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EFFORTS TO IMPROVE ACCURACY OF INFORMATION ABOUT ELECTROCONVULSIVE THERAPY GIVEN TO PATIENTS AND FAMILIES.

ABSTRACT

Objective: Many thousands of people still receive Electroconvulsive Therapy [ECT] but it remains highly contested. A recent audit of UK patient information-leaflets found multiple inaccuracies and omissions, minimising risks and exaggerating benefits, (e.g. only six leaflets mentioned cardiovascular events). This study reports efforts to improve accuracy for patients and families.

Methods: Letters were sent, twice, to managers of all 51 UK NHS Trusts, detailing the audit's findings and the accuracy of their own Trust's leaflet, also asking what changes would be undertaken.

Results: Only nine Trusts responded. Three committed to improvements. The Royal College of Psychiatrists released a slightly better but still highly misleading information-sheet. Efforts to engage Government and all other relevant UK bodies failed.

Conclusions: Information leaflets do not have to present balanced information.

Keywords: "Electro-convulsive therapy", ECT, consent, safety, efficacy, information.

1. Introduction

1.1.Electroconvulsive therapy

Electroconvulsive therapy involves approximately ten administrations of electricity to the brain, under general anaesthesia, over three or four weeks, to cause convulsions. Despite decline over several decades, it is still used on several hundred thousand people internationally annually (Leiknes et al., 2012; Read et al., 2013), including about 2,500 in England (Read et al., 2018; Read et al., 2021) down from about 50,000 in the 1970s. Women are approximately twice as likely as men to be recipients. The average age tends to be about 60. A significant proportion of administrations are given, under mental health legislation, against the will of recipients; in about a third of cases in England (Read et al., 2018; Read et al., 2021).

A review of 70 studies found 'large variation between continent, countries and regions in utilization, rates and clinical practice' (Leiknes et al., 2012). Audits in England found 12-fold (Read et al., 2018) and 47-fold (Read et al., 2021) differences in the rates of ECT usage between the highest and lowest using areas. Such extreme variability suggests there may be a range of views among psychiatrists about the efficacy and safety of this controversial intervention.

Some of the controversy stems from there having been no placebo controlled studies comparing ECT with 'sham'/'simulated' ECT (SECT), in which the general anaesthetic is administered but the electricity is not, since 1985. All 11 such studies failed to meet today's methodological standards (Read and Bentall, 2010; Read and Moncrieff, 2022). A recent review (Read et al., 2019) found:

> Only two studies describe their randomisation process and tested their blinding. None were genuinely double-blind. Only four reported any ratings by patients. None assessed Quality of Life. The studies were small, involving between eight and 77 participants, with an average of 37.2. Four of the 11 found ECT significantly

> superior to SECT at the end of treatment, five found no difference and two found that psychiatrists reported a difference and patients did not. Neither of the only two high Quality studies reporting data at one or six months post-treatment produced a significant difference between ECT and SECT and, when combined, they produced a very small pooled effect size (0.017) in favour of SECT.

A review focussed explicitly on placebo response to ECT (Rasmussen, 2009) reported 'an unexpectedly high rate of response in the sham [SECT] groups" (p. 59).

The controversy is also fuelled by uncertainty about how many patients develop long term memory problems. The 2019 review found rates of 'persistent of permanent memory loss' from 12% (Sackeim et al., 2007) to 55% (Rose et al., 2003) of patients. A New Zealand Government report (Ministry of Health, 2004) concluded 'ECT may permanently affect memory and sometimes this can be of major personal significance' and bemoaned the 'slowness in acceptance by some professional groups that such outcomes are real and significant in people's lives' (p. 16). A manufacturer of ECT machines, Somatics, includes 'permanent brain damage' in its list of risks (Schwartzkopff, 2018; Somatics, 2018). The American Psychiatric Association acknowledges that ECT causes 'permanent gaps in memory'(American Psychiatric Association, 2001). The USA's Food and Drug Administration requires notices to be displayed next to ECT machines stating 'The long term safety and effectiveness of ECT has not been demonstrated.' (Food and Drug Administration, 2020).

