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Research methods in clinical investigation: a case study analysis of medication levels and self-harm

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This paper uses a case study to illustrate an application of the scientist-practitioner model to clinical practice. Through consultation with a clinical psychologist, a simple method of obtaining an objective overview of the therapeutic use of medication was developed. Focusing on a woman in a Regional Secure Unit, data were gathered from incident forms of self-harm and the corresponding drug charts. Using basic statistical techniques (such as frequencies and measures of central tendency) to summarize these data, useful clinical information was obtained. Actual data from the case study are presented, as an example of a research process that can be applied to understanding the role of extraneous variables when pursuing a course of chemical treatment. Analyses of drug effects suggest that additional variables such as environmental, interpersonal and engagement factors needed to be considered. The paper advocates the ease of applicability of research methods to clinical investigation.

Keywords: case-study, forensic psychiatry, regional secure unit, research methods, scientist-practitioner, self-harm

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Introduction

The use of research based methods in clinical psychology training and practice within the NHS has received much support over the last decade (The British Psychological Society 1982, Watts 1984). Deriving from notions articulated in the Trethowan Report (DHSS 1977), the scientist-practitioner model purports that the clinician should aim to be a *Consumer* of research findings, an *Evaluator* of their own interventions, a *Researcher*, generating new data and publishing findings, and should aim to use a *Theoretical* basis in the ongoing development of academic study.

It is accepted that efficient scientific practice is desirable; however, whilst the scientist-practitioner model is an example of an attempt to re-affirm the scientific nature of clinical practice (Watts 1984), few clinical psychologists have found sufficient financial and temporal resources to pursue specific research projects and thus increase their rate of data gathering and publication (Salkovskis 1984).

The management of patients who self-harm offers a constant challenge to services. Flannigan *et al.* (1994) found that 21% of admissions to psychiatric services were due to a risk of self-harm. Burrow (1992) found that within a Special Hospital, over a 6-month period, there were 475 incidents of deliberate self-harm, 64% of which had been conducted by female patients. The research

literature has attempted to identify the predispositional factors of people who self-harm (e.g. Favazza & Conterio 1988, Hassenyah *et al.* 1989), propose theoretical explanations (e.g. Van Moffaert 1990, Wilkins & Coid 1991, Coid *et al.* 1992, Favazza & Rosenthal 1993), and discuss pharmacological and psychological treatment efficacies. However, the daily management of patients who deliberately self-harm has received less attention. Furthermore, practical methods of monitoring progress of patients who self-harm rarely includes the use of objective data in addition to details of the self-harm behaviour itself (Valente 1991).

In writing this paper, the authors hope to demonstrate how the gap between theoretical and practical application of the scientist-practitioner model can be bridged. To this end, a case study is presented where relevant clinical data were gathered, analysed, summarized and written up, not only for internal consumption to guide case management, but also for publication within the academic literature. It is hoped that the intentions behind writing this paper and the methods it exemplifies will encourage future attempts to utilize research methods in clinical practice.

This study arose from the clinical investigation into the relationship between episodes of self-harm and the fluctuating use of pharmacological treatment. The importance of investigating the baseline variables (e.g. of self-harm incidents and medication levels), prior to investigating other potentially confounding variables, such as activity levels and interpersonal relationships, was accepted throughout the multidisciplinary team. The purpose of presenting this formally is to exemplify a simplistic method of conducting preliminary analyses to investigate possible relationships, that can then be used as baseline information. Once such baseline information has been established it may then be referred to in future clinical decisions for case management.

Case history

Because of the large amount of time that Anne (name changed to ensure confidentiality) has been institutionalized, there are very few details of premorbid history. She was born in England during the early part of the 1950s. Both parents are alive and well, with no history of mental illness within the family. From an early age she displayed signs of maladaptive behaviour (such as absconding from school) which her parents found difficult to cope with. Having attempted placement in a number of boarding schools Anne settled for a short while before being admitted to a psychiatric hospital at the age of 13. She was re-admitted on another two occasions. During the last admission she exhibited signs of aggression towards patients and staff, extreme destructive behaviour and intense jealousy, all of which led to her transfer to special hospital.

On admission to hospital Anne received a diagnosis of psychopathy and temporal lobe epilepsy. Whilst in the special hospital she exhibited signs of psychotic illness and received treatment for schizophrenia. During this admission Anne was prescribed a variety of doses of medications including carbamazepine, ethosuximide, lithium carbonate, sodium amytal, haloperidol, chlorpromazine and flurazepam. She was treated with 108 sessions of electroconvulsive therapy, which she received in blocks of six over a 10-year period.

