so. Our privacy notice can be found online via the following link:

https://www.rcpsych.ac.uk/about-us/legal/data-protection/pomh-privacy-notice

This privacy notice is provided in addition to POMH's data control statement. The data collected by POMH are pseudonymous.

Appendix B: Participating Trusts

Avon and Wiltshire Mental Health Partnership NHS Trust
Barnet, Enfield and Haringey Mental Health NHS Trust
Belfast Health and Social Care Trust
Berkshire Healthcare NHS Foundation Trust
Betsi Cadwaladr University Health Board
Birmingham and Solihull Mental Health NHS Foundation Trust
Birmingham Women's and Children's NHS Foundation Trust
Black Country Healthcare NHS Foundation Trust
Bradford District Care NHS Foundation Trust
Calderdale and Huddersfield NHS Foundation Trust
Cambridgeshire and Peterborough NHS Foundation Trust
Camden and Islington NHS Foundation Trust
Central and North West London NHS Foundation Trust
Cheshire and Wirral Partnership NHS Foundation Trust
Cornwall Partnership NHS Foundation Trust
Coventry and Warwickshire Partnership NHS Trust
Cumbria, Northumberland Tyne and Wear NHS Foundation Trust
Cwm Taf Morgannwg University Health Board
Derbyshire Healthcare NHS Foundation Trust
Devon Partnership NHS Trust
Dorset Healthcare University NHS Foundation Trust
East London NHS Foundation Trust
East Sussex healthcare NHS Trust Community Paediatrics
Elysium Healthcare Limited
Essex Partnership University NHS Foundation Trust
Herefordshire and Worcestershire Health and Care NHS Trust
Hertfordshire Partnership University NHS Foundation Trust
Kent and Medway NHS and Social Care Partnership Trust
Lancashire and South Cumbria NHS Foundation Trust
Leeds and York Partnership NHS Foundation Trust
Leicestershire Partnership NHS Trust
Manx Care
Mersey Care NHS Trust
Midlands Partnership NHS Foundation Trust
NAViGO Health and Social Care CIC
Norfolk and Suffolk NHS Foundation Trust
North East London NHS Foundation Trust
North Staffordshire Combined Healthcare NHS Trust

Northern Health and Social Care Trust
Nottinghamshire Healthcare NHS Trust
Oxford Health NHS Foundation Trust
Oxleas NHS Foundation Trust
Pennine Care NHS Foundation Trust
Rotherham, Doncaster and South Humber Mental Health NHS Foundation Trust
Solent NHS Trust
Somerset NHS Foundation Trust
South Eastern Health and Social Care Trust
South Tyneside and Sunderland NHS Foundation Trust
South West London and St George's Mental Health Trust
South West Yorkshire Partnership NHS Foundation Trust
Southern Health and Social Care Trust
Southern Health NHS Foundation Trust
St Andrew's Healthcare
St Patrick's Mental Health Services
Surrey and Borders Partnership NHS Foundation Trust
Sussex Community Foundation Trust
Sussex Partnership NHS Foundation Trust
Swansea Bay University Health Board
Tees, Esk and Wear Valleys NHS Foundation Trust
University Hospital of North Midlands NHS Trust
West London NHS Trust

Appendix C: Patient demographics and clinical characteristics

Figure 38: Proportion of males and females. Total national sample(n = 5097) and each participating Trust/healthcare organisation sample.

