

RESEARCH ARTICLE

An independent audit of electroconvulsive therapy patient information leaflets in Northern Ireland, Scotland and Wales

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Abstract

Objectives: To evaluate the accuracy of patient information leaflets about electroconvulsive therapy (ECT) used in Northern Ireland, Scotland and Wales, and their compliance with the principle of informed consent.

Design and Methods: To replicate an audit in England, Freedom of Information Act requests were sent to the 26 providers of ECT for their ECT patient information leaflet. These were scored, by two independent raters, on the same 40-item accuracy measure used in the England audit.

Results: The number of accurate statements (out of a possible 29) ranged from seven to 20, with a mean of 16.9. The most frequently omitted statements included: cardiovascular risks (mentioned by five leaflets), that it is not known how ECT works (3), risk of mortality (2), risks from multiple general anaesthetic procedures (2), how to access a legal advocate (2) and that there is no evidence of long-term benefits (1). The leaflets made between six and nine inaccurate statements (out of 11) with a mean of 7.0. Nineteen minimised memory loss, blamed the memory loss on depression, claimed that ECT is the ‘most effective treatment’ and asserted it has very high response rates without mentioning similar placebo response rates. All 23 leaflets wrongly told patients that ECT saves lives.

Conclusions: Electroconvulsive therapy information leaflets in these three nations are barely more accurate than those in England and do not comply with the ethical principle of informed consent. Patients and families across the UK are systematically being misled about the risks they are taking and the limited nature of ECT's benefits.

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KEYWORDS

adverse effects, electroconvulsive therapy, ethics, informed consent

Practitioner points

- Psychologists and other mental health professionals have a shared responsibility to implement the ethical principle of informed consent.
- All mental health professionals need to inform themselves of the research evidence for the efficacy and safety of all treatments offered to their patients.
- Managers of mental health services, and government agencies, need to actively oversee ECT clinics, including the information given to patients.

INTRODUCTION**Informed consent**

The obligation to ensure informed consent is a core ethical principle of all health and mental health professionals. The World Psychiatric Association's *Code of Ethics* (2020) succinctly states:

In pursuing informed consent, psychiatrists should offer patients accurate information about their diagnoses, proposed treatments, risks, potential benefits and alternatives (p. 4)

The British Psychological Society's (BPS) *Practice Guidelines* (2017) offer more detail:

The concept of informed consent relates to the client's right to choose whether to receive psychological services and to make this choice on the basis of the best information available ... (p. 48)

The psychologist should consider providing information about the following:

- What the psychological activity involves.
- The benefits of the activity.
- Any alternative assessment or treatment options and their known availability.
- Foreseeable risks and how minor or serious they may be.
- What might be the benefits and potential costs and risks to them of engaging or not engaging in the proposed psychological activity.
- The client's right to withdraw their consent from assessment, treatment or intervention at any stage, along with information about any likely consequences of such withdrawal. (p. 49)

The BPS also identifies two potentially biasing dynamics that are of central importance to the current study:

Psychologists should be aware that a client's desire for help, and the immediate impact of the psychologist's supportive listening, may affect the client's ability to make informed choices about the help they wish to receive. They should also be aware that their own

desires to help a client may bias their presentation of information, such as the probability of successful outcomes.

(p. 49)

Electroconvulsive therapy

Electroconvulsive therapy (ECT) remains one of the most controversial treatments in psychiatry (Read, Cunliffe, et al., 2019; Weeks et al., 2021). This is unsurprising since just one course of ECT involves passing sufficient electricity across the human brain to cause a seizure, about 10 times (Read, Kirsch, et al., 2019; Royal College of Psychiatrists, 2022a). The authors of one meta-analysis found that views vary from ‘it is probably ineffective but certainly causes brain damage... through to those who think it is the most effective treatment in psychiatry and completely safe’ (UK ECT Review Group, 2003, p. 799).

Systematic reviews (Read & Bentall, 2010; Read, Kirsch, et al., 2019) have established that there have only ever been 11 placebo-controlled studies of ECT for depression, most recently in 1985 (Gregory et al., 1985). The reviews reported that the studies were small and severely flawed. The more recent review concluded:

There is no evidence that ECT is effective for its target demographic—older women, or its target diagnostic group—severely depressed people, or for suicidal people, people who have unsuccessfully tried other treatments first, involuntary patients or adolescents. Given the high risk of permanent memory loss and the small mortality risk, this longstanding failure to determine whether or not ECT works means that its use should be immediately suspended until a series of well-designed, randomised, placebo-controlled studies have investigated whether there really are any significant benefits against which the proven significant risks can be weighed.