The controversy and uncertainty are acknowledged in the guidelines written in 2009 by the National Institute of Health and Care Excellence (NICE), the government body responsible for providing evidence-based recommendations for the NHS:

> … opinion varies from those who consider that its adverse effects are tolerable to those who consider that it is associated with unacceptable side effects including brain damage, severe confusion and considerable cognitive impairment in both the short and longer terms,p. 14)

For a defence of ECT, and critique of two reviews that have raised serious safety and efficacy concerns, (Read et al., 2013; Read et al 2019) see Meechan et al. (2021). Multiple 'errors, misrepresentations, omissions, inconsistencies and logical flaws' in their commentary have, however, been identified (Read, 2022). So, the long-lasting controversy continues (Read and Moncrieff, 2022; Read et al., 2019; Read et al., 2021; Read, 2021) with some ECT proponents recently becoming somewhat vitriolic (Read, 2022b).

1.2.Informed consent

There is general consensus that informed consent is an important ethical principle. The Code of Ethics of the UK's Royal College of Psychiatrists (RCPsych) states (Royal College of Psychiatrists, 2014):

> Psychiatrists shall seek valid consent from their patients before undertaking any procedure or treatment. . . . All treatments and procedures have potential detrimental as well as beneficial effects, and so it is important that the patient, and their family if appropriate, is involved in partnership with the treating psychiatrist in the decision-making process. Valid consent must be obtained before embarking on a treatment course or procedure. [This involves] the sharing of sufficient and understandable information to enable the patient to make an informed decision regarding the accepting or rejecting of treatment,p.11)

In 2003 the UK's National Institute for Health and Care Excellence, recommended, in its Guidance on the Use of ECT (National Institute for Health and Care Excellence, 2003):

> National information leaflets should be developed through consultation with appropriate professional and user organisations to enable individuals and their carers/advocates to make an informed decision regarding the appropriateness of ECT for their circumstances. The leaflets should be evidence based, include information about the risks of ECT and availability of alternative treatment.,.

1.3 An audit of ECT information leaflets

We therefore conducted an audit (Harrop et al., 2021) to assess the accuracy of ECT information leaflets given to patients in England, and, thereby, determine whether NHS Trusts, ECT prescribers and the RCPsych are providing evidence-based information, which is necessary for informed consent.

Freedom of Information Act requests were sent to all 51 National Health Service Trusts (healthcare providers) that offer ECT, asking for a copy of their information leaflet. These leaflets, as well as three published by the RCPsych, and one by Mind, the UK's largest mental health NGO, were scored on a 40-item measure of accuracy (see Table 1). Thirty-six Trusts (71%) provided leaflets. The number of accurate statements, from a possible 29, ranged from four to 20, with a mean of 12.8. The number of inaccurate statements, out of 11, ranged from two to nine, with a mean of 5.8. The most accurate leaflet was produced by Mind, with 19 accurate, and no inaccurate, statements. The RCPsych leaflet at that time contained 15 accurate statements and seven inaccurate statements. We concluded:

> Information about ECT currently provided to patients in England complies neither with NICE recommendations nor the ethical principle of informed consent. Patients are being misled about the seriousness of the risks they are taking and the limited nature of the benefits they can expect. (Harrop et al., 2021)

[Table 1 around here]

Similar findings resulted from a subsequent audit of ECT information leaflets given in Northern Ireland, Scotland and Wales (Read, Morrison & Harrop, 2023)

1.3.1. How reliable is the 40-point measure of accuracy?

Most of the 40 items assessing accuracy are merely descriptive or factual and beyond dispute (see Table 1). Others, however, require analysis of the relevant research. We do not have space to provide the evidence for all the items, other than to reference some key studies and reviews (Duma et al., 2019; Fosse and Read, 2013; Rami-Gonzalez et al., 2001; Rasmussen, 2009; Read and Arnold, 2017; Read and Bentall, 2010; Read and Moncrieff, 2022; Read et al., 2019; Robertson and Pryor, 2006; Rose et al., 2003; Ross, 2006; Sackeim et al., 2007).

1.3.2 Does ECT prevent suicide?

We will, nevertheless, discuss one item in some detail. Twenty two of the 36 Trusts had claimed that ECT saves lives by preventing suicide. Our measure scores that as an inaccurate statement. A 2019 review found that none of the five meta-analyses of ECT vs placebo studies for depression reported a single study showing that ECT is more effective than sham ECT at preventing suicide (Read et al., 2019). The only one ECT vs placebo study to include suicidal intent (Lambourn and Gill,1978) found no difference.

