

*Dedicated to the Health
Of the Whole Community*



DEPARTMENT OF
MENTAL HEALTH

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Santa Clara County
Mental Health Board Report
January 2008- January 2009

Santa Clara County Mental Health Board January 2009

Board Members:

Chair : Carol Irwin D.C.
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Cheryl Crose
Ronald Henninger D.C.
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Due to the impending and severe budget shortfalls of the county, the Mental Health Board is concerned that the access to care for the severely mentally ill and uninsured will be greatly jeopardized as existing programs are dismantled and underfunded. Clinics have closed and clients who were receiving treatment are now finding long waiting lists and lack of support. We understand that budget cuts are necessary for Santa Clara County, however, we ask that these continued reductions not be placed on the disabled and mentally ill. The **mentally ill are the most vulnerable of all populations** and that thoughtful considerations must be made regarding cuts to programs. The promise made in President Obama's inaugural speech regarding the "high costs of health care" must be addressed in reforms. Reforms do not always mean cuts to vital programs such as mental health. We need to have parity with physical health programs.

We ask that support to the Mental Health community be stabilized in these very trying times, and allow the Mental Health Department to implement the new programs that are being funded by the Mental Health Services Act (MHSA).

Since much of the emphasis of the Mental Health Department has been dedicated to planning for these reductions this has taken time away from the implementation of the MHSA systems of care. The Mental Health Department has lost vital full time employees and these responsibilities have been shifted to the remainder of the workers. The department is at a fragile point and further budget reductions will jeopardize the effectiveness of the department.

Adult System of Care: Chair Carol Irwin D.C.

This was an innovative year for the Adult System of Care, as I had the opportunity to participate in committee work with the staff from Barbara Arons Pavilion to improve services. In a joint effort with NAMI Santa Clara County, and the staff at the hospital a NAMI Family Resource Table was situated in the lobby during visiting hours for families seeing their loved ones. This resource table was staffed by either a NAMI Family member or NAMI Consumer. The staffers gave information about mental illness, educational programs and community resources available for the public. The concept of this table was indorsed by the Adult System of Care Committee unanimously to include its placement at the new Urgent Care Clinic located next to Emergency Psychiatric Services (EPS). The hospital staff and the NAMI staff developed a unique relationship in an effort to help families deal with the trauma of having a loved one in a locked facility. The Mental Health Board encourages the further development of this concept in all the portal of entry clinics for mental health services.

Issues regarding 24 hour care services:

The emergency psychiatric, acute and chronic systems of care in the county continue to be underfunded. Recently, the 24 hour care services have run 8.1 million over budget. While the population of Santa Clara County has continued to increase, the number of acute and chronically ill clients has remained at a rather constant number in the IMD's(Institute of Mental Disease). Some clients due to the nature of their illness are unable to maintain stability in the community and continue to recycle back into these hospitals for needed care. However, the number of clients needing this service has been constant, in number ranging

from 250-285. There has not been adequate budget funding to maintain this population and each year the Mental Health Department has gone over the budget to treat these patients. As the budget deficit has created less available out patient services, relapse rates have increased resulting in the need for these acute and chronic services. These patients are at greater risk for suicide, homelessness, victims of crime and abuse and are medically at risk. The need for relapse prevention programs will cut the costs of recidivism. According to the British Journal of Psychiatry (2004), costs for patients with schizophrenia who relapsed were over four times higher than those who did not relapse. (See attachment 1). While the MHD currently dealing with decisions to cut existing programs and lay off workers, on the one hand, new programs are being planned and funded from the Mental Health Services Act for clients who have been undeserved or have not successfully benefitted from the existing programs. The paradox is that the department is tearing down programs and while building new ones. Thus we have a two tier system. These two systems are running parallel to one another. In an effort to encourage transparency and increase effectiveness of the planning the Mental Health Board has requested data concerning outcomes measures of the MHSA programs, more specifically the program called Full Service Partnership (FSP). We have been unable to determine the effectiveness of this program as the data and outcomes are scant. This is an example of how the continued budget cuts have decreased the number of staff available to compile this information. Planning continues for the new programs while existing programs have not been evaluated. We hope to review in the upcoming year more complete information so as to make informed recommendations concerning access, and quality of care by using outcomes measures. This committee will also be advocating for bringing primary care into the system of care to reduce diabetes, cardiovascular illnesses, and smoking related health hazards that are on the rise with this population. Wellness care by relapse prevention through education and early access to care is a component of a prevention program. These needs are unmet and could be funded under the Prevention and Early Intervention section of the MHSA.

The following is a summary of needs and recommendations to the Board of Supervisors in regards to the Santa Clara County Mental Health Department and System of Care:

Categories:

Revenue Generating

1. Create a centralized mental health benefits department to qualify uninsured patients countywide. This department will both qualify and track applications and assist patients in future benefit administration which will increase revenues to the county. Maintain continuity with contracting agencies to monitor entitlement programs for clients countywide. This will minimize redundancy in the delivery system and streamline the process for establishing entitlements.

Post Hospitalization Programs

2. Develop Outpatient Day Programs which are funded by Medicare to serve clients post hospitalization to further stabilize them and generate income for the county. This may reduce the recidivism rate for the acute services. Further study of this issue is recommended.
3. Develop fund raising initiatives in the community to generate revenues. Partner with the Valley Medical Foundation to generate fund raising. Partner with other non profit agencies to have yearly fund raising initiatives for mental health.

Direct Services

4. Increase funding to direct patient services with improved access to out patient treatment. Reduce the ratio of one psychiatrist per 400 patients to one psychiatrist per 200 patients, thus minimizing the wait between visits and thus reducing the number of relapses.

Mental Health Services Act (MHSA)

5. Comply with MHSA doctrines by having a dedicated Family Support and Education Department headed by 1st degree family members (parents, siblings, or adult children) to develop outreach

and education for families who are burdened with the emotional trauma and responsibilities of dealing with a loved one with a mental illness. Fund these programs equitably as compared to other MHSA programs. Station NAMI Family Resource Tables at all portal of entry clinics within the county. Staff these tables with family members or consumers who have navigated through the system and familiar with how the system works. Who are trained by NAMI(National Alliance on Mental Illness) to assist families in seeking help for their loved ones and learning about resources in the community.