(p. 64)

Proponents of ECT have critiqued these reviews, arguing that ECT is indeed effective, that it even saves lives, and that it is safe (Gergel et al., 2021; Meechan et al., 2021). The critiques have been rebutted (Read, 2022; Read, Harrop, & Geekie, 2022; Read & Moncrieff, 2022). While proponents of ECT claim a high response rate, a review of research into the placebo response with ECT (where the general anaesthetic is administered but the electric shock is withheld and no convulsion occurs) found ‘an unexpectedly high rate of response’ in placebo patients (Rasmussen, 2009, p.59).

Twenty years ago, the UK's National Institute for Health and Care Excellence (NICE, 2003) bemoaned the absence of clear, evidence-based information for patients and recommended:

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 treatments, and be produced in formats and languages that make them accessible to a wide range of service users.

Audit of ECT information leaflets in England

In order to evaluate the extent to which the principle of informed consent, and the 2003 NICE recommendation, are being complied with, an independent audit sent Freedom of Information Act

requests to the 51 National Health Service Trusts in England, asking for their information leaflet (Harrop et al., 2021). These leaflets, together with three consecutive Royal College of Psychiatrists (RCPsych) leaflets, and one from the largest mental health NGO in England, Mind, were scored on a 40-item accuracy measure (also used in the current study). Thirty-six Trusts 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, from a possible 11, ranged from two to nine, with a mean of 5.8. Table 1 shows how often each of the criteria was met. The 2020 RCPsych leaflet in use at the time contained seven inaccurate statements and scored worse than two previous RCPsych leaflets (Harrop et al., 2021). The Mind leaflet was the most accurate. The audit concluded:

Information leaflets about ECT comply neither with NICE recommendations nor the principle of informed consent. Patients are being misled about the risks they are taking and the limited nature of ECT's benefits.

(p. 5)

The current study reports the findings of an identical audit of ECT information leaflets being used in Northern Ireland, Scotland and Wales.

METHODS

In April 2022, requests for 'ECT Patient Information Leaflets' were sent, under the Freedom of Information Act (2000), to 26 providers of ECT, specifically: five NHS Health Boards in Wales, five NHS Health & Social Care Trusts in Northern Ireland (listed by the ECT Accreditation Service, 2022), and 16 ECT facilities in Scotland, located across 11 Health Boards (listed by the Scottish ECT Accreditation Network, 2019). Follow-up emails were sent to non-responders in August.

When data collection ended, on September 30, 23 information leaflets had been received. The Betsi Cadwaladr Health Board in Wales failed to respond. The Royal Cornhill Hospital in Scotland's Grampian Health Board sent only a document focussing on procedures on the day of treatment. Scotland's Highland Health Board reported that Hairmyres Hospital does not use ECT. However, the Scottish ECT Accreditation Network (SEAN), in response to a follow-up email after data collection had ended, informed us that the hospital does use ECT. Thus, 23 of the 26 facilities that use ECT (assuming SEAN is correct about Hairmyres) provided their ECT information leaflets. This is a response rate of 88%.

The leaflets were scored independently by two researchers (LM, JR) on the 40-item instrument used in the previous audit of ECT leaflets in England (Harrop et al., 2021; see Table 1). In that previous audit, the level of agreement between two independent raters was 92%, representing an inter-rater reliability $kappa$ (which corrects for agreements expected by chance) of 0.83, which falls in the 'almost perfect agreement' range (Landis & Koch, 1977).

The scale consists of 29 accurate statements and 11 inaccurate statements. An overall accuracy score is calculated by subtracting the number of inaccurate statements included in a leaflet from the number of accurate statements (producing a potential range of 29 to minus 11). The topics covered by the scale are: ECT Description (8 items), Compliance with NICE Guidelines (5), Efficacy (5), Risks (12), ECT Mechanism (2), Causes of Depression (2) and Consent (6). As in the previous audit, two researchers scored the information leaflets blind to the scores of the other researcher. Where discrepancies occurred, a resolution was reached via discussion (see Results).

The original scale development did not involve people who had experienced ECT. The current paper, however, is co-authored by someone who received 96 ECT treatments, mostly in Northern Ireland, most recently in 2016 (Morrison, 2021, 2022). She reviewed the scale items and confirmed their face validity based on her extensive experience of ECT and her subsequently gained knowledge. (She has worked in the Southern Health and Social Care Trust Mental Health and Disability Division as the

TABLE 1 The 40 accuracy criteria for ECT information leaflets, with the number of ECT clinics in Northern Ireland, Scotland and Wales meeting each criterion.

