Review of the Helsinki Declaration for research ethics

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CITATION
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Abstract
The Helsinki Declaration is a statement of clinical research ethical standards and has recently been revised. This paper briefly reviews the history of the Helsinki Declaration and gives an overview of some of its main statements.

Keywords
Declaration of Helsinki; research ethics; review

Introduction
The Declaration of Helsinki is an important document in the history of research ethics as it was the first significant effort of the medical community to regulate research and forms the basis of most subsequent research ethics documents. In the middle of the 20th century, the Nuremberg trials laid bare the abuse of medical knowledge and techniques used in human experimentation. The outcomes of the trials included the Nuremberg Code – a legal document intended to stop such abuse – and the establishment of the World Medical Association (WMA). Both were intended to ensure that doctors never again performed such inhuman experiments.

Over the next two decades, the newly formed WMA began to put together a core set of policies, designed to reflect ethical thinking, to which doctors were expected to conform. The Declaration of Helsinki (first published in June 1964) set out rules and limits for human experimentation based on the findings of the Nuremberg trials and an unshakeable conviction that human experimental subjects have fundamental rights that drive a series of duties for the experimenter. The Declaration was originally adopted in Helsinki, Finland. It has since undergone several revisions and is the basis for good clinical practices used today. The WMA established recommendations guiding medical doctors in biomedical research involving human participants. The Declaration governs

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for post-trial access for all participants who still need an intervention identified as beneficial in the trial.

Research registration, and publication and dissemination of results
- Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.
- Researchers, authors, sponsors, editors, and publishers all have ethical obligations with regard to the publication and dissemination of the results of research.

Conclusion
In an effort to update ethical practices for clinical trials, the WMA has revised various principles found in the Helsinki Declaration on medical research (BMJ, 2013). The main principals include recognition that the wellbeing of human subjects should take precedence over the interests of science and society, adding protection for vulnerable patient groups and a more systematic approach to using placebos when no proven intervention exists. The revision introduces the requirement that patients should be provided with compensation and treatment must be ensured if they suffer harm as a result of participating in research.

Although the Declaration is primarily aimed at medical practitioners, the WMA encourages all clinical researchers using human participants to consider the ethical requirements. In the UK, many of these requirements are reflected in the ethical review processes necessary for research studies to be implemented within the NHS. The ethics form from the Integrated Research Application System (IRAS) requires examples of consent protocols, is very protective of vulnerable groups, and requires statements regarding dissemination. Research governance in the NHS ensures that the ethical principles of the Helsinki Declaration are embedded in UK research practice.

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References


RESEARCH REPORTS
A qualitative study of bipolar disorder: The experiences of members of a self-help group

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Abstract
This qualitative investigation examines members of a self-help group’s experience with regards to aspects of everyday living with a diagnosis of bipolar disorder. Thematic analysis was used as a means to analyse the data produced. From this investigation it would appear that receiving a formal diagnosis of bipolar disorder can have a positive impact in terms of the answers it provides and the support that can be accessed following the formal diagnosis. Relationships were seen as the backbone of maintaining good health, however, ‘caregiver burden’ remained problematic for some, although on a smaller scale than previous literature had suggested.

Keywords
bipolar; self-help groups; patient experience
**Introduction**

Bipolar disorder is a cyclical mood disorder involving periods of profound disruption to mood and behaviour (McKeon, 2007). Bipolar disorder is characterised by extreme swings of mood from depression, where individuals experience severe lows, to mania where extreme highs are present (Court, 2001). Extremes of behaviour can be interspersed with periods of more or less full recovery; however these periods are often only temporary (Denicoff et al., 2000). Bipolar disorder is a serious, potentially lifelong, condition that is often accompanied by other illnesses meaning initial diagnosis can be a long and difficult process (Cutler, 2004).

Around one in every hundred adults in the UK will be diagnosed with bipolar disorder at some point in their lifetime with both men and women equally affected (Goodwin, 2007). The symptoms of bipolar disorder can occur at any age, however the age of onset usually differs dramatically from the age of diagnosis and it is estimated that it takes an average of five years from the onset of symptoms to reach the correct diagnosis (Evans, 2000). The dual nature of the disorder is a primary reason for the difficulties involved in diagnosing bipolar disorder (Johnson et al., 2000) as well as the number of signs and symptoms associated with other psychiatric illnesses, such as anxiety disorders and schizophrenia, that can mimic the presentation of, or have similar symptoms to bipolar disorder (Wells, 2005).