Currently there is design for a new out patient clinic which serves clients who are not insured by medi-cal. This clinic will offer treatment and initiate benefit applications for entitlements for them. We support this new design and urge the department to expand this access county wide.

Planning and Implementation MHSA

6. Limit the number of MHSA planning sessions and quickly implement plans approved thru the MHSA funds. Limit the number of new programs and finely tune them to meet expectations. As stated earlier the available staff are dedicated to maintaining the needs of the mental health department and are stretched in their available time to implement the new programs, causing unreasonable delays.
Develop a county wide system to set up outcome measures and collect the relevant data for these programs on an on going basis, so as to reduce redundancy of services, recidivism and the use of expensive systems of care. Data from existing programs should be evaluated to assist in future program development thus eliminating programs which have poor outcomes.

Programs Collaboration: Prevention and Early Intervention

7. Develop county wide relapse and suicide prevention programs by early detection and intervention.
8. Partner with schools of nursing for collaborative care to improve life styles choices and physical health for clients, with smoking cessation, exercise and dietary education. Partner with schools of occupational therapy for collaborative care for gainful and meaningful employment.

Data Collection and Outcomes Measures

9. Evaluate county patient access to care, quality of care rendered and outcome measures for the county systems of care on a month to month basis, quarterly and bi annual basis to determine which programs are efficient and efficacious and eliminate programs which do not produce results. Analyze and fine tune programs where outcomes are efficacious.
10. Improve interdepartmental communications by having a system of data sharing for the services rendered. Link psychiatric needs of patients at Valley Medical with access to care in the Mental Health System.

Emerging Unmet Needs

11. Develop a link with the Veterans Administration and family members of soldiers returning from Iraq and Afghanistan who are suffering from Post Traumatic Stress Disorder, depression, and suicide ideation who do not qualify to receive mental health treatment at the VA. Or are not receiving treatment because of the stigma of mental illness as they think that symptoms will disappear.

The Following Reports Have Been Compiled by the Sub-Committee Chairs and Co-Chairs:

System Planning and Fiscal Committee: Co-Chairs Robert Williams, Hilbert Morales

The System Planning and Fiscal Committee meets monthly (except August and December) on the first Thursday of each month. During the past twelve months the progress of the Department in several areas has been monitored and input from the community, contractor, and client stakeholders has been provided.

1. Budget Cuts and Program reorganization. The monthly meetings of the committee have reviewed the planned budget cuts. Several references summarize the past 12 months of budget reductions and program restructuring [1], [2], [3]. Budget reductions currently planned for the FY2008-09 fiscal year that will end June 30, 2009, are shown in Table 1.
 - Projected budget reduction targets from the Office of the County Executive for the coming fiscal year, FY2009-10, are \$22.5 Million, based on the presumed discretionary amount of \$58 Million county general fund money identified in the Mandate Study by Harvey Rose, consultants.
 - The chairs of the System Planning and Fiscal Committee of the Mental Health Board believe the "Mandate Study" did not correctly take into account the "non-supplantation" and "maintenance of effort" requirements of the MHSA for county eligibility of funds under the MHSA, which if corrected would require about \$71 Million of General Fund overmatch, the amount from the base year overmatch without inflation adjustment, be continued. See Table 3 for the past five years of MHSA funding under the MHSA. (Table 3 page 2)
 - There is over \$200 Million MHSA funds "in the pipe line" representing funds for 2005, 2006, 2007, 2008, and 2009 that have not yet been distributed to Santa Clara County, under the formula in State Mental Health Department letter DMH 05-02. The state report shows \$4 Million in FY2006-07, \$25 Million in 2007-08, and \$21 Million in FY2008-09, a total of \$50 Million remain unapproved for country programs.

2. The past five years of budget reductions have resulted in an Administrative overload that is near crisis proportions. For example,
 - Three division director positions are open. The Deputy Department Director is the Acting Division Director in all three divisions giving him a total of 24 direct reports.
 - After four years under the Mental Health services Act, the administrative burden of grant applications and restructuring of programs has been such that only \$22 Million dollars of MHSA funds have been spent on county programs thru FY2007-08. The current fiscal year forecasts that \$32 Million of MHSA funds will be spent in Santa Clara County, a sign that the program is finally beginning to gain momentum. See Table 2, FY2008-09 MHD Income and Expenses.
 - Note that the overmatch funds from the County General Fund are forecast to be about \$71 Million, near the level required from the Base Year FY2004-05 under the Mental Health Services Act to maintain eligibility for MHSA funds.
 - While in principle we have the data in UNICARE to determine the extent to which budget cuts and service reductions have resulted in increased recidivism as measured by client admissions to the county jail, more costly crisis services or to homelessness, we lack the administrative staff to prepare such reports in a timely fashion.
 - We do not have a meaningful monitoring system to determine what practices and policies are "best practices" in the medical sense, and conversely where programmatic changes are exacerbating the plight of the mentally ill in Santa Clara County.
 - We are nearly "flying blind" when it comes to having actual data about program effectiveness.

3. Mental Health Department Goals in system transformation. A stated goal of the Mental Health Services Act was to transform the mental health system to a model that has been labeled the "Wellness and Recovery" model. In its broadest sense it requires that the system be transformed to a kinder, friendlier system that is directed by a partnership between mental health professionals, clients with mental illness, and family members and support groups that have the interests of those with mental illness at heart.
- The budget cuts over the past five years are having a very negative impact on achieving this goal, as evidenced by the following changes and reductions in the System of Care.
- After four years, there are just two half time positions for family coordinators and only one of them is currently filled.
 - After four years, we are just beginning to hire consumers in paid part time positions, and fewer than 60 are now on the payroll, in part time up to 10 hour per week positions at a cost of under \$ 300,000 per year.
 - The reduction in paid case management services to adults in the outpatient program provide one case manager per 80 plus clients. This number of clients is expected to rise to an even higher level. This reduction in numbers of case managers flirts with disaster because many consumers on a stable treatment program require talk therapy and periodic adjustments to the level of medication that are not currently actively provided by the reduced level of service in the new Urgent Care program. Additionally, the new Urgent Care program is limited to 60 days of service.