| Criteria | Definition for scoring | No. of units meeting criteria [n=23] | % of England units meeting criteria* [n=36] | Key sources re. efficacy and risks |
|-------------------------------------|---|--------------------------------------|---|------------------------------------|
| Descriptive | | | | |
| General anaesthetic | + Mention of <i>general</i> anaesthetic | 23 (100%) | (94%) | |
| Electric current | + Mention of application of electricity/electric current to head/brain | 23 (100%) | (94%) | |
| Minimising size/strength of current | - Use of 'small' 'very small' or other diminutive terms | 17 (74%) | (53%) | |
| Voltage | + Amount of electricity (volts, milliamperes etc) and/or the fact that dosage increases during the course of treatment | 0 (0%) | (0%) | |
| Convulsion | + Mention of convulsion/seizure/fit | 23 (100%) | (94%) | |
| Minimising the convulsions | - Use of 'mild' 'short' etc. ('controlled' is acceptable) | 2 (9%) | (33%) | |
| Number | + Average number of ECTs in a series stated (about 10) | 23 (100%) | (97%) | |
| Unilateral vs. 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 | 18 (78%) | (39%) | |
| Nice guidelines | | | | |
| Guidelines | + Any mention of NICE guidelines (or Scottish Intercollegiate Guidelines Network in Scotland) | 20 (87%) | (50%) | |
| Limits on diagnostic group | + Mention of 'severe depression', catatonia and mania | 20 (87%) | (89%) | |
| Previous treatment | + Mention that medication <i>and</i> psychological therapies should have been tried and did not work failed | 17 (74%) | (33%) | |
| Evidence-based | + Any accurate reference to a research study | 16 (70%) | (50%) | |
| Co-production with patients | + Mention of involvement of patients/service users in writing the leaflet | 2 (9%) | (3%) | |
| Efficacy | | | | |
| False claims of 'most effective' | - Any use of 'most effective' in general or in relation to other treatments | 19 (83%) | (31%) | 1-3 |
| False claims of high improvement %s | - Claim of >60% percentage recovery/improvement without reference to placebo response rates. | 19 (83%) | (53%) | 1, 2, 4, 5 |
| False life-saving claims | - Claim that ECT 'saves lives/prevents suicide | 23 (100%) | (61%) | 6-9 |

(Continues)

TABLE 1 (Continued)

| Criteria | Definition for scoring | No. of units meeting criteria [n=23] | % of England units meeting criteria ^a [n=36] | Key sources re. efficacy and risks |
|---|------------------------|--------------------------------------|---|------------------------------------|
| Placebo response rates | + | 1 (4%) | (17%) | 1, 2, 4, 5 |
| Lack of long-term benefits | + | 1 (4%) | (17%) | 1-3, 10 |
| Risks | | | | |
| Immediate confusion/headaches/nausea etc. | + | 23 (100%) | (86%) | 1, 2, 10, 11 |
| Short-term memory loss | + | 23 (100%) | (94%) | 1, 2, 10-13 |
| Long-term/permanent memory loss | + | 21 (91%) | (72%) | 1, 2, 10, 11, 14, 15 |
| Higher for women/older people | + | 12 (52%) | (9%) | 14 |
| Monitoring | + | 16 (70%) | (33%) | |
| Minimisation re memory | - | 19 (83%) | (64%) | 1, 2, 10, 11, 14, 15 |
| Blames depression | - | 19 (83%) | (42%) | 1, 2, 16, 17 |
| Cardiovascular problems | + | 5 (22%) | (17%) | 1, 18 |
| Mortality | + | 2 (9%) | (6%) | 1, 2, 18-21 |
| False claims re low mortality risk | - | 10 (43%) | (78%) | 1, 2, 18-21 |
| Risk of multiple general anaesthetics | + | 2 (9%) | (19%) | |
| Driving | + | 18 (78%) | (58%) | 22 |

TABLE 1 (Continued)

| Criteria | Definition for scoring | No. of units meeting criteria [n=23] | % of England units meeting criteria ^a [n=36] | Key sources re. efficacy and risks |
|---|---|--------------------------------------|---|------------------------------------|
| Mechanism of ECT | | | | |
| Do not know | + Any acknowledgement that we do not know how it works (even if it goes on to make suggestions/theories) | 3 (13%) | (28%) | |
| False claims about correcting bio-deficits | - Claims that ECT corrects biological causes of depression such as biochemical imbalance/activity, brain connectivity, etc. | 19 (83%) | (78%) | |
| Causes of depression | | | | |
| Illness | - Unsubstantiated biological causes of depression such as chemical imbalance, genetics, etc. <i>or</i> framing of problems as 'illness' or disease, <i>without</i> mention of psycho-social causes | 12 (52%) | (58%) | |
| Psycho-social | + Any mention of psycho-social causes of depression, such as loss, abuse, poverty etc | 11 (48%) | (0%) | |
| Consent | | | | |
| Rights | + Information about rights under Mental Health Act | 18 (78%) | (61%) | |
| Access to legal support | + How to access legal advocate | 2 (9%) | (25%) | |
| CQC leaflet given | + Provided with Care Quality Commission <i>Your rights about consent to treatment</i> leaflet, or equivalent, and this is verbally explained and documented. Or Link to leaflet on CQC website | 11 (48%) | (11%) | |
| False claim that most/all are given ECT voluntarily | - False claim that most/all are given ECT voluntarily | 3 (13%) | (31%) | 23, 24 |
| 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 | 23 (100%) | (80%) | |
| 24-h to discuss | + For every new course of ECT, except in an emergency, patients are given at least 24 h to reflect on information about ECT and discuss this with relatives, friends or advisers before making an informed decision regarding consent | 14 (61%) | (3%) | |

N/A: + accurate statement; - inaccurate statement.