The purpose of this study is to understand more about the lived experiences of individuals diagnosed with bipolar disorder, with specific attention to their experiences accessing employment (e.g., Bland et al., 2002), the impact on relationships (e.g., Sajatovic, 2005) and the support offered by community based self-help groups (Kalifon, 2004). It is important for medical and mental health professionals to know how this illness impacts on an individual's relationships and socio-economic status as well as the sources of community support found useful when managing specific symptoms. With this understanding, professionals can better assist individuals and families affected by the diagnosis when they seek help and support.

**Method**

The main objective for this study is to understand the impact on an individual of receiving a diagnosis of bipolar disorder and how this affects relationships, employment opportunities, and social inclusion. A qualitative method was selected for this study because it is ideal for generating rich descriptions of complex phenomena (Coolican, 2004). This qualitative methodology enabled the capturing of rich descriptions of the emotional impact of receiving a diagnosis, how this affects individual relationships and employment opportunities, and the support offered by self-help groups.

**Participants**

Participants for this study were recruited through a self-help group set up specifically for individuals who have a diagnosis of bipolar disorder and their carers. To be considered for the study, participants were required to have a formal diagnosis of bipolar disorder and not have experienced any 'episodes' within the three months prior to the commencement of the interviews. They also had to be willing to discuss the diagnosis and issues surrounding this. An overview of the study including the inclusion criteria was presented at the end of a self-help meeting and, if potential participants indicated an interest in the study, further information was provided.

A total of six interviews were conducted with four women and two men. Interviewee ages ranged from 25 to 61 years (M = 49 years). Length of diagnosis varied from one year to 23 years. Participant demographic information regarding education, income etc. was not specifically collected. All of the participants in this study consented to be contacted for follow-up questions and for purposes of participant validation.

**Interviews**

Participants were interviewed at either the day centre where the self-help meetings were held or at their own home depending on their preference. An interview guide with open-ended questions was structured using an initial question and a series of follow-up questions. The follow-up questions were points of reference or guiding markers, not constrictors of conversation. Therefore, true to qualitative research, each interview was unique in its direction, emphasis, and depth, as co-directed by the participant. The initial question asked was "Can you tell me about the impact receiving a diagnosis of bipolar disorder has had on your life?". There were three areas that the sub-questions examined: comparing life before diagnosis with life prior to diagnosis, the impact receiving the diagnosis had on relationships, employment and social inclusion, coping strategies that had been developed, and the impact the self-help group had in adapting to the diagnosis. Interviews ranged from 60–90 mins and were audio recorded for transcription.
Analysis
Thematic analysis was used as a method for identifying, analysing, and reporting patterns or themes within data. It minimally organises and describes your data set in rich detail. However, frequently it goes further than this and interprets various aspects of the research topic (Boyatzis, 1998). Each interview was read several times to gain a general sense of any themes prevalent in the data, bearing in mind the research aims but also keeping an open mind to any themes which had not been considered at the offset. An initial list of recurring patterns within the data was made in order to code the information in a meaningful way and begin to derive themes. Going back and forth between phases of data allowed themes to go beyond surface meanings and tell an accurate story of the meaning of the data.

Results
The data were organised into four themes: (1) impact of the diagnosis; (2) effects of the diagnosis on relationships; (3) consequences for employment; and (4) coping and self-help. Each theme is presented below with an accompanying description and examples from the interviews.

**Theme 1: Impact of diagnosis**
Every participant discussed at length the impact the diagnosis had on their lives. Most participants emphasised a sense of relief at receiving the diagnosis as an explanation for unanswerable questions and behaviours they had experienced throughout their lives leading up to the point of diagnosis:

> It was just extraordinary because I’d spent so much of my time thinking I’m a crazy person, I’m going to get locked away, I’ve got multiple personalities, I’ve got to hide away all these mechanisms for trying to avoid being seen as a mad person and suddenly I was told actually there is a reason.

In contrast, a few of the participants indicated that the diagnosis was a negative experience and saw the diagnosis as taking away their sense of ‘self’.

> Just that I was a victim of mental health that my life had been stolen away and I felt victimised really yeah that’s the right word victimised by mental illness and ill health and I just felt like I wasn’t myself anymore.

**Theme 2: Effects of the diagnosis on relationships**
Most of the people interviewed indicated that relationships with people were put under strain as a result of the unpredictability of the disorder, particularly during manic phases:

> But he put up with lots of depression when I was working for the bank when I’d just be in bed for ages he put up with the depression because you become harmless and not aggravational but it’s the nuisance of me being high.

