

Neuroleptics do much more harm than good and should not be used

By Peter C Gøtzsche
Professor and Director
Institute for Scientific Freedom
Copenhagen
Denmark
e-mail: pcg@scientificfreedom.dk

This is the accepted chapter 4 in *Psychological Interventions for Psychosis: Towards a Paradigm Shift*, edited by Juan Antonio Díaz-Garrido, Raquel Zúñiga, Horus Lafitte and Eric Morris, published in 2023 by Springer. The book is available online at <https://doi.org/10.1007/978-3-031-27003-1>.

Abstract: The current paradigm in psychiatry is that psychosis should be treated with neuroleptics as first-line therapy. Neuroleptics should not be used at all. Randomised trials have shown that they kill many patients and do not have clinically relevant effects but cause permanent brain damage in most patients treated long-term and prevent them from coming back to a more normal life. If an acutely disturbed patient feels that a drug is needed, benzodiazepines work faster than neuroleptics, are much less toxic, and are also what virtually all patients prefer if asked. Psychiatry seems to be the only area in society where the law is systematically being violated all over the world. We need to respect the patients' rights and the law, which will also lead to better outcomes.

1. Introduction

When you see a patient with a psychosis, the first thing it is important to realise is that neuroleptics are *not* the solution. Yet, the current paradigm in psychiatry is that psychosis should be treated with neuroleptics as first-line therapy.

I have stopped calling these drugs by their official name, antipsychotics, because it is a misnomer. Neuroleptics do not have any specific antipsychotic effect. They work by impairing important brain functions, and they do this in the same way, whether given to patients with psychosis, to healthy volunteers or to animals (Breggin, 2008; Gøtzsche, 2015). They cannot cure people, only dampen their symptoms, which come with a lot of harmful effects. For example, they do not just dampen psychotic thoughts but all thoughts, which tend to render the patients inactive and passive. Two physicians have described how a single dose of haloperidol knocked them down (Belmaker & Wald, 1977). They experienced a marked slowing of thinking and movement, profound inner restlessness, a paralysis of volition and a lack of physical and psychic energy, being unable to read or work. David Healy found the same in 20 staff from his hospital who received droperidol (Moncrieff, 2013). Everyone felt anxious, restless, disengaged and demotivated to do anything; a psychologist volunteer found it too complicated just to obtain a sandwich from a sandwich machine.

By contrast, antibiotics do not make false promises. They work as intended, and the best of them kill bacteria and save lives, with virtually no harms, e.g. penicillin for meningitis or sepsis with streptococci.

Neuroleptics do the opposite. They kill many patients, and they make it difficult for those who survive to come back to a more normal life. This is true for all psychiatric drugs. They change brain functions and bring the patient to an unknown territory where the patient has not been before. This is problematic because you cannot bring the patient from a chemically induced new condition back

to a more normal state unless you taper off the drugs, and even then, it will not always be possible, as the patient might have developed irreversible brain damage (Gøtzsche, 2022a). In contrast, the aim of psychological treatments is to change a brain that is not functioning well back towards a more normal state.

It is therefore not surprising that in all countries where this has been investigated, the increased use of psychiatric drugs has been accompanied by an increase in disability pensions (Whitaker, 2015). If they had worked like insulin for diabetes, which psychiatrists sometimes say to convince the patients to take drugs they don't like, we would have seen *fewer* disability pensions.

2.1 What is the effect of neuroleptics on psychosis?

The effect in the placebo-controlled trials is less than the minimal clinically relevant effect, which corresponds to about 15 points on the Positive and Negative Syndrome Scale (PANSS) (Leucht et al., 2006) commonly used in the trials. Yet, what was reported in placebo-controlled trials of newer drugs submitted to the FDA was only 6 points (Khin et al., 2012) even though scores easily improve when someone is knocked down by a tranquillizer and expresses abnormal ideas less frequently (Moncrieff, 2013).

It should also be considered that these trials were seriously flawed and exaggerated the effect. There are at least four reasons for this (Gøtzsche, 2022a).

Cold turkey in the placebo group

In every single trial but two, the patients were already on a drug similar to the one being tested against placebo. After a short wash-out period without this drug, the patients were randomised to the new drug or placebo. There are three main problems with this design.

First, the patients who are recruited for the trials are those who have not reacted too negatively on getting such a drug before (Moncrieff & Cohen, 2006). They will likely therefore not react negatively to the new drug, which means that the trials will underestimate the harms of neuroleptics.

Second, when patients who have tolerated a drug are randomised to placebo, they will likely react more negatively to this than if they had not been in treatment before. This is because all psychiatric drugs have a range of effects, some of which can be perceived as positive, e.g. emotional numbing.

Third, the cold turkey that some patients in the placebo group go through harms them. It is therefore not surprising that the new drug seems to be better than placebo. Introducing longer wash-out periods does not remove this problem. If people have been permanently brain damaged before entering the trials, wash-out periods cannot compensate, and even if that is not the case, they could suffer from withdrawal symptoms for months or years (Breggin, 2008, 2012).

When my research group searched for placebo-controlled trials in psychosis that only included patients who had not received such a drug earlier, we found only one trial (Wang et al., 2013). It was from China and appeared to be unreliable (Danborg & Gøtzsche, 2019).

The first trial that was not flawed was published in March 2020 (Francey, 2020), 70 years after the discovery of the first neuroleptic, chlorpromazine.

However, even 70 years wasn't enough for the psychiatrists to come to their senses. They were not yet ready to draw the consequences of their results, which their abstract demonstrates:

“group differences were small and clinically trivial, indicating that treatment with placebo medication was no less effective than conventional antipsychotic treatment (Mean Difference = -0.2, 2-sided 95% confidence interval -7.5 to 7.0, $t = 0.060$, $p = 0.95$). Within the context of a specialised

early intervention service, and with a short duration of untreated psychosis, the immediate introduction of antipsychotic medication may not be required for all cases of first episode psychosis in order to see functional improvement. However, this finding can only be generalised to a very small proportion of FEP [first episode psychosis] cases at this stage, and a larger trial is required to clarify whether antipsychotic-free treatment can be recommended for specific subgroups of those with FEP.”

