

# Risk management in community-based psychiatry: an overview from global perspectives to the Italian context

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**Summary.** The management of risk associated with clinical processes is gaining increasing importance in both health policy and medical research. Data show that among mental health professionals, cases of violence and burnout are on the rise. Implementing appropriate risk management strategies in psychiatry should be considered a key objective. This study aims to provide an overview of the current state of psychiatric risk management, with particular focus on Italian community-based mental health services. Through a non-systematic review of international and national literature, we identify the main areas of risk in psychiatry, which can be summarized as: interpersonal violence, coercive interventions, environmental safety, adverse drug events, clinical errors, and professional burnout. In the Italian context, critical issues mainly concern the protection of staff well-being and safety, the management of forensic patients according to Law 81/2014, and the acquisition of informed consent. The National Action Plan for Mental Health 2025-2030 formally recognizes risk management as a field of action, outlining related priorities and operational strategies. For the effective implementation of risk management in community-based psychiatry, it appears to be necessary the dissemination of standardized assessment and monitoring tools, promote workforce continuous training, and strengthen the culture of consent and shared decision-making.

**Key words.** Community-based psychiatry, forensic patients, informed consent, patient safety, risk management, staff burnout.

## Introduction

The management of risks associated with clinical processes is gaining increasing importance both in health policy and medical research. Ensuring high-quality and effective treatments, while safeguarding the safety of patients and healthcare professionals, has become a priority for many health systems worldwide. However, as of now these efforts appear to have largely focused on medicine and surgery in hospital settings.

Psychiatric patients, by contrast, are exposed not only to the same risks as other inpatients but also to specific risks linked to their psychopathological

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**Riassunto.** La gestione dei rischi associati ai processi clinici ha acquisito crescente importanza sia nelle politiche sanitarie sia nella ricerca medica. I dati mostrano che tra gli operatori della salute mentale si registra un aumento sia dei casi di violenza sia del fenomeno del burnout. Pertanto, implementare opportune strategie di gestione del rischio in psichiatria è da considerarsi un obiettivo chiave. Questo studio mira a fornire una panoramica dell'attuale stato dell'arte del risk management psichiatrico, con particolare attenzione ai servizi italiani di salute mentale. Attraverso una rassegna non sistematica della letteratura internazionale e nazionale, individuiamo le principali aree di rischio in psichiatria, che possiamo elencare in: violenza interpersonale, interventi coercitivi, sicurezza ambientale, eventi avversi da farmaci, errori clinici e burnout degli operatori. Nel contesto italiano, le criticità emergono soprattutto nella tutela del benessere e della sicurezza degli operatori, nella gestione dei pazienti forensi alla luce della legge 81/2014 e nell'acquisizione del consenso informato. Il Piano Nazionale per la Salute Mentale 2025-2030 individua formalmente il risk management come campo d'azione, declinando priorità e strategie operative correlate. Al fine di una corretta implementazione del risk management in psichiatria territoriale dunque appare necessario diffondere strumenti standardizzati di valutazione e monitoraggio, promuovere la formazione continua e rafforzare la cultura del consenso e della condivisione decisionale.

**Parole chiave.** Burnout operatori, consenso informato, pazienti forensi, psichiatria territoriale, risk management, sicurezza del paziente.

conditions. Ensuring the quality of psychiatric care and the well-being of mental health professionals is a pressing need, both in hospital settings and at the community level. Implementing risk management strategies in psychiatry – particularly in community-based mental health services – can be seen as a key objective at both the international and Italian level.

In Italy, this need has become even more pivotal following the reform of forensic psychiatry under Law 81/2014 and the development of the National Mental Health Action Plan (also known with the Italian acronym PANSM) 2025-2030. This study aims to provide an overview of the current state of risk management in psychiatry, with particular focus on the Italian context and community-based mental health services.