References

1. Mental Health FY09, Town Hall Meetings-Budget Reduction Plan and Next Steps, June and July 2008, prepared by Mental Health Department.
2. Pete Kutras to Board of Supervisors, October 1, 2008, 1) Update on the FY 2009 State Budget and 2) Second Round of Reductions-Department / Agency Targets. And October 6 addendum, highlights relative the mental health
3. Gary Graves to Board of Supervisors, December 9, 2008, "The FY2010 Budget Planning and Solution Package addressing a projected \$ 220 Million General Fund deficit..."
4. MHD Report to Santa Clara county, Agreement number 07-77343-000, thru Modification a4, December 28, 2008, 8 pages
5. DMH Information Notice 08-36, MHSA Planning Estimates for 2009-10, December 11, 2008

Family and Children's Committee: Co-chairs, Cheryl Crose and Victor Ojakian

Family, Adolescent and Children's Committee of the Mental Health Board meets every other month (the odd number months, e.g., January, March, etc) on the 2nd Thursday of the month.

Our meetings discuss some standard business matters, including a staff report (by our liaison Michael Ichinaga) and a Mental Health Services Act update (by Ky Le). Each meeting also attempts to introduce information on programs or resources being used or provided to families, adolescents, or children.

Some of these presentations included:

- In March a discussion by Jim Raphael of pending foster care legislation.
- In July discussions on wrap around services by Laura Champion (EMQ) and a countywide report on public school children mental health (Every Child Has A Story) by Carla Holtzclaw (Red Code Training Associates)
- In September a presentation on Positive Behavioral Intervention and Support by Lisa Davis (EMQ)
- In November a brief discussion by Vic Ojakian on teen suicide prevention videos on YouTube.

A recent state DMH review identified areas of service improvement including improving the call center 1-800 operation, better and more cultural competency training, improved Q1 process, and improved authorization for services, fees for service, etc.

In 2009 goals will include how to better understand and improve public school services and how to identify directing more adolescents and teens to mental health services.

Minority Advisory Committee: Chair: Richard Alvarez

The Minority Advisory Committee continues to meet on a regular basis on the third Tuesday of the month. All are invited to attend.

We are guided by our Mission Statement which states, 'that we advocate for the service needs of the diverse community by addressing these needs and forwarding them to the Mental Health Board'.

The topics discussed during our meetings cover a multitude of subjects. We have discussed legislation that directly effects mental health services. We have advocated support for AB 1887, the mental health parity bill for instance. We have discussed cultural competency in the MHSA programs. We have talked about housing and have invited Bob Dulci to our meeting to clarify certain aspects of the housing program, specifically shared housing. We have asked our staff person, Maria Fuentes to keep us up to date on ECAC activities, as well as changes to the MHSA programs and other areas of concern to our committee.

Currently and into 2009, we will continue to monitor PEI programs to assure that cultural competency is written into the plan.

Older Adult System of Care: Chair : Wesley Mukoyama

The Older Adults Committee convened for the first time since 1999 as a separate committee from the Adults and Older Adults Committee. This is because the content of the latter was more focused on Adults 59 and younger. Little attention had been given to older adults and the unique problems of aging.

In light of the new programs brought forth by MHSA, much hope was given to reaching out to older adults who become isolated and depressed. There have been no funds directed toward this population's need for in home assessments for clinical depression due to isolation, physical immobility, dementia and just the aging process.

It has been the committee's plan and aspiration that this would be addressed by the Prevention and Early Intervention (PEI) process. Sheila Yuter from Mental Health Administration was assigned to this committee and has been most informative. Her explanations of the process have been very thorough. However, we had hoped that the process of PEI would have started last April. This has not happened and we are fearful that because of severe cuts in funding from the County, this process could be delayed longer. Furthermore, we were disappointed that there were no specific funds earmarked for the elderly. We await and hope for a more optimistic outlook from PEI for more directed and relevant programs for the older adults.

We also have been convening with non mental health agencies e.g., Department of Aging and several ethnic agencies to encourage and advocate for "wraparound services."

Ad-Hoc Committee: Performance Measures and Outcomes: Chair Ronald Henninger D.C.

An Ad Hoc Committee was convened by the Mental Health Board to assist in the development and the analysis of information as to the efficacy of services delivered by the Mental Health Department to patients. The rationale for this committee is to fulfill the Mental Health Board duty to evaluate services rendered. This process began by requesting data relevant to the services rendered from the Full Service Partnership Program(FSP). The FSP program is part of the Mental Health Services Act (MHSA) funding. This Ad Hoc Committee serves as a go between to help the MHD understand what information the MHB wants and to help explain to the MHB what the data from the MHD represents. Therefore, this committee could help develop data correlating quality of care, access of care, and outcomes of care. This process to date has been deficient. The MHD has been struggling with lack of staffing due to the budget deficits.

One serious short coming that exists is the lack of clear meaningful outcomes that could be used to evaluate care across the system. It is clear in the current health care environment that payers want outcomes that demonstrate you are doing what you say you are doing. This same standard should be used in the MHD. Along with the generation of meaningful outcomes, there needs to be a collection system that

is consistent across the many facilities that are contracted by the MHD. Without these two parts being in place, it is impossible to know what is working and what is not, who is doing a good job and who is not. Without the knowledge provided by outcomes and the collection of the data that these outcomes provide, planning and development of new programs is little more than a guess of what is working and what needs to be changed.

One aspect of the data collection problem arises when there are continual cut backs and loss of funding. This results in staffing shortages for the collection of data. The question becomes whether we choose between staffing cuts or data collection. Decisions made using data reflecting outcomes will provide the necessary information needed to plan for new programs, improved programs and the elimination of poor performing programs.

We are anticipating productive collaboration with the MHD and specifically Deane Wiley. Dr. Wiley has been very helpful in the process of data collection. We look forward to continued improvement in the development of this process.

Respectfully submitted by

A handwritten signature in cursive script that reads "Carol Irwin D.C." followed by a period.

Carol Irwin D.C.