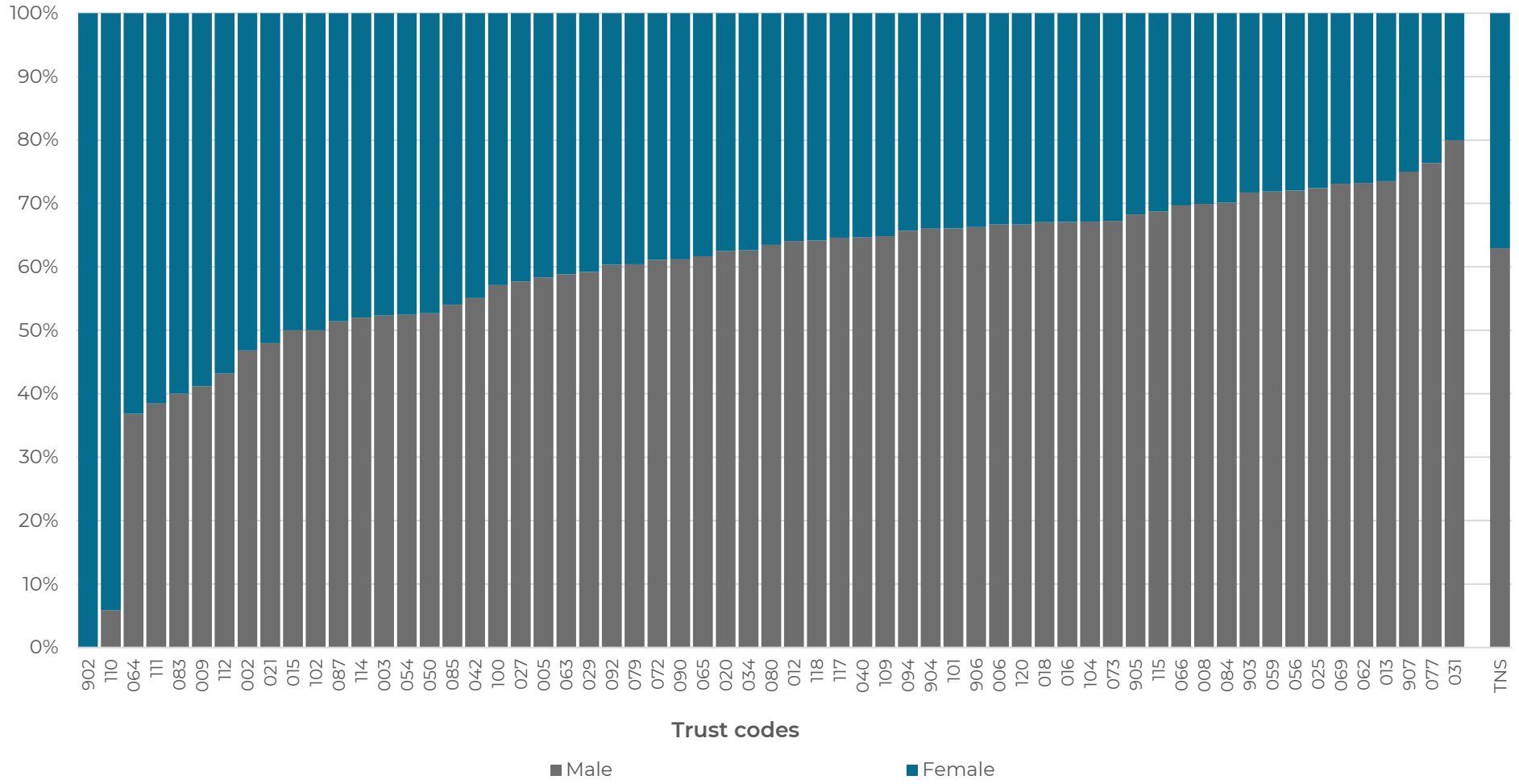


Figure 39: Age bands. Total national sample(n = 5097) and each participating Trust/healthcare organisation sample.