Anne was admitted to a locked ward in the Regional Secure Unit from the Intensive Care Unit at the special hospital. Initially, she settled well into the unit but displayed evidence of poor social skills and increased anxiety during interactions with male patients and staff.

Anne spent two months on the locked unit presenting few management problems but requiring considerable support for daily living. Following her initial assessment she was transferred to an open rehabilitation unit. Her stay on this unit was characterized by fluctuations in her mental state and maladaptive behaviour. Anne was granted escorted community leave during this time which she used occasionally, developing basic skills in handling money and road safety.

Anne's care was managed by her multidisciplinary clinical team. Her treatment package was primarily pharmacological intervention, supported by individual occupational therapy sessions. Anne received no direct psychological intervention due to lack of compliance from her, but psychology remained involved in her case management.

Analysis of records

A retrospective data collection, using medication cards and incident forms, was performed for all incidents within an 11-month period. Medication cards and incident record forms are standard recording procedures for nursing staff, and thus no additional form completion was necessary. By entering a record for each day of medication administered and, for each incident, specifying its type, on a computerized database, it was quickly possible to interrogate the data.

Due to strategies of long-term treatment, Anne has been taking various medications since the age of 13. On admission to the Regional Secure Unit, Anne was prescribed the medication detailed in Table 1.

Table 1
Medication levels on admission to the Regional Secure Unit

Medication	Dose	Description
Chlorpromazine	250 mg qds	Anti-psychotic
Risperidone	3 mg bd	Anti-psychotic
Benzhexol	5 mg tds	Anti-muscarinic
Flurazepam	15 mg nocte	CNS Hypnotic
Carbamazepine	200 mg qds	Anti-epileptic
Ethosuximide	250 mg bd	Anti-epileptic

Table 2
Frequency of incident types

Type of incident	Frequency
Banging head or hand	27
Cutting self	16
Scratching self	5
Swallowing objects/substances	5
Attacking staff	5
Smashing fire alarm	4
Inserting fingers/object into self (e.g. rectum)	5
Verbal aggression	2

Type of incidents

Incidents of self-harm were categorized according to the observed behaviour rather than the resulting injury. Therefore, whilst it was not possible to rate the severity of each incident from a basic analysis of the notes, the actions directly causing the self-harm are identified. Table 2 summarizes the different types of incidents recorded and the frequency of their occurrence. It is clear from this table that 62% of incidents have resulted from Anne either banging her head or hand against something or cutting herself with an implement.

Relationship between time and incident

Table 3 summarizes the frequency of incidents across time periods. From this table it can be seen that relatively few incidents had occurred during morning periods, and 46% of incidents had occurred between 6 PM and 12 AM. This finding is consistent with that of Hemkendreis (1992), who noted a significantly greater number of

Table 3
Frequency of incidents across daily time periods

Time period	Frequency of incidents
Morning (06.01–12.00)	6
Afternoon (12.01–18.00)	21
Evening (18.01–00.00)	32
Night (00.01–06.00)	10

Table 4
Type of incident and mean daily dose of medication

Type of incident	Risperidone (mg)	Chlorpromazine (mg)
Banging head or hand	6.4	318.5
Cutting self	7.1	240.6
Scratching self	7.2	280.0
Swallowing objects/substances	6.8	280.0
Attacking staff	6.0	240.0
Smashing fire alarm	6.0	437.5
Inserting fingers/object into self	7.6	150.0
Verbal aggression	6.0	175.0

incidents between the hours of 7 PM and 11 PM. Hemkendreis (1992) argued that this finding was not indicative of reduced activity levels, as an equivalent number of activities were on offer, but hypothesized that it was more indicative of raised anxiety levels before going to sleep.

The day of the week on which incidents occurred was also examined. Figure 1 depicts the number of incidents that have occurred on each day of the week.

Figure 2 illustrates the time periods during which these particular behaviours are occurring. Clearly, a similar pattern as in Table 3 is evident. But the frequency of incidents involving banging her head or hand is more pronounced during the evening period (6 PM–12 AM), with 59% of such incidents occurring during this time period.