Chair, Mental Health Board 2008-2009

Santa Clara Valley Health & Hospital System
Mental Health Department
Fiscal Year 2007-08

Description	COST ANALYSIS				REVENUE ANALYSIS										Total Revenue	Net CCF
	County FTEs	Staff Expense	Contract Expense	Other Expense	Total Expense	Short Doyle	Medi-Cal	Medicare	MHSA	IDEA SB90	Pharmacy	Realign	Reimburse			
F&C Inpatient	0.00	\$0	\$453,320	\$0	\$453,320	\$217,599	\$0	\$0	\$0	\$0	\$0	\$94,346	\$0	\$311,945	\$141,375	
Residential/CI/F	0.00	\$0	\$6,426,117	\$0	\$6,426,117	\$1,705,377	\$2,577,589	\$0	\$0	\$2,142,250	\$0	\$361	\$0	\$6,425,577	\$541	
Wraparound	0.00	\$0	\$12,465,871	\$0	\$12,465,871	\$4,461,537	\$4,543,922	\$0	\$0	\$2,770,525	\$0	\$0	\$0	\$11,875,984	\$589,887	
IPD Hall/Ranches	19.00	\$2,346,715	\$0	\$5,471	\$2,352,186	\$0	\$69,168	\$0	\$0	\$1,067,963	\$0	\$0	\$1,016,473	\$2,193,604	\$198,582	
Children's Shelter	3.00	\$802,805	\$0	\$84,019	\$886,824	\$1,806,943	\$184,032	\$0	\$0	\$1,07,062	\$0	\$0	\$0	\$291,094	\$595,730	
School Day Tx	0.00	\$7,662,925	\$16,625,127	\$3,316,054	\$27,404,106	\$2,497,327	\$8,897,852	\$0	\$0	\$7,084,862	\$0	\$2,766,801	\$2,011,257	\$23,258,099	\$4,146,007	
Specialized OP	6.00	\$627,756	\$0	\$22,528	\$650,284	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$650,284	\$650,284	\$0	
CAIWORKS OP	95.50	\$11,440,201	\$41,100,823	\$3,497,944	\$56,038,968	\$10,688,783	\$19,093,204	\$0	\$0	\$13,964,661	\$0	\$2,861,508	\$3,678,014	\$50,286,170	\$5,752,196	
Total Family & Children's Services Division																
State Hospital	0.00	\$0	\$5,418,394	\$0	\$5,418,394	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$5,418,394	\$0	
A/OA Inpatient	0.00	\$0	\$5,182,952	\$0	\$5,182,952	\$2,145,372	\$0	\$0	\$0	\$0	\$0	\$1,215,769	\$0	\$3,967,183	\$1,821,811	
DMH/SNF/OBS	0.00	\$0	\$14,198,929	\$0	\$14,198,929	\$0	\$0	\$0	\$0	\$0	\$0	\$5,264,446	\$1,045,796	\$6,310,242	\$7,888,687	
Residential Tx	0.00	\$0	\$6,696,351	\$0	\$6,696,351	\$0	\$2,376,225	\$0	\$0	\$0	\$0	\$1,729,099	\$0	\$4,105,324	\$2,591,027	
Supplement RCF	0.00	\$0	\$1,460,653	\$0	\$1,460,653	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$1,460,653	\$0	
Supported Housing	0.00	\$0	\$137,256	\$0	\$137,256	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$137,256	\$0	
Day Rehab	127.50	\$15,743,357	\$15,935,219	\$2,198,092	\$33,876,668	\$0	\$1,856,130	\$0	\$0	\$0	\$339,753	\$9,000,602	\$1,189,529	\$20,389,410	\$13,487,258	
Outpatient Teams	0.00	\$0	\$258,318	\$0	\$258,318	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$258,318	\$0	
Homeless Shelter	0.00	\$0	\$573,711	\$0	\$573,711	\$0	\$0	\$0	\$0	\$0	\$0	\$132,413	\$45,000	\$177,413	\$196,420	
Vocational	0.00	\$265,976	\$0	\$109,857	\$375,833	\$0	\$0	\$0	\$0	\$0	\$0	\$108,267	\$196,096	\$304,363	\$162,236	
Rep Payee	0.00	\$0	\$466,599	\$0	\$466,599	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$466,599	\$0	
Legal Advocacy	127.50	\$16,009,333	\$54,484,418	\$2,307,949	\$72,801,700	\$2,145,372	\$14,071,881	\$0	\$0	\$0	\$359,753	\$18,558,514	\$2,582,123	\$37,717,643	\$35,084,058	
Total Adult & Older Adult Services Division																
Call Center	13.50	\$1,769,827	\$0	\$82,293	\$1,852,120	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$1,852,120	\$0	
Gateway	32.00	\$2,775,458	\$0	\$208,341	\$2,983,799	\$0	\$0	\$0	\$0	\$0	\$0	\$1,194,244	\$0	\$1,194,244	\$1,789,555	
24-Hour Care	0.00	\$0	\$0	\$80,743	\$80,743	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$80,743	\$0	
Suicide Hot Line	1.00	\$119,326	\$0	\$30,834	\$150,160	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$108,124	\$108,124	\$42,036	
Suicide Prevention	1.50	\$162,972	\$0	\$0	\$162,972	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$162,972	\$0	
Drug Tx Court	0.25	\$37,000	\$0	\$0	\$37,000	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$37,000	\$0	
Disaster Response	0.00	\$0	\$0	\$391,993	\$391,993	\$0	\$0	\$0	\$0	\$0	\$0	\$156,892	\$0	\$156,892	\$255,101	
Self Help	48.25	\$5,339,424	\$0	\$803,872	\$6,143,296	\$0	\$0	\$0	\$0	\$0	\$0	\$1,351,136	\$526,215	\$1,877,351	\$4,265,945	
Total Call Ctr, 24-Hour, Suicide, DTC & Disaster Resp																
MHSA	27.00	\$2,995,381	\$6,644,339	\$2,432,552	\$12,092,272	\$0	\$330,574	\$0	\$11,761,698	\$0	\$6,808,180	\$949,552	\$0	\$13,532,099	\$923,797	
Pharmacy	0.00	\$0	\$0	\$14,055,896	\$14,055,896	\$0	\$0	\$6,374,367	\$0	\$0	\$0	\$925,727	\$0	\$2,272,553	\$1,387,187	
Managed Care	1.00	\$158,335	\$9,907,404	\$44,000	\$4,109,740	\$1,289,211	\$507,514	\$0	\$0	\$0	\$0	\$0	\$0	\$2,872,003	\$3,037,482	
MIOCR	6.00	\$628,334	\$1,203,640	\$1,205,508	\$3,037,482	\$72,013	\$1,431,466	\$0	\$0	\$0	\$0	\$0	\$0	\$2,872,003	\$3,037,482	
Total MHSA, Pharmacy, Managed Care & MIOCR																
Inpatient/Outpatient Jail	0.00	\$0	\$0	\$9,633,768	\$9,633,768	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$9,633,768	\$3,855,845	
APS/BAP	0.00	\$0	\$0	\$35,576,538	\$35,576,538	\$1,021,368	\$3,490,852	\$5,183,101	\$0	\$0	\$0	\$8,946,247	\$3,529,163	\$22,170,731	\$13,465,807	
Total APS/BAPS & Custody MH Services																
General Admin	17.25	\$4,060,642	\$0	\$16,845,900	\$20,906,542	\$0	\$4,794,564	\$0	\$0	\$0	\$0	\$6,425,179	\$95,772	\$11,315,515	\$9,591,027	
QI/Research	8.50	\$1,228,594	\$0	\$117,440	\$1,346,034	\$0	\$71,974	\$0	\$0	\$0	\$0	\$0	\$0	\$71,974	\$1,274,060	
Total MH Administration	25.75	\$5,289,236	\$0	\$16,963,340	\$22,252,576	\$0	\$4,866,538	\$0	\$0	\$0	\$0	\$6,425,179	\$95,772	\$11,387,488	\$10,865,088	
GRAND TOTAL	331.00	\$41,840,245	\$107,560,624	\$86,520,767	\$235,741,636	\$15,166,747	\$42,504,129	\$11,557,468	\$11,761,698	\$13,964,661	\$7,167,933	\$43,273,707	\$13,283,290	\$158,679,633	\$77,062,003	

