

Original Research Article

A review of the practice and position of monitoring in today's rapid tranquilisation protocols

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Abstract

Background: Rapid tranquilisation (RT) is one of the highest risk clinical procedures currently undertaken by mental health services, yet it is underpinned by a surprisingly weak evidence base. The evidence base is weaker still when applied to post RT monitoring.

Aims: To review current clinical monitoring practice contained within adult RT documents in the UK.

Method: A review of adult RT documents currently in use in NHS or HSC trusts providing adult mental health services in the UK.

Findings: A total of 44 RT documents were examined. A picture of wide ranging practice was observed that prevented us from undertaking a full analysis of the data collected. Even when analysis was confined to the intramuscular route, there were concerning differences between documents in: when monitoring was initiated; what was being monitored; and the frequency and duration of this monitoring.

Conclusions and implications for clinical practice: There is a fundamental need for consensus in this high risk practice. The College of Mental Health Pharmacists, Royal College of Nursing and Royal College of Psychiatrists should have a key role in fashioning this consensus in both practice and policy.

Keywords

Rapid tranquilisation; monitoring; review

INTRODUCTION

Rapid tranquillisation (RT) is a treatment of last resort which is one of the highest risk procedures currently undertaken by mental health services in the United Kingdom (UK).

The National Institute for Clinical Excellence (NICE) defined RT as '*the use of medication to calm/lightly sedate the service user and reduce the risk to self and/or others. The aim is to achieve an optimal reduction in agitation and aggression, thereby allowing a thorough psychiatric evaluation to take place, whilst allowing comprehension and response to spoken messages throughout.*' (NICE, 2005).

Whilst medication should normally be offered orally, if this is refused or is inappropriate to the situation then the parenteral route

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should be used. NICE advocates the use of the intramuscular (IM) route over the intravenous (IV) route, reserving the latter for extreme situations only. Clearly any parenteral administration in this context would likely involve forcible administration and consequently restraint.

The risks associated with RT are well documented. In the context of parenteral administration, these constitute both drug and non drug related risks; recommendations from an independent enquiry into the death of a detained patient emphasised the importance of improved physical safety measures (Blofeld et al. 2003). Adverse effects of drugs used in RT, excited delirium, prolonged struggling and exhaustion have been cited as enhancing the possibility of positional asphyxia occurring (Police Complaints Authority, 2002; Joint Committee on Human Rights, 2004).

A plethora of adverse effects are associated with the drugs used in RT including cardiac effects, extrapyramidal effects (EPSE), respiratory depression, seizures, sedation progressing to loss of consciousness, hypotension and neuroleptic malignant syndrome. Of particular concern are sudden cardiac death, arrhythmias and acute dystonic reactions which can all be associated with the antipsychotics (NICE, 2005).

The parenteral administration of any medication will always confer additional risks over the oral route. In 2007, the National Patient Safety Agency¹ (NPSA) acknowledged this, issuing recommendations to promote the safer use of injectable medicines. Within the context of this review, it is particularly relevant that increased absorption may occur following IM administration in RT, especially when the patient is agitated, excited or physically overactive. (NICE, 2005).

RT is a common cause of high dose antipsychotic prescribing in the UK. Evidence about the inherent risks of high dose medication has been highlighted by the Royal College of Psychiatrists (2006) and the Prescribing Observatory for Mental Health (Paton et al. 2008).

¹ <http://www.nrls.npsa.nhs.uk/resources/?entryid45=59812>

Given the widely held view that RT is a high risk procedure, there is surprisingly little clinical evidence available to underpin this process. Many research articles have emphasised the need for further work in this field, but this has been limited by the fact that patients are too disturbed to consent to and therefore participate in clinical trials. A combination of clinical experience, theoretical consideration and research data are the basis of recommendations in RT (Taylor et al. 2009).

RT is not just a process of administering medication. It also involves the careful monitoring of the patient by specialist healthcare professionals until such a point that it is considered safe for this to stop. Whilst there is limited evidence surrounding the efficacy of medicines in RT, there is even less regarding post RT monitoring.

AIM

To review current clinical monitoring practice contained within adult RT documents in the UK.

REVIEW METHOD

Sixty eight National Health Service (NHS) or Health and Social Care (HSC) Trusts providing adult mental health services in England, Northern Ireland, Scotland and Wales were contacted requesting access to their adult RT documents between the 7th July 2010 and the 11th August 2010. All documents received by 13th August 2010 were examined.