A 2010 review found multiple studies, with a range of methodologies, showing no difference in suicides between ECT and non-ECT groups, and no studies where ECT was superior. It did find two studies where ECT patients were five (Munk-Olsen et al., 2007) and three times (Sharma, 1999) more likely to have killed themselves than patients who had not had ECT.

A meta-analysis by the UK Government's ECT Review Group (2003, p.806) states: 'Although ECT is sometimes thought to be a lifesaving treatment, there is no direct evidence that ECT prevents suicide'. Another UK government report states: 'The evidence did not allow any firm conclusions to be drawn regarding the . . . impact of ECT on all-cause mortality.'

(Greenhalgh et al., 2005, p. 81). An investigation by the New Zealand Government found 'no definitive randomised evidence that ECT prevents suicide' (Ministry of Health, 2004).

Thus by 2019, multiple reviews and government reports had failed to find any studies, placebo-controlled or otherwise, substantiating the claim that ECT reduces the risk of suicide (Greenhalgh et al., 2005; Ministry of Health, 2004; Read and Bentall, 2010; Read and Arnold, 2017; Read et al., 2019; UK ECT Review Group, 2003). Since the 2019 review, six large-scale studies (all without placebo groups) have compared patients who did and did not have ECT.

A Canadian study found a statistically significant difference, in favour of ECT, of less than 0.2 of one percent, becoming the first ever study to have found any such difference. The rate of suicide, however, was unrelated to the number of ECT treatments received (Kaster et al., 2021, 2022). A second, using the Swedish national registry (Ronnqvist et al., 2021), also found a very small but statistically significant difference in suicides, over 12 months, between the ECT group (1.1%) and the non-ECT group (1.6%). The difference, however, was only significant for a small subset of the depressed patients, those who were also psychotic. Nor was the difference significant for people under 45. At three months (at which point any difference might more convincingly be attributed to ECT than at 12 months) there had been no significant differences at all. Furthermore 'Suicide was defined as death caused by intentional self-harm (ICD-10 codes X60-X80) or by an event of undetermined intent (ICD-10 codes Y10-Y35).'

A third study, of US veterans, found that those who had had ECT were 16 times more likely to try to kill themselves in the year after ECT than a matched group of veterans (Peltzman et al., 2020). After controlling for 'demographic, clinical, and service use characteristics,' the ECT patients were still 1.3 times more likely to have killed themselves (a non-significant difference). Another study of US veterans found 'no evidence that an ECT course decreased the risk of death by suicide', after 30 days and one year (Watts et al., 2022). A fifth study, using the Danish National Patient Registry, also found an increased risk of suicide in patients

who received ECT compared to equally depressed non-ECT patients, after one year. (Jorgensen et al., 2020). Finally, a study of homeless US veterans who received ECT had reported significantly more suicidal ideation and made significantly more suicide attempts, at 30 days, 90 days and one year, than matched homeless veterans who hadn't had ECT (Tsai et al., 2021).

Thus after 85 years of ECT most studies trying to prove that ECT does, as claimed, prevent suicide in depressed people, have found no difference between those who did and did not receive ECT; several have found that ECT is associated with increased suicide; and just one has found in favour of ECT. The difference in that study was less than 0.2 of one percent (Kaster et al., 2021, 2022), and the number of ECTs received was unrelated to suicide.

1.4 The current study

The current paper reports on our efforts to use our audit's findings to improve the quality of information provided to patients and, thereby, compliance with the principle of informed consent.

2. Methods

Following publication of our audit (Harrop et al., 2021), CH and JR wrote, in June 2021, to the 51 NHS Trusts that had been asked to provide information leaflets. The emails were addressed to both the Chief Executive and the Chair of each Trust. A copy of our audit was attached. We wrote:

> In 2003 the National Institute for Health and Care Excellence (NICE) recommended that: "National information leaflets should be developed through consultation with appropriate professional and user organisations to enable individuals and their carers/advocates to make an informed decision regarding the appropriateness of ECT for their circumstances. The leaflets should be evidence based, and include information about the risks of ECT and availability of alternative treatments.

Besides summarising the overall results of the audit, the 36 Trusts that had provided their leaflet were given specific outcomes for their leaflet:

> Your Trust's leaflet includes X pieces of accurate information, which is worse/better than the disappointing national average. Among the basic facts it fails to tell patients are: [LISTED]
> The leaflet also includes X inaccurate statements, which is worse/better than the national average [LISTED].
> We therefore recommend that the Trust immediately withdraws, and updates, its information leaflet and, in the meantime, refers patients to Mind's information document, which has 19 accurate statements and no inaccurate statements. We also recommend that the Trust does not use, or refer patients to, the current Royal College of Psychiatry information document. It includes seven inaccurate statements.