Mental Health Board Priorities

The Mental Health Board of the County of Santa Clara is composed of members of the community at large, clients and family members of clients of the mental health system. The board's mission and duties are established in state (See attached Welfare and Institution Code, Section 5600) and county law (See attached Chapter VII, Sections A18 — 141 and A18 — 142). They include: review and evaluation of the community's mental health needs, facilities and special problems; advise the Board of Supervisors and the county mental health director as to any aspect of the county mental health program; and, submit an annual report to the Board of Supervisors on the needs and performance of the county's mental health system.

1. Act as a forum for clients, families and other constituents about the needs and quality of services for the mentally ill.
2. Work with the director and the staff of the Mental Health Department as an advisor to provide input for planning programs and budgets prior to final decisions.
 - Provide to the Board of Supervisors an annual report of the Department of Mental Health. Communicate to the Board of Supervisors as necessary in an on-going dialogue. Make specific recommendations to assist the Board of Supervisors in making decisions concerning mental health services.
3. Collect, review, and evaluate information about delivery of care for the mentally ill provided by the Mental Health Department in order to understand and evaluate services to clients that promote recovery, maintenance and return to the community.
4. Promote outreach and education about mental health services
5. As informed stakeholders, communicate pertinent information leading to desired public policy outcomes at local, state and federal levels.
6. Gain an understanding of the etiology, diagnosis, treatment and advancements in the field of mental health.
7. Recognize people and organizations that have contributed to mental health.

Relapse in schizophrenia: costs, clinical outcomes and quality of life

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Background Relapse is one of the most costly aspects of schizophrenia.

Aims To compare costs, clinical outcomes and quality of life for patients who experienced relapse in schizophrenia with a control group who did not relapse.

Method Patients were randomly selected from current psychiatric case-loads drawn from urban and suburban areas of Leicester. Differences in costs and outcomes by relapse status in the previous 6 months were examined using parametric and non-parametric tests, and multivariate analysis was used to examine factors associated with relapse and costs.

Results Costs for the patients who relapsed were over four times higher than those for the non-relapse group. There were few statistically significant differences in clinical and quality of life measures by relapse status. Multivariate analyses suggested some significant correlates of relapse and costs.

Conclusions The higher costs associated with relapse will be of interest to policy-makers who face difficult choices concerning new but more expensive treatments for patients with schizophrenia.

Declaration of interest None. Funding detailed in Acknowledgements.

Symptomatic relapse in schizophrenia is both distressing and costly. It can devastate the lives not only of patients, but also of their families. The debilitating symptoms require specialist health care interventions and targeted treatments, with potentially high costs. It has been estimated, for example, that relapse cost \$2 billion just for readmissions to hospital in the USA, almost a decade ago (Weiden & Olsson, 1995). There is no equivalent estimate for the UK. This study aimed to compare costs, clinical outcomes and quality of life (QoL) for patients with schizophrenia in the UK according to whether or not they had experienced a relapse in the previous 6 months.

METHOD

Study sample

Patients were randomly selected from current (active) psychiatric case-loads drawn from urban and suburban areas of the English city of Leicester. Consultant psychiatrists or senior responsible medical staff were approached by a project research psychiatrist and asked for a list of patients with a possible diagnosis of schizophrenia. Full lists were obtained from five consultants covering city and suburban catchment areas of Leicester. An additional five consultants were also approached to identify patients with the diagnosis who had experienced a relapse within the past 6 months. Patients were excluded if they were living outside this area when the sampling was undertaken. Patients from rural areas of Leicestershire were excluded. The sampling procedure was designed to recruit equal numbers of relapse and non-relapse cases.

Patients were included as participants if they had received a diagnosis of schizophrenia according to DSM-IV criteria (American Psychiatric Association, 1994), had no other psychosis, were aged 18-64 years, and gave their informed consent.

Patients were excluded from the study if they were roofless, continuously hospitalised for 12 months or more, about to move residence, already participating in a clinical trial, or unable to participate for language reasons. Although such biases were not specifically controlled for, clinicians took every step to avoid biases in the socio-economic and demographic profiles of patients.

Relapse criteria

Many alternative definitions of relapse in schizophrenia have been published (see Lader, 1995, for review). These include number of admissions to hospital, detention under a section of the Mental Health Act, attendance at an acute day care centre, change of antipsychotic agent, increased staff input and/or more intensive case staff management, and a significant change in accommodation. Relapse was identified retrospectively in this study as the re-emergence or aggravation of psychotic symptoms for at least 7 days during the 6 months prior to the study. In addition to instances of relapse pointed out by clinical staff, recorded changes in mental state were regarded as significant and amounting to relapse if there was a clearly documented assessment of a relapse. A change in management as appropriate might also have occurred but not necessarily, and not all relapses led to readmission. Relapse could thus be identified in cases of patients who had been admitted to hospital in the past 6 months, who had consulted their psychiatrist and had had their medication changed for deterioration in their condition, or who had had an increase in intensive support at home from the community mental health team. A planned hospital admission was not classed as a relapse. A research team specialist registrar advised the researcher on any case-note descriptions or accounts from staff that were unclear.