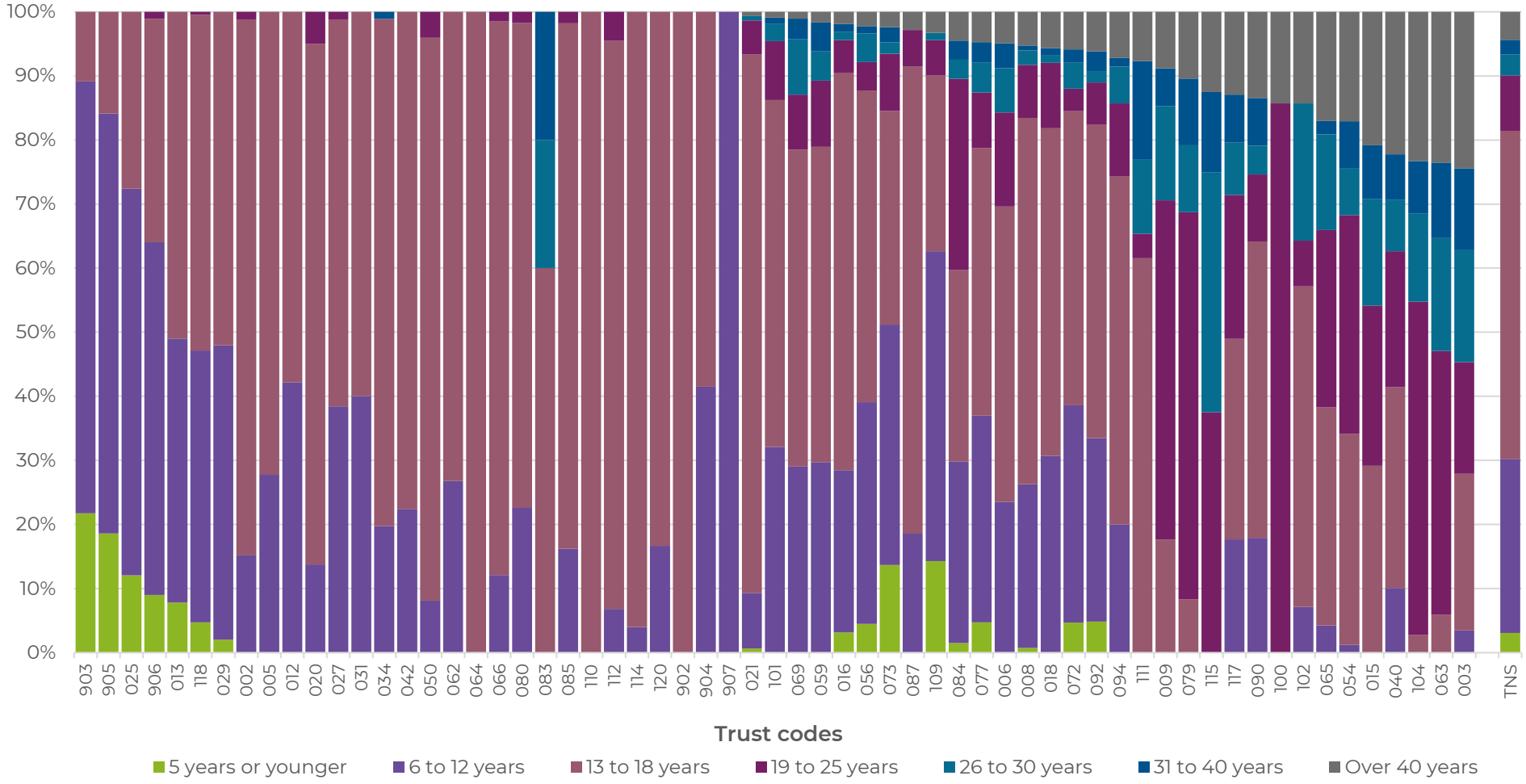
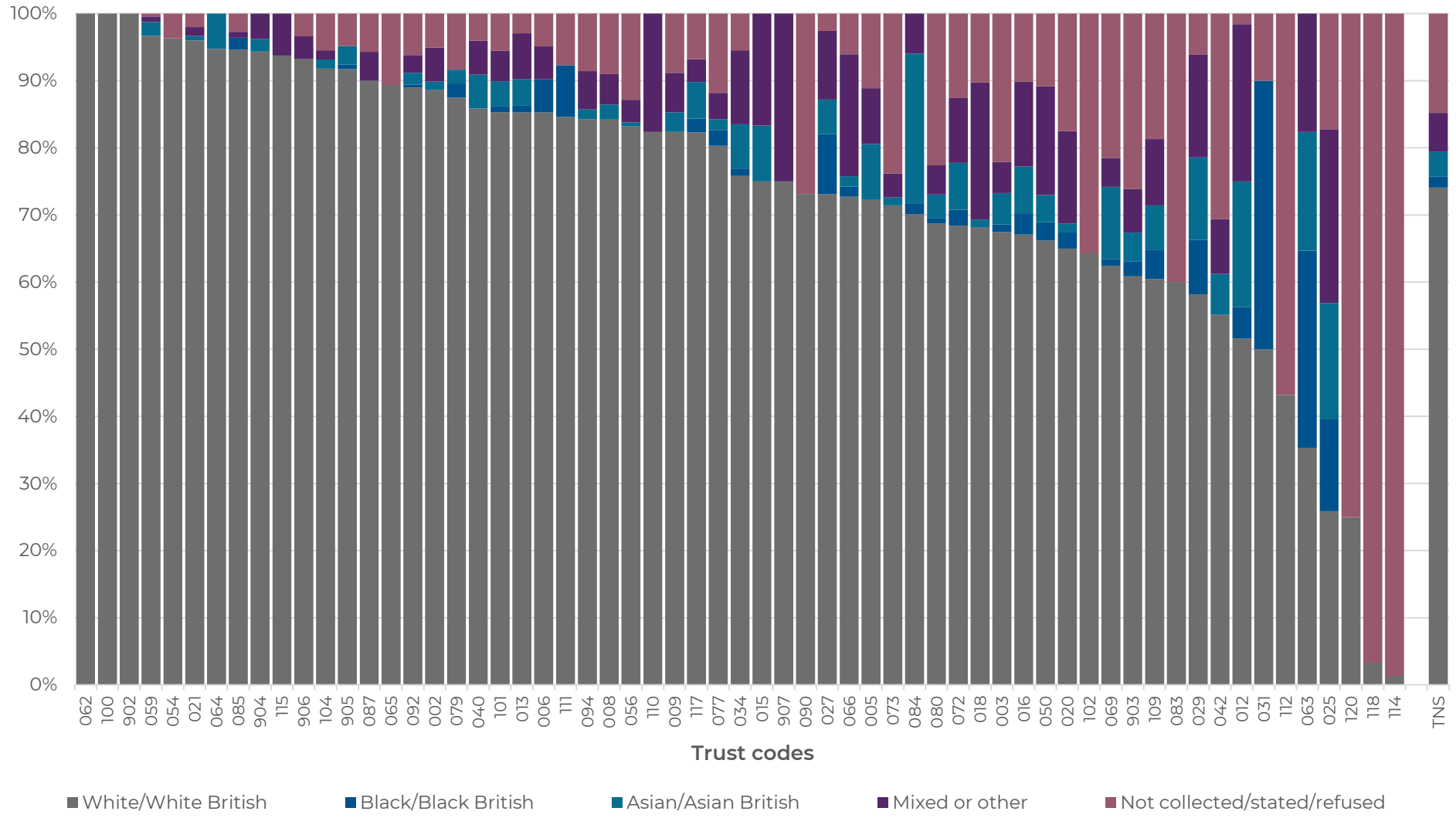