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## Methods

Our work is based on a narrative and conceptual review that aims exploring the main dimensions of risk management in community-based psychiatry from a global to an Italian perspective. From 15th July to 31st August 2025, a non-systematic literature search was conducted using scientific databases (PubMed, Scopus, and Google Scholar) and institutional websites. The search combined keywords such as *risk management, mental health services, community psychiatry, patient safety, professional burnout, forensic patients* and *informed consent*. Priority was given to studies, policy papers, and official documents that addressed organizational, clinical, ethical, or legal aspects of risk management in mental health care. Sources were selected for their relevance and conceptual contribution rather than for exhaustive coverage. The analysis focused on identifying recurring themes, critical issues, and contextual specificities, with particular attention to the implications for Italian community-based psychiatry. With the exception of the first US studies on risk management in healthcare<sup>1,2</sup> selected for their historical relevance, publications published before 2005 or in languages other than Italian or English were excluded.

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## Risk management in healthcare

In recent decades, international medical research and health policies have increasingly focused on patient and workplace safety in healthcare settings, assuming Risk Management (RM) as a cornerstone in healthcare, essential for ensuring both treatment quality and effectiveness, as well as the well-being of healthcare professionals.

RM plays a critical role in increasing awareness of the inherent risks within clinical processes and supports the formulation of targeted intervention and prevention strategies. Its overarching aim is the prevention of adverse events (AEs), achieved through intermediate objectives such as the systematic identification, evaluation, monitoring, and mitigation of clinical risks<sup>3</sup>. According to the Institute for Healthcare Improvement (IHI), an AE is defined as «an unintended physical injury resulting from or contributed to by medical care that requires additional monitoring, treatment, or hospitalization, or that results in death» and the rate of adverse events is a significant indicator of safety<sup>4</sup>.

In order to detect AEs, RM relies on structured methodologies, including incident reporting (IR), root cause analysis (RCA) and clinical auditing. IR enables the collection of data on adverse events and near misses<sup>5</sup>; RCA provides a retrospective, multidisciplinary investigation into underlying system and

process deficiencies<sup>6</sup>; and clinical auditing systematically compares clinical performance against defined standards to implement and monitor practice improvements<sup>7</sup>.

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## Detecting adverse events: the global trigger tool

Closely related to the concept of AE is that of a “trigger”, which the IHI describes as «an occurrence, prompt, or flag found during review of the medical record that triggers further investigation to determine the presence or absence of an AE»<sup>4</sup>.

The identification of triggers forms the basis of the Global Trigger Tool (GTT), a recent and frequently used method for detecting AEs in hospital settings. The GTT involves a retrospective review of randomly selected medical records of discharged patients, carried out by a team of clinicians following a time-limited methodology. The first phase of the review focuses on identifying triggers; if any are found, the second phase investigates the presence of a potential and corresponding AE<sup>4</sup>.

Recent studies have compared the effectiveness of the GTT in identifying AEs with that of other methods commonly used in hospital settings (e.g., IR, RCA, clinical auditing). The existing literature suggests that one reason hospitals fail to adequately detect AEs and monitor their prevalence is the reliance on incident reporting systems (IRs) as the primary source of patient safety data<sup>8</sup>. Indeed, IRs tend to collect low-quality data regarding the frequency of patient harm, and certain categories of incidents – such as diagnostic errors – appears to be systematically under-reported<sup>9</sup>.

In contrast, the GTT has been shown to detect up to ten times more AEs compared to these other methods<sup>10</sup>, with an estimated average in-hospital AE incidence of 9.2%<sup>11</sup>. Notably, a systematic review by Hibbert et al. aimed to quantify the discrepancy between the proportion of AEs identified using the GTT and those also captured through IRs. The review found that the majority of AEs identified by the GTT are unlikely to be detected by IRs. In 12 out of the 14 studies reviewed, the detection rate of AEs by IRs was less than 10% of those identified by the GTT, with an average overlap of only 7%<sup>12</sup>.