Instrumentation

Data were collected especially for this study. Data collection was based on information obtained directly from case notes and from interviews with the patients in which rating scales were completed (patients gave informed written consent). The information had not been extracted for any other or prior reason.

We used the Positive and Negative Syndrome Scale (PANSS; Kay *et al.*, 1987), one question from the Clinical Global Impression scale (CGI; Guy, 1976) covering

severity of illness, the Global Assessment of Functioning (GAF; American Psychiatric Association, 1987), the Lehman Quality of Life scale (Lehman, 1996), the visual analogue scale from the EuroQoL EQ-5D health-related quality of life measure (Kind, 1996) and the Client Service Receipt Inventory (CSRI; Beecham & Knapp, 1992, 2001). Unit costs attached to services were national average figures for the period over which clinical and service use data were collected, at 1998-9 prices (Netten *et al*, 1999).

Statistical analyses

Depending on the distribution of key variables, parametric (independent *t*-test) and non-parametric (Mann-Whitney, Kruskal-Wallis) tests were carried out to check for significant differences in mean costs, clinical and QoL outcomes by relapse status. The Pearson chi-squared statistic was used to test for significant differences between categorical measures and relapse status, and for other relapse criteria.

The survey design also permitted multivariate analysis to examine simultaneously some of the potential correlates of relapse status and costs, although it should be noted that the study did not include a full range of possible associations with relapse (see for example, Robinson *et al*, 1999). First, a generalised linear model (GLM) with a logit link function was used to predict whether a patient had experienced a relapse or not. The logit GLM is similar to the standard logistic model but also produces a measure of dispersion (the variance of the unexplained part of the model). Odds ratios are presented which show the likelihood of relapse given particular patient characteristics. Second, because costs were skewed to the right (although only 5% were zero values), standard ordinary least squares estimates were inappropriate (cf. Dunn *et al*, 2003). The results presented are based on a reduced-form GLM model, with a log link function and a Gaussian variance function. Compared with other standard GLM specifications, this produced the best-fitting model in terms of mean predicted cost levels. It also produced the most efficient estimates in terms of lower standard errors and smaller confidence intervals. The statistical analyses were carried out using the Statistical Package for the Social Sciences version 9 for descriptive comparisons and STATA version 6 for the multivariate analyses.

RESULTS

Sample

We identified 257 patients potentially eligible to participate in the study. Of these, 12 refused to take part, 67 were not interviewed because of staff concerns, 12 could not be contacted, and 9 were judged by the interviewer to be too ill; in three cases it was felt to be unsafe to see the patient at home.

A total of 145 patients completed interviews in the study: 77 relapse cases and 68 non-relapse cases. Another 9 patients who were also interviewed were excluded because of incomplete records or inconsistent data. The limited information available on them suggests that most would have been assigned to the non-relapse group and, if included, their cases would have had little impact on average costs.

Relapse and patient characteristics

Relapse status was defined on the basis of re-emergence or aggravation of psychotic symptoms. Table 1 lists other patient characteristics previously employed to define relapse (Lader, 1995). Not surprisingly, relapse cases were characterised by higher rates of hospitalisation (63%), re-emergence of psychotic symptoms (60%) and aggravation of positive or negative symptoms (43%), and an increased level of staff input or more intensive case staff management (33%) (all $P < 0.05$).

Compared with the non-relapse group, patients who had recently experienced a

relapse had been more recently admitted to a psychiatric ward (using actual years: 1997 and 1992, $P < 0.05$), and experienced a higher number of admissions (5.6 and 3.3, $P < 0.05$). Although patients in the non-relapse group appeared to have spent longer in hospital, the difference was not significant (Table 2). There was no difference between the relapse and non-relapse groups with respect to gender, ethnic group, marital status, employment status or highest level of education (Table 3). Relapse patients were more likely to be living alone ($P < 0.05$). Mean ages were 37.9 (s.d.=10.7) years for relapse patients and 41.1 (s.d.=11.1) years for non-relapse patients (not significantly different).

Clinical health and quality of life

Although higher scores on the PANSS and the CGI suggested worse symptoms for relapse compared with non-relapse cases, the differences were not statistically significant. However, GAF scores indicated worse symptoms for relapse patients ($P < 0.05$; Table 4).

Using the Lehman 'delighted-terrible' (D-T) scale and scores, relapse patients appeared to experience lower QoL than non-relapse patients on most dimensions, but the differences were small and not statistically significant, except for the items 'living arrangements' and 'feelings about current health' ($P < 0.05$). There was perhaps some inconsistency in the QoL findings since relapse patients scored slightly better

Table 1 Criteria for assignment to relapse or non-relapse study group

Variable	Non-relapse	Relapse
	(n=68) %	(n=77) %
Significant change in management directly related to illness or treatment side-effects ¹	0	100
Change in clinical state		
Re-emergence of psychotic symptoms ²	0	60
Aggravation of positive or negative symptoms ²	0	43
Change in management		
Hospital admission in past 6 months ²	0	63
Detention under section of Mental Health Act ²	0	20
Acute day care ³	0	5
Change of antipsychotic agent ²	0	21
Increased staff input, more intensive case staff management ²	0	33
Significant change in accommodation ³	0	5

1. Chi-squared test not computed.

2. Chi-squared test significant at $P < 0.05$.

3. Chi-squared test not significant at $P=0.05$.

Table 2 Characteristics of service contact prior to study entry

Variable	Non-relapse (n=68) mean (s.d.)	Relapse (n=77) mean (s.d.)
Year of first contact with mental health services because of psychotic illness ¹	1985 (8.7)	1987 (8.3)
Year first admitted to psychiatric ward ²	1986 (8.7)	1989 (7.7)
Year of most recent admission to psychiatric ward ²	1992 (7.0)	1997 (3.9)
Number of times admitted to psychiatric ward ²	3.3 (4.1)	5.6 (4.8)
Longest admission to psychiatric ward (months) ¹	7.1 (29.6)	4.6 (2.8)

1. Independent t-test not significant at $P=0.05$.

2. Significant at $P < 0.05$ (similar results achieved using non-parametric tests).

on the EQ-5D visual analogue scale compared with non-relapse patients ($P < 0.05$). However, the EQ-5D measures own health state today, whereas the Lehman score covers broader dimensions of quality of life.