Figure 40: Distribution of ethnic groups. Total national sample(n = 5097) and each participating Trust/healthcare organisation sample.



Appendix D: Audit data collection tool

RC PSYCH ROYAL COLLEGE OF PSYCHIATRISTS | POMH PRESCRIBING OBSERVATORY FOR MENTAL HEALTH UK

This data collection tool relates specifically to the following quality improvement programme:

The use of melatonin

QI Topic 21a

Eligibility criteria

Patients of any age who are currently prescribed melatonin and are under the care of CAMHS, community paediatrics or learning disability services.

Patients under the care of adult, forensic or old-age psychiatry services should not be included.

Collecting data

To complete this audit form, you should refer to the patient's clinical records. Clinical records include all electronic and paper notes, letters, and other patient information available to the clinical team. Given the nature of the information required to answer some questions, there may be the need to involve a doctor and/or pharmacist.

Before collecting data, please refer to the **Guidance Notes** at the end of this tool.

Submitting data

Data should be submitted online via the **POMH Data Entry webpage**. You will need your POMH username and password. Before submitting, please read the **Guidance for Online Data Submission** document, available on the POMH Data Entry webpage. If you realise that you have made a mistake in data submission, you will be able to correct this before the data entry period ends. To do this, you will need to ensure you keep a note of the receipt number displayed when the data were submitted. You will not be able to correct your submitted data after the data entry period ends.

To aid the data cleaning process, you may wish to keep a record of the patient ID on the front page of each paper form, for easier identification of cases (you cannot use the submission receipt number).

Data collection & entry: 1 June – 29 July 2022*
Data entry closes: 29 July 2022, 4pm

* Members may submit data to POMH from the start of the data collection period – members can choose to run data collection and entry at the same time, or as two separate periods within the specified dates.

Please contact the POMH-UK team if you have any questions or require further assistance.
Email: pomh-uk@rcpsych.ac.uk / Telephone: 0208 618 4010

Please note that this form is intended for use as part of the POMH-UK Topic 21a quality improvement programme only and may not be suitable for other purposes.