Inclusion criteria

RT documents currently in use in NHS or HSC Trusts in the UK. Only adult documents were considered for this review.

Exclusion criteria

Any other RT documents not pertaining to adults or not currently in use.

Outcomes

1. To identify when monitoring is being initiated (position).
2. To identify what is being monitored.
3. To identify the duration and the frequency of this monitoring.

Data analysis

Data was extracted by a single reviewer and evidence tables compiled. Where data was defined as a range in the document (e.g. monitoring frequency of every 5–10 minutes) the lowest value of this range was recorded. One document was used twice as it covered two separate NHS Trusts. All data presented in the results of this article were anonymised to prevent individual Trust identification.

EVIDENCE SUMMARY

In total, 45 trusts responded and sent 48 RT documents. Three of these documents were excluded as they either related to RT in the elderly or children and adolescents. One further policy was excluded because it was incomplete.

FINDINGS

A total of 44 RT documents met the inclusion criteria for this review. 84% of these documents originated from England, 2% from Northern Ireland, 9% from Scotland and 5% from Wales.

Of these documents, 7% were classified as protocols, with 43% classified as guidelines, 41% classified as policies, 5% classified as procedures, 2% classified as standard operating procedures and 2% classified as an algorithm.

The RT documents reviewed displayed a picture of wide ranging practice:

- All documents examined featured the intramuscular (IM) route of administration, but 95% also featured the oral route, 40% the intravenous route and 5% the buccal route.
- All documents examined featured an ‘acute’ phase of monitoring, but 70% also featured

a step down ‘post acute’ phase of monitoring and 5% a ‘tertiary’ phase of monitoring.

- In addition to featuring mandatory monitoring parameters (95%), 55% of RT documents also featured conditional monitoring parameters dependent on set variables.

With the exception of position of monitoring, analysis was confined to the IM route only, as this featured in all documents examined. This enabled us to search for variations in practice between the documents.

Position of monitoring in RT documents

Half the documents reviewed recommended that monitoring should be carried out when any route of medication for RT was administered. In contrast, 46% recommended monitoring only after medication was administered parenterally. The remaining 4% of documents either recommended that monitoring was optional after oral therapy and mandatory after parenteral (2%), or mandatory after high dose oral therapy and mandatory after parenteral therapy (2%).

Clinical parameters monitored following IM administration of RT medication

The majority of RT documents (97%) specified set monitoring parameters that were required to be measured following administration of medication. Half of the documents reviewed also included monitoring proformas; these were used to actively record specific parameters following administration of IM medication.

In addition to mandatory observations, 55% of documents also used the concept of conditional monitoring that was only required to be undertaken if certain clinical criteria were satisfied.

As Figure 1 demonstrates, a total of 14 monitoring parameters were specified in the RT documents reviewed. The most common mandatory observations were blood pressure, pulse, temperature and respiratory rate. Level of consciousness featured in just over 50% of the RT documents followed by hydration status which featured in 34% of RT documents.