All 51 letters concluded:

> When you have had time to consider the issues raised in this letter, and formulated a plan as to how to address them, please write to us to share that plan. . . . Please feel free to contact us if we can be of any further assistance in achieving our shared goal of ensuring patient safety and adhering to ethical principles and national guidelines.'

In October CH wrote a reminder to the 49 Trusts who had not yet responded, which included:

> 'Before publishing the results of our request we would like to give you an additional month (until 9/11/2021) to let us know what changes you have made/are planning; or, if you do not intend to amend your leaflet, to explain why that is the case'.

Meanwhile efforts were made to engage with the RCPsych, the Minister for Mental Health and the NICE committee reviewing its 'Guidance on Depression in Adults'.

3. Results

3.1 NHS trusts

Nine out of the 51 Trusts (18%) responded (two within three months and seven following the reminder). This included one that had not provided their leaflet for the initial audit (Tees, Esk and Wear Valleys). Five of the responses were written by Chief Executives (including one in conjunction with the Chair of the Trust) and four were from Medical Directors.

One wrote that 'the points which you make in your email will be considered' as part of ongoing review. Three stated that they would definitely be acting on our findings.

Leeds and York :

> 'We will be acting on your recommendations, particularly as a co-designed leaflet seems like a really good idea.'

Tees, Esk and Wear Valleys:

> 'We are acting to strengthen our informed consent processes immediately and also through co-creation with patients and carers of an updated information leaflet that accommodates your findings, for use within the trust'

Mersey Care:

> 'Many thanks for your e-mail, and for its inclusions. I have had the opportunity to discuss its content with Dr XXX XXX, Medical Director, who has in turn shared your observations with Dr XXX XXX, ECT Lead for our trust.
> Whilst as a trust we are confident that we have adequate governance and assurance around the appropriate use and monitoring of ECT, we are currently reviewing our processes in the context of your observations.
> In direct response to your correspondence, we have committed to completely re-write our patient information leaflet, ensuring that it is co-produced with service users having lived experience of receiving ECT at the trust.'

The need to co-produce leaflets with patients/service users, a NICE recommendation, was mentioned by all three of the Trusts that committed to making changes. In addition, Lancashire and South Cumbria wrote:

> ‘We support the changes being made (by RCP) in light of some of your comments and fully support that people with lived experience should be at the heart of the design of patient leaflets.’

Co-production with patients/service users was the only specific change mentioned by any Trusts that related to any of our audit’s 40 criteria.

Six Trusts referred to their use of the RCPsych’s information document (although two of these thought it was published by ECTAS). Five of the six wrote that they had been informed by the RCPsych that their leaflet was being updated in response to our research. For example:

Lancashire and South Cumbria:

> ‘The College {RCP} have informed us that the leaflet will be updated imminently in response to your feedback. We agree that amendments are required in light of updated reviews but also to ensure that patients have the best information available with which to make informed decisions.’

Tees, Esk and Wear Valleys:

> ‘I have been led to understand that the Royal College of Psychiatrists is reviewing their own information leaflet in the light of your findings.’

Dorset followed suit but was premature:

> ‘Communication from Professor XXX XXX, Chair of Public Engagement Editorial Board Royal College of Psychiatrists on 25th October 2021 confirms that ECTAS have looked at the criticism from your audit carefully. In light of this revisions have been made to their leaflet to reflect the outcome of their analysis with the addition of high-quality recent evidence to support the safety of the treatment.’ . . . The letter from Professor XXX states that Trusts using the Royal College of Psychiatrists information leaflet are conforming to high standards of practice in this area’.

Three Trusts referred to the MIND leaflet, which had scored highest in our audit.

Tees, Esk and Wear Valleys:

> 'I have immediately recommended that we consistently make full use of the MIND leaflet as our preferred information source as you have advocated'.

Merseycare:

> 'We will seek to incorporate the information included within the excellent leaflet from 'Mind' that you have shared. In fact, we have chosen to adopt and share the Mind leaflet with any service users pending ECT, as an interim position, while we compose our new trust information leaflet.'

Worcester already used the Mind leaflet (as well as the RCP leaflet), which they described as 'an impartial document for balance'.