Medication levels and incidents

Mean daily doses of medication at the time the incidents occurred are summarized in Table 4. For the purpose of this table, only the medications that have been most

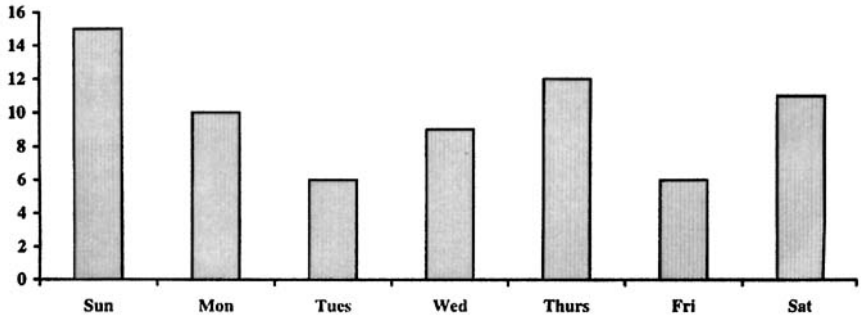

Figure 1
Number of incidents occurring on each weekday.

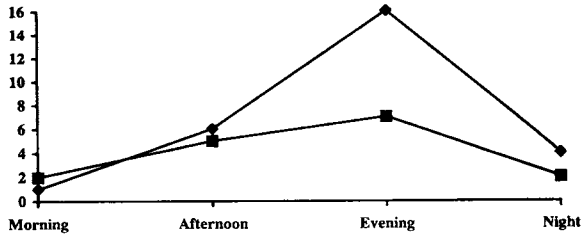

Figure 2
Time period and occurrence of (◆) banging head and (■) cutting self.

frequently varied, Risperidone and Chlorpromazine, have been included, as other forms of medication remained constant across the period being analysed and therefore it is not possible to estimate the effects of these on types of self-harming behaviour. PRN medication is excluded from the mean daily dose of Chlorpromazine for Table 4.

Figure 3 depicts the frequency of incidents per month and the use of medication, including Chlorpromazine, Risperidone and Chlorpromazine (PRN). It is clear from this graph that as use of Chlorpromazine was reduced, and Risperidone increased, the frequency of incidents per month decreases. Another interesting finding evident in this figure is that there were no incidents during month nine, whereas during month eight there had been more incidents than during any other month. From the records it is clear that during month eight Chlorpromazine was reduced to 50 mg tds and then stopped on 21st day of that month, at the same time as Risperidone was increased to 4 mg bd This suggests that 50 mg tds Chlorpromazine combined with 3 mg bd Risperidone was an ineffective level of medication with regard to controlling episodes of self-harm and other incidents. This is particularly evident when month 1 and months 9–12 are considered. During these periods, it would seem that high doses of chlorpromazine or high doses of risperidone are associated with a reduced frequency of self-harming behaviour, suggesting, simply, that high levels of antipsychotic medication *per se* is effective.

Table 5 illustrates a statistically significant difference between the occurrence and non-occurrence of incidents for the following types of medication: Risperidone, Ethosuximide and Chlorpromazine (PRN). Therefore, it appears that fewer incidents occur on higher doses of Risperidone. Fewer incidents also occur on higher doses of ethosuximide. The findings for Chlorpromazine (PRN), that more incidents occur on higher doses, is simply explained by the fact that PRN medication was administered in response to an incident.

Implications for this case

The findings indicated that incidents were more frequent at particular times. 77% of incidents occurred during the afternoon (between 12 PM and 6 PM) and the evening (between 6 PM and 12 AM). Future investigation should consider whether some other factor may explain why so many of the incidents have occurred during these time periods, for example levels of activity either for Anne or for other patients on the unit, or a number of patients restricted to the same space. In addition, Sunday afternoons and evenings, Wednesday afternoons, Thursday evenings and Friday evenings, are times when incidents have occurred more frequently. It was suggested that reviewing Anne's environment (e.g. activities and interactions) during these times may provide further insight into these patterns. No incidents occurred during month nine. At this point in time, Chlorpromazine had been withdrawn and Ethosuximide had been increased by 250 mg. As there had been such a large number of incidents during the preceding month it would be worth