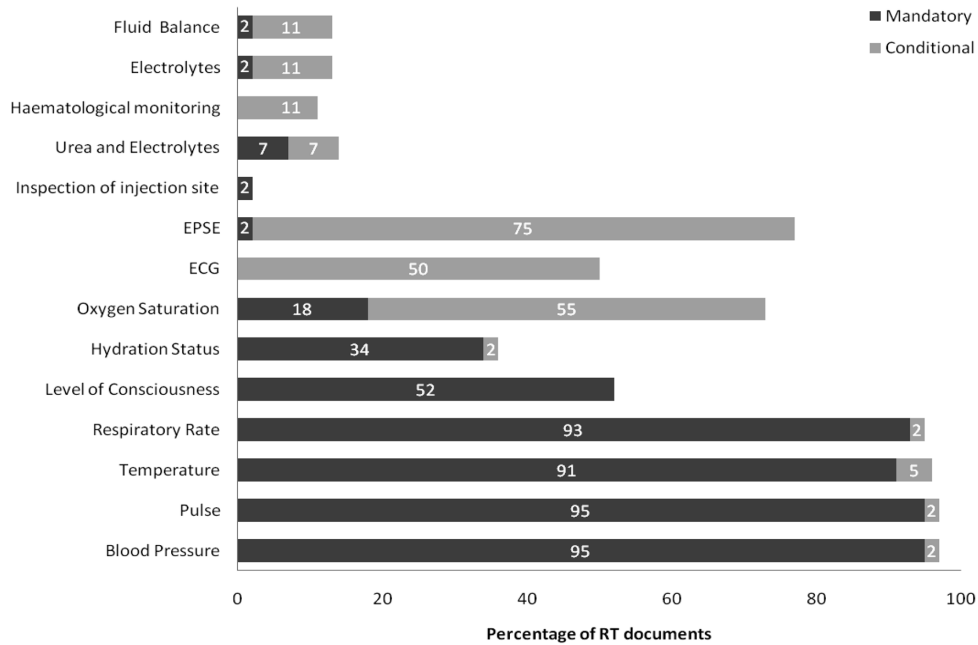


Figure 1. Monitoring undertaken following IM RT

Measurement of oxygen saturation featured both in mandatory and conditional monitoring. However, it was more common in the latter and was indicated if the patient either became unconscious or fell asleep.

Monitoring for EPSE, especially dystonic reactions, featured in 77% of documents, with the majority (75%) recommending this after the administration of IM antipsychotics. However, this parameter proved difficult to categorise, with only 11% of documents explicitly stating that monitoring of EPSE should be undertaken within the ‘monitoring’ section of documents. The remaining 66% of documents included a complications or remedial action section, where dystonia was listed as a complication of RT and clinical solutions to this and other problems were suggested.

ECG monitoring was indicated in over 50% of RT documents following administration of either parenteral antipsychotics or in those receiving high doses of antipsychotic.

Inspection of the injection site was mandatory in 2% of documents whilst fluid balance

was mainly conditional and was indicated when considered clinically appropriate.

Monitoring of blood samples was recommended in a total of 38% of RT documents reviewed. However, recommendations for what should be monitored were variable, with 14% of all documents recommending urea and electrolytes (U+Es), 13% electrolytes and 11% ‘haematological’ monitoring with specific regard to potassium. The situations in which this monitoring should be initiated were mostly under the conditional basis of ‘as clinically indicated’. However 14% of documents suggested this should occur following administration of parenteral antipsychotics.

Eleven percent of documents stated the parameters that should be monitored if the patient was not cooperative. However, these varied widely between documents, with visual observations of respiratory rate, pallor, rigidity, sweating, pupil size and whether the patient was vomiting being suggested in one and observation of signs or symptoms of pyrexia, hypotension, over sedation and general physical well being suggested in others.

Duration and frequency of monitoring following IM administration of RT medication

In the RT documents reviewed, the duration and frequency of monitoring could be divided into three distinct phases:

Acute phase

An acute phase featured in all the documents examined and began immediately after administration of medication. It finished either after a set period of time or after a condition had been met, for example the patient becoming ambulatory.

As demonstrated in Table 1, three quarters of RT documents examined indicated that the acute phase should last for 1 hour after administration. Two hours was the next common length followed by when the patient became ambulatory.

Whilst there was a general consensus regarding the length of the acute phase, there was a large degree of variation in the frequency of monitoring.

Table 1. Duration of acute phase monitoring following IM administration of RT medication

Duration of monitoring	Percentage of RT documents
1 hour	75
2 hours	8
4 hours	5
Until pt ambulatory	7
Not stated	5

Table 2. Frequency of acute phase monitoring following IM administration of RT medication

Frequency of monitoring*	Percentage of RT documents
Every 5 minutes	22
Every 10 minutes	16
Every 15 minutes	41
Every 30 minutes	2
Varies depending on monitoring parameter	9
Regular intervals	5
Not stated	5

* Where data was defined as a range (e.g. frequency of every 5–10 minutes), the lowest value of this range was recorded (e.g. 5 minutes)

As Table 2 demonstrates, there were seven variations regarding frequency of monitoring, with 41% of documents recommending a monitoring frequency of 15 minutes, 22% suggesting 5 minutes and 16% advising 10 minutes.

Post acute phase

The post acute phase featured in 70% of policies and was a step down phase where monitoring frequency was reduced. This started immediately following the end of the acute phase and finished either after a set period of time or after a condition had been met, for example the patient becoming ambulatory.

As demonstrated in Table 3, 81% of documents continued this phase until the patient was ambulatory, although 13% of policies documents stated a duration of time up to four hours post administration of medication.

As with the duration of the post acute phase, there was clear consensus as to the frequency of monitoring during the post acute phase. As Table 4 demonstrates, 82% of documents suggested a frequency of 30 minutes, with the remaining 18% split between 15 minutes, 60 minutes and a variable frequency dependent on the monitoring parameter.