No.	Practice standards	Related questions
1	Evidence-based, non-pharmacological interventions should be tried before melatonin is prescribed	Q20
2	The target symptoms for melatonin treatment should be documented (e.g. sleep onset, sleep duration, sleep quality)	Q18
3	A licensed melatonin preparation should be prescribed where possible	Q16
4	Where an unlicensed melatonin preparation is prescribed, an explanation should be given to the patient and/or parent and/or guardian and/or carer, as appropriate	Q17
5	The efficacy and safety/tolerability of melatonin medication should be reviewed within 3 months of starting	Q22, Q23
6	The need for continuing melatonin treatment should be reviewed annually, based on efficacy and side effects	Q24, Q25

References

The practice standards were derived from the following:

- General Medical Council (2021) *Good Practice in Prescribing and Managing Medicines and Devices*. GMC. https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices
- Anon. Melatonin for sleep problems in children with neurodevelopmental disorders. *Drug and Therapeutics Bulletin* 2015;53;117-120
- Anon. Melatonin for primary insomnia? *Drug and Therapeutics Bulletin* 2009;47:74-77.
- National Institute for Health and Care Excellence, 2013. *Autism: The management and support of children and young people on the autism spectrum (CG 170)*. https://www.nice.org.uk/guidance/cg170
- Use of licensed medication for unlicensed applications in psychiatric practice (2nd edition). Royal College of Psychiatrists, CR210, 2017. https://www.rcpsych.ac.uk/improving-care/campaigning-for-better-mental-health-policy/college-reports/2017-college-reports/use-of-licensed-medicines-for-unlicensed-applications-in-psychiatric-practice-2nd-edition-cr210-dec-2017
- Wilson S, Anderson K, Baldwin D, et al. British Association for Psychopharmacology consensus statement on evidence-based treatment of insomnia, parasomnias and circadian rhythm disorders: An update. *Journal of Psychopharmacology* 2019;33:923–947.

Data collection

Our privacy notice provides full details on how we use your data and the data submitted as part of a national clinical audit, along with our legal basis for doing so. Our privacy notice can be found online via the following link:

https://www.rcpsych.ac.uk/about-us/legal/data-protection/pomh-privacy-notice

This privacy notice is provided in addition to POMH-UK's data control statement.

The data collected by POMH-UK are pseudonymous. Please ensure that the data submitted are limited to data specifically requested by this tool and you do **not** supply any personally identifiable data, such as a service user's **name**, **full date of birth** or **NHS number**.

If you have any queries concerning the collection and use of personal data, please contact:

Gavin Herrington, Programme Manager Gavin.herrington@rcpsych.ac.uk

Trust and team information

Q1. Trust identifier
Your Trust identifier is a 3-digit code (e.g. 044)

Q2. Team identifier
Your team codes are known only to your Trust. The POMH-UK team does not know your team code.

N	N	N

Q3. Optional additional identifier
This field gives your Trust the option of identifying data by site, directorate, lead consultant, or any other relevant variable you wish. Your Trust can decide whether or not to use this field.
Enter any assigned numerical code in this field and keep a record for yourselves of what it means. If you don't want to use an additional identifier, simply leave this field blank.

Q4. Initials of data collector
Enter your own initials in this field (e.g. SB). This will enable your team to identify you, should we need to query something about the data that have been entered.

Patient information (complete for ALL patients)

Q5. Patient identifier
Please assign a numerical code to each patient on whom data are collected, for example Joe Bloggs=1, Jane Bloggs=2. Keep a record of these codes so you can identify patients should there be data cleaning queries.

N	N	N	N

Q6. Patient's year of birth
(YYYY e.g. 1988)

Y	Y	Y	Y

Q7. Patient's sex *(as recorded in the clinical records)*

☐ *Male* ☐ *Female*

Q8. Patient's ethnicity *(as recorded in the clinical records) (These are the standard NHS ethnic categories currently in use)*

☐ *Asian/Asian British (includes any Asian background e.g. Bangladeshi, Chinese, Indian, Pakistani)*

☐ *White British/Irish (includes any White background)*

☐ *Mixed or multiple ethnic groups (includes any mixed background)*

☐ *Black African, Black British or Caribbean (includes any Black background)*

☐ *Another ethnic group (includes any other ethnic group, e.g. Arab)*

☐ *Unknown/Not documented*

4

Q9a. Patient's current clinical psychiatric diagnoses (ICD-10 categories provided for guidance)
(Please tick all that apply)

