

# Systematic evaluation of the QualityRights programme in public mental health facilities in Gujarat, India

Soumitra Pathare, Michelle Funk, Natalie Drew Bold, Ajay Chauhan, Jasmine Kalha, Sadhvi Krishnamoorthy, Jaime C. Sapag, Sireesha J. Bobbili, Rama Kawade, Sandeep Shah, Ritambhara Mehta, Animesh Patel, Upendra Gandhi, Mahesh Tilwani, Rakesh Shah, Hitesh Sheth, Ganpat Vankar, Minakshi Parikh, Indravadan Parikh, Thara Rangaswamy, Amritkumar Bakshy and Akwatu Khenti

## Background

Recognising the significant extent of poor-quality care and human rights issues in mental health, the World Health Organization launched the QualityRights initiative in 2013 as a practical tool for implementing human rights standards including the United Nations Convention on Rights of Persons with Disabilities (CRPD) at the ground level.

## Aims

To describe the first large-scale implementation and evaluation of QualityRights as a scalable human rights-based approach in public mental health services in Gujarat, India.

## Method

This is a pragmatic trial involving implementation of QualityRights at six public mental health services chosen by the Government of Gujarat. For comparison, we identified three other public mental health services in Gujarat that did not receive the QualityRights intervention.

## Results

Over a 12-month period, the quality of services provided by those services receiving the QualityRights intervention improved significantly. Staff in these services showed substantially improved

attitudes towards service users (effect sizes 0.50–0.17), and service users reported feeling significantly more empowered (effect size 0.07) and satisfied with the services offered (effect size 0.09). Caregivers at the intervention services also reported a moderately reduced burden of care (effect size 0.15).

## Conclusions

To date, some countries are hesitant to reforming mental health services in line with the CRPD, which is partially attributable to a lack of knowledge and understanding about how this can be achieved. This evaluation shows that QualityRights can be effectively implemented even in resource-constrained settings and has a significant impact on the quality of mental health services.

## Declaration of interest

None.

## Keywords

Human rights; low and middle income countries; in-patient treatment; psychosocial interventions; service users.

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Poor-quality care and human rights violations are common in mental health services globally including India. Reports in many countries have highlighted considerable violence, abuse, and coercion occurring in these settings including forced admission and treatment and the use of seclusion and restraint.<sup>1</sup> The United Nations Convention on Rights of Persons with Disabilities (CRPD)<sup>2</sup> provides a framework for human rights-oriented change to mental health services. The Convention is legally binding on countries that have ratified it. Several recent United Nations resolutions and reports have denounced the unacceptable human rights situation in the field of mental health and specifically the violations against people with mental health conditions or psychosocial disabilities and people using mental health services.<sup>3,4</sup> Recognising the significant extent of poor quality and human rights issues in mental health, the World Health Organization (WHO) launched the QualityRights initiative in 2013.<sup>5,6</sup> The initiative has five overarching objectives: build capacity to understand and promote human rights, recovery and independent living in the community; create community-based and recovery-oriented services that respect and promote rights; improve quality of care and human rights in mental health and social services; develop a civil society movement to conduct advocacy; and influence decision-making in line with the CRPD and other international human rights standards.<sup>5</sup> This paper describes the implementation and impact of QualityRights as a scalable solution in public mental health services in Gujarat, India.

## Method

### Design

This is a pragmatic implementation trial and not a randomised controlled clinical trial. The Department of Health and Family Welfare, Government of Gujarat decided to implement the QualityRights programme at six public mental health services (three mental hospitals, two psychiatric units in general hospitals attached to medical colleges, and one psychiatric unit at a district general hospital). For comparison, we identified three other public mental health services (one mental hospital, one psychiatric unit in a general hospital attached to a medical college and one psychiatric unit at a general hospital) that did not receive the QualityRights programme.

The six services assigned to receive the QualityRights programme (intervention group) and those in the comparison group were similar in organisational arrangements (see supplementary Table 1 available at <https://doi.org/10.1192/bjp.2019.138>). WHO's QualityRights programme is not a fixed intervention delivered uniformly to all, but a framework with associated training and guidance to improve services considering local priorities, resources and needs. For example, the improvement plans at different facilities are created by facility staff, who identify areas for improvement and create their own improvement strategies.

Mental health services in the intervention group received the WHO QualityRights programme to improve quality of care and

protect human rights, whereas mental health services in the comparison areas continued with usual care.

### Site

Gujarat (population 60.4 million; density 308/km<sup>2</sup>),<sup>7</sup> was the site for implementation of QualityRights in India. Gujarat has four public mental hospitals and 10 mental health wards in public general hospitals, serving approximately 280 000 individuals (out-patients and in-patients) annually in 2014.

Gujarat was selected for the following reasons: (a) the State Government had recognised the need to improve quality of care and human rights and there was preparedness and willingness for mental health reforms; (b) the public health department announced its readiness to be involved in implementing QualityRights; (c) pre-existing health systems conditions for scaling up services were present, including a significant budget for mental health (3% of the total public healthcare expenditure) and; (d) a mental health policy and strategic plan was already in place promoting access to quality services and respect for human rights in mental health.<sup>8</sup> Importantly, the State Nodal Officer for Mental Health agreed to be a member of the project team and participate in the design, implementation and evaluation of the project. The project implementation activities were conducted from May 2015 to June 2016 and study data collection started in Jan 2015 and ended in November 2016.