What this means for people who are willing to interpret the evidence clearly is:

“Our study was small, but it is unique because it only included patients who had not been treated with a neuroleptic before. We found that neuroleptics are not needed for patients with untreated psychosis. This is great progress for patients, as these drugs are highly toxic and make it difficult for them to come back to a normal life. Based on the totality of the evidence we have, the use of neuroleptics in psychosis cannot be justified. Such pills should only be used in placebo-controlled randomised trials of drug-naïve patients.”

The authors of a 2011 systematic review of neuroleptics for early episode schizophrenia pointed out that the available evidence doesn't support a conclusion that neuroleptic treatment in an acute early episode of schizophrenia is effective (Bola et al., 2011). This is one of the very few Cochrane reviews of psychiatric drugs that can be trusted (Gøtzsche, 2015, 2022a). There are huge problems with most Cochrane reviews, e.g. Cochrane reviews in schizophrenia routinely include trials in a meta-analysis where half of the data are missing.

To find out for how long patients should be advised to continue taking their drugs, so-called maintenance studies, also called withdrawal studies, have been carried out. These studies are also highly misleading because of cold turkey effects. A large meta-analysis of 65 placebo-controlled trials found that only three patients needed to be treated with neuroleptics to prevent one relapse after one year (Leucht et al., 2012), which looks very impressive, but the result is totally unreliable. The apparent benefit of continued treatment with neuroleptics decreased over time and was close to zero after three years. Thus, what was seen after one year was iatrogenic harm, which was described as a benefit.

When follow-up is longer than three years, it turns out that discontinuing neuroleptics is the best option. There is only one appropriately planned and conducted maintenance trial, from Holland. It has seven years of follow-up, and patients who had their dosages decreased or discontinued fared much better than those who were randomised to continue taking their pills: 21 of 52 (40%) versus 9 of 51 (18%) had recovered from their first episode of schizophrenia (Wunderink et al., 2012).

Leading psychiatrists interpret the maintenance studies to mean that the drugs are highly effective at preventing new episodes of psychosis (Gøtzsche, 2015, 2022b), and that the patients should therefore continue taking the drugs for years or even for life. But why would drugs that have almost no effect in the acute situation, apart from knocking patients down, be expected to be highly effective for preventing relapse? Using a little common sense tells us that this can hardly be correct.

Danish researchers tried to repeat the Dutch study, but their trial was abandoned because the patients were scared about what would happen if they did not continue taking their drugs (Gøtzsche, 2022a). They have learned – heavily assisted by their psychiatrists - to identify themselves with pill takers and have forgotten what life was about before they came on the pills.

A psychiatrist involved with the failed trial told me about another, recent withdrawal trial, carried out in Hong Kong (Hui et al., 2018). The researchers treated first-episode patients with quetiapine (Seroquel) for two years; discontinued the treatment in half of the patients by introducing placebo; and reported the results at ten years. A poor clinical outcome occurred in 35 (39%) of 89 patients in the discontinuation group and in only 19 (21%) of 89 patients in the maintenance treatment group.

I immediately suspected that the trial was flawed - as this result was the exact opposite of the Dutch result - and that they had tapered off the neuroleptic far too quickly and had caused a cold turkey. As there was nothing about their tapering scheme in the article, I looked up an earlier publication, of the results at three years (Chen et al., 2010). They didn't taper at all; all patients randomised to placebo were exposed to a cold turkey.

The ten-year report was highly revealing: "A post-hoc analysis suggested that the adverse consequences of early discontinuation were mediated in part through early relapse during the 1-year period following medication discontinuation." The manufacturer of quetiapine funded the trial in Hong Kong that was seriously flawed in favour of their drug.

The investigators defined a poor outcome as a composite of persistent psychotic symptoms, a requirement for clozapine treatment, or death by suicide. They called their trial double-blind, but it is impossible to maintain the blind in a trial with cold turkey symptoms, and it is highly subjective whether there are any psychotic symptoms and whether clozapine should be given. I'm much more interested in whether the patients return to a normal life, and a table showed that after ten years, 69% of those who continued taking their drug were employed versus 71% in the cold turkey group, a quite remarkable result considering the iatrogenic harms inflicted on the latter group.

I consider this trial highly unethical because some patients commit suicide when they experience cold turkey effects. Robert Whitaker has demonstrated that this trial design is lethal (Whitaker, 2002). One in every 145 patients who entered the trials for risperidone, olanzapine, quetiapine and sertindole died, but none of these deaths were mentioned in the scientific literature, and the FDA didn't require them to be mentioned. The suicide rate in these clinical trials was 2-5 times higher than the norm.

The Hong Kong investigators' attempt at explaining away what they found is breathtaking. They wrote that their result in the third year raised the suggestion that, "there might be a time window or critical period during which a relapse might be course-modifying." The plausibility of the existence of such a time window between year two and three is zero. As it is highly variable when or if a patient relapses, there cannot exist any such time window. The psychiatrists deliberately harmed half of their patients, but they concluded they did nothing wrong and that their patients, or their disease, or a "time window" were to blame.

Lack of blinding

Because of the conspicuous harms of psychiatric drugs, trials labeled double-blind are not double-blind. Quite a few patients - and their doctors - know who is on drug and who is on placebo (Gøtzsche, 2015). It takes very little unblinding in a trial before the small differences recorded can be explained purely by bias in the outcome assessment on a subjective rating scale (Moncrieff et al., 2004; Hróbjartsson et al., 2013).