^aData from Harrop et al. (2021).

1, Read et al. (2019); 2, Read & Bentall (2010); 3, Read & Arnold (2017); 4, Rasmussen (2009); 5, Ross (2006); 6, Munk-Olsen et al. (2007); 7, Peltzman et al. (2020); 8, Jorgensen et al. (2020); 9, Tsai et al. (2021); 10, FDA (2020); 11, APA (2001); 12, Somatics (2018); 13, Chen et al. (2022); 14, Sackeim et al. (2007); 15, Rose et al. (2003); 16, Robertson & Pryor (2006); 17, Schauder et al. (2022); 18, Duma et al. (2019); 19, Shwach et al. (2001); 20, Pippard & Ellam (1981); 21, Tecoult & Nathan (2001); 22, Driver and Vehicle Licensing Agency (2022); 23, Read et al. (2018); 24, Read et al. (2021).

Lead Peer Trainer for the Recovery College, and is now a self-employed trainer and consultant teaching trauma-informed practice in health and social care organisations).

RESULTS

Types of leaflets

Table 2 shows that 11 respondents submitted the most recent information leaflet published by the UK's Royal College of Psychiatrists (Royal College of Psychiatrists, 2022a), which had already been scored (Harrop et al., 2023). Three ECT facilities submitted an old (2020) version of the RCP document, also previously scored (Harrop et al., 2021). The two hospitals in Scotland's Lothian Health Board submitted a document published by the Scottish ECT Accreditation Network (2017). The other seven hospitals submitted their own unique leaflets.

Inter-rater reliability

The level of agreement between the initial scores of the two independent (blind) raters for the 320 (8 x 40) ratings of the eight newly scored leaflets (seven hospitals and the SEAN document) was 272/320, 85%. This equates to an inter-rater reliability *kappa* score, which adjusts for agreement expected by chance, of 0.69. This is categorised as 'substantial agreement' (Landis & Koch, 1977).

Most of the discrepancies were simple errors where one of the two raters missed a statement found by the other. In the rare instances where a discrepancy resulted from different interpretation of the criteria, an effort was made to score generously wherever possible. For example, two leaflets referred to access to a general 'advocate' rather than a 'legal advocate'. One of the raters had scored this as not meeting the criterion for 'access to legal support'; but on discussion, it was agreed to score this as meeting the criterion. Of the 48 discrepancies between the two raters, 27 (56%) were resolved in a way that gave the 'benefit of the doubt' to the hospital, thereby increasing the accuracy score.

Accuracy

The scores for the 23 ECT clinics are listed, by nation, in Table 2. The number of accurate statements (out of a possible 29) ranged from seven to 20, with a mean of 16.9. The leaflets made between six and nine inaccurate statements (out of 11) with a mean of 7.0. The overall accuracy scores (subtracting inaccurate items from accurate items) ranged from 13 to minus one, with a mean of 9.9. There was little difference between the three nations (see Table 3).

All 23 leaflets correctly informed patients that ECT includes general anaesthesia, an electric current, and a convulsion, in a series of about 10 treatments, and also told of the immediate, temporary adverse effects (headaches, confusion, etc.) and informed patients of the risk of short-term memory loss, and of the right to withdraw consent at any time.

Many accurate statements were frequently omitted, including: cardiovascular risks (mentioned by five leaflets), that it is not known how ECT works (3), risk of mortality – without minimising the risk (2), the risks of multiple general anaesthetic procedures (2), how to access a legal advocate (2). Only two leaflets reported that they had been co-produced with patients. The most frequently omitted facts were that there is no evidence of long-term benefits (1), that ECT efficacy studies find high placebo rates (1), and information about how much electricity is involved (0).