Four Trusts referred to ECTAS. Some Trusts seemed to think ECTAS evaluated the information leaflet they were using while others seemed to think ECTAS wrote it.

Birmingham and Solihull:

> 'We similarly to most ECT services are governed internally by our Clinical Governance system and externally by the ECT Accreditations Service (ECTAS) which works with the Royal College of Psychiatrists. We are regularly inspected by ECTAS as a process of quality assurance, audit and evaluation. We also understand that the ECTAS has a system of reviewing these standards, as more information emerges with respect to ECT and its practice across the country and more widely. As is usual practice across the country, we use the Patient Information Leaflet produced by the Royal College of Psychiatrist as a standard document. This is supported by the ECTAS'.

Dorset:

> ‘Dorset Healthcare University NHS Foundation Trusts ECT service is accredited by the Royal College of Psychiatrists Electroconvulsive Therapy Accreditation Services (ECTAS). . . . The information leaflet used by the Trust is the revised ECTAS leaflet 2021 which is attached.’ [The attachment was the RCP leaflet]

Lancashire and South Cumbria:

> ‘As a service that is accredited by the College Centre for Quality Improvement via their ECTAS scheme we adhere closely to those standards which encompass many aspects of effective patient care. Following discussion, we have taken the decision to continue to use the leaflet that is produced via ECTAS and therefore consistent with a large number of other trusts around the country.

Worcester:

> ‘Our patient information packs were passed through our most recent ECTAS review and coincidentally, the Worcester ECT suite actually received a special commendation from ECTAS for "patient experience"..... this included the quality of our information packs.’

3.2 Royal College of Psychiatrists

Meanwhile, CH received an email, in July 2021, from an unidentified member of the RCPsych’s ‘Patient Information Team’ asking for the ‘scoring sheet which shows what rating you have assigned to the Royal College of Psychiatrists resource on each of the criteria of your rating scale’. The data was provided and we sought an appropriate, named individual to liaise with, in the hope of working collaboratively towards an improved RCP document. The Chair of the RCP’s ‘Public Engagement Editorial Board’ (the same person who had written to the Trusts to say the RCP was revising its leaflet in the light of our findings) emailed CH saying ‘Thank you very much for your openness in sending this. We will take a careful look at it, as you say, we are committed to ensuring that our patient information resources are complete and balanced.’

Nothing else was forthcoming for three months. In October, CH asked:

> 'Have you and your colleagues had time to decide which of the 14 points we suggested are missing from your document and the seven statements which we assessed as inaccurate you will be changing in an amended document? As I said, I don't expect you to agree with all 21 of our points. If there are some you are not sure about and would like to discuss, do let me know.'

No meeting, or collaboration, was offered by RCPsych. In March 2022 the RCPsych published its revised document,[25] but declined to respond to CH's repeated requests to identify which of the 21 recommended changes had and had not been made and why, or to engage in any discussion with CH.

CH and JR independently scored the new RCPsych document on the 40 criteria from the original audit. Both scored the document as including 19 accurate statements (out of the possible 29). One identified eight inaccurate statements, and the other seven (out of the possible 11). There were three discrepancies between CH and JR on specific criteria. This represents a 92.5% level of agreement (37/40) and a Cohen's kappa inter-rater reliability score (which allows for expected agreement by chance) of 0.80, categorised as 'substantial agreement' (0.61-0.80; Landis and Koch,1977).

Discussion of the three discrepancies led to final agreed scores of 20 accurate statements and seven inaccurate statements (a total score of 13). Where it was not immediately clear whether a criterion had been met the raters erred towards the positive. For example, acknowledgement that 'the risks of side effects is slightly increased if you are a woman or if you are elderly' was accepted as meeting the criterion 'memory loss is more common in women and older people, despite the 'slightly' and the lack of specificity re memory loss. The final, agreed, scores represent an improvement from the total score of 8 (15 accurate and seven inaccurate statements) in the previous RCPsych document (Harrop et al, 2021).