### Intervention

All six intervention services received QualityRights interventions. The core elements of the programme included the following.

- (a) The WHO QualityRights toolkit for assessing services along five CRPD-based dimensions: theme 1 (right to adequate standard of living based on Article 28 of CRPD); theme 2 (the right to enjoyment of the highest attainable standards of physical and mental health based on Article 25 of the CRPD); theme 3 (the right to exercise legal capacity and the right to personal liberty and security of the person based on Articles 12 and 14 of the CRPD); theme 4 (freedom from torture or cruel, inhumane or degrading treatment or punishment and from exploitation, violence and abuse based on Articles 15 and 16 of the CRPD) and theme 5 (the right to live independently and be included in the community based on Article 19 of the CRPD). The toolkit assessment was undertaken at baseline and at 12-month follow-up.
- (b) Improvements to the service environment within existing service and government resources. This included improving sanitation and hygiene standards, the quality of the social and built environment (for example cooling, ventilation) and establishing committees including service users to monitor food served.
- (c) Healthcare professionals, family members and service users are trained on the following: (i) recovery-oriented care (2 days); (ii) rights of individuals with mental health conditions (3 days); (iii) effective communication skills (2 days); and (iv) alternatives to seclusion and restraints (2 days).
- (d) To encourage participation of family members and service users, self-help groups are established across all intervention sites. *Saathi* (family) groups provide emotional support and enable members to participate in their relative's care. *Maitri* (service user) groups build a peer network of people able to actively support each other and participate in planning service delivery at the intervention services. Key individuals from each site are trained in running these groups and supporting their peers. An important contribution is the introduction of peer-support volunteers (PSVs) at the intervention services.

PSVs are individuals with lived experiences of mental health conditions who support others with similar experiences in their personal recovery. PSVs are trained in recovery-oriented care and basic communication skills.

- (e) Introducing service-level policy and processes to protect against inhumane/degrading treatment, violence and abuse (including the use of restraints). Specific operational policies for various functions at the services are produced and staff are trained in their implementation. Some examples include policies for admission, discharge, informed consent and monitoring use of restraints.

### Comparison group

Services in the comparison group were assessed with the WHO QualityRights toolkit at baseline (and 12-month follow-up) and were given the results of this assessment. They were encouraged to develop and implement an improvement strategy, but the project team did not get involved in developing an improvement plan or delivery of any of the above activities (usual care).

### Implementation approach

Project implementation was overseen by an advisory group, which comprised representatives from the State Department of Health and Family Welfare, human rights advocates and senior mental health professionals. Overall project management was handled by a management team, which comprised members of the project team, heads of all mental health services involved in this project and representatives of service users and family caregivers.

Immediately following the QualityRights toolkit assessment, workshops were conducted at all mental health services and the toolkit assessment findings were discussed with healthcare staff of the services, service users and caregivers. In the intervention services the project team assisted the management and staff to develop strategic plans to address gaps in the five assessment areas of the QualityRights toolkit. These plans were developed using a participatory approach involving further discussions with service users, family caregivers and healthcare staff.

Improvement plans were developed to address: (a) improvements to the facility environment, emphasising the social environment and the quality of interactions and using existing available resources from services and government; (b) training of health workers, service users and families on human rights and changes in attitudes and practice required to move towards a recovery approach to enhance autonomy and engage service users in recovery plans; (c) introducing facility-level policy and mechanisms to govern practices to protect against inhumane, degrading treatment, violence and abuse (including the use of restraints); and (d) building peer and family groups. These activities were completed over the 12 months following baseline assessment of the services.

### Evaluation and measures

The impact evaluation of the QualityRights programme in Gujarat considered a mixed methods approach. This involved (a) service assessments based on the QualityRights toolkit; (b) a survey of staff, service users and carers at both intervention and comparison services. All assessments were conducted at baseline (before the start of the QualityRights programme for the intervention group) and at 12 months following baseline. The same group of staff were seen twice (at baseline and follow-up). All staff employed at the services are public servants employed by the Government of Gujarat and are routinely transferred accordingly to the Government's transfer policy. As a result, only 58% (61% from the intervention and 41% from comparison groups) of the staff enrolled at baseline were

working at these services and available for follow-up. Thus, data from 232 staff members from the intervention group and 31 from the comparison group, where both baseline and end-of-study data were available and were used in the analysis.

Service user and carer assessments were based on independent samples drawn at baseline and follow-up and did not involve re-interviews. They were only recruited for the study if service users and caregivers had used the service in the 3 months before interview. This method was followed as many service users (and their caregivers) are not necessarily involved in follow-up on a regular basis and sometimes only use the service for one visit. Data were analysed from 698 service users at baseline and 652 service users at 12-month follow-up in the intervention group, and from 345 service users at baseline and 290 service users at follow-up in the comparison group. Similarly, data from 303 caregivers at baseline and 291 caregivers at 12-month follow-up in the intervention group, and from 117 caregivers at baseline and 109 caregivers at follow-up in the comparison group were included in the analysis.

Validated Gujarati versions of scales and questionnaires were used when they were available (for example the Zarit Burden Interview<sup>9</sup>). Other scales were translated into Gujarati and validated in a pilot before use in the main study.