Table 3 Socio-economic and demographic characteristics of the participants

Variable	Non-relapse (n=68) %	Relapse (n=77) %
Gender		
Female	47.1	32.8
Ethnic group ¹		
White	82.4	83.1
Black Caribbean	4.4	2.6
Indian	11.8	13.0
Other	1.4	1.3
Marital status ¹		
Single	55.9	74.0
Married/cohabiting	26.5	11.7
Divorced/separated	16.2	10.4
Widowed	1.4	3.9
Highest educational level ¹		
Primary	4.4	1.3
Secondary	88.2	76.6
Tertiary/further	4.4	13.0
Other (not specified)	2.9	9.1
Living arrangements ²		
Alone at home	19.1	37.7
With family/others	53.0	35.1
Collective accommodation	22.1	11.7
Other (not specified)	5.8	15.6
Employment ¹		
Not working	94.1	97.4

1. Pearson χ^2 not significant at $P=0.05$.

2. Significant at $P < 0.05$.

by in-patient days. During the 6 months prior to the study, patients in the relapse group spent a mean of 58 days in hospital – although this figure was inflated by six patients who were continuously in hospital for the entire period. By design and selection, nobody in the non-relapse group experienced any hospitalisation in this period.

Psychiatric out-patient visits were also significantly more common in relapse than in non-relapse cases (mean cost £209 v. £135, $P < 0.05$). On the other hand, there was slightly higher use by patients in the non-relapse group of day care centres, group therapy, sheltered workshops, specialist education, general practitioners and community psychiatric nurse (CPN) visits, but apart from day care centres none of the differences was statistically significant at the 5% level. Services are complements, in the sense that patients with greater morbidity are likely to use more of a number of

Resources and costs

Six-month service use rates and costs per patient are summarised in Table 5. Costs for relapse cases were four times higher than those for non-relapse cases – £8212 compared with £1899 ($P < 0.05$) – with much of the cost difference accounted for

Table 4 Clinical characteristics and quality of life

Clinical and QoL scales	Non-relapse (n=68) %	Relapse (n=77) %
PANSS		
Positive scale ¹	12.9	15.4
Negative scale ¹	15.0	15.8
General psychopathology ¹	31.0	32.1
CGI ¹	3.5	4.6
GAF ²	57.8	52.6
Lehman QoL		
General life satisfaction (D–T scale) ¹	4.3	3.8
Living arrangements (D–T scale) ²	15.0	13.3
Daily activities (score) ¹	4.1	3.8
Functioning (D–T scale) ¹	2.7	2.8
Family		
Talk/get together (score) ¹	7.5	7.2
Relationship (D–T scale) ¹	9.6	9.3
Social relations		
Frequency/type (score) ¹	9.1	10.6
Relationship (D–T scale) ¹	13.6	13.2
Finances		
Enough money (score) ¹	3.9	3.6
Money available (D–T scale) ¹	12.7	12.1
Health		
General well-being ¹	13.1	12.5
Feelings about health (D–T scale) ²	8.9	7.9
EQ-5D ²		
Health state score	57.7	59.5

CGI, Clinical Global Impression; D–T, 'delighted–terrible'; EQ-5D, EuroQoL EQ-5D; GAF, Global Assessment of Functioning; PANSS, Positive and Negative Syndrome Scale; QoL, quality of life.

1. Independent t-test not significant at $P=0.05$.

2. Significant at $P < 0.05$ (similar results achieved using non-parametric tests).

Table 5 Mean 6-month service use and costs (£, 1998) per patient by relapse status

Service	Non-relapse (n=68)		Relapse (n=77)	
	Mean usage	Costs (£)	Mean usage	Costs (£)
In-patient care (days) ¹	0.0	0	57.8	6451
Out-patient				
Psychiatric visits ¹	1.4	135	2.1	209
Other ²	0.1	8	0.3	19
Day hospital (visits) ²	2.3	133	2.1	126
Community mental health centre (visits) ^{2,3}	2.4	44	1.4	25
Day care centre (visits) ¹	5.9	106	0.9	15
Group therapy ^{2,3}	0.4	6	0.1	2
Sheltered workshop ²	1.1	45	0.0	0
Specialist education ^{2,3}	2.9	52	0.0	0
Other (not specified) ³	0.6	12	0.0	0
Visits by				
Psychiatrist ¹	2.5	103	2.3	269
Psychologist ³	0.0	0	0.0	2
General practitioner ³	1.8	217	1.6	152
District nurse ³	0.1	1	0.0	0
Community psychiatric nurse ³	12.6	1014	5.2	791
Social worker ³	0.1	24	0.4	106
Occupational therapist ³	0.0	1	0.8	44
Home help/care worker ³	0.4	0	0.6	0
Total costs ¹		1899		8212

1. Independent t-test significant at $P < 0.05$ (similar results achieved using non-parametric tests).

2. Costs not available – set equal to cost for day care centre.

3. Independent t-test not significant at $P=0.05$.

services, but are also substitutes, in that (for example) hospital in-patients will have less need and less opportunity to use day care, primary care and CPN support. These two tendencies may have cancelled out for this sample.

Relapse correlates

Given the (expected) high costs associated with illness relapse, correlates of relapse and non-relapse status were examined. The odds ratios in Table 6 indicate that,

controlling for all other explanatory factors, there was an increased risk of relapse associated with:

- each year of age (OR=1.07);
- fewer years since recent hospital admission (converting the tabulated OR: $1/0.79=1.27$);
- previous suicide or self-harm attempts (OR=3.93);
- increased social functioning (OR=1.29);

Table 6 Factors associated with relapse status: multivariate analyses ($n=131$)¹

Variable	Odds ratio ²	95% CI
Age (years)	1.07	1.01–1.13
Number of years since most recent hospital admission	0.79	0.69–0.90
Previous suicide or self-harm attempts	3.93	1.39–11.07
Social relationships score (Lehman)	1.29	1.13–1.48
GAF score	0.93	0.87–0.98

GAF, Global Assessment of Functioning.