In trials supposed to be double-blind, investigators may report positive effects that only exist in their imagination. This occurred in a famous trial funded by the US National Institute of Mental Health in 1964, which is still highly cited as evidence that neuroleptics are effective. It was a trial of 344 newly admitted patients with schizophrenia who were randomised to phenothiazines such as chlorpromazine, or to placebo (Cole, 1964). The investigators reported, without offering any numerical data, that the drugs reduced apathy and made movements less retarded, the exact opposite of what these drugs do to people, which the psychiatrists had admitted a decade earlier (Whitaker, 2015). The investigators claimed a huge benefit for social participation (effect size of 1.02) and that the drugs make the patients less indifferent to the environment (effect size 0.50). The drugs do the opposite. They also claimed, with no data, that 75% versus 23% were markedly or moderately improved and suggested that the drugs should no longer be called tranquillizers but antischizo-

phrenic drugs. Their study contributed to shaping the erroneous beliefs that schizophrenia can be cured with drugs and that neuroleptics should be taken indefinitely (Whitaker, 2002).

Irrelevant outcomes

A score on a rating scale doesn't tell us whether the patient is well. Hundreds of placebo-controlled trials of neuroleptics have been carried out, but I have not seen any that measured whether the patients came back to a normal productive life. If such trials existed, I would have known about them because the drug companies and many psychiatrists would have used the results incessantly in their marketing of the benefit of these drugs. Unless, of course, they showed that the drugs made the situation worse and were therefore buried in company archives.

The situation is the same for other psychiatric drugs. According to the American Psychiatric Association's disease manual, DSM-5, major depression is present when the patient exhibits 5 or more of 9 symptoms that "cause clinically significant distress or impairment in social, occupational, or other important areas of functioning." Given how the disorder is defined, it makes no sense that drug trials don't use these outcomes (Gøtzsche, 2015).

Industry sponsored trials

Almost all placebo-controlled trials are planned, conducted, and analysed by the drug industry. A Cochrane review that included 48 papers that in total comprised thousands of individual trials found that industry-sponsored studies more often had favourable efficacy results, favourable harms results and favourable conclusions for the drug or medical device of interest, compared with non-industry sponsored studies (Gøtzsche, 2013).

2.2 What is the effect of neuroleptics on mortality?

Eight years ago, I tried to find out how many people are killed by psychotropic drugs (Gøtzsche, 2015). My results were shocking. Based on the most reliable studies I could find, randomised trials and good comparative cohort studies, I estimated that psychiatric drugs are the third leading cause of death, after heart disease and cancer. Perhaps they are not quite that harmful, but there is no doubt that they kill hundreds of thousands of people every year. I have estimated that just one neuroleptic drug, olanzapine, had killed 200,000 patients up to 2007 (Gøtzsche, 2013).

If we want to find out how many people psychiatric drugs kill, we might think that placebo-controlled randomised trials would be ideal, but that's not the case, and schizophrenia is a prime example. As just noted, the cold-turkey design of these trials has caused some patients to commit suicide in the placebo group.

We would therefore need to find patients who were not already in treatment with neuroleptics before they were randomised. In trials in dementia, pretreatment is not so likely. A meta-analysis of such trials showed that neuroleptics kill people (Schneider et al., 2005). The meta-analysis included trials of newer drugs, aripiprazole, olanzapine, quetiapine and risperidone, in patients with Alzheimer's disease or dementia, and deaths were recorded up till 30 days after discontinuing the double-blind treatment. For every 100 patients treated, there was one additional death on the drug (3.5% versus 2.3% died, $p = 0.02$).

This is bad enough, but it is actually worse than this. The trials generally ran for only 10-12 weeks although most patients in real life are treated for years. Moreover, in published psychiatric drug trials, half of the deaths are missing, on average (Hughes et al., 2014). I therefore looked up the corresponding FDA data based on the same drugs and trials (FDA, 2022).

As expected, some deaths had been omitted from the publications, and the death rates were now 4.5% versus 2.6%, which means that neuroleptics kill two patients in a hundred in less than three months.

I also found a Finnish study of 70,718 community-dwellers newly diagnosed with Alzheimer's disease, which reported that neuroleptics killed 4-5 people per year compared to patients who were not treated (Koponen et al., 2017). If the patients received more than one psychosis pill, the risk of death was increased by 57%. As this was not a randomised trial, the results are not fully reliable, but taken together, these data show a death rate so high that I cannot recall having seen any other drug the patients don't need that is so deadly.

Elderly patients are often treated with several drugs and are more vulnerable to their harmful effects, which means that the increase in the death rate is likely higher than in young patients. Yet, I still think we will need to extrapolate these results to young people with schizophrenia, as they are the best we have. In evidence-based healthcare, we base our decisions on the best available evidence. This means the most reliable evidence, which are the data just above. Thus, absent other reliable evidence, we will need to assume that neuroleptics are also highly lethal for young people. We should therefore not use these drugs for anyone, also because a clinically relevant effect on psychosis has never been demonstrated in reliable trials (see above).

According to the FDA, most of the deaths in the demented patients appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia). Young people on neuroleptics also often die suddenly from cardiovascular causes. And I would expect some of them to die from pneumonia. Neuroleptics and forced admission to a closed ward make people inactive. When they lie still in their bed, they can get pneumonia, which the psychiatrists might not detect, as they have not had much training in internal medicine, and as their focus is on the patients' mental state.

The psychiatrists are fully aware - and have often written about it - that the lifespan for patients with schizophrenia is 15 years shorter than for other people (Hjorthøj et al., 2017), but they don't blame their drugs or themselves, but the patients. It is true that these people have unhealthy lifestyles and may abuse other substances, in particular tobacco. But it is also true that some of this is a consequence of the drugs they receive. Some patients say they smoke because it counteracts some of the harms of neuroleptics, which is correct because tobacco increases dopamine while the drugs decrease dopamine.

It is also indisputable that neuroleptics kill some patients with schizophrenia because they can cause huge weight gains, hypertension and diabetes, but how common is it?

When I tried to find out why young people with schizophrenia die, I faced a roadblock, carefully guarded by the psychiatric guild. It is one of the best kept secrets about psychiatry that the psychiatrists kill many of their patients with neuroleptics (Gøtzsche, 2015, 2022a).