Service assessment was undertaken using the WHO QualityRights toolkit

The assessment of services was conducted by committees who were independent of the project team and health services they assessed. To ensure a broad range of skills and knowledge required for the assessment process and to distribute the workload of assessing nine mental health services, two committees of six members were established, consisting of mental health professionals, service users, family and non-family caregivers, human rights advocates and representatives of non-governmental organisations working in mental health. Each committee participated in a 5-day training programme from the project team on quality care and human rights standards and how to conduct the assessment and report findings using the QualityRights toolkit.<sup>10</sup>

In line with the methodology outlined in the toolkit, assessments were based on the following: interviews with service users, caregivers and staff; direct observation of conditions in mental health services and reviews of relevant documentation (for example policy documents, administrative records, service user files). Based on their findings, the assessment committee assigned quantitative ratings for the themes and the standards and criteria of the toolkit.

The toolkit has five themes, each theme has multiple standards and each standard has multiple criteria (supplementary Fig. 1). Ratings are first assigned to the criteria and based on the criteria ratings, a particular standard is rated. Based on standard ratings, a composite rating is assigned to the theme. These ratings are consensus ratings assigned by the assessment committee and are made on a four-point scale as follows: '3' A/F = criterion/standard/theme achieved in full; '2' A/P = criterion/standard/theme achieved partially; '1' A/I = criterion/standard/theme achievement initiated; and '0' N/I = criterion/standard/theme not initiated.

#### Staff measures

All clinical and non-clinical staff at the intervention and comparison services were administered two self-report scales. The Staff Attitude to Coercion Scale, used in other Indian studies,<sup>11</sup> consists of 15 items<sup>12</sup> and respondents are asked to rate on a five-point Likert scale how much they agree or disagree with each of the 15 statements, with labels from 'disagree strongly'<sup>1</sup> to 'agree strongly'.<sup>5</sup> The second, the Community Attitudes to Mental Illness (CAMI) Questionnaire,<sup>13</sup> has 40 items that emphasise community contact with the individuals

with mental illness and mental health services. The response format for each statement is a standard Likert five-point labelled scale ranging from 'strongly agree' to 'strongly disagree'. Both scales were translated into local language using standard methodology and validated in a pilot before being used in the main study.

#### Caregiver measures

Caregivers were administered the CAMI Questionnaire, the CANHELP questionnaire (Caregiver version)<sup>14</sup> and the Zarit Burden Interview.<sup>9</sup> The CANHELP caregiver self-report questionnaire evaluates satisfaction with care for older service users with life-threatening illnesses and their family members. The questionnaire has been translated and used in India in other studies.<sup>15</sup> The questionnaire was adapted for use with mental illness. It assesses the following five domains: relationship with doctors; characteristics of doctors and nurses; communication and decision-making; the caregiver's involvement in their family member's care; and the caregiver's well-being. Responses are rated on a five-point rating scale ranging from 'not at all satisfied' to 'completely satisfied.'

The Zarit Burden Interview (using a pre-existing validated Gujarati version) assesses caregiver burden related to supporting a person with mental illness across five domains: burden in the relationship; emotional well-being; social and family life; finances; and loss of control over one's life. Responses are rated on a five-point rating scale from 'never' to 'nearly always.'

#### Service user measures

Service users were assessed on measures for disability (Sheehan Disability Scale),<sup>16</sup> empowerment (Empowerment Scale),<sup>17</sup> recovery (Recovery Assessment Scale)<sup>18</sup> and satisfaction with services (Vermont Mental Health Consumer Survey<sup>19</sup> and CANHELP (patient version)<sup>20</sup>).

The Sheehan Disability Scale (a self-report 11-point visual analogue scale) provides a quick assessment of the extent of disruptions in an individual's social and occupational functioning because of mental health symptoms. It also takes into consideration the number of days lost and underproductive days resulting from symptoms. The Empowerment Scale (a self-report measure) captures key elements of change among service users related to empowering activities and/or experiences when using services across the following factors: self-esteem/self-efficacy; power–powerlessness; community activism and autonomy; control over failure; and righteous anger.

The Recovery Assessment Scale (another self-report five-point scale) assesses five components of recovery: personal hope and confidence; willingness to ask for help; goal and success orientation; reliance on others; and not being dominated by others. The Vermont Mental Health Consumer Survey (a self-report measure) evaluates service users' satisfaction with mental health services and the level of improvement they attribute to the services. Survey items assess the service user's evaluation of access, service, respect, autonomy and outcomes. Responses are rated across a five-point scale ranging from 'strongly disagree' to 'strongly agree.' The CANHELP patient questionnaire (another self-report measure) also evaluates service users' level of satisfaction with health services. It assesses five domains: relationship with doctors; characteristics of doctors and nurses; communication and decision-making; service user's involvement in decisions about their care; and service user's well-being. Responses are rated on a five-point rating scale ranging from 'not at all satisfied' to 'completely satisfied.'

#### Statistical analysis

The detailed statistical analysis plan is included in supplementary File 1 and is only summarised here. The QualityRights toolkit



assessment data were organised on an ordinal scale of 0 to 3 for the intervention and comparison group services were analysed using chi-square test for changes at the 'themes' level and at the 'standards' level.