The five new accurate statements were:

- Provided with Care Quality Commission's leaflet 'Your rights about consent to treatment'
- Patients right to have 24 hours to think and consult before making a decision regarding consent
- Information about rights under the Mental Health Act
- Memory loss is more common in women and older people
- Mention of psycho-social causes of depression rather than just portraying depression as an 'illness'

Two inaccurate statement had been removed:

- False claims re very low mortality rates
- Depression framed as an 'illness' without mention of psycho-social causes

Two inaccurate statements, however, had been added:

- Minimizing size/strength of electric current ('use of small, very small of other diminutive terms')
- False claims of 'most effective' treatment

Five inaccurate statements were carried over from the previous leaflet;

- False claims of high percentage recovery rates without reference to placebo response rates
- Claim that ECT is life-saving
- Minimisation of memory loss re severity or prevalence
- Blames memory loss on depression
- Claims that ECT corrects biological deficits

The nine missing accurate statements, in both documents:

- Amount of electricity (volts, milliamperes etc.) and/or dosage increases over the course of treatments
- Mention of co-production with patients
- Some/many people in placebo/sham ECT groups recover
- No evidence of benefits beyond end of treatment, or mention of high relapse rates
- Risk of cardiovascular events
- Acknowledgment of mortality risk
- ECT has higher risk than one general anesthetic because course of ECT involves about ten
- It is not known how it works
- How to access legal advocate

3.3 National Institute of Clinical and Health and Care Excellence (NICE)

As noted earlier, NICE mandated in 2003 that quality evidence-based and balanced information leaflets should be developed.

Psychiatry's failure to comply with this recommendations, despite it being repeated in subsequent versions of the Guidance, had been a primary reason for our 2021 audit. In 2021 NICE was reviewing its Guidance on treatments for 'Depression in Adults'. The audit of information leaflets (Harrop et al., 2021) was submitted to the NICE review process, along with two audits of the administration and monitoring of ECT in England (Read et al., 2018, 2021), research studies on efficacy and safety, and 'Electroconvulsive Therapy for depression: A Review of the quality of ECT vs sham ECT trials and meta-analyses' (Read et al., 2019).

When NICE issued the draft of its revised Guidance, for consultation, in November 2021, all recommendations about information leaflets had disappeared. In January 2022, 50 people (including 14 ECT recipients and three relatives thereof, 12 psychiatrists and seven Professors in mental health disciplines) wrote an open letter to NICE (Read et al, 2022):

> 'We call upon NICE to radically rewrite the ECT section of its draft Depression in Adults guidelines; to reiterate and uphold the unimplemented recommendations from the 2003 Guidelines; and to take into account recent evidence on serious deficiencies in safety, effectiveness and regulation'.

One of NICE's 'Top 10 failures to ensure safe, effective and properly regulated ECT practice' identified in the letter was:

> **'No statement about the failure to produce evidence-based patient information leaflets, as recommended by NICE 2003.** A recent audit (Harrop et al., 2021) shows that current leaflets contain numerous serious inaccuracies, confirming NICE 2003 concerns about informed consent: '….the potential for cognitive impairment following ECT may not be highlighted during the consent process.'

The letter concluded:

> Ongoing failure to address these concerns would represent a wilful neglect of patient safety, and a breach of NICE's own core commitment to evidence-based practice. . . . We trust the committee will, even at this late stage, and in line with its own principles and procedures, reconsider the draft in its entirety.

When the final guidance was published it became clear that NICE had abandoned most of its 20 year old recommendations, including the one calling for evidence-based information leaflets (NICE, 2022, pp. 75-78).

3.4 Ministry of Health

Meanwhile, our submission of our audit to the then Minister for Mental Health, Nadine Dorries, MP, led to an incoherent response that did not address any of the issues raised by our audit. In August, we tried again:

> 'We think . . . . you may have misunderstood our concerns. NICE clearly called for *one*, national ECT leaflet and made it clear that this must be *evidence-based*. Our audit found that both of these NICE recommendations are still being ignored, 18 years later. Patients are being given divergent information and are being misinformed on a range of issues, including risks (i.e. memory loss/brain damage) and efficacy.
>
> This means that the NHS Trusts in question are currently not meeting legal requirements for informed consent.
>
> Indeed, the Nottingham legal firm Freeths is currently preparing several cases for ECT patients against the NHS based on failure to warn patients of the risks of ECT.
>
> Under these circumstances we feel that the Minister may wish to look into the matter with the goal of ensuring informed consent and patient safety.'

No response was forthcoming.