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## Risk management in psychiatry

A critical limitation of the GTT is its explicit exclusion of adverse events occurring in psychiatric wards, recommending «excluding psychiatric and rehabilitation patients» from the random selection of medical records to be reviewed<sup>4</sup>.

This exclusion reflects a broader, persistent gap: psychiatry seems too often marginalized from patient

safety researches and policies since the early emergence of risk management in healthcare, presumably due to stigma and discrimination associated with mental health problems<sup>13</sup>. For instance, in the United States, neither the pioneering Harvard Medical Practice Study<sup>1</sup> nor subsequent influential reports by the Institute of Medicine<sup>2</sup> and the National Patient Safety Foundation<sup>14</sup> included mental health in their observations. This initial omission appears to have led to a significant lack of data concerning psychiatric patients in major international studies on adverse events, adverse drug reactions, and medical or treatment errors<sup>15</sup>. Furthermore, research in psychiatry, when it comes to safety, seems to have thus far been characterized by generally low methodological quality and the absence of a comprehensive, systematic approach, often focusing only on isolated aspects of risks<sup>13</sup>.

It is instead to underline that patients admitted to psychiatric hospital wards are not only exposed to the same types of risks as those hospitalized in other medical units, but also to safety hazards specifically related to behavioural dysfunctions characteristic of certain conditions (e.g., self-harm and agitation), as well as to the interventions implemented to manage them (e.g., mechanical restraint)<sup>13</sup>. In this context, a recent Italian study involving a sample of 216 psychiatric inpatients in the acute phase reported that aggressive behaviours were more commonly exhibited by male patients and by individuals with an early onset of illness. These results are consistent with previous evidence highlighting sex differences and illness-related factors in the manifestation of aggression, and emphasize the need for systematic monitoring of this dimension within these specific patient subgroups<sup>16</sup>.

Consequently, the most commonly understood notion of risk in mental health is associated with the psychopathological and dimensions of self-injury,

suicide, and violence towards others, particularly family members or healthcare professionals<sup>17</sup>. However, a broader spectrum of significant risks is also to be acknowledged, including adverse effects of psychopharmacological treatments, difficulties in fostering a culture of informed consent, issues related to involuntary treatment and mechanical restraint, and the complexities of providing care to individuals with specific vulnerabilities such as dual diagnosis, cognitive impairments, pregnancy and motherhood, or those under forensic psychiatric care.

Acknowledging this need for a more comprehensive approach, for the first time in their 2019 review, Thibaut et al. applied a systematic methodology to patient safety in psychiatric inpatient settings. Their work identified ten main categories of risk: interpersonal violence, coercive interventions, safety culture, harm to self, safety of the physical environment, medication safety, unauthorized leave, clinical decision making, falls, and infection prevention and control<sup>13</sup>. In a more recent study, Marcus et al. further refined patient safety in inpatient psychiatry within the broader framework proposed by the IOM-2001 for inpatient care. They categorized events into two main groups: adverse events (including drug adverse events and non-drug adverse events such as self-harm/injury to self, assault, sexual contact, patient falls, and other injuries) and medical errors (including medication errors such as wrong drug, wrong dose, wrong route, delayed dose, and missed dose; as well as non-drug errors such as errors related to elopement and contraband, and other types of errors)<sup>15</sup>.

Table 1 summarizes these main risk domains and the distinction between adverse events and medical errors. This visual synthesis helps readers quickly compare the systematic classification of risk domains with the operational categorization of events and errors in psychiatric settings.