1. Dispersion parameter 0.99 (a value of 1 indicates constant variance of the error term).

2. Significant at $P < 0.05$ controlling for gender, ethnicity, marital status, education and living arrangements (all $P > 0.05$).

(e) lower scores on the GAF (converting the tabulated OR: $1/0.93=1.08$) (all $P < 0.05$).

Cost correlates

The log link method of GLM estimation was used to examine the factors associated with cost differences (Table 7). Coefficient values represent the percentage change in total costs (from the average) following a one-unit change in the explanatory variable (compared with a reference category if the variable is categorical). Holding constant all other explanatory factors in the model, average costs were increased by patients who relapsed (147%), and were reduced by patients who were older (3.6% per year of age), and living with family/others compared with those in collective accommodation (58%).

DISCUSSION

Costs of relapse of schizophrenia

Studies of the overall costs of schizophrenia in the UK (Davies & Drummond, 1993) and in other countries (Knapp *et al*, 2004) confirm the high proportion of the total that is attributable to in-patient care. This study shows that illness relapse is a major factor in generating these high hospitalisation rates and costs. We have gone further, however, in providing an estimate of the full service costs of schizophrenia relapse in the UK. Patients who experienced a relapse during the 6 months prior to data collection had mean service costs of £8212 compared with £1899 for those who had no relapse during this period. The only previous UK estimate of the costs of relapse of which we are aware was based on expert opinion and assumed (rather than observed) service utilisation in a simulation model that compared three antipsychotic drugs (Almond & O'Donnell, 2000). Average relapse costs at 1997 prices were estimated to be just over £10 000 per patient during three monthly cycles and included both service use costs and accommodation costs (the latter not included here).

Clinical and QoL correlates

Surprisingly, perhaps, there were few differences in clinical and QoL outcomes between patients who had relapsed and those who had not. However, some of the patients in the former group would have recovered well from their relapse by the time these clinical and QoL instruments were

Table 7 Factors associated with differences in costs: multivariate analyses ($n=145$)

Variable	Coefficient (β) ¹	95% CI
Age (years)	-0.04	-0.06 to -0.16
Gender (male)	0.08	-0.32 to 0.48
Ethnicity (White)	-0.11	-0.64 to 0.43
Ethnicity (Black Caribbean)	0.99	-0.15 to 2.12
Marital status (single)	-0.16	-0.70 to 0.38
Marital status (married/cohabiting)	0.35	-0.33 to 1.03
Further education (higher)	0.26	-0.44 to 0.94
Living alone at home	-0.05	-0.58 to 0.48
Living with family/relatives	-0.58	-1.07 to -0.08
Relapse status	1.47	1.88 to 1.06
Constant	9.15	8.07 to 10.14

1. Percentage change in total costs following a one-unit change in the explanatory variable; all variables significant at $P < 0.05$.

administered. This time lapse is probably the reason for the lack of difference.

Associations

Multivariate analyses confirmed some significant correlates of relapse, and a reduced-form cost equation found, as expected, that relapse status significantly increased total costs. The cost equation was estimated in reduced form for two main reasons. First, relapse status as a regressor captured some of the important partial effects already identified in the relapse function – for example, suicide attempts, previous hospital admissions and social functioning – and reduced the need to include these variables further as independent effects in the cost analyses. Second, clinical and QoL variables were excluded from the cost equation because it was difficult to relate current measures with costs in the previous 6 months. This is a problem of endogeneity: it is difficult to ascertain the direction of causation between variables. Although higher levels of service use (and costs) might have improved health and reduced the likelihood of relapse, relapse status might have increased service use and costs. However, given that relapse often resulted in hospitalisation (for about two-thirds of the people in the relapse group) and in-patient costs accounted for around three-quarters of total costs, the problem of endogeneity with relapse status was less of an issue.

Finally, a cautionary note is required on measuring differences in costs and health outcomes between the relapse and

non-relapse groups. Although this method is valid, a superior comparison would come from panel or longitudinal data that measure changes in outcomes prospectively for a given population (cf. Robinson *et al*, 1999). The costs of relapse would then be estimated by examining the differences in costs, before, during and after relapse. Cost-effectiveness comparisons are also required based on experimental evaluations of relapse minimisation strategies.

Policy implications

The significant costs found to be associated with relapse confirm the scale of the impact – in this case measured by service uptake – of a worsening of symptoms for people with schizophrenia. These costs will be of interest to clinicians and other decision-makers who face difficult choices about new but more expensive treatments for patients with schizophrenia. Subject to the above cautionary comment, delaying the time to relapse should mean delaying the escalation of costs. More importantly, a slower or reduced rate of relapse means slower or reduced damage to the health and quality of life of patients, and in some cases also less adverse impact on their families.

Psychoeducation and related programmes have been shown to reduce medication non-adherence, detect prodromal symptoms of relapse and reduce the rate of hospitalisation (e.g. Birchwood *et al*, 1989; Kemp *et al*, 1996; Herz *et al*, 2000). A relatively inexpensive evidence-based intervention for reducing relapse is

family work for patients with schizophrenia living with a relative with high levels of expressed emotion (e.g. Xiong *et al*, 1994). There is no evidence that these effective interventions have yet come into widespread use.

If new antipsychotic treatments in schizophrenia can improve efficacy and compliance rates compared with conventional neuroleptic therapy, and thereby reduce relapse rates, this might bring about reductions in the service costs of schizophrenia. In turn, as demonstrated in some international studies (Hamilton *et al*, 1999), and as concluded by the National Institute for Clinical Excellence (2002), the overall costs of the treatment could be reduced.

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CLINICAL IMPLICATIONS

■ Compared with the non-relapse group, patients who relapsed scored higher on the Positive and Negative Syndrome Scale and Clinical Global Impression scale, and lower on the Global Assessment of Functioning, but only the latter was statistically significant.

■ The strongest predictor of illness relapse was associated with patients who had made previous suicide or self-harm attempts.

■ Differences in the quality of life between relapse and non-relapse cases, as measured by the Lehman scale, were generally not significant.

LIMITATIONS

■ The study was cross-sectional, and limited to one geographical area of the UK.

■ Relapse was not studied as it occurred, but in a retrospective design.

■ Multivariate analysis was applied to a small sample of patients and with only a few explanatory variables.

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