In 2012, Wenche ten Velden Hegelstad and 16 colleagues published 10-year follow-up data for 281 patients with a first-episode psychosis (the TIPS study) (Hegelstad et al., 2012). Although their average age at entry into the study was only 29 years, 31 patients (12%) died in less than 10 years. However, the authors' detailed article was about recovery and symptom scores. They took no interest in all these deaths, which appeared in a flowchart of patients lost to follow-up and were not commented upon anywhere in their paper.

This was remarkable but not uncommon for psychiatry. I wrote to Hegelstad and asked for details about the deaths, and she replied that they were preparing a manuscript detailing the information I asked for. The paper came out the next month, in *World Psychiatry* (Melle et al., 2017), but the number of deaths was now different from their first paper, and the information I had requested wasn't anywhere.

Robert Whitaker and I therefore wrote to the editor of this journal, professor Mario Maj, asking for his help in getting a unique insight into why so many patients had died so young. We hoped he would ensure that the knowledge the investigators had in their files became public by publishing our short letter to the editor and by asking them to respond: “That would be a great service to psychiatry, the patients, and everyone else with an interest in this vitally important issue.”

We explained in our letter that the authors had reported that 16 patients died by suicide, 7 by accidental overdoses or other accidents, and 8 from physical illnesses, including 3 from cardiovascular illness. But it was not clarified, for example, if the psychiatrists had overdosed the patients, which is not uncommon, or if “accidental overdoses” meant something else.

Eight days later, we were told by Maj that, “Unfortunately, although it is an interesting piece, it does not compete successfully for one of the slots we have available in the journal for letters.”

So, there was no space in the journal for our letter of 346 words, no longer than a journal abstract, and no interest in helping young people survive by finding out what kills them at such a young age. This was psychiatry at its worst, protecting itself while literally killing the patients.

I appealed Maj’s decision explaining that people I had talked to in several countries about deaths in young people with schizophrenia - psychiatrists, forensic experts and patients - had all agreed that we desperately need the kind of information we asked Maj to ensure we got from the very valuable cohort of patients Melle et al. reported on in his journal (Gøtzsche, 2022a). I ended my letter this way:

“What Melle et al. have published in your journal is not an adequate account of why these young people died. Therefore, we call on you to ensure these data get out in the open, for the benefit of the patients. We believe it is your professional and ethical duty - both as a journal editor and as a doctor - to make this happen. This is not a matter about the slots you have available in the journal for letters. It is a matter of prioritization.”

We did not hear from Maj again.

TIPS was supported by grants from 15 funders, including the Norwegian Research Council, the US National Institute of Mental Health, three drug companies (Janssen-Cilag, Eli Lilly and Lundbeck), and other funders in Norway, Denmark and USA. I asked all the funders for detailed information on the deaths, emphasizing that funders have an ethical obligation to ensure that information of great importance for public health, which has been collected in a funded study, gets published.

The silence was daunting.

Janssen-Cilag replied: “We find the data on mortality published by Melle et al. 2017 in *World Psychiatry* fully satisfactory.” Both they and Eli Lilly encouraged us to contact the authors, which was absurd, as I had written to the companies that the authors had refused to share their data with us.

Lundbeck did not reply.

In December 2017, the Norwegian Research Council published its policy about making research data accessible for other researchers, which left no doubt that this should happen, without delay, and not later than when the researchers published their research. Five months after I had written to the Norwegian Research Council, I received a letter from Ingrid Melle who had been asked by the council to respond to me. This led to some clarification, e.g. Melle explained that accidental drug overdose means taking too much of an illegal substance, or substance, or too strong a substance by accident, and that it does not refer to prescription drugs. If information about overdoses was ambiguous, it was defined as probable suicide.

The really interesting question was why 16 young people (6%) committed suicide in just 10 years? And why this vitally important information was not explored by the researchers? We cannot conclude it was their schizophrenia that led to suicide. It is more likely the drugs enforced upon

them, other forced treatments, involuntary admissions to psychiatric wards, humiliation, stigmatisation and loss of hope, e.g. when patients are told that their disease is genetic, or can be seen in a brain scan, or is lifelong, or requires lifelong treatment with neuroleptics. I am not making this up (Gøtzsche, 2015, 2022b). Some textbooks recommend lifelong treatment for some or even most patients (Gøtzsche 2022b). It is no wonder they might kill themselves when there is no hope.

There are countless unreliable studies that purport to show that neuroleptics decrease mortality. You should not pay any attention to these studies, which are all fatally flawed. I have done post-mortem dissections on some of them (Gøtzsche, 2015). The main problem is that the patients that are being compared - those on neuroleptics and those not - are not comparable to begin with. Whitaker once wrote to me that it requires extraordinary mental gymnastics by the psychiatrists to conclude that these drugs, which cause obesity, metabolic dysfunction, diabetes, tardive dyskinesia, lethal cardiac arrhythmias, and so on, protect against death.

2.3 Are patients' rights being respected?

Apart from cancer chemotherapy, neuroleptics are some of the most toxic drugs ever invented. It therefore makes no sense that many patients are forced to take them against their will. This is unethical and a huge violation of basic human rights.

Virtually all psychiatrists claim that they cannot practice without coercion, but this isn't true (Gøtzsche, 2015). Examples from several countries have shown that coercion is not needed. According to Italy's Mental Health Law, the danger criterion is not a legal justification for forced treatment; it is a case for the police, just as in Iceland, where no chains, belts or other physical constraints have been used since 1932. Physical restraint is an enormous assault on patients who have experienced sexual abuse, which many patients have, some even while they were locked up.

At Akershus University Hospital in Norway, they don't have a regime for rapid tranquillisation and have never needed one (Gøtzsche, 2015). At a psychosis ward in London, they waited on average about two weeks before starting neuroleptic medication on newly admitted people. In the end, most patients chose to take some medication, often in very small doses, so it is very well possible that it was respect, time and shelter that helped them, not the "sub-treatment threshold doses." Germany has also shown how it can be done (Zinkler & von Peter, 2019).

With good management and training of staff in de-escalation techniques, it is possible to practice psychiatry without coercion (Fiorillo et al., 2011; Scanlan, 2010).