Tertiary phase

Two documents (5%) featured a tertiary step down phase of monitoring that extended from the end of the post acute period until the end of a set period of time. In both of these documents the monitoring frequency was every 4 hours and duration up to 12 hours post administration in one document and up to 48 hours after administration in the other.

Table 3. Duration of post acute phase monitoring following IM administration of RT medication

Duration of monitoring	Percentage of RT documents
4 hours	13
5 hours	3
Until pt ambulatory	81
Until reviewed by doctor	3

Table 4. Frequency of post acute phase monitoring phase following IM administration of RT medication

Frequency of monitoring*	Percentage of RT documents
Every 15 minutes	6
Every 30 minutes	82
Every 60 minutes	6
Varies depending on monitoring parameter	6

* Where data was defined as a range (e.g. frequency of every 30–60 minutes), the lowest value of this range was recorded (e.g. 30 minutes)

In addition to the three phases of monitoring, a total of 18% of RT documents contained a condition that physical observations should be restarted if clinically required. A further 11% of documents stated that more frequent and intensive monitoring should be undertaken if the patient was asleep/sedated, the BNF limit had been exceeded or in high risk situations. However, no documents quantified this.

DISCUSSION

The findings of this review identified that RT documents in use in the UK display a picture of wide ranging practice. Moreover, the wide scope of these documents prevented us from undertaking a full analysis of the data collected. Even when analysis was confined to the IM route, the differences between documents in when monitoring was initiated, what was being monitored and how frequent this monitoring should occur, were concerning.

This variability in RT monitoring is not a new finding. In 2005, Pereira et al. demonstrated a number of differences in physical observations undertaken following RT. They also identified high levels of concern amongst psychiatrists in the quality of physical monitoring following RT. It was assumed that the publication of clinical guidelines by NICE (2005) and later on that year Macpherson et al. (2005), both of which made specific recommendations regarding post RT monitoring, would have gone some way to remedying this situation. However, our review demonstrates that this variation still exists and may be wider than previously thought.

It is possible that these differences exist because the NICE guidelines, against which most trusts are audited, are open to interpretation, whilst the guidelines from Macpherson et al. (2005) were far more prescriptive. It appears that most trusts have attempted to find their own middle ground between these two documents.

Differences were apparent from the outset when the types of documents were considered, with 43% classed as guidelines and 41% as policies. Arguably, the difference between a guideline and a policy is significant given that the former set out what is best practice whilst the latter dictates what must be adhered to.

Position of monitoring

The point at which monitoring was initiated after RT polarised trusts in the UK. Half the documents examined stated that monitoring should be initiated after any RT medication, whilst almost the same number stated after parenteral therapy only. Although the two routes can clearly be differentiated on the grounds of differing bioavailability and injection related risks, perhaps the main difference in this context is that the IM route would likely involve the forcible administration of medication and consequently, restraint. As alluded to in the introduction, this confers many well documented risks, some of which are not necessarily drug related. NICE (2005) stated that monitoring should be initiated after RT, which at a most basic level could be interpreted to mean after any route of administration. Other published evidence, however, is contradictory stating that monitoring should be initiated after parenteral administration of medication (Macpherson et al. 2005). This contradiction appears to have been borne out in clinical practice.

Clinical parameters being monitored

In their clinical practice guideline in 2005, NICE recommended monitoring vital signs (blood pressure, pulse, temperature, respiratory rate and hydration) after administration of RT. They also stated that pulse oximeters should be available and that particular attention should be paid to the service user's respiratory effort,

airway, and level of consciousness in higher risk clinical situations, for example if the patient was asleep or sedated or above BNF doses had been used.

Macpherson et al. (2005) added to this evidence base later in the same year. Monitoring parameters were similar to those recommended by NICE, with the exception of hydration status which was replaced by 'chart fluid intake if necessary'. They also recommended that an ECG should be recorded if there were any concerns about cardiac function, or if the patient had recently received increased high dose antipsychotics.

Nearly all the RT documents examined in this review (97%) specified set monitoring parameters that were required to be measured following administration of IM medication. Most ensured that these monitoring parameters were achieved by setting out both mandatory parameters (must be monitored regardless of the patient's clinical presentation) and conditional parameters (only carried out if the patient satisfied particular clinical criteria).