Data collected on staff was analysed as paired data, whereas service user and caregivers' data were analysed as independent samples at baseline and at follow-up for both arms. The baseline data were analysed using the *t*-test and chi-squared test to explore any differences in characteristics between the comparison and intervention samples as well as pre- and post-intervention data. Necessary adjustments were undertaken during analysis for the clustering effect and imbalances across the groups, if any. To assess the effect of the intervention, generalised linear models were fitted for follow-up scores as dependent variables. Analyses were carried out using survey data analysis tools and the margins command to estimate and interpret adjusted predictions and marginal effects<sup>21</sup> of Stata 14. The results are presented as mean and 95% confidence intervals. The effect size was calculated as the standardised mean difference (Hedges' *g*) between the intervention and comparison arms: this is the ratio of the mean difference to the pooled standard deviation.<sup>22</sup>

### Ethical considerations

This study was performed in accordance with the Declaration of Helsinki. This human study was approved by Institutional Ethics Committee at the Indian Law Society – approval: ILS/121/2014 (dated 18 April 2014). All adult participants provided written informed consent to participate in this study.

## Results

At baseline, there were no differences in themes and standards ratings between the intervention and comparison group services (Table 1). At 12-month follow-up there were significant differences between the intervention and comparison group services, with intervention services significantly more likely to report partial or full achievement of the QualityRights toolkit Standards in theme 1 (31.5% *v.* 2.4%,  $P < 0.05$ ), theme 2 (55% *v.* 16.7%,  $P < 0.05$ ) and theme 4 (64% *v.* 28%,  $P < 0.05$ ); no improvement was observed in standards in theme 5 and a non-significant improvement was observed in standards in theme 3 (26.6% to 16.7%) (Table 1).

Because the QualityRights ratings are broad categories, there is a possibility the above analysis may not capture improvements happening at the comparison facilities but not reaching a rating of 2 or 3 (partial or full achievement) on a standard, for example a rating increasing from 0 at baseline to 1 at follow-up. We therefore examined the data for any 1-point improvement in ratings for standards at follow-up (a rating going up from 0 to 1 or from 1 to 2 or from 2 to 3 from baseline to follow-up) between the intervention and comparison group services and the results were similar to above findings. Intervention services showed significant improvement in standards versus the comparison group services in standards from themes 1 (37.8% *v.* 12.2%,  $\chi^2 = 9.217$ ,  $P < 0.001$ ), theme 2 (42.5% *v.* 0%,  $\chi^2 = 18.454$ ,  $P < 0.001$ ), theme 3 (59.4% *v.* 8.3%,  $\chi^2 = 18.34$ ,  $P < 0.001$ ), theme 4 (49.3% *v.* 7.7%,  $\chi^2 = 14.124$ ,  $P < 0.001$ ) and theme 5 (18.8% *v.* 0%,  $\chi^2 = 5.211$ ,  $P < 0.022$ ) (supplementary Table 2).

### Staff outcomes

Clinical as well as non-clinical staff were mostly men, with 3–10 years of clinical experience and there were more attendants and fewer doctors in the intervention as compared with comparison services. These differences were statistically non-significant (see

supplementary Table 3). No significant difference was noted in baseline attitude scores between staff members who were available for follow-up and who were unavailable because of transfer.

Adjusted for education, baseline scores and clustering effects, at follow-up, staff at intervention services showed improved attitudes about coercion as measured by the Staff Attitude to Coercion Scale; they were more likely to see coercion as offensive behaviour at follow-up, compared with staff at control services (effect size 0.48), and were less likely to see coercion as either protection (effect size 0.35) or as treatment (effect size 0.50) (Table 2).

At 12-month follow-up, staff at the intervention services also showed improved attitudes on the CAMI Questionnaire, as compared with staff at comparison services. They scored lower for fear and avoidance (effect size 0.27) and displayed non-significant improvements for tolerance and pro-integration factors (effect size 0.17) (Table 2). The attitudes of nurses and attendants showed consistent and significant change, but this was less so for doctors (non-significant differences for doctors in the coercion as protection subscale of the Staff Attitude to Coercion Scale and both subscales of CAMI Questionnaire). Supplementary Figs 2–6 present the differences in scores by different staff subgroups: doctors, nurses, attendants/cleaning staff, and administrative staff.

### Service user outcomes

During the 12-month intervention period, there were 27 active PSVs at the six intervention services; by the end of the project, the Gujarat State Mental Health Authority created a protected budget for 35 PSVs, who are now funded and supported from the public health budget.

A non-significant difference of higher proportion of service users with common mental disorders, and a lower proportion of those with severe mental disorders, was observed at comparison services as compared with intervention services (see supplementary Table 4 for sociodemographic characteristics of service users at intervention and control services at baseline and follow-up).

Adjusted for type (in-patient/out-patient) and diagnosis, the service users at intervention services were significantly more likely to report an increase in empowerment as measured by the Empowerment Scale at follow-up compared with those at comparison services, but the effect size was small (0.10). Similarly, they were significantly more likely to score higher on the CANHELP questionnaire, indicating increased satisfaction with services; again, the effect size was small (0.09). Service users at comparison services scored significantly lower for satisfaction on the Vermont Mental Health Consumer Survey at follow-up, also with a small effect size (0.07) (Table 3). No differences were observed in Sheehan Disability Scale scores, indicating that baseline and follow-up cohorts in both the intervention and comparison services experienced similar levels of disability (Table 3). No significant differences were observed in the various subscales of the Recovery Assessment Scale between the intervention and comparison group service users.