Nineteen of the 23 (83%) made misleading statements, minimising memory loss, blaming the memory loss on depression, claiming that ECT is the 'most effective treatment', and asserting that it has very

TABLE 2 Accuracy scores for information leaflets at ECT units in Northern Ireland, Scotland and Wales.

| | Accurate statements (out of 29) | Inaccurate statements (out of 11) | Accuracy score |
|---|------------------------------------|--------------------------------------|-------------------|
| Scotland | | | |
| Ayrehire & Arran–Woodland View ^a | 20 | 7 | 13 |
| Borders–Huntlyburn House ^a | 20 | 7 | 13 |
| Dumfries & Galloway–Midpark | 7 | 8 | –1 |
| Fife–Queen Margaret ^a | 20 | 7 | 13 |
| Forth Valley–Royal | 13 | 9 | 4 |
| Greater Glasgow & Clyde–Leverndale ^a | 20 | 7 | 13 |
| Greater Glasgow & Clyde–Stobhill ^a | 20 | 7 | 13 |
| Highland–New Craigs ^a | 20 | 7 | 13 |
| Lanarkshire–Wishaw ^a | 20 | 7 | 13 |
| Lothian–St Johns ^b | 14 | 6 | 8 |
| Lothian–Royal Edinburgh ^b | 14 | 6 | 8 |
| Tayside–Carseview ^c | 15 | 7 | 8 |
| Tayside–Murray Royal ^a | 20 | 7 | 13 |
| Tayside–Susan Carnegie ^a | 20 | 7 | 13 |
| Wales | | | |
| Aneurin Bevan HB–Maindiff Court | 13 | 7 | 6 |
| Cardiff & Vale HB–Llandough ^a | 20 | 7 | 13 |
| Hywel Dda HB–Hafan Derwen ^a | 20 | 7 | 13 |
| Swansea Bay University HB–Cefn Coed | 14 | 7 | 7 |
| Northern Ireland | | | |
| Belfast HSCT–Mater | 17 | 7 | 10 |
| Northern HSCT–Holywell ^c | 15 | 7 | 8 |
| South Eastern HSCT ^c | 15 | 7 | 8 |
| Southern HSCT–Craigavon | 12 | 6 | 6 |
| Western HSCT–Omagh | 20 | 7 | 13 |
| Mean ($n = 23$) | 16.9 | 7.0 | 9.9 |

^aRoyal College of Psychiatrists 2022 leaflet.^bScottish ECT Accreditation Network (SEAN) leaflet.^cRoyal College of Psychiatrists 2020 leaflet.

TABLE 3 ECT information leaflets' accuracy: national means and professional leaflets.

| | Accurate statements (out of 29) | Inaccurate statements (out of 11) | Accuracy score |
|--|------------------------------------|--------------------------------------|-------------------|
| Scotland mean ($n = 14$) | 17.4 | 7.1 | 10.3 |
| Wales mean ($n = 4$) | 16.7 | 7.0 | 9.7 |
| N. Ireland mean ($n = 5$) | 15.8 | 6.8 | 9.0 |
| England mean ^a ($n = 36$) | 12.8 | 5.8 | 7.0 |
| RCPsychiatry 2020 ^a | 15 | 7 | 8 |
| RCPsychiatry 2022 ^b | 20 | 7 | 13 |
| Scottish ECT Accreditation Network | 14 | 6 | 8 |
| Mind ^a | 19 | 0 | 19 |

^aData from Harrop et al., 2021.^bData from Harrop et al., 2023.

high response rates (with no mention of similar placebo response rates). All 23 wrongly claimed that ECT saves lives.

The seven individual leaflets designed by local ECT clinics were extremely varied, and were, on average, slightly worse than leaflets provided by professional bodies. They included between seven and 20 accurate statements, with a mean of 15.1; and between six and nine inaccurate statements, with a mean of 7.3. Overall accuracy scores ranged from minus one to 13, with a mean of 7.8.

DISCUSSION

Comparison to England audit

The 88% response rate of the current audit compares favourably with the 71% rate achieved for the England audit (Harrop et al., 2021).

Table 1 compares the results of the two audits on each of the 40 criteria. Overall, the leaflets assessed in the current audit (mean 9.9) were slightly more accurate than the England leaflets (mean 7.0). This was partly because 11 of the 23 clinics in the current audit were using the 2022 version of the RCPsych document, which was a marginal improvement on the 2020 version (see below) that had been used by seven of the NHS Trusts in England. The individual leaflets in the current audit were also of slightly higher quality (7.3 vs. 6.7) than the individual leaflets in England (Harrop et al., 2021).

Royal College of Psychiatrists

The 2020 RCPsych leaflet had produced a very low overall score of 8 (Harrop et al., 2021). The RCPsych asked us, and received, the detailed scoring of their leaflet by our England audit, and then produced a new leaflet, in March 2022. Using the same instrument and scoring process this current RCPsych leaflet has been assessed as containing 20 accurate statements and seven inaccurate statements, producing an improved, but still problematic, total score of 13 (Harrop et al., 2023).

The RCPsych is to be commended for responding to the 2021 audit by reviewing its leaflet. Its new document includes three new statements about patients' rights. It also acknowledges, for the first time, that 'the risk of side effects is slightly increased' ... 'if you are a woman or if you are elderly'. The leaflet also now states that there are 'reasons for your depression' that might be addressed by 'talking therapies'. Furthermore, the leaflet has removed false claims about low mortality rates that had been made in its 2020 leaflet (Harrop et al., 2021).