**Table 1.** Main risk domains in psychiatry.

| Source                       | Risk domains                       | Examples reported in the text  |
|------------------------------|------------------------------------|--|
| Thibaut et al. <sup>13</sup> | 10 systematic categories.          | <ul style="list-style-type: none"> <li>• interpersonal violence;</li> <li>• coercive interventions;</li> <li>• safety culture;</li> <li>• self-harm;</li> <li>• environmental safety;</li> <li>• drug safety;</li> <li>• absconding/unauthorized leave;</li> <li>• clinical decision errors;</li> <li>• falls;</li> <li>• infection prevention.</li> </ul> |
| Marcus et al. <sup>15</sup>  | AE vs. medical errors distinction. | <ul style="list-style-type: none"> <li>• <i>AE</i>: adverse drug events, self-harm, assaults, sexual contacts, falls.</li> <li>• <i>Medical errors</i>: prescribing/administration errors (drug, dose, route, delay/omission), non-drug errors (elopement, contraband, management errors).</li> </ul>  |

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## Detecting psychiatric adverse events: the mental health trigger tool

In addition to the systematic categorization of AEs in psychiatry, recent years have seen the development of trigger tools specifically aimed at identifying such events in mental health. The Mental Health Trigger Tool<sup>18</sup> is a 25-item trigger tool designed to detect both traditionally defined adverse events and Mental Health Patient Safety Incidents (MHPSIs). The MHTT demonstrated a sensitivity of 98.6% and a specificity of 100%, although it is applicable exclusively within inpatient settings. To date, and to the best of our knowledge, only one Swedish study has extended the scope of observation to outpatient psychiatry. This study included a random review of patient records covering the first three months post-discharge and highlighted that the main adverse events affecting psychiatric patients in community settings are suicide attempts and so-called prolonged disease progression. This latter phenomenon is presumably due to limited accessibility and/or adaptability of services, as well as low involvement of patients' relatives in the treatment process<sup>19</sup>.

Critically, a systematic risk management plan specifically dedicated to outpatient mental health patients remains largely absent. This lacuna has significant consequences for the right to health and safety of care for users, the well-being and professional liability of clinicians, and the shaping of health and research policies at both international and Italian levels.

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## The Italian context and its challenges

### LAW 81/2014

In Italy risk management in mental health must address two particularly specific challenges: Law n. 81 of 2014 (L.81/2014) and the National Mental Health Action Plan (PANSM) 2025-2030.

In the last decade psychiatry in Italy has witnessed a pivotal deinstitutionalization process resulting from the promulgation of L.81/2014. Indeed, the abolition of Judicial Psychiatric Hospitals and the subsequent implementation of Residences for the Execution of Security Measures (REMS), administered solely by the National Health Service (NHS), have resulted in a paradigmatic shift in the management of mentally disordered offenders from a judicial framework to a healthcare-oriented model<sup>20</sup>.

REMS facilities are forensic psychiatric residential structures primarily oriented toward treatment and rehabilitation. They accommodate individuals with psychiatric disorders who have committed criminal offenses but are not placed within the ordinary prison system, as they have been deemed

mentally impaired and socially dangerous. The core objectives of REMS include the stabilization and management of psychiatric symptoms, as well as the gradual reintegration of patients into society<sup>21</sup>. Consequently, the prevention of recurrence of violent behaviour in forensic patients has become a core mandate entrusted to local Departments of Mental Health (also known with the Italian acronym DSMs) that are therefore responsible for individualized rehabilitative treatment plans for both patients with a social danger profile requiring a custodial regimen and those with a lower profile and a non-custodial security measure.

Nonetheless, a structured assessment designed to collect, integrate, and evaluate the multifactorial variables contributing to the risk of recurrence of antisocial behaviour has not yet been fully incorporated into routine clinical practice. This gap has significant implications for patients' rights, the professional liability of psychiatrists, and public safety<sup>22</sup>. Additionally, the consequences of criminal further exacerbate the forensic burden placed on DSMs, leading to substantial human, professional, and economic costs<sup>20</sup>.

Internationally, the Structured Professional Judgment (SPI) approach represents an analytical methodology for assessing and mitigating the risk of interpersonal violence posed by individuals. Although inherently discretionary, this approach is grounded in empirically supported guidelines<sup>23</sup>. Furthermore, individualized rehabilitative treatment plans should be developed based on evidence-based decision-making frameworks that provide objective clinical data to inform expert evaluations of social dangerousness. Given these considerations, seems urgent the need for DSMs to integrate structured risk management of violent behaviour into clinical workflows. This would enable identification and prevention of conditions that may expose forensic psychiatric patients, potential victims, and mental health professionals and administrators to the recurrence of antisocial and violent incidents<sup>24</sup>.