There must be 24-hour support facilities without any compulsion, so that the hospital is no longer the only place you can go to when you are in acute crisis (Zinkler & von Peter, 2019). For example, there could be refuges with the possibility of accommodation and where the money follows the patient and not the treatment. We also need social and worthy services for people who are on their way back into society after having been in contact with psychiatry.

Psychiatry seems to be the only area in society where the law is systematically being violated all over the world - even Supreme Court and Ombudsman decisions are being ignored and psychiatrists lie routinely in court to obtain what they want (Gøtzsche, 2015, 2022a). In my research group, we studied 30 consecutive cases from the Psychiatric Appeals Board in Denmark and found that the law had been violated in every single case (Gøtzsche, Vinther & Sørensen, 2019; Gøtzsche & Sørensen, 2020).

All 30 patients were forced to take neuroleptics they didn't want, even though less dangerous alternatives could be used, e.g. benzodiazepines. The psychiatrists had no respect for the patients' views and experiences. In all 21 cases where there was information about the effect of previous drugs, the psychiatrists stated that neuroleptics had had a good effect whereas none of the patients shared this view (Gøtzsche & Sørensen, 2020).

The harms of prior medication played no role either in the psychiatrist's decision making, not even when they were serious, e.g. we suspected or found akathisia or tardive dyskinesia in seven patients, and five patients expressed fear of dying because of the forced treatment. An expert confirmed our suspicion that a patient had developed akathisia on aripiprazole but on the same page, the expert - a high-ranking member of the board of the Danish Psychiatric Association - recommended forced treatment with this drug even though it was stopped because of the akathisia.

The power imbalance was extreme. We had reservations about the psychiatrists' diagnoses of delusions in nine cases. There is an element of catch-22 when a psychiatrist decides on a diagnosis and the patient disagrees. According to the psychiatrist, the disagreement shows that the patient has a lack of insight into the disease, which is a proof of mental illness. The abuse involved psychiatrists using diagnoses or derogatory terms for things they didn't like or didn't understand; the patients felt misunderstood and overlooked; their legal protection was a sham; and the harm done was immense (Gøtzsche & Sørensen, 2020).

The patients or their disease were blamed for virtually everything untoward that happened. The psychiatrists didn't seem to have any interest in trauma, neither previous ones nor those caused by themselves. Withdrawal reactions were not taken seriously - we didn't even see this, or a similar term, being used although many patients suffered from them.

It is a very serious transgression of the law and of professional ethics when psychiatrists exaggerate the patients' symptoms and trivialise the harms of the drugs to maintain coercion, but this often happens, and the patient files can be very misleading or outright wrong, too. In this way, the psychiatrists can be said to operate a kangaroo court, where they are both investigators and judges and lie in court about the evidence, where after they sentence the patients to a treatment that is deadly for some of them and harmful for everyone.

When the patients complain about this unfair treatment, which isn't allowed in any other sector of society, it is the same judges (or their friends that won't disagree with them) whose evidence and judgments provide the basis for the verdicts at the two appeal boards, first the Psychiatric Patients' Complaints Board, and next, the Psychiatric Appeals Board. It doesn't matter the slightest bit what the patients say. As they have been declared insane, no one finds it necessary to listen to them. This is a system so abominable that it looks surreal, but this is the reality, not only in Denmark, but all over the world. When we assessed the records for 30 consecutive petitions for mental health commitment in which an involuntary medication order was requested from Anchorage, Alaska, we found that the legal procedures can best be characterized as a sham where the patients are defenseless (Tasch & Gøtzsche, 2023).

When anyone proposes to abolish coercion, psychiatrists often mention rare cases, such as severe mania where the patients may be busily spending their entire wealth. But this can be handled without forced hospitalization and treatment. For example, an emergency clause could be introduced that removes the patients' financial decision-making rights at short notice.

Furthermore, a few difficult cases cannot justify that massive harm is inflicted on the patients, which also makes it difficult to recruit good people to psychiatry. No one likes coercion, and it destroys the patient's trust in the staff, which is so important for healing and for the working environment in the department.

In many countries, a person considered insane can be committed to a psychiatric ward involuntarily if the prospect of cure or substantial and significant improvement of the condition would be significantly impaired otherwise. No drugs can accomplish that.

The other lawful reason for forcing drugs on people is if they present an obvious and substantial danger to themselves or others. This is also an invalid argument. Psychiatric drugs cause violence (Gøtzsche, 2015) and they cannot protect against violence unless the patients are drugged to such an extent that they have become zombies.

Treatment with neuroleptics kill many patients, also young people, and many more become permanently brain damaged. There are videos of children and adults with akathisia and tardive dyskinesia that show how horrible these brain damages can be ([What does akathisia and tardive dyskinesia look like? Undated](#)). It took psychiatry 20 years to recognize tardive dyskinesia as a iatrogenic illness (Breggin, 2008), even though it is one of the worst harms of neuroleptics and affects about 4-5% of the patients per year (Moncrieff, 2015), which means that most patients in long-term treatment will develop it. In 1984, Poul Leber from the FDA extrapolated the data and indicated that, over a lifetime, all patients might develop tardive dyskinesia (Breggin, 2008). Three years later, the president of the American Psychiatric Association said at an Oprah Winfrey show that tardive dyskinesia was not a serious or frequent problem (Karon, 2009).

Coercion should be abolished. This is our duty, according to the United Nations Convention on the Rights of Persons with Disabilities, which virtually all countries have ratified (Gøtzsche, 2015). The Psychiatry Act is not necessary, as the Emergency Guardian Act provides the opportunity to intervene when it is imperative, and the science shows that it is not rational or evidence-based to argue that forced treatment is in the best interests of patients (Gøtzsche, 2019).

If you are not convinced, you should read “The Zyprexa Papers” by lawyer Jim Gottstein (Gottstein, 2020). It is a book about illegal, forced drugging that destroyed patients. Gottstein needed to go to the Supreme Court in Alaska before he got any justice, and he ran a great personal risk by exposing documents that were supposed to be secret.