### Caregiver outcomes

The intervention group had a higher proportion of caregivers from mental hospitals compared with the comparison group at baseline (71% *v.* 12%) and follow-up (70% *v.* 15%). Caregivers aged 50 years or older composed 30% of the cohort at baseline and follow-up at the intervention services, but only 24% of both cohorts at the comparison services (see supplementary Table 5 for sociodemographic characteristics of caregivers at the intervention and comparison services at baseline and follow-up).

Adjusted for gender, caregivers at the intervention services were significantly more likely to score lower on the Zarit Burden

**Table 1** Assessment of scores for standards in intervention and control services at baseline and follow-up

Theme and scores	Baseline, <i>n</i> (%)		Follow-up, <i>n</i> (%)	
	Intervention	Comparison	Intervention	Comparison
Theme 1: standards – right to adequate standard of living (CRPD Article 28)				
0–1	107 (96.4)	39 (95.1)	76 (68.5)	40 (97.6)
2–3	4 (3.6)	2 (4.9) <sup>a</sup>	35 (31.5)	1 (2.4) <sup>b</sup>
Total	111 (100.0)	41 (100.0)	111 (100.0)	41 (100.0)
Theme 2: standards –right to enjoyment of the highest attainable standards of physical and mental health (CRPD Article 25)				
0–1	60 (75.0)	25 (83.3)	36 (45.0)	25 (83.3)
2–3	20 (25.0)	5 (16.7) <sup>a</sup>	44 (55.0)	5 (16.7) <sup>b</sup>
Total	80 (100.0)	30 (100.0)	80 (100.0)	30 (100.0)
Theme 3: standards – right to exercise legal capacity and right to personal liberty and security of the person (CRPD Articles 12 and 14)				
0–1	61 (95.3)	22 (91.7)	47 (73.4)	20 (83.3)
2–3	3 (4.7)	2 (8.3) <sup>a</sup>	17 (26.6)	4 (16.7) <sup>c</sup>
Total	64 (100.0)	24 (100.0)	64 (100.0)	24 (100.0)
Theme 4: standards – freedom from torture or cruel, inhumane or degrading treatment or punishment and from exploitation, violence and abuse (CRPD Articles 15 and 16)				
0–1	54 (72.0)	19 (76.0)	27 (36.0)	18 (72)
2–3	21 (28.0)	6 (24.0) <sup>a</sup>	48 (64.0)	7 (28) <sup>b</sup>
Total	75 (100.0)	25 (100.0)	75 (100.0)	25 (100.0)
Theme 5: standards – right to live independently and be included in the community (CRPD Article 19)				
0–1	64 (100.0)	24 (100.0)	64 (100.0)	24 (100.0)
2–3	0	0	0	0
Total	64 (100.0)	24 (100.0)	64 (100.0)	24 (100.0)

*n*, number of standards; CRPD, Convention on Rights of Persons with Disabilities.  
a. Non-significant difference between intervention and control at baseline ( $P > 0.05$ ).  
b. Significant difference between intervention and control at follow-up ( $P < 0.05$ ).  
c. Non-significant difference between intervention and control at follow-up ( $P < 0.05$ )

Interview at follow-up compared with baseline, indicating a reduced caregiver burden, but the effect size was small (0.15). No changes were observed for caregivers at the intervention and control services in terms of satisfaction as measured by the CANHELP questionnaire or attitudes as measured by the CAMI scale (Table 4).

## Discussion

### Main findings

This is the first large-scale implementation and systematic evaluation of mental health services taking steps towards adopting a human rights-based approach through WHO QualityRights interventions. Recently, the United Nations Special Rapporteur on the Right to Health<sup>5</sup> specifically mentioned the WHO QualityRights initiative as a process for implementing rights-based policies and practices and encouraged countries to seek technical assistance from this initiative. This paper thus strengthens the evidence base for countries considering its implementation in their own mental health system.

Over a 12-month period, services receiving the intervention improved significantly in quality. Staff at these services also

showed substantially improved attitudes towards service users, and service users at the intervention services reported feeling significantly more empowered and satisfied with the services. Caregivers also reported a moderately reduced ‘burden’ of care.

Improvements in service quality were most prominently noted in standards related to themes 1, 2, 3 and 4 whereas hardly any improvements were observed in scores for standards in theme 5, reflecting the lack of community programmes or outreach and the lack of social care integration by these services. These gaps reflect the organisation of hospital and community services in Gujarat, where different government departments (health, social justice and empowerment) and their respective service providers are responsible for different aspects of health and social care and have their own independent management structures. It also reflects the relative lack of community programmes although this is gradually changing with new initiatives being implemented in the State.<sup>23</sup>

### Interpretation of our findings

The data revealed large effect size for changes in staff attitudes and service assessments, and significant but small ones in user

**Table 2** Effect of intervention on scores on the Staff Attitude to Coercion Scale and Community Attitude towards Mentally Ill questionnaire at follow-up<sup>a</sup>