The new RCPsych document, which is used by nine hospitals in Scotland and two in Wales, still, however, has seven inaccurate statements and nine omissions (Table 4).

The RCPsych document is prefaced by a rather unusual 'Disclaimer', which includes:

'... we make no representations, warranties or guarantees, whether express or implied, that the content in this leaflet is accurate, complete or up to date'.

Scottish ECT accreditation network

The SEAN document, used by the two hospitals in Lothian, is even more problematic. This is not only because of its low overall accuracy score of 8 (gained by making most of the same inaccurate statements made by the RCPsych but including fewer accurate statements). The principle of informed consent involves portraying positive and negative information impartially. Indeed, SEAN describes its booklet as 'designed to give an impartial presentation of the current evidence and advice on ECT' (p. 1). SEAN,

TABLE 4 Royal College of Psychiatrists (2022a) omissions and inaccurate statements.

| Omissions ^a | Inaccurate statements ^a |
|---------------------------------------|--|
| Cardiovascular problems | Minimising size/strength of current |
| Mortality | False claims of 'most effective' |
| Risk of multiple general anaesthetics | False claims of high improvement %s |
| Lack of long-term benefits | False life-saving claim |
| Placebo response rates | Minimisation re memory loss |
| Co-production with parents | Blames depression for memory loss |
| Voltage | False claims about correcting bio-deficits |
| Access to legal support | |
| Do not know how it works | |

^aSee Table 1 for definitions of criteria.

however, unlike any other leaflet, actively seeks to discredit information that the psychiatrists who wrote the document consider unfavourable. For example:

The concerns most frequently expressed are that ECT is ineffective, creates unacceptable side effects and is given disproportionately to the elderly, women and the disadvantaged. There is little or no scientific evidence to back up these concerns.

(p. 3)

(Two pages later the document reports that SEAN's own survey found that 69% of ECT recipients in Scotland are women and that their average age is 62).

Elsewhere the document misrepresents legitimate concerns by exaggeration, while trying to discredit them as 'anti-psychiatry', all without providing references or examples.

There is a lot of misinformation about ECT. ECT has become an important target for anti-psychiatry groups. Several such groups want ECT to be banned. Claims are made that ECT always causes brain damage, irreversibly changes personality or even causes breast cancer. The majority of ECT websites on the internet are strongly anti-ECT. The most extreme ones state that ECT never does any good, if patients appear to get better it is because they are stunned, shocked or brain damaged.

(p. 11)

The editorialising even includes a section on 'HOW TO DEAL WITH MISINFORMATION'. The disservice to the public is augmented with an incomprehensible statement on the vitally important issue of mortality risk: 'The most commonly quoted low death rate for ECT does not adequately account for all the risks of treatment.' (p. 9). (If they mean ECT is more dangerous than usually admitted, patients surely need to know more). SEAN does, however, mention the risk of cardiovascular failure, which is ignored by the RCPsych leaflet.

Relevant studies

Space limitation precludes detailed discussion of all the research evidence in support of each of the 40 criteria used in the two audits. Many of the criteria do not require research evidence, including describing the elements of the treatment, outlining patients' rights, stating that patients were involved in writing the document, citing at least one research study, etc.

However, some of the key sources underlying the scale items regarding risks and efficacy are listed in [Table 1](#). Some of the relevant studies are summarised next.

Safety

Most of the leaflets (83%) minimised the prevalence or severity of memory loss. This is despite research showing that between 12% (Sackeim et al., 2007) and 55% (Rose et al., 2003) of ECT recipients suffer persistent or permanent memory loss (Dubey, 2017; Read & Bentall, 2010; Read, Kirsch, et al., 2019).

A recent review identified 16 studies of 'subjective memory impairment' (a term used for studies using patients' self-report) and found 'considerable between-study heterogeneity in clinical population, ECT modality and assessment scales used.... limiting meaningful conclusions' (Vann Jones & McCollum, 2019).

The American Psychiatric Association (2001), however, acknowledges that 'ECT can result in persistent or permanent memory loss.' Even an ECT machine manufacturer includes 'permanent brain damage and permanent memory loss' as risks (Somatics, 2018).

A recent study in China found that 189 of 278 (68%) ECT recipients reported memory complaints (Chen et al., 2022). Consistent with the minimising in the leaflets, however, the researchers described this level of memory loss as 'acceptable'. Their subjects were all 12–17 year olds, whose brains are still developing (Read et al., 2023).