### PANSM 2025-2030

The National Action Plan for Mental Health (PANSM) is a strategic policy document developed by the Italian Ministry of Health to guide national healthcare policies concerning mental health. Its primary objective is to enhance the quality, equity, and accessibility of mental health services across the country. Additionally, the Plan promotes service integration, user involvement, the reduction of regional disparities, and the protection of the rights of individuals with mental disorders. It stems from the work of the National Conference on Mental Health and the policy guidelines formally adopted at the institutional level<sup>25</sup>.

For the first time in 2025, the PANSM formally recognized the urgency of addressing clinical risk in psychiatry, incorporating risk management and patients and professionals' safety into its operational framework. The Plan emphasizes the identification, monitoring, and prevention of risks within hospital-based diagnostic and treatment services, particularly in relation to self-harm/suicidality and agitation/aggressiveness.

However, it also highlights the urgent need for mental health departments to identify critical issues within care pathways and implement corrective actions. These departments are currently managing an increasing number of service users with highly complex needs, requiring specialized and diversified treatment approaches. Moreover, persistent staff shortages are frequently reported, with significant implications for patient safety and an elevated risk of professional burnout.

The challenges described above underscore that community psychiatry is characterized by a distinctive and multifaceted risk profile, shaped by staff burnout, safety concerns, and the ongoing effort to

ensure continuity of care in resource-limited settings.

Table 2 synthesizes these key risk areas, outlining the critical issues reported in the literature and the strategies proposed to improve safety and quality of care. This table serves as a bridge between theoretical risk management frameworks and practical, implementable actions for mental health departments.

PANSM identifies three priority areas for intervention: the occupational well-being and safety of mental healthcare personnel, the management of forensic psychiatric patients, and the acquisition of informed consent to treatment. Additional objectives include strengthening continuity of care between hospital and community settings, training staff in the use of evidence-based guidelines, upgrading the structural adequacy of care environments, and evaluating the care experience from the perspective of both patients and their families<sup>26</sup>.

Table 3 provides a concise overview of these strategic priorities and their operational objectives, offering a clear framework for aligning risk management practices with national policy goals.

**Table 2.** Key risk areas and management strategies in community psychiatry.

| Risk area               | Critical issues described   | Proposed strategies   |
|-------------------------|---|---|
| Staff burnout           | <ul style="list-style-type: none"> <li>high emotional load;</li> <li>lack of resources;</li> <li>perceived slow clinical progress.</li> </ul> | <ul style="list-style-type: none"> <li>regular supervision;</li> <li>focus on incremental improvements;</li> <li>person-centered organizational culture.</li> </ul>         |
| Staff safety            | <ul style="list-style-type: none"> <li>home visits in unsafe settings; isolated work;</li> <li>lack of immediate support.</li> </ul>          | <ul style="list-style-type: none"> <li>pre-visit risk assessment;</li> <li>team or paired visits;</li> <li>post-event reporting and debriefing.</li> </ul>                  |
| Continuity of care      | <ul style="list-style-type: none"> <li>chronic illness course;</li> <li>limited access to services.</li> </ul>                                | <ul style="list-style-type: none"> <li>family engagement;</li> <li>reduction of barriers to care;</li> <li>proactive post-discharge follow-up.</li> </ul>                   |
| Violence and aggression | <ul style="list-style-type: none"> <li>increased risk in patients with comorbidities or substance abuse.</li> </ul>                           | <ul style="list-style-type: none"> <li>crisis management training;</li> <li>effective communication techniques;</li> <li>involvement of social support networks.</li> </ul> |