Scale and subscales	Mean (95% CI)		Mean difference (95% CI)	<i>P</i>	Effect size (95% CI)
	Intervention ( <i>n</i> = 232)	Comparison ( <i>n</i> = 31)			
Staff Attitude to Coercion					
Coercion for protection	2.81 (2.72 to 2.90)	3.06 (2.76 to 3.36)	−0.24 (−0.62 to 0.12)	0.161	−0.35 (−0.73 to 0.02)
Coercion for treatment	2.25 (2.15 to 2.34)	2.60 (2.54 to 2.67)	−0.36 (−0.49 to −0.22)	0.000	−0.50 (−0.88 to 0.12)
Coercion is offending	3.62 (3.47 to 3.77)	3.09 (2.82 to 3.35)	0.53 (0.15 to 0.90)	0.012	0.48 (0.10 to 0.85)
Community Attitude towards Mentally Ill					
Fear and avoidance	4.08 (4.03 to 4.12)	3.99 (3.95 to 4.03)	0.08 (0.01 to 0.15)	0.031	0.27 (−0.10 to 0.65)
Tolerance and pro-integration	1.84 (1.80 to 1.88)	1.79 (1.74 to 1.83)	0.05 (−0.01 to 0.12)	0.093	0.17 (−0.20 to 0.54)

<sup>a</sup> Data are adjusted for education, baseline scores and clustering effect. Negative effect sizes imply that mean scores are decreased after intervention.

**Table 3** Service user outcome measures<sup>a</sup>

Scale	Intervention				Comparison				Effect size
	Baseline (n = 698)	Post (n = 652)	Mean difference	P	Baseline (n = 345)	Post (n = 290)	Mean difference	P	
Empowerment Scale: overall scores <sup>b</sup>	2.73 (2.68 to 2.78)	2.67 (2.63 to 2.71)	-0.06 (-0.09 to -0.01)	<b>0.012</b>	2.71 (2.70 to 2.72)	2.70 (2.68 to 2.71)	-0.01 (-0.03 to 0.02)	0.462	<b>-0.10 (-0.19 to 0.01)</b>
Vermont Mental Health Consumer Survey: overall scores <sup>c</sup>	3.98 (3.85 to 4.11)	3.99 (3.89 to 4.08)	0.01 (-0.08 to 0.09)	0.895	3.97 (3.90 to 4.05)	3.90 (3.87 to 3.93)	-0.07 (-0.14 to 0.01)	0.037	0.07 (-0.04 to 0.17)
CANHELP: overall scores <sup>c</sup>	69.94 (66.20 to 73.67)	74.08 (72.64 to 75.51)	4.14 (0.33 to 7.94)	<b>0.036</b>	69.34 (68.18 to 70.49)	69.82 (68.29 to 71.35)	0.48 (-0.05 to 0.91)	0.320	<b>0.09 (-0.02 to 0.19)</b>
Sheehan Disability Scale <sup>b</sup>	41.49 (36.99 to 45.98)	38.58 (31.30 to 45.85)	-2.91 (-8.34 to 2.51)	0.321	42.35 (41.48 to 43.22)	40.88 (38.81 to 42.94)	-1.47 (-3.07 to 0.12)	0.104	0.02 (-0.12 to 0.08)
Recovery Assessment Scale									
Personal confidence and hope	3.86 (3.75 to 3.97)	3.89 (3.80 to 4.00)	0.03 (-0.08 to 0.14)	0.529	3.93 (3.89 to 3.97)	3.89 (3.85 to 3.94)	-0.03 (-0.06 to -0.01)	0.016	0.05 (-0.05 to 0.16)
Willingness to ask for help	3.98 (3.91 to 4.04)	3.95 (3.88 to 4.01)	-0.03 (-0.1 to 0.03)	0.297	4.04 (4.00 to 4.08)	3.97 (3.94 to 4.00)	-0.07 (-0.14 to -0.01)	0.077	0.04 (-0.06 to 0.14)
Goal and success orientation	3.86 (3.73 to 3.98)	3.89 (3.81 to 3.97)	0.03 (-0.10 to 0.16)	0.591	3.87 (3.87 to 3.90)	3.90 (3.87 to 3.90)	0.02 (-0.01 to 0.06)	0.063	0.00 (-0.10 to 0.11)
Reliance on others	3.73 (3.64 to 3.83)	3.77 (3.72 to 3.83)	0.04 (-0.11 to 0.19)	0.586	3.80 (3.76 to 3.83)	3.72 (3.67 to 3.76)	-0.07 (-0.12 to -0.03)	0.005	0.05 (-0.05 to 0.16)
Not dominated by symptoms	3.42 (3.30 to 3.55)	3.48 (3.32 to 3.63)	0.05 (-0.08 to 0.18)	0.407	3.58 (3.53 to 3.63)	3.53 (3.50 to 3.56)	-0.05 (-0.12 to -0.02)	0.140	0.06 (-0.04 to 0.16)

a. Data are given as mean (95% CI) to adjusted for type of service user (in-/out-patient) and diagnosis and clustering effect. Negative effect sizes imply that mean scores are decreased after intervention.  
b. Reduction in scores indicate: empowerment and better decision-making, reduction in disability and non-recovery on Recovery Assessment Scale.  
c. Increase in scores indicate: positive evaluation of services in the Vermont Mental Health Consumer Survey and satisfaction in CANHELP.