A systematic review of the neurobiological basis of adverse cognitive effects of ECT recently found that 'advances in brain imaging have allowed us to identify ECT-induced volumetric and functional changes in several brain structures closely related to memory performance' and 'changes at a cellular, structural, and functional level may simultaneously play a role in both the mechanism of action and adverse effects subsidiary to ECT' (Bassa et al., 2021). This is consistent with an earlier review that had concluded that 'ECT affects the brain in a similar manner as severe stress or brain trauma which activates the HPA axis and the dopamine system and may compromise frontotemporal functions (Fosse & Read, 2013).

Most leaflets (83%) blamed the memory loss on depression, despite a review of the relevant research having concluded that 'There is no evidence of a correlation between impaired memory/cognition after ECT and impaired mood, much less a causal relationship' (Robertson & Pryor, 2006). A recent USA study found that patients' perceptions of ECT-related memory impairment were not related to their depression scores, before or after ECT (Schauder et al., 2022).

The 2020 RCPsych leaflet had stated that 'Death caused by ECT is extremely rare' and 'The death rate following ECT is less than that for other minor surgical procedures'. The College's latest, 2022 leaflet does not mention mortality caused by ECT at all. Nearly half (43%) of leaflets made 'Unevidenced claims of very low mortality rates (eg 1:10,000 patients or 1:80,000 treatments)' (see [Table 1](#)). These unevidenced numbers have been repeated for many years by official bodies (American Psychiatric Association, 2001; Benbow, 2004; Food and Drug Administration, 2011). Numerous studies have, however, found mortality rates many times greater than these claims (Read & Bentall, 2010; Read, Cunliffe, et al., 2019; Read, Kirsch, et al., 2019). For example, of 8148 ECT recipients in Texas, seven died within 48 h (Shiwach et al., 2001). Excluding the two deaths considered 'unlikely to have been related to ECT' this is one per 1630. Eight more died within 2 weeks of 'cardiac event,' a common ECT-related cause of death (Duma et al., 2019). If these are included the rate becomes one per 627. A study of 20,225 people given ECT in Sweden found that 216 had died within 30 days (Lindblad et al., 2023). Although cardiovascular failure (the most common cause of ECT-related deaths) was the main cause of deaths in this study (40%) older age, atrial fibrillation, kidney disease, reflux disease, dementia and cancer were also associated with increased risk of death. A study by the Royal College of Psychiatry in the UK found that four out of 2594 ECT patients had died within 72 h (Pippard & Ellam, 1981). It could not be determined whether the one death (4 days post-ECT) among 75 French ECT recipients was ECT-related. This study found a 'potentially life-threatening complication' in 16% of patients (Tecoult & Nathan, 2001).

A review of 82 studies, involving over 100,000 patients, found that one in 39 ECT patients experience 'major adverse cardiac events' (Duma et al., 2019). The researchers paralleled the minimising found in some of the leaflets. They described their finding of one in 39 as 'about one in 50' in the article's Abstract, and then dismissed this high rate of cardiac events as 'infrequent'.

Efficacy

Only one of the 23 leaflets tells patients there is no evidence of long-term benefits of ECT compared to placebo. None of the five meta-analyses of ECT for depression found a single study in which ECT was superior to placebo beyond the end of treatment (Read, Kirsch, et al., 2019). The Food and Drug Administration (2020) in the US mandates that ECT machines must have signs next to them stating: 'The long-term safety and effectiveness of ECT treatment has not been demonstrated.'

No leaflets inform patients that efficacy findings are largely explicable in terms of placebo response. There have still been no new placebo-controlled studies of ECT to confirm or disconfirm the 11 pre-1986 studies that had found very high placebo response rates. (Rasmussen, 2009; Read and Bentall, 2010; Read, Kirsch, et al., 2019; Ross, 2006).

There have, however, been several new studies confirming previous studies (see Read & Bentall, 2010; Read, Kirsch, et al., 2019) that ECT does not save lives by preventing suicide, as claimed by all 23 ECT providers (and 61% of those in England). The meta-analyses have all failed to identify any evidence that ECT prevents suicide. Numerous studies have actually found ECT recipients are *more* likely than other patients to kill themselves (Munk-Olsen et al., 2007; and see Read et al., 2013; Read, Kirsch, et al., 2019). In one recent study, 14,810 ECT patients were 16 times more likely to try to kill themselves than a matched control group of 58,369 (Peltzman et al., 2020). Even after controlling for 'demographic, clinical, and service use characteristics', the ECT patients were 1.3 times more likely to have killed themselves. A 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 (Jorgensen et al., 2020).

Another recent study found that 1524 homeless US veterans who received ECT had made significantly more suicide attempts, at 30 day, 90 day and 1 year follow-ups, than 3025 matched homeless veterans who had not had ECT (Tsai et al., 2021).

Recommendation

Psychologists, and all other mental health professionals, share the responsibility with psychiatrists to ensure that patients and families are given accurate, evidence-based information so that informed consent is meaningful. They should intervene at a clinical and managerial level if that is found not to be the case.