**Table 3.** Strategic priorities of the Italian National Mental Health Plan (PANSM 2025-2030).

| Priority area                               | Operational objectives highlighted in the manuscript  |
|---|---|
| Staff well-being and safety                 | <ul style="list-style-type: none"> <li>burnout and violence prevention;</li> <li>reporting systems;</li> <li>training in de-escalation techniques.</li> </ul>                                       |
| Forensic psychiatric patient management     | <ul style="list-style-type: none"> <li>structured risk assessment for recidivism; personalized PTRI;</li> <li>DSM-REMS collaboration.</li> </ul>  |
| Informed consent and shared decision making | <ul style="list-style-type: none"> <li>regular capacity assessment;</li> <li>use of standardized tools (MacCAT-T, EICT); promotion of shared decision-making and recovery-oriented care.</li> </ul> |
| Hospital-to-community continuity            | <ul style="list-style-type: none"> <li>strengthening of transition pathways;</li> <li>reduction of barriers to service access;</li> <li>family engagement.</li> </ul>                               |
| Training and guidelines                     | <ul style="list-style-type: none"> <li>continuous education on evidence-based guidelines and safety outcome indicators.</li> </ul>  |

## Occupational well-being and safety of mental healthcare personnel

Among the priority areas of intervention outlined in the PANSM 2025-2030 we find the promotion of occupational well-being and workplace safety for mental health professionals. Globally, cases of burnout and workplace violence have been steadily increasing, driven by increasingly critical working conditions.

In a 2025 publication, Ballout reports that between 21% and 67% of clinicians working in psychiatric settings report experiencing burnout, while 16% to 85% report symptoms of compassion fatigue<sup>27</sup>. Acute psychiatric wards, together with emergency and urgent care units, represent the clinical environments with the highest prevalence of assaults against healthcare personnel<sup>28</sup>. Furthermore, between 24% and 80% of psychiatric staff report having experienced at least one assault during their careers, with verbal aggression being more common than physical violence<sup>29</sup>.

In Italy, the incidence of violent acts against healthcare professionals, including psychiatric staff, is reported to be on the rise<sup>30</sup>. Approximately 45% of workers have already been victims of aggression by patients or their relatives<sup>31</sup>. A nationwide pre-pandemic survey of 1,200 psychiatrists found that 91% reported verbal aggression, 72% reported threats with objects, and 65% experienced physical violence<sup>32</sup>. Post-pandemic data from the National Institute for Insurance against Workplace Accidents (INAIL) indicate an additional increase in reported incidents<sup>33</sup>. Moreover, exposure to verbal assaults or object-related threats within the previous year is significantly associated with higher scores on the Maslach Burnout Inventory (MBI), indicating a substantial negative impact on occupational well-being<sup>34</sup>.

Multiple factors contribute to the demanding and often detrimental working conditions in mental healthcare. Psychiatric professionals are continually exposed to high emotional burdens and to the traumatic experiences of their patients. Additionally, recent estimates highlight that the global demand for psychiatric care far exceeds the system's capacity to respond. According to the World Health Organization (WHO), approximately 50% of the global population lives in countries with fewer than one psychiatrist per 100,000 inhabitants. In the United States, about 169 million individuals live in federally designated Mental Health Professional Shortage Areas (MHPAs)<sup>27</sup>. In Italy, despite progressive aspects of its psychiatric care system stemming from the closure of psychiatric hospitals and forensic psychiatric institutions, the country remains one of the European Union members with the lowest investment in mental health services<sup>34</sup>.

Staff shortage, increased workloads, and inadequate institutional support further exacerbate these

challenges. Systemic shortcomings and performance-driven policies are frequently perceived by clinicians as barriers to providing high-quality, individualized care. This perceived moral injury, superimposed on the already elevated emotional burden, amplifies psychological distress<sup>27</sup>.

These same factors also contribute to overcrowding in care facilities and prolonged waiting times. Mental health staff often work under pressure and may lack sufficient training in de-escalation techniques. Combined with patient-related factors, such as substance abuse, this significantly heightens the risk of violent incidents.