- ☐ *Organic, including symptomatic, mental disorders (F00-F09)*
- ☐ *Mental and behavioural disorders due to psychoactive substance use (F10–F19)*
- ☐ *Schizophrenia, schizotypal, delusional disorders and other non-mood psychotic disorders (F20-F29)*
- ☐ *Mood (affective) disorders (F30-F39)*
- ☐ *Anxiety, dissociative, stress-related, somatoform and other nonpsychotic mental disorders (F40-F48)*

Behavioural syndrome associated with physiological disturbance and physical factors (F50-F59)

- ☐ *Parasomnias such as night terrors (F51.4)*
- ☐ *Other insomnia (Other F51)*
- ☐ *Other behavioural syndrome (F50, F52-59)*
- ☐ *Disorders of adult personality and behaviour (F60-F69)*

Intellectual disabilities (F70-F79)

- ☐ *Mild (F70)*
- ☐ *Moderate (F71)*
- ☐ *Severe (F72)*
- ☐ *Profound (F73)*
- ☐ *Other or unspecified (F78, F78)*

Disorders of psychological development (F80-F89)

- ☐ *Autism/autistic spectrum disorder (F84)*
- ☐ *Rett's syndrome (F84.2)*
- ☐ *Other disorder of psychological development (F80-F83, F88, F89)*

Behavioural and emotional disorders with onset in early childhood and adolescence (F90-F98)

- ☐ *Hyperkinetic disorders including ADHD (F90)*
- ☐ *Conduct disorders (F91)*
- ☐ *Mixed disorders of conduct and emotions (F92)*
- ☐ *Emotional disorders with onset specific to childhood (F93)*
- ☐ *Disorders of social functioning with onset specific to childhood and adolescence (F94)*
- ☐ *Tic disorders (F95)*
- ☐ *Other behavioural and emotional disorders with onset usually occurring in childhood and adolescence (F98)*
- ☐ *Unspecified mental disorder (F99)*
- ☐ ***None of the above diagnoses documented***
- ☐ ***Not known/unclear***

Q9b. Patient's other relevant clinical diagnoses relating to diseases of the nervous system (ICD10)

- ☐ *Sleep related breathing disorders, including sleep apnoea (G47.3)*
- ☐ *Hypersomnias, including narcolepsy (G47.1)*
- ☐ *Circadian rhythm sleep disorders, including delayed sleep phase syndrome (G47.2)*
- ☐ *Parasomnias, including night terrors and sleep walking (G47/G51)*
- ☐ *Sleep-related movement disorders, including restless legs syndrome (G25.81)*
- ☐ *Cerebral palsy (G80)*
- ☐ *None of the above/not clear*

Q9c. Patient's other relevant current clinical diagnoses relating to chromosomal abnormalities (ICD10)

- ☐ *Smith-Magenis syndrome (Q93.88)*
- ☐ *Down syndrome (Q90)*
- ☐ *Angelman's syndrome (Q93.51)*
- ☐ *Tuberous sclerosis (Q85.1)*
- ☐ *Williams syndrome (Q93.82)*
- ☐ *Other congenital malformations, deformations and chromosomal abnormalities (please state which in the 'other' free text box below)*

- ☐ *None of the above diagnoses documented*
- ☐ *Other clinical diagnoses (please state below)*

Q9d. Does this patient have a documented diagnosis of epilepsy? (G40)

- ☐ *Patient has a diagnosis of epilepsy*
- ☐ *A diagnosis of epilepsy is being considered/under investigation*
- ☐ *Neither of the above are documented*

Q10. Which service/clinical team is currently responsible for this patient's care?

- ☐ *CAMHS team*
- ☐ *Community paediatrics team*
- ☐ *Learning disability team*

Q11. Which of the other following medications is this patient currently prescribed for sleep disturbance?

- ☐ *A benzodiazepine*
- ☐ *Chloral*
- ☐ *Clonidine*
- ☐ *Gabapentin*
- ☐ *Guanfacine*
- ☐ *Promethazine*
- ☐ *Trazodone*
- ☐ *Trimeprazine*
- ☐ *A Z-hypnotic*
- ☐ *Other medication for sleep disturbance, please state:* ☐
- ☐ *No medication other than melatonin prescribed for sleep disturbance*

Preparation of melatonin currently prescribed and source of supply

Q12. What formulation of melatonin is this patient currently prescribed?