4. Discussion

4.1. Successes

Three Trusts made clear commitments to amend their leaflets on the basis of our audit, including use of the Mind leaflet that the audit endorsed. The RCPsych's new leaflet has three new statements about patients' rights that the audit had identified as missing. It also acknowledged that 'the risks of side effects is slightly increased' … 'if you are a woman or if you are elderly'. This is an important step in the right direction since none of the Trusts, or Mind, acknowledge this fact. The leaflet also now acknowledges that there are 'reasons for your depression' that might be addressed by 'talking therapies' (accepted by the raters as meeting the 'psychosocial causes' criterion). Furthermore, the leaflet has removed false claims about low mortality rates, made by 28 of the Trusts (Harrop et al, 2021).

4.2 Failures

Most of the 51 NHS Trusts were unresponsive. Fifteen (29%) failed to comply with the original FoI request for their leaflet, despite a reminder, and also failed to even acknowledge our letter sent to Chief Executives and Board Chairpersons. This suggests disinterest in, or lack of resources to enable, both taking part in research and acting on research findings. Only eight (16%) provided their leaflet and then responded to the follow-up letter. The responses of the nine Trusts that did respond to the letter ranged from an enthusiastic decision to 'completely re-write our patient information leaflet' to rather vague promises to 'consider' our findings or statements about continuing to use the RCP document.

The RCPsych document still has five inaccurate statements and nine omissions, including failing to mention cardiovascular events, the leading cause of ECT related deaths, despite a recent review of 82 studies and over 100,000 patients, which found that one in 39 ECT patients experience 'major adverse cardiac events' (Duma et al., 2019).

The responses of most NHS Trusts, government and NICE can reasonably be described as negligent.

4.3. The need for regulation and review

Our parallel efforts to have the equally disturbing findings of our two audits on how ECT is administered and monitored in England (Read et al, 2018; Read et al, 2021) have made it clear that no body is effectively monitoring or regulating. The RCPsych's 'ECT Accreditation Service' (ECTAS) has recently stressed that it has no monitoring or regulatory responsibilities (Sivasanker et al., 2021). Indeed, ECTAS' reports on ECT Clinics (who are not obliged to join ECTAS) are not publicly available, and patients and families are not told whether the clinic they are attending is accredited. Among the many inadequate ECTAS 'standards' is the one

that requires that patients are ‘provided with an ECT patient information’ with no specification whatsoever of what the leaflet should contain or that it should be evidence-based. So even the lowest scoring Trust leaflets in our audit can meet that that ECTAS requirement on the way to becoming accredited.

This study suggests that psychiatrists and managers mostly rely on the RCPsych’s ECTAS, even when made aware of a substantial research literature about serious dangers from ECT, and significant concerns with ECTAS, such as apparent failure to monitor for cognitive damage or effectiveness. It is problematic that patients are just not given accurate information about serious risks and presented with such misleading claims as: “68% of people who had been treated with ECT were “much-improved” or “very much improved” on a highly subjective measure of depression, a single 1-7 scale rated by the treating doctors themselves. There is no body holding ECTAS to account. The regulatory body, the Care Quality Commission has acknowledged they ‘do not currently identify it [ECT] as an aspect of services that must be checked on inspections, and about which data is routinely collated’ (Wyman, 2021).

The findings of our audits and the current paper add credence to the campaign for an independent, enquiry into the administration of ECT (Johnstone and Cunliffe, 2020). It is backed by many mental health and health organisations, including Mind (the UK’s largest mental health NGO), Headway (the brain injury association), the Association of Clinical Psychologists, and more than 20 cross party MPs including the Shadow Mental Health Minister.

4.4. Limitations

The most obvious limitation is that the Covid pandemic placed extreme pressure on Trusts and the Ministry of Health which almost definitely impeded more positive responses. Another limitation is our own limited time and resources, which precluded developing the

direct, personal relationships which are more conducive to change than emails (although efforts were made, and rebuffed, with the RCPsych).

Our audit is already out of date. A subsequent large-scale study has found that people subjected to at least ten ECTs (the average course) are more than twice as likely as psychiatric patients not subjected to ECT to develop amyotrophic lateral sclerosis, with patients over 65 more susceptible (Mezei et al., 2022).

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Table 1
Definitions, and scores, for 40 criteria for evidence-based information leaflets about ECT (from Read et al, 2019).