**Table 4** Caregiver outcomes<sup>a</sup>

Scales	Intervention				Comparison				Effect size
	Pre (n = 303)	Post (n = 291)	Mean diff	P	Pre (n = 117)	Post (n = 109)	Mean diff	P	
ZBI	2.04 (2.00 to 2.08)	1.91 (1.85 to 1.98)	-0.12 (-0.24 to -0.01)	<b>0.039</b>	1.80 (1.64 to 1.96)	1.89 (1.82 to 1.95)	0.08 (-0.13 to 0.29)	0.396	<b>-0.15 (-0.17 to 0.14)</b>
CANHELP: overall score	75.35 (71.29 to 79.42)	77.00 (74.67 to 79.26)	1.61 (-5.66 to 8.88)	0.623	71.56 (68.97 to 74.16)	73.99 (71.96 to 76.03)	2.43 (-2.88 to 7.74)	0.323	-0.01 (-0.17 to 0.14)
CAMI: fear and avoidance	3.64 (3.40 to 3.87)	3.68 (3.58 to 3.76)	0.04 (-0.30 to 0.38)	0.809	3.75 (3.55 to 3.95)	3.66 (3.55 to 3.76)	-0.09 (-0.28 to 0.09)	0.292	0.04 (-0.11 to 0.21)
CAMI: tolerance and pro-integration	1.87 (1.78 to 1.95)	1.86 (1.84 to 1.89)	-0.01 (-0.10 to 0.09)	0.947	1.84 (1.76 to 1.92)	1.90 (1.85 to 1.94)	0.05 (-0.01 to 0.12)	0.081	-0.09 (-0.24 to 0.07)

ZBI, Zarit Burden Interview, CAMI, Community Attitudes to Mental Illness.  
a. Data given are mean and 95% CI for mean, adjusted for gender and clustering effect. Negative effect size imply that mean scores are decreased after intervention.

satisfaction and empowerment and caregiver 'burden'. This may be as a result of a lack of sensitivity in picking up change because of the different cohorts of service users and family members at baseline and follow-up. Another possible explanation is an expected lag between changes in staff attitudes and consequent changes in staff behaviour, leading to perceived changes for users and caregivers. The follow-up assessments were completed 12 months after interventions began, which may be insufficient time for changes in service quality to percolate to user and caregiver level. It is possible that a later follow-up with these groups will reveal larger effect sizes for changes at the user and caregiver level. A later follow-up will also allow assessment of persistence of service quality improvement and whether changes in staff attitudes are maintained over time.

A lag time between service and staff improvements and users benefiting from these improvements may also explain the lack of significant findings in terms of recovery measures (Recovery Assessment Scale) at the user level. Recovery is also associated with access to other services such as those related to education and employment, which are insufficient or unavailable in the community. Finally, the changes achieved were substantial for such a low-intensity intervention over a relatively short period. Had there been the possibility to deliver the interventions for longer than 1 year, even more substantial staff attitudinal and practice changes may have been possible together with a more positive impact for people using the services and caregivers.

### Use of peer-support workers

Peer support workers have been effective in high-income countries such as the USA, UK, Canada and Australia. In low- and middle-income countries, peer support has been used effectively for non-mental health conditions such as HIV/AIDS and diabetes. A recent Cochrane systematic review<sup>24</sup> found that involving peer-support workers in mental health teams resulted in psychosocial mental health symptoms and service use outcomes for clients that were no better or worse than those achieved by professionals employed in similar roles. Another systematic review of 20 studies found that peer support reduced in-patient use, improved relationships with service providers and improved some recovery-related outcomes such as empowerment among persons with severe mental illness.<sup>25</sup>

This study was the first to introduce PSVs in any mental health service in India. PSVs were recruited from previous and current service users who expressed a desire for such work. They work 24 h a week in both out-patient and in-patient settings at these services. They assist other service users in preparing their own recovery plans and facilitate peer-support groups in these services. A qualitative assessment of peer support was undertaken during the study and will be reported separately.

One major consideration of any health service quality improvement programme is its long-term sustainability. The PSVs were initially financially supported from project funds. At the end of the project, the Department of Health and Family Welfare, Government of Gujarat, made provisions to financially support 35 PSVs across the six intervention mental health services and committed to extend the PSV intervention into other public mental health services over time. To ensure the long-term sustainability of the QualityRights approach, discussions have been initiated with the State Mental Health Authority to require all mental health services in Gujarat to have QualityRights accreditation. India's new Mental Health Care Act (2017) also mandates that all mental health services undergo social audit every 3 years, and QualityRights can be one component of this audit.

### Staff engagement

An important element of any successful intervention is achieving buy-in from all participants, especially those expected to implement the interventions. We were able to secure good engagement with all staff at the intervention and comparison facilities. Senior mental health staff were involved from the start, including designing the project, choosing the interventions, measurement tools and in implementing the interventions. There was also a project management committee made up of heads of all the mental health facilities from the intervention and comparison groups which met regularly every 3 months to review the progress of the project and finding solutions to local difficulties in implementation.