This review indicates that overall, there was considerable variation between the 14 monitoring parameters that were listed for use. However, embedded within the findings were also clear trends. Four of the five vital monitoring parameters set out by NICE were mandatory in nearly all RT documents examined. However, the fifth, hydration status, fared poorly with only 36% of documents recommending that this be undertaken on a largely mandatory basis. Fluid balance, a key component of assessing hydration status, featured as a mainly conditional parameter in 13% of documents, when 'clinically indicated'. The combination of these two parameters still totalled fewer than 50% of all policies examined, highlighting this as a key discrepancy against NICE recommendations. Monitoring of oxygen saturations by pulse oximeter was listed in almost three quarters of RT documents; the majority recommending monitoring if the patient became sedated, unconscious or fell asleep. Given that NICE only recommended that pulse oximeters be available, it is interesting to see that now, five years later,

three quarters of all trust RT documents include measurement of oxygen saturations as an integral part of the monitoring process.

Ultimately, the monitoring that a healthcare professional undertakes in clinical practice needs to reflect the known adverse effect profile of the medication being administered. There was certainly evidence of this when antipsychotics were considered, with many RT documents recommending conditional monitoring following their administration.

ECG monitoring

The ability of some antipsychotics to prolong the QTc interval (Taylor, 2003) and the association of antipsychotics and sudden cardiac death (Taylor et al. 2009) are increasingly impacting on both the prescribing and administration of these medicines. A defining moment was the decision by the manufacturers of Haldol® (haloperidol) in 2004 to recommend that a baseline ECG should be undertaken prior to any treatment with this drug (Janssen-Cilag Ltd, 2010). This culminated in the latest update of NICE (2009) guidance for schizophrenia recommending that all patients with schizophrenia started on antipsychotics on inpatient units should be offered an ECG.

This information is particularly relevant when applied to RT, partly because antipsychotics are commonly used for this indication, but also because antipsychotics prescribed for RT are a common cause of high dose and/or combination antipsychotics (Paton et al. 2008). The latter have been clearly linked with an increased risk of QTc prolongation (Beelen et al., 2001; Ray et al. 2009).

Although this review did not focus on the drugs being used in RT, it did demonstrate that ECG monitoring following IM administration of antipsychotics or high dose antipsychotics was recommended in 50% of documents. The practicality of ECG determination in a situation requiring the use of RT is questionable, which may explain why only 50% of Trusts chose to include this in their RT documents. However, what is clear is that an ECG at the earliest opportunity following admission

is essential in order to pick up any underlying cardiac issues that could be aggravated by the use of some antipsychotics, or other pro-arrhythmic drugs.

Monitoring for EPSE

NICE (2005) highlighted EPSE (particularly dystonic reactions) as an area of concern surrounding the use of antipsychotics in RT. Following the IM administration of antipsychotics, monitoring for EPSE was recommended in three quarters of RT documents examined. Interestingly, only 11% of documents reviewed included monitoring of EPSE together with other monitoring parameters, for example, blood pressure. The remaining 66% of documents contained a complications or remedial actions section, where dystonia was listed as a complication of RT and clinical solutions to this and other problems were suggested. This appears to have stemmed directly from NICE (2005), where monitoring of EPSE was not included with other vital signs that should be monitored, following RT.

Blood tests

A total of 14% of RT documents examined stated that either 'haematological monitoring' or U+Es should be undertaken following the parenteral administration of antipsychotics. All RT documents that stated haematological monitoring should take place, paid particular attention to potassium and hypokalaemia. To date, there is no published guidance as to which specific haematological parameters should be monitored following administration of RT, although Macpherson et al. (2005) did recommend 'a screen of blood tests following recently increased high dose antipsychotics to exclude serious coexisting or underlying pathology'.

Hypocalcaemia, hypomagnesaemia and hypokalaemia are all well known underlying risk factors for QTc prolongation and arrhythmia. Furthermore, there is growing evidence to suggest that hypokalaemia related QTc prolongation is prevalent in acute psychotic patients, possibly as a result of adrenergic stimulation associated with the acute phase of psychiatric disorders (Hatta et al. 2000; Trojak et al. 2009). This information underlines why meas-

urement of electrolytes, and in particular potassium, is essential as soon as possible following admission.

Other parameters

There was no evidence of any other conditional monitoring for other pharmacological classes of drug.

Whilst monitoring is essential, it also needs to be practical. It is plausible that a violent or disturbed patient may choose to be uncooperative with monitoring following RT. A small number of trust documents chose to address this issue by suggesting monitoring parameters that could be measured from a distance, without the need for invasive procedures. Although these parameters varied from document to document, they did provide a practical solution to ensuring that some level of monitoring was still occurring.