2.4 What should doctors do instead of using neuroleptics?

Neuroleptics are not needed and should be taken off the market. Their availability is immensely harmful because doctors cannot handle them but use them far too much, in far too high doses, and for far too long, with devastating consequences.

I cannot imagine any situation in psychiatry where these drugs are needed, apart from the very tragic situation where they have changed the patients' brain so much that it is too painful for the patients to taper off them even if done very slowly. Some of the brain damage these pills cause is permanent and dose related, i.e. tardive dyskinesia (Ho et al., 2011).

If acutely disturbed patients need something to calm them down, benzodiazepines are far less dangerous and even seem to work better (Dold et al., 2012). When I have asked patients if they would prefer a benzodiazepine or a neuroleptic next time, they developed a psychosis and felt they needed a drug, all of them have said they preferred a benzodiazepine. Why don't they get it then?

I know psychiatrists in several countries that don't use psychiatric drugs or electroshock. They handle even the most severely disturbed patients with empathy, psychotherapy and patience (Gøtzsche, 2015).

The aim of psychological treatments is to change a brain that is not functioning well back towards a more normal state. Psychiatric drugs also change the brain, but they create an artificial third state - an unknown territory - that is neither normal nor the malfunctioning state the patient came from.

This is problematic because you cannot go from the chemically induced third state back to normal unless you taper off the drugs, and even then, it will not always be possible, as the patient might have developed irreversible brain damage.

A human approach to emotional pain is very important, and treatment outcomes depend more on therapeutic alliances than on whether psychotherapy or pharmacotherapy is used (Krupnick et al., 1996).

Most of the problems patients face are caused by maladaptive emotion regulation, and psychiatric drugs make matters worse, as their effects constitute maladaptive emotion regulation. In con-

trast, psychotherapy aims at teaching patients to handle their feelings, thoughts and behaviour in better ways. This is called adaptive emotion regulation. It may permanently change patients for the better and make them stronger when facing life's challenges.

There are substantial issues to consider when reading reports about trials that have compared psychotherapy with drugs. The trials are not effectively blinded, neither for psychotherapy nor for drugs, and the prevailing belief in the biomedical model would be expected to influence the psychiatrists' behaviour during the trial and to bias their outcome assessments in favour of drugs over psychotherapy. Trials that show that the effects of a drug and psychotherapy combined are better than either treatment alone should also be interpreted cautiously, and short-term results are misleading. We should only take long-term results into consideration, e.g. results obtained after a year or more.

I will not advocate combination therapy. Doing effective psychotherapy can be difficult when the patients' brains are numbed by psychoactive substances, which may render them unable to think clearly or to evaluate themselves. The lack of insight into feelings, thoughts and behaviours is called medication spellbinding (Breggin, 2006, 2008). The main biasing effect of medication spellbinding is that the patients underestimate the harms of psychiatric drugs.

For psychotherapy, there are many competing schools and methods, and it is not so important which method you use. It is far more important that you are a good listener and meet your fellow human being where that person is, as Danish philosopher Søren Kierkegaard advised us to do two centuries ago.

Psychotherapy seems to be useful for the whole range of psychiatric disorders, also psychoses (Morrison et al., 2014). A comparison between Lapland and Stockholm illustrates the difference between an empathic approach and immediately enforcing drugs upon patients with a first-episode psychosis (Seikkula et al., 2006; Svedberg et al., 2001). The Open Dialogue Family and Network Approach in Lapland aims at treating psychotic patients in their homes, and the treatment involves the patient's social network and starts within 24 hours after contact. The patients were closely comparable to those in Stockholm, but in Stockholm, 93% were treated with neuroleptics against only 33% in Lapland, and five years later, ongoing use was 75% versus 17%. After five years, 62% in Stockholm versus 19% in Lapland were on disability allowance or sick leave, and the use of hospital beds had also been much higher in Stockholm, 110 versus only 31 days, on average. It was not a randomised comparison, but the results are so strikingly different that it would be irresponsible to dismiss them. There are many other results supporting the non-drug approach (Gøtzsche, 2015), and the Open Dialogue model is now gaining momentum in several countries.

Psychotherapy does not work for everyone. We need to accept that some people cannot be helped no matter what we do, which is true also in other areas of healthcare. Some therapists are not so competent or do not work well with some patients; it may therefore be necessary to try more than one therapist.

Physical and emotional pain have similarities. Just like we need physical pain in order to avoid dangers, we need emotional pain to guide us in life (Nilsonne, 2017). An acute condition like psychosis is often related to trauma and tends to self-heal if we are a little patient. Through the process of healing - whether assisted by psychotherapy or not - we learn something important that can be useful if we get in trouble again. Such experiences can also boost our self-confidence, whereas pills may prevent us from learning anything because they numb our feelings and thoughts. Pills can also provide a false sense of security and deprive the patient of real therapy and other healing human interactions - doctors may think they need not engage themselves as much when a patient is taking drugs.

Being treated humanely is difficult in today's psychiatry. If you panic and go to a psychiatric emergency ward, you will probably be told you need a drug, and if you decline and say you just need rest to collect yourself, you might be told that the ward is not a hotel (Nilsonne, 2017).

3. Conclusions

Neuroleptics should not be used for psychosis, indeed for anything. They are far too harmful compared to the unspecific dampening of symptoms they may accomplish, which can be obtained with other methods, e.g. with a short-term course of benzodiazepines. If we break a leg, we would not be satisfied with a treatment that reduces the pain so little that we cannot feel the difference, while the leg is still broken. But this is where we are with neuroleptics and most other psychiatric drugs (Gøtzsche, 2015, 2022a, 2022b).

What is most important is to take an interest in the patients and listen to them, going many years back in time, which will often reveal that traumas have played an important role for the patients' current condition.