This project and associated evaluation were conducted before India adopted new mental healthcare legislation (the Mental Healthcare Act in 2017). This Act is based on the CRPD and covers all the rights in the QualityRights initiative. The QualityRights initiative thus provides a practical tool and methodology for reform of mental health services to realise rights protected in India's new mental health legislation. The study also collected cost and economic impact data that are being published separately.

### Limitations

There are several limitations related to this research that need to be taken into account in order to understand the overall impact of QualityRights in this project as well as its potential to produce change over a longer period of time. This is not a randomised control trial but a pragmatic trial. QualityRights interventions in this study were conducted over a limited duration and more sustained interventions and follow-up could have shown more changes, especially when one considers the fact that we are fundamentally changing mindsets and practices that have been entrenched for decades.

### Challenges

In order to achieve sustainable change, QualityRights advocates for the implementation of a much broader range of interventions to complement those operationalised in the present study. Other interventions would include the development of new community-based services that are compliant with international human rights standards. This would not only increase access to care and support but also reduce institutionalisation and promote a new approach to care that is recovery and human rights-oriented.

The high rate of staff turnover because of transfers is a potential sustainability challenge. However, transfers are usually from one public mental health facility to another similar facility within the state, so if QualityRights is implemented across the entire state at all mental health facilities, resources invested in training staff will not be wasted.

In conclusion, this study demonstrates that positive change can be achieved within existing legal and policy frameworks even if these are not fully aligned with international human rights standards such as the CRPD. It also demonstrates it is possible to reform and implement human rights-oriented mental health services in low-resource settings.

**Soumitra Pathare**, MRCPsych, MD, PhD, Consultant Psychiatrist and Director, Centre for Mental Health Law & Policy, Indian Law Society, India; **Michelle Funk**, MA, PhD, Co-ordinator, Mental Health Policy & Service Development, Department of Mental Health and Substance Abuse, World Health Organization, Switzerland; **Natalie Drew Bold**, MA, Technical Officer, Mental Health Policy & Service Development, Department of Mental Health and Substance Abuse, World Health Organization, Switzerland; **Ajay Chauhan**, MD, Consultant Psychiatrist and State Nodal Officer, Hospital for Mental Health, Ahmedabad, India & Department of Health & Family Welfare, Government of Gujarat, India; **Jasmine Kalha**, MPhil, Program Manager and Research Fellow, Centre for Mental Health Law & Policy, Indian Law Society, India; **Sadhvi Krishnamoorthy**, MA, Programme Manager, Centre for Mental Health Law & Policy, Indian Law Society, India; **Jaime C. Sapag**, MD, MPH, PhD, Associate Professor, Office of Transformative Global



Health, Institute of Mental Health Policy Research, Centre for Addiction & Mental Health, Canada; Division of Public Health & Family Medicine, School of Medicine, Faculty of Medicine, Pontificia Universidad Católica de Chile, Chile; and Division of Clinical Public Health, Dalla Lana School of Public Health, University of Toronto, Canada; **Sireesha J. Bobbili**, BHSc, MPH, Project Manager, Office of Transformative Global Health, Institute of Mental Health Policy Research, Centre for Addiction & Mental Health, Canada; **Rama Kawade**, MSc, PhD, Co-ordinator of Data Management and Analysis, Centre for Mental Health Law & Policy, Indian Law Society, India; **Sandeep Shah**, MD (Psychiatry), Professor of Psychiatry and Head, Department of Psychiatry, GMERS Medical College, Gotri, Vadodara, India; **Ritambhara Mehta**, MD, Professor of Psychiatry and Head, Department of Psychiatry, Government Medical College, Surat, India; **Animesh Patel**, MD, Consultant Psychiatrist, Department of Psychiatry, General Hospital, Mehesana, India; **Upendra Gandhi**, MD, Assistant Director, Medical Services, General Hospital, Mehesana, India; **Mahesh Tilwani**, MD, Psychiatrist, Gujarat medical services Class 1, Hospital for Mental Health, Bhuj, India; **Rakesh Shah**, MD, Psychiatrist and Superintendent, Hospital for Mental Health, Vadodara, India; **Hitesh Sheth**, MD, Psychiatrist, Gujarat Health Services, Class I, Hospital for Mental Health, Jamnagar, India; **Ganpat Vankar**, MD, Professor of Psychiatry and Head, Department of Psychiatry, B J Medical College, Ahmedabad, India; **Minakshi Parikh**, MD, Professor of Psychiatry and Head, Department of Psychiatry, B J Medical College, Ahmedabad, India; **Indravadan Parikh**, MD, Psychiatrist, Gujarat Health Services, Class I, Department of Psychiatry, M G General Hospital, India; **Thara Rangaswamy**, FRCPsych, MD, PhD, Vice-Chairman and Chair, Research, Schizophrenia Research Foundation, India; **Amritkumar Bakshy**, MA, President, Schizophrenia Awareness Association, India; **Akwatu Khenti**, PhD, Senior Scientist, Director of the Office of Transformative Global Health, Office of Transformative Global Health, Institute of Mental Health Policy Research, Centre for Addiction & Mental Health, Canada

**Correspondence:** Soumitra Pathare, Director Centre for Mental Health Law and Policy, Indian Law Society, Pune 411004, India. Email: [spathare@cmhlp.org](mailto:spathare@cmhlp.org)

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