- ☐ *Tablets*
- ☐ *Slow/controlled release tablets*
- ☐ *Capsules*
- ☐ *Slow/controlled release capsules*
- ☐ *Liquid solution or suspension*
- ☐ *Melatonin gummies*
- ☐ *Formulation unclear*

Q13a. How is the melatonin currently prescribed?

- ☐ *For regular use/administration only*
- ☐ *For PRN (as required) administration only*
- ☐ *For both regular and PRN administration*

Q13b. What is the total daily dose of a melatonin preparation currently prescribed?

(See guidance notes)

Regularly prescribed melatonin

Total daily dose

☐☐ . ☐ mg/day

PRN melatonin prescription

Minimum daily dose that could be administered

☐☐ . ☐ mg/day

Maximum daily dose that could be administered

☐☐ . ☐ mg/day

Q13c. When is the prescribed melatonin to be taken/administered?

Timing of melatonin administration	***Regularly prescribed melatonin***	***Melatonin to be taken as required (PRN)***
Prescribed to be taken before (age appropriate) bedtime	☐	☐
Prescribed to be taken if the patient wakes during the night	☐	☐
When the melatonin is to be taken is unclear	☐	☐
*Other specified timing of melatonin administration** **Please describe:*	☐	☐

☐

Q14. Which specific brand of melatonin is this patient prescribed? *(See guidance notes)*

- ☐ *Circadin*
- ☐ *Slenyto*
- ☐ *Melatonin (Colonis)*
- ☐ *Syncrodin*
- ☐ *Adaflex*
- ☐ *Other brand, please specify:*
- ☐ *Brand unclear*

Q15. Who currently prescribes melatonin for this patient?

- ☐ *Doctor from a CAMHS team*
- ☐ *Doctor from a community paediatrics team*
- ☐ *Doctor from a learning disability team*
- ☐ *Non-medical prescriber*
- ☐ *GP*
- ☐ *Other, please state:*
- ☐ *Unclear*

Licensed use or off-label use

Q16. Into which of the following categories does this patient's melatonin current prescription fall? (*See guidance notes*)

- ☐ *Slenyto is prescribed for a child/adolescent aged 2-18 years, with a diagnosis of an autism spectrum disorder (go to Q18)*
- ☐ *Slenyto is prescribed for a child/adolescent aged 2-18 years, with a diagnosis of Smith-Magenis syndrome (go to Q18)*
- ☐ *Circadin or Melatonin Mylan is prescribed for an adult age 55 years or older (go to Q18)*
- ☐ *Adaflex is prescribed for a child/adolescent aged 6-17 years, with a diagnosis of ADHD (go to Q18)*
- ☐ *None of the above categories apply (by exclusion, this patient's melatonin prescription is off-label, so please go to Q17)*
- ☐ *It is unclear into which of the above categories the melatonin prescription falls (go to Q17)*

Q17. Is it documented in the clinical records that it was explained to the patient and/or parent/carer that this is an off-label prescription? (*Please tick one box only*)

- ☐ *It is documented in the clinical records that the patient and/or parent/carer was informed that melatonin is being used off-label.*
- ☐ *There is no documented evidence that the patient and/or parent/carer was informed that melatonin is being used off-label.*

Reason for prescribing melatonin and duration of treatment

Q18. According to the clinical records, what was the reason (i.e. target symptoms) for prescribing melatonin? (*Please tick all that apply*)

- ☐ *To reduce sleep latency (get to sleep quicker)*
- ☐ *To reduce night-time awakenings (improve sleep quality)*
- ☐ *To increase the total duration of sleep (sleep longer)*
- ☐ *As part of the management of delayed sleep phase disorder*
- ☐ *As part of the management of ADHD symptoms*
- ☐ *To improve daytime mood and concentration*
- ☐ *To improve daytime behaviour*
- ☐ *To reduce caregiver burden/improve caregiver quality of life*
- ☐ *Other reason for prescribing melatonin, not listed above (please state below)*
- ☐ *Unclear*

Q19. How long has melatonin been prescribed for?