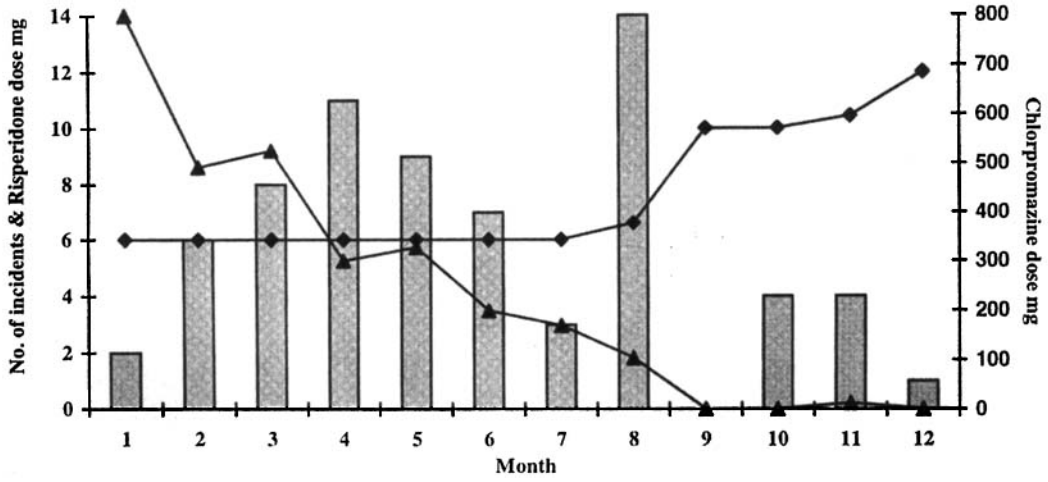

Figure 3
Occurrence of incidents varying with use of (▲) Chlorpromazine and (◆) Risperidone.

Table 5
T-tests for medication level effects on occurrence of incidents. Standard deviations are shown in parentheses

Medication	Mean daily dose		*t*-value	df	*P*
	No incidents	Incidents			
Risperidone	7.42 (2.07)	6.67 (1.48)	2.84	359	0.0047
Ethosuximide	600.17 (169.72)	550.72 (139.46)	2.25	359	0.0253
Chlorpromazine	275.86 (277.09)	279.71 (220.68)	−0.11	359	0.9143
PRN Chlorpromazine	6.42 (19.09)	27.54 (47.19)	−5.89	359	0.0000
PRN Lorazepam	0.14 (0.47)	0.25 (0.55)	−1.58	359	0.1158
Total Chlorpromazine (PRN + daily dose)	282.28 (277.38)	307.25 (223.28)	−0.70	359	0.4868

considering what factors may have contributed to the lack of incidents during month nine. It is worthy of note that investigation of this may be confounded by the removal of Chlorpromazine and the increased level of Ethosuximide, and the possible interaction of this needs to be considered further when addressing future treatment.

The relationship of medication to observed incidents was of interest for a number of reasons: there is clear evidence that, as the dose of Risperidone increases, the frequency of incidents decreases. However, it is also clear that there is no significant difference in effect between doses of 8 mg and 12 mg. Use of Chlorpromazine at high doses was related to fewer incidents occurring. A decreasing dose, particularly in relation to a seemingly ineffective dose of Risperidone, was related to an increase in the frequency of incidents. This finding may be relevant if future use of Chlorpromazine is considered. Higher doses of Ethosuximide are related to fewer incidents, but it must be remembered that higher doses of Ethosuximide are also related to higher doses of Risperidone. One of the side effects of Ethosuximide may be sexually disinhibited behaviour. As one of Anne's incident types is the insertion of fingers or other objects into her rectum, it was recommended that the relationship between this behaviour and the dose of Ethosuximide be investigated.

These findings raise a number of issues that are worthy of further investigation. One area that was not available from the data but that may be important was Anne's context before, during and after an incident. Other aspects such as nature of interactions and overall mood state should also be considered. The findings related to medication may have implications for future consideration of type and level of medication.

Conclusions

This paper proposes a method of applying the scientist-practitioner approach to multidisciplinary case management. Data were gathered from clinical sources, analysed and led to recommendations for future care. The work was done within the course of routine clinical practice by the Psychology Department. However, there are a number of limitations of applying these approaches, which need to be considered. To begin with, it is important not to regard the results gained by the use of more rigorous research methods in clinical practice as being more reliable or valid than they actually may be. Furthermore, when interpreting the results of such methods, the context in which the individual exists, and in which those measures were taken, needs to be considered. As with any research and, indeed, clinical investigation, a valuable precaution is to consider the applicability of the methods applied and the extent to which interpretations may be drawn from the findings. For instance, in this case study, it was not possible to conduct a full functional analysis of Anne's self-harming behaviour, as this quality of data had not been recorded. This means that the specific environmental and interpersonal contexts of the episodes of self-harm are unknown. It is crucial to consider this when interpreting the findings of this analysis, as such variables may have had more effect on the behaviour than those available for measurement. However, the typical clinical setting is not a laboratory and, as such, we cannot expect to affect adequate control over all the salient variables.

It is clear from the findings that have been discussed that this approach to clinical investigation highlighted the potential significance of interactional effects when monitoring an individual's response to medication. It is also evident that the greater the levels and variety of medication administered, the more complex the analysis of the effects become. The potential for the presence of confounding variables was established. In sum, this approach facilitated the authors in performing an in-depth, yet simplistic, clinical analysis.

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