Another useful concept was the inclusion of a monitoring proforma in 50% of documents, acting as an aide memoire for health care professionals regarding the parameters to be monitored and the frequency with which these observations should be performed. These proformas were designed to be active documents either attached to the patient's drug chart or placed in their medical notes.

The duration and frequency of monitoring

Whilst NICE (2005) were explicit with regards to the parameters that should be monitored following RT, their recommendations regarding both the duration and frequency of monitoring were considerably more relaxed. They stated that monitoring should occur on a regular basis at a frequency agreed by the multidisciplinary team until such a point that the patient became active again. Macpherson et al. (2005) were much more prescriptive in their guidelines, suggesting that following parenteral administration pulse, temperature, blood pressure and respiratory rate should be monitored every 5–10 minutes for the first hour, then every 30–60 minutes until the patient became ambulatory. For patients receiving recently increased high-dose antipsychotics temperature, pulse and

respiration should be checked every 6 hours and serial ECGs should be considered to pick up arrhythmia or QT prolongation.

The dataset for the duration and frequency of monitoring was the most varied of all collected.

An acute phase of monitoring featured in all documents examined. Three quarters of the policies examined mirrored the recommendations set out by Macpherson et al. (2005) with regard to the duration of this phase, being 1 hour following administration of medication for RT. Whilst there was a general consensus regarding the duration of this phase, the opposite was true for frequency of monitoring, with 7 variations regarding how this should be practiced. In total, 38% of the policies examined featured a monitoring frequency of either every 5 or 10 minutes, illustrating that most trusts had chosen to not follow the recommendation made by Macpherson et al. (2005). Other trusts favoured a reduced frequency of monitoring, most of these opting for a frequency of every 15 minutes. It is possible that a reduced frequency of monitoring proved more practical within real life clinical settings in the UK.

A post acute phase featured in 70% of documents examined. Both the duration and frequency of monitoring in this phase was much more consistent across the UK and also closely mirrored published guidelines. Over 80% of monitoring occurring in the post acute phase was conditional on the basis that the patient became ambulatory. Until this occurred, 88% of trusts recommended a monitoring frequency of every 30–60 minutes, in line with the monitoring recommendations set out by Macpherson et al. (2005).

Two trust documents (5%) went as far as implementing a tertiary step down period of monitoring, which extended as far as 48 hours following administration of RT medication.

However, no documents followed the recommendations set out by Macpherson et al. (2005) for patients receiving recently increased high-dose antipsychotics, although this would likely fall under the remit of Trust High Dose

Antipsychotic Guidelines rather than RT documents.

CONCLUSIONS

Developing an RT document is not a simple process. Selection of appropriate medicines, consent to treatment, risk management and monitoring to safeguard the patient from side effects are just some of the issues that need to be considered.

This review has focussed on just one of these aspects: current clinical monitoring practice contained within adult RT documents in the UK. Our findings demonstrate a wide range of practice and in certain areas, concerning variations in procedures ultimately used in high risk situations.

There is currently considerable focus on RT in the UK and many providers are in the process of reviewing their RT documents. Whether this is related to recent ECG requirements with haloperidol, the ongoing supply issues with lorazepam injection, issues surrounding treatment without consent or simply scrutiny from organisations such as the Care Quality Commission, remains to be seen.

What is clear is that there is a fundamental need for consensus in this high risk practice. The College of Mental Health Pharmacists, Royal College of Nursing and Royal College of Psychiatrists should have a key role in fashioning this consensus in both practice and policy.

In conclusion, we suggest the following points for consideration:

1. Trusts should look at the position that RT documents occupy within their own organisations. The processes around a procedure as high risk as RT should, in our opinion, sit at a level equivalent to policy.
2. Clarification is required from a national level as to whether monitoring should be initiated after any RT medication or only after IM administration. In our opinion this should

- be mandatory after the latter, only being initiated after oral if the patient exhibits signs of CNS depression.
3. Clarification is required from a national level as to the baseline requirement for what monitoring needs to happen following RT, its frequency and duration. Monitoring must be evidence based, easy to follow and above all practical. The guidelines from NICE (2005) and Macpherson et al. (2005) provide a good foundation. However, they are also contradictory in a number of key areas. We believe this has been a major driver behind the variation in clinical practice demonstrated in this review.
 4. This exercise should be repeated in a more structured way, for example as an audit. We invite trusts to continue to participate on an annual basis to allow UK practice regarding this vital intervention to continue to be benchmarked.

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