Limitations

Information leaflets are not the only source of information for patients. But if a major source of additional information is the psychiatrists who wrote the inaccurate leaflets, the value of that additional information is questionable.

Inter-rater reliability was lower than in the audit of English ECT clinics (Harrop et al., 2021). Our data do not allow us to determine why that was the case. One possible, partial explanation might be that one of the raters was not involved in the selection and wording of the items and was, therefore, less familiar with them. The reliability level is, nevertheless, within the 'substantial agreement' range (Landis & Koch, 1977) and discrepancies were easily resolved via discussion.

Information leaflets are updated from time to time, so some of the data may be out of date by the time of publication. For example, SEAN informed us, in October, 2022, that their 2017 leaflet had been ‘superseded by guidance published by the Royal College of Psychiatrists’ (although NHS Lothian confirmed their two hospitals were still using it, alongside the RCPsych document, in October, 2022).

The 40-item instrument requires continuous updating. For example, a recent large-scale study (Mezei et al., 2022) just found that people given ECT are more than twice as likely as patients not given ECT to develop amyotrophic lateral sclerosis (a progressive disease affecting nerve cells in the spinal cord and brain, leading to loss of muscle control).

The tool used for the audit was developed by a research group that brought their own perspectives to the selection of audit criteria. A tool developed by another research group may have included different items. The tool is the first of its kind. It was developed because of the absence of any such tool having been developed to measure the accuracy of ECT information leaflets by ECT proponents in the 85 years since its introduction. We hope other tools may now be developed, perhaps using a Delphi approach (Linstone & Turoff, 1975), including ECT recipients with a range of experiences of the treatment.

CONCLUSIONS

None of the leaflets submitted for this audit come close to being sufficiently accurate and comprehensive to facilitate genuine informed consent for patients and their families. Even the highest-scoring documents omit nine basic statements about ECT and include seven misleading, unevidenced, claims.

The equally disturbing findings of two recent audits about how ECT is administered and monitored in England (Read et al., 2021; Read, Harrop, Geekie, & Cunliffe, 2022) suggest, in conjunction with the two audits of information leaflets, that no official body is effectively monitoring or regulating ECT. The RCPsych's ‘ECT Accreditation Service’ (ECTAS) has, in fact, recently stressed that it has no monitoring or regulatory responsibilities (Read, Harrop, Geekie, & Cunliffe, 2022; Sivasanker et al., 2021). Indeed, membership of ECTAS by ECT Clinics is voluntary, ECTAS reports on clinics are not publicly available, and patients and families are not told in information leaflets whether the clinic they are attending is accredited. In October 2022, only three of the five ECT clinics in Wales and two of the five in Northern Ireland were listed by ECTAS as accredited (Royal College of Psychiatrists, 2022b). It should be noted that whereas SEAN's standards are currently being reviewed by Public Health Scotland, the RCPsych's ECTAS has no such oversight.

An example of the laxness of ECTAS standards is the standard that requires that patients are ‘provided with an ECT patient information leaflet’ with no specification of what it should contain or that it should be evidence-based and co-produced with patients' groups. Meanwhile, SEAN's parallel standard merely states ‘Information should be given both verbally and in writing’ (Scottish ECT Accreditation Network, 2019). So, even the lowest-scoring, most misleading leaflets in our audit can tick the relevant ECTAS or SEAN box on the way to accreditation.

Sending the results of our previous audit to the Chief Executives of the NHS trusts in question (Harrop et al., 2023) produced some promising responses from some, but by no means all, including:

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

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.

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.

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.

We hope that the current audit will also facilitate changes that will lead to proper informed consent for patients and families in Northern Ireland, Scotland and Wales.

The findings of our audits add weight to the campaign for an independent enquiry into the administration of ECT in the UK (Johnstone & Cunliffe, 2020), which is backed by several mental health organisations, including Mind (the UK's largest mental health charity), Headway (the brain injury association), the Association of Clinical Psychologists, the Green Party, and more than 20 cross-party MPs including the Shadow Mental Health Minister.

Meanwhile, legal cases are in preparation based on the apparent failure of the NHS to provide informed consent regarding ECT (McGough, 2020, 2021). Similar cases in Canada and the USA (Wisner Baum, 2023) are in process. This may accelerate progress, internationally.

AUTHOR CONTRIBUTIONS

John Read: Conceptualization; formal analysis; methodology; writing – original draft. **Lisa Morrison:** Conceptualization; data curation; formal analysis; writing – review and editing. **Chris Harrop:** Conceptualization; methodology; writing – review and editing.

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CONFLICT OF INTEREST STATEMENT

JR receives royalties for his book 'Models of Madness' (2013, Routledge) which includes a chapter on ECT. He has also received fees for being an expert witness on several ECT legal cases.

DATA AVAILABILITY STATEMENT

Data (the leaflets) are available on request from the corresponding author.


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