A paper that analysed the 41 most rigorous studies found that people who had suffered childhood adversity were 2.8 times more likely to develop psychosis than those who had not ($p < 0.001$) (Varese et al., 2012). Nine of the ten studies that tested for a dose-response relationship found it. Another study found that people who had experienced three types of trauma (e.g. sexual abuse, physical abuse and bullying) were 18 times more likely to be psychotic than non-abused people, and if they had experienced five types of trauma, they were 193 times more likely to be psychotic (95% confidence interval 51 to 736 times) (Shevlin et al., 2008).

Patients with severe traumas in their past can sometimes be cured by psychotherapy. Drugs have never cured anyone.

It is of course much more challenging for psychiatrists to take a keen interest in their patients and their uniqueness, which also makes themselves vulnerable, but it is also much more rewarding. Sometimes, patients the system had given up upon and put on disability pension, were brought back to life this way. Nothing can be more rewarding for a psychiatrist than this.

We clearly need a revolution in psychiatry, nothing less. The current paradigm, with a focus on biological psychiatry with all its hundreds of receptors and genes, each of which predisposes just a little bit to the condition (Gøtzsche 2022b), has been a disaster. It is time to realise this. We cannot change people's genes anyway, so why this obsession with heredity? Its only purpose is that it makes psychiatry look more "scientific," but this is not the way to go in research if we want to help our patients.

References

Belmaker RH, Wald D. Haloperidol in normals. *Br J Psychiatry* 1977;131:222-3.

Bola J, Kao D, Soydan H. Antipsychotic medication for early episode schizophrenia. *Cochrane Database Syst Rev* 2011;6:CD006374.

Breggin PR. Intoxication anosognosia: the spellbinding effect of psychiatric drugs. *Ethical Hum Psychol Psychiatry* 2006;8:201-15.

Breggin PR. *Brain-disabling treatments in psychiatry: drugs, electroshock, and the psychopharmaceutical complex*. New York: Springer; 2008.

Breggin P. Psychiatric drug withdrawal: A guide for prescribers, therapists, patients and their families. New York: Springer; 2012.

Chen EY, Hui CL, Lam MM, Chiu CP, Law CW, Chung DW, et al. Maintenance treatment with quetiapine versus discontinuation after one year of treatment in patients with remitted first episode psychosis: randomised controlled trial. *BMJ* 2010;341:c4024.

Cole JO. Phenothiazine treatment in acute schizophrenia; effectiveness: the National Institute of Mental Health Psychopharmacology Service Center Collaborative Study Group. *Arch Gen Psychiatry* 1964;10:246-61.

Danborg PB, Gøtzsche PC. Benefits and harms of antipsychotic drugs in drug-naïve patients with psychosis: A systematic review. *Int J Risk Saf Med* 2019;30:193-201. Free access.

Dold M, Li C, Tardy M, Khorsand V, Gillies D, Leucht S. Benzodiazepines for schizophrenia. *Cochrane Database Syst Rev* 2012;11:CD006391.

FDA package insert for risperidone (Risperdal). https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020272s056,020588s044,021346s033,021444s031bl.pdf. Accessed 30 May 2022.

Fiorillo A, De Rosa C, Del Vecchio V, Jurjanz L, Schnall K, Onchev G, et al. How to improve clinical practice on involuntary hospital admissions of psychiatric patients: suggestions from the EUNOMIA study. *European Psychiatry* 2011;26:201-7.

Francey SM, O'Donoghue B, Nelson B, Graham J, Baldwin L, Yuen HP, et al. Psychosocial intervention with or without antipsychotic medication for first episode psychosis: a randomized noninferiority clinical trial. *Schizophr Bull Open* 2020; Mar 20. <https://doi.org/10.1093/schizbullopen/sgaa015>.

Gottstein J. The Zyprexa papers. Anchorage: Jim Gottstein; 2020.

Gøtzsche, PC. Deadly medicines and organised crime: How big pharma has corrupted health care. London: Radcliffe Publishing; 2013.

Gøtzsche PC. Deadly psychiatry and organised denial. Copenhagen: People's Press; 2015.

Gøtzsche PC. [Forced drugging with antipsychotics is against the law: decision in Norway](#). Mad in America 2019; May 4.

Gøtzsche PC. Mental health survival kit and withdrawal from psychiatric drugs. Ann Arbor: L H Press; 2022a.

Gøtzsche PC. [Critical psychiatry textbook](#). Copenhagen: Institute for Scientific Freedom; 2022b.

Gøtzsche PC, Sørensen A. [Systematic violations of patients' rights and safety: Forced medication of a cohort of 30 patients](#). *Ind J Med Ethics* 2020;Oct-Dec;5(4) NS: 312-8. Free access.

Gøtzsche PC, Vinther S, Sørensen A. [Forced medication in psychiatry: Patients' rights and the law not respected by Appeals Board in Denmark](#). *Clin Neuropsychiatry* 2019;16:229-33. Free access.

Hegelstad WT, Larsen TK, Auestad B, Evensen J, Haahr U, Joa I, et al. Long-term follow-up of the TIPS early detection in psychosis study: effects on 10-year outcome. *Am J Psychiatry* 2012;169:374-80.

Hjorthøj C, Stürup AE, McGrath JJ, Nordentoft M. Years of potential life lost and life expectancy in schizophrenia: a systematic review and meta-analysis. *Lancet Psychiatry* 2017;4:295-301.

Ho BC, Andreasen NC, Ziebell S, Pierson R, Magnotta V. Long-term antipsychotic treatment and brain volumes: a longitudinal study of first-episode schizophrenia. *Arch Gen Psychiatry* 2011;68:128-37.

Hróbjartsson A, Thomsen AS, Emanuelsson F, Tendal B, Hilden J, Boutron I, et al. Observer bias in randomized clinical trials with measurement scale outcomes: a systematic review of trials with both blinded and nonblinded assessors. *CMAJ* 2013;185:E201-11.

Hughes S, Cohen D, Jaggi R. Differences in reporting serious adverse events in industry sponsored clinical trial registries and journal articles on antidepressant and antipsychotic drugs: a cross-sectional study. *BMJ Open* 2014;4:e005535.