CRITERION DESCRIPTION	*	DEFINITION FOR SCORING	NUMBER OF TRUSTS [out of 36]
General anaesthetic	+	Mention of general anaesthetic	34
Electric current	+	Mention of application of electricity/electric current to head/brain	34
Minimising size/strength of current	--	Use of 'small' 'very small' or other diminutive terms	19
Voltage	+	Amount of electricity (volts, milliamperes etc) and/or fact that dosage increases during the course of treatment	0
Convulsion	+	Mention of convulsion/seizure/fit	34
Minimising the convulsions	--	Use of 'mild' 'short' etc,'controlled' is acceptable)	12
Number	+	Average number of ECTs in a series stated (about ten)	35
Unilateral v bilateral	+	Information about the two electrode placement options, and that bilateral is more effective and causes more memory loss and unilateral less effective with less memory loss	14
NICE GUIDELINES			
Guidelines	+	Any mention of NICE guidelines	18
Limits on diagnostic group	+	Mention of 'severe depression', catatonia and mania.	32
Previous treatment	+	Mention that medication and psychological therapies should have been tried and did not work failed	12
Evidence-based	+	Any accurate reference to a research study	18
Co-production with patients	+	Mention of involvement of patients/service users in writing the leaflet	1
EFFICACY			
False claims of 'most effective'	-	Any use of 'most effective' in general or in relation to other treatments	11
False claims of high improvement %s	-	Claim of > 60% percentage recovery/improvement without reference to placebo response rates	19
False life-saving claims	-	Claim that ECT saves lives/prevents suicide	22
Placebo response rates	+	Statement that some/many people in placebo/sham ECT groups improve/recover	6
Lack of long term benefits	+	Statement that that there is no evidence of long-term benefits (ie beyond end of treatment) or use of 'short-term'/'temporary' to describe benefits, or mention of relapse rates	6
RISKS			

Immediate confusion/headaches /nausea etc.	+	Mention of temporary effects immediately after regaining consciousness	31
Short term memory loss	+	Acknowledgement of memory loss/dysfunction or other cognitive dysfunction	34
Long term/permanent memory loss	+	Acknowledgement that for some people memory loss/cognitive dysfunction is 'long-term'/'persistent'/'permanent or represents 'brain damage'	26
Higher for women/older people	+	Statement that the memory loss is more common in women and older people	0
Monitoring	+	Informs that patient will be monitored for memory loss/cognitive dysfunction following each ECT	12
Minimisation re memory	-	Any minimisation/denial of memory loss in terms of severity or prevalence (other than blaming depression)	23
Blames depression	-	Blames the memory loss on depression rather than ECT	15
Cardiovascular problems	+	Any mention of risk of cardiovascular events following ECT	6
Mortality	+	Acknowledgement of mortality risk, without minimising statements (eg comparing to safety of general anaesthetic)	2
False claims re low mortality risk	-	Unevidenced claims of very low mortality rates (eg 1:10,000 patients or 1:80.000 treatments)	28
Risk of multiple general anaesthetics	+	Acknowledgement that ECT has higher risk than one general anaesthetic because it involves about ten treatments	7
Driving	+	Directions not to drive during the course of treatment (not just 24 hours after each individual treatment)	21
MECHANISM OF ECT			
Don't know	+	Any acknowledgement that we don't know how it works (even if it goes on to make suggestions/theories)	10
False claims about correcting bio-deficits	-	Claims that ECT corrects biological causes of depression such as biochemical imbalance/activity, brain connectivity etc	28
CAUSES OF DEPRESSION			
Illness	-	Unsubstantiated biological causes of depression such as chemical imbalance, genetics etc. or framing of problems as 'illness' or disease, without mention of psycho-social causes	21
Psycho-social	+	Any mention of psycho-social causes of depression, such as loss, abuse, poverty etc.	0
CONSENT			
Rights	+	Information about rights under Mental Health Act	22
Access to legal support	+	How to access legal advocate	9

CQC leaflet given	+	Provided with Care Quality Commission *Your rights about consent to treatment* leaflet, or equivalent, and this is verbally explained and documented. Or Link to leaflet on CQC website.	4
False claim that most/all are given ECT voluntarily	-	False claim that most/all are given ECT voluntarily	11
Consent can be withdrawn	+	Patients are informed by both the referring clinician and the ECT team that their consent can be withdrawn at any time. Consent will then be required before any further ECT treatments can take place	32
24 Hours to discuss	+	For every new course of ECT, except in an emergency, patients are given at least 24 hours to reflect on information about ECT and discuss this with relatives, friends, or advisers before making an informed decision regarding consent	1

* + = accurate statement; - = false/inaccurate statement