- ☐ *Less than 3 months (go to Q20)*
- ☐ *3 months to a year (go to Q22)*
- ☐ *More than a year (go to Q24)*
- ☐ *Unclear (go to Q24)*

All patients prescribed melatonin for less than 3 months

Q20. Were any of the following treatment interventions tried <u>before</u> melatonin was prescribed? (*Please tick all that apply*)

- ☐ *CBTi (cognitive behavioural therapy for insomnia)*
- ☐ *Advice given to keep a sleep diary*
- ☐ *Advice given about establishing a standard bed-time regimen*
- ☐ *Advice given about the bedroom environment (dark, quiet with minimal distractions, no phone, tablet or computer screens)*
- ☐ *Advice given about limiting caffeine*
- ☐ *Advice given about limiting alcohol*
- ☐ *A trial of analgesic medication to exclude pain as a cause of insomnia*
- ☐ *None of the above*
- ☐ *Other measure to improve sleep (please state below)*

Q21. Were any of the following discretionary investigations conducted before melatonin was prescribed?

- ☐ *Actigraphy*
- ☐ *Polysomnography*
- ☐ *EEG*
- ☐ *None of the above*

Go to the end of this form, finish, and submit data

All patients prescribed melatonin for between 3 months and 1 year

Q22. Was the response to melatonin reviewed within the first 3 months of treatment?

(*Please tick all that apply*)

- ☐ *Yes, and the therapeutic effect on the sleep problem was reviewed and quantified (e.g. the reduced time taken to fall asleep or increase in total sleep time were documented)*
- ☐ *Yes, but although the therapeutic effect on the sleep problem was reviewed it was not quantified*
- ☐ *Yes, and it was documented that the need for continuing treatment was considered/discussed*
- ☐ *Yes, but the content of the review is unclear*
- ☐ *No, there was no documented review*

Q23. Were side effects reviewed within the first 3 months of treatment? *(See guidance notes)*

- ☐ *No documented review of side effects*
- ☐ *Yes, side effects were reviewed but none were identified*
- ☐ *Yes, a review was conducted and side effects were identified (please state which side effects in the text box below)*

Go to the end of this form, finish, and submit data

All patients prescribed melatonin for more than 1 year

Q24. Was the prescription for melatonin reviewed within the last year?

(*Please tick all that apply*)

- ☐ *Yes, and therapeutic effect on the sleep problem was reviewed and quantified (e.g. the reduced time taken to fall asleep or increase in total sleep time were documented)*
- ☐ *Yes, but although the therapeutic effect on the sleep problem was reviewed it was not quantified*
- ☐ *Yes, and it was documented that the need for continuing treatment was considered/discussed*
- ☐ *Yes, and a melatonin treatment break was tried*
- ☐ *No, there was no documented review*

Q25. Were side effects reviewed in the past year? *(See guidance notes)*

- ☐ *No documented review of side effects*
- ☐ *Yes, side effects were reviewed but none were identified*
- ☐ *Yes, a review was conducted and side effects were identified (please state which side effects in the text box below)*

END

Finish and submit

These data should be submitted online to POMH-UK by:

29 July 2022, 4pm

If you realise that you have made a mistake submitting the data on this form online, you are able to edit submitted data before the data entry period ends. Keep a note of the receipt number shown after submission. You will need this to access this submitted form to correct any data entry errors.

You will not be able to correct your submitted data after the data entry period ends.

For further information please contact **POMH-UK@rcpsych.ac.uk**

Guidance notes

Q13b. PRN melatonin: if this is prescribed at a fixed dose (e.g. 2mg at night, as required), enter this dose in both the minimum and maximum daily dose boxes.

If current dose of melatonin is unknown, please contact the POMH team at **020 8618 4010**

Q14. If the melatonin is prescribed as a generic formulation with no brand name, select 'brand unclear'.

Q16. The first two options describe specific licensed indications for a particular brand of melatonin. A pragmatic approach has been taken for the third option, which is therefore rather broader than the detailed licensed indications for these two brands of melatonin.

Q23. Common side effects include headaches, nausea, dizziness and drowsiness

Q25. Common side effects include headaches, nausea, dizziness and drowsiness

Appendix E: POMH central team

Professor Thomas Barnes, Professor Emeritus, Imperial College London: Joint-Head POMH
Carol Paton, Honorary Research Fellow Imperial College London: Joint-Head POMH
Gavin Herrington: Programme Manager
Olivia Rendora: Deputy Programme Manager
Gaia Bove: Project Officer
Sylvia Ly: Project Officer

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Appendix F: References

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