Hui CLM, Honer WG, Lee EHM, Chang WC, Chan SKW, Chen ESM, et al. Long-term effects of discontinuation from antipsychotic maintenance following first-episode schizophrenia and related disorders: a 10 year follow-up of a randomised, double-blind trial. *Lancet Psychiatry* 2018;5:432-42.

Karon BP. All I know about Peter Breggin. In: *The International Center for the Study of Psychiatry and Psychology. The Conscience of Psychiatry. The reform work of Peter R. Breggin, MD*. New York: Lake Edge Press; 2009.

Khin NA, Chen YF, Yang Y, Yang P, Laughren TP. Exploratory analyses of efficacy data from schizophrenia trials in support of new drug applications submitted to the US Food and Drug Administration. *J Clin Psychiatry* 2012;73:856-64.

Koponen M, Taipale H, Lavikainen P, Tanskanen A, Tiihonen J, Tolppanen AM, et al. Risk of mortality associated with antipsychotic monotherapy and polypharmacy among community-dwelling persons with Alzheimer's disease. *J Alzheimers Dis* 2017;56:107-18.

Krupnick JL, Sotsky SM, Simmens S, Moyer J, Elkin I, Watkins J, et al. The role of the therapeutic alliance in psychotherapy and pharmacotherapy outcome: Findings in the National Institute of Mental Health Treatment of Depression Collaborative Research Program. *J Consult Clin Psychol* 1996;64:532-9.

Leucht S, Kane JM, Etschel E, Kissling W, Hamann J, Engel RR. Linking the PANSS, BPRS, and CGI: clinical implications. *Neuropsychopharmacology* 2006;31:2318-25.

Leucht S, Tardy M, Komossa K, Heres S, Kissling W, Salanti G et al. Antipsychotic drugs versus placebo for relapse prevention in schizophrenia: a systematic review and meta-analysis. *Lancet* 2012;379:2063-71.

Melle I, Olav Johannesen J, Haahr UH, Ten Velden Hegelstad W, Joa I, Langeveld J, et al. Causes and predictors of premature death in first-episode schizophrenia spectrum disorders. *World Psychiatry* 2017;16:217-8.

Moncrieff J. *The bitterest pills*. Basingstoke: Palgrave Macmillan; 2013.

Moncrieff J. Antipsychotic maintenance treatment: time to rethink? *PLoS Med* 2015;12:e1001861.

Moncrieff J, Cohen D. Do antidepressants cure or create abnormal brain states? *PLoS Med* 2006;3:e240.

Moncrieff J, Wessely S, Hardy R. Active placebos versus antidepressants for depression. *Cochrane Database Syst Rev* 2004;1:CD003012.

Morrison AP, Turkington D, Pyle M, et al. Cognitive therapy for people with schizophrenia spectrum disorders not taking antipsychotic drugs: a single-blind randomised controlled trial. *Lancet* 2014;383:1395-403.

Nilsson Å. *Processen: möten, mediciner, beslut*. Stockholm: Natur & Kultur; 2017.

Scanlan JN. Interventions to reduce the use of seclusion and restraint in inpatient psychiatric settings: what we know so far, a review of the literature. *Int J Soc Psychiat* 2010;56:412–23.

Schneider LS, Dagerman KS, Insel P. Risk of death with atypical antipsychotic drug treatment for dementia: meta-analysis of randomized placebo-controlled trials. *JAMA* 2005;294:1934–43.

Seikkula J, Aaltonen J, Alakare B, Haarakangas K, Keränen J, Lehtinen K. Five-year experience of first-episode nonaffective psychosis in open-dialogue approach: Treatment principles, follow-up outcomes, and two case studies. *Psychotherapy Research* 2006;16:214-28.

Shevlin M, Houston JE, Dorahy MJ, Adamson G. Cumulative traumas and psychosis: an analysis of the national comorbidity survey and the British Psychiatric Morbidity Survey. *Schizophr Bull* 2008;34:193-9.

Svedberg B, Mesterton A, Cullberg J. First-episode non-affective psychosis in a total urban population: a 5-year follow-up. *Soc Psychiatry Psychiatr Epidemiol* 2001;36:332-7.

Tasch G, Gøtzsche PC. [Systematic violations of patients' rights and safety: forced medication of a cohort of 30 patients in Alaska](#). *Psychosis* 2023; March 28 (online first).

Varese F, Smeets F, Drukker M, Lieverse R, Lataster T, Viechtbauer W, et al. Childhood adversities increase the risk of psychosis: a meta-analysis of patient-control, prospective- and cross-sectional cohort studies. *Schizophr Bull* 2012;38:661-71.

Wang CH, Li Y, Yang J, Su LY, Geng YG, Li H, et al. A randomized controlled trial of olanzapine improving memory deficits in Han Chinese patients with first-episode schizophrenia. *Schizophr Res* 2013;144:129-35.

What does akathisia and tardive dyskinesia look like? Videos of children and adults who have been permanently brain damaged by neuroleptics. Undated. <https://www.deadlymedicines.dk/lectures/>.

Whitaker R. *Mad in America: bad science, bad medicine, and the enduring mistreatment of the mentally ill*. Cambridge: Perseus Books Group; 2002.

Whitaker R. *Anatomy of an epidemic*, 2nd edition. New York: Broadway Paperbacks; 2015.

Wunderink L, Nieboer RM, Wiersma D, Sytema S, Nienhuis FJ. Recovery in remitted first-episode psychosis at 7 years of follow-up of an early dose reduction/discontinuation or maintenance treatment strategy: long-term follow-up of a 2-year randomized clinical trial. *JAMA Psychiatry* 2013;70:913-20.

Zinkler M, von Peter S. End coercion in mental health services - toward a system based on support only. *Laws* 2019;8:19.

Springer required this text:

“Users may only view, print, copy, download and text- and data-mine the content, for the purposes of academic research. The content may not be (re-)published verbatim in whole or in part or used for commercial purposes. Users must ensure that the author’s moral rights as well as any third parties’ rights to the content or parts of the content are not compromised.”