The sense of isolation when people do not understand the diagnosis or the symptoms was also discussed by many of the participants, highlighting the difficulties which can result within all relationships for people living with this illness:

> My mother disowned me she didn’t know what was wrong with me I was writing her strange letters from Greece about people being on street corners with guns and knives wanting to kill me and she didn’t seem to think perhaps there’s something wrong here. She just wrote to me and said you’re no longer my daughter.

This highlights the distress which can occur within families prior to understanding the cause and nature of the symptoms of being in a psychotic phase.

Nearly all of the participants interviewed, however, touched on the support offered by family and relationships in terms of ‘staying well’ and how receiving the diagnosis has facilitated understanding within relationships:

> It’s about a relationship with somebody... It’s just being around him and having him around... And that’s been for me an incredible thing about actually addressing the problem of not wanting to move the paralysis that can be there and thinking hang on a minute I love him so much I’m not going to let this happen today and just taking it day by day.

**Theme 3: Consequences for employment**
Unemployment is known to be harmful to the health of the general population as well as being an element of the social exclusion that those with severe mental illness face (Bland et al., 2002). It was a theme that was prominent in all of the interviews undertaken with many similarities with regards to its effect on health. One participant talked about how she was able to thrive within a working environment and how being in gainful employment with the appropriate support helped her to manage some of her symptoms; however, when the nature of the job changed, she found lack of understanding from her employer and attempting to remain in work precipitated a relapse in her mental health:

> I didn’t have too much trouble for the first few years... I didn’t feel any real stress... then they brought in targets and...
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I just couldn’t deal with it... I couldn’t push people to buy products, I couldn’t memorise the details of the products and it just turned into a nightmare.

Theme 4: Coping and self-help

The self-help groups and the benefits given from them in terms of coping with certain symptoms of the illness was a unanimous theme from all participants interviewed. Sub-themes were identified which highlighted the varying levels of support taken from the group.

Support

One participant in particular emphasised the great support taken from the group as a vital part of her maintaining her symptoms and staying well. This participant, for the most part of her illness, has not relied on medication, instead choosing alternative therapies and relying on self-help to manage when she recognises symptoms of becoming unwell:

I just find it so important I mean it’s probably more important for me because I don’t have the medication but I think even people with medication find it an anchor in that you can tell people how your months been and it’s an extremely important anchor for you.

Networking

Many of the participants interviewed viewed the self-help group as an opportunity to meet people who shared the same diagnosis, who they could share experiences with and, of particular importance for participants with a relatively recent diagnosis, it was seen as an opportunity to learn from others.

I think it’s good to be able to go to a group where it’s not formal therapy or anything like that it’s just people with the same illness getting together, sharing experiences and supporting one another and hopefully I’ll get some support from it.

Education

The theme of education was one which was particularly important to many of the participants interviewed. It was seen as important to develop an understanding of the disorder and the symptoms of it alongside learning from the various experiences of others and different ways to manage and recognise symptoms. For one participant in particular, the group served as a means to understand himself through learning from others.

It’s just an amazing place to learn and there’s such incredible wisdom in that room and pain and all sorts of things and I come out and I always feel as though I’m walking on air every time.

Discussion

Clinical implications

Some important factors were observed in this study which could serve to inform professional practice and everyday life for individuals with this particular mental illness. Perhaps the most important factor was the benefits that are to be found from accessing self-help groups. It could be extremely beneficial both for the health sector and those accessing it if individuals receiving a diagnosis are made aware of self-help groups and voluntary sector agencies.

Future considerations

There were a number of specific areas which could be considered for future research. The use of thematic analysis served the purpose of allowing the research questions to be addressed in a detailed manner. Despite its usefulness as a research tool in terms of its flexibility, which means that multiple theories can be applied across a variety of epistemologies, there are some limitations to using this particular method. Thematic analysis, although widely used, has no clear agreement about what it is and how you go about doing it (Boyatzis, 1998; Tuckett, 2005). Further to this, thematic analysis is not tied to any theoretical framework which, although in light of this project, was deemed as a positive as it allowed for flexibility; others approaching the same title from a fixed theoretical perspective would see this particular method of analysis as a limitation. With this in mind, future research could approach the data from a slightly different methodological angle.

A second area for consideration pertains to the relationships of individuals receiving a diagnosis of bipolar disorder. The majority of the literature surrounding maintaining relationships with individuals with mental illness has focussed around care-giver burden and negative aspects of this role, however, this study highlighted the numerous benefits to be had from maintaining relationships, particularly in regard to keeping well and managing symptoms.

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