The mental healthcare sector is therefore facing a profound crisis, with increasing professional disaffection fuelling a negative spiral of resource depletion and high turnover rates. As such, effective risk management strategies are essential to mitigate these challenges.

Evidence consistently demonstrates that systemic interventions are more urgent and effective than those solely targeting individual professionals. At the national level, a noteworthy example is the Psychiatric Fast Track Unit implemented at Bolzano Hospital, which specifically addresses psychiatric single-specialty emergencies through the joint collaboration of specialized nurses and both hospital-based and community psychiatrists. Although conclusive data are still lacking, preliminary evidence seems to suggest that this model has contributed to reducing waiting times and improving clinicians' satisfaction<sup>35</sup>.

Therefore, the establishment of robust systems for reporting, analysing and monitoring adverse events, coupled with comprehensive staff training in prevention, represents a critical first step<sup>34</sup>. Furthermore, fostering a person-organizational culture, reducing bureaucratic barriers, and creating professional development opportunities for staff can play a pivotal role in improving well-being and retention<sup>36</sup>.

Within this context, community-based psychiatry warrants specific attention. Similar to hospital-based psychiatry, community mental health services face resource shortages and high staff turnover. Community-based professionals are similarly at risk of burnout and workplace violence, although both phenomena exhibit context-specific characteristics.

Client-related burnout refers to emotional exhaustion arising from the perception of slow or absent clinical progress, a condition particularly prevalent among community mental health workers caring for individuals with chronic, severe mental disorders. The lack of visible improvement over time is associated with increased job dissatisfaction, psychological distress, and intent to leave the field. Consequently, effective risk management strategies for preventing work-related stress should include regular supervi-

sion, emphasizing recognition of even minor positive changes and promoting a clinical perspective focused on individualized recovery rather than organizational performance metrics<sup>37</sup>.

Regarding violence, specific operational characteristics of community-based psychiatry contribute to heightened risk. Home visits, work in unsecured environments, operational isolation, and the absence of immediate support or physical safety barriers increase the vulnerability of community-based psychiatric staff<sup>38</sup>. Although verbal threats and aggression are most frequent, approximately one-third of these professionals report experiencing physical violence during their careers<sup>39</sup>. Effective risk management in these settings should therefore prioritize pre-visit risk assessments<sup>40</sup>, encourage paired or team-based fieldwork<sup>41</sup>, and implement structured post-incident reporting and support systems<sup>42</sup>. Finally, targeted training for managing crises in community and home environments, along with strategies to enhance effective communication and active engagement of patients, families, and social networks in care processes, is critical<sup>43</sup>.

### Forensic psychiatric patients' management

Another priority highlighted in the PANSM 2025-2030 is the management of forensic psychiatric patients. This population includes individuals with a mental disorder who have committed a crime, encompassing both those deemed criminally responsible and incarcerated, as well as those found not criminally responsible and subject to security measures to mitigate social dangerousness. While both subpopulations fall under the remit of mental health departments, the Italian context is unique regarding the latter, resulting from the permanent closure of judicial psychiatric hospitals and their replacement with healthcare-managed residential facilities for the execution of security measures (REMS).

Currently, 31 REMS are active in Italy, hosting 577 patients, with a total capacity of approximately 600 beds. Women constitute 11% of residents, and 25% are non-Italian nationals<sup>44</sup>. A 2024 study demonstrated that female forensic patients exhibit a higher prevalence of depressive and personality disorders compared to males and are more frequently committed for severe crimes such as homicide and attempted homicide<sup>45</sup>. Foreign nationals often lack familial, occupational, and social networks, complicating their management by psychiatric services. The most common diagnosis among residents is schizophrenia, followed by personality disorders, frequently co-occurring with substance use<sup>46</sup>. A single-study of 46 inpatients over five years found that most (28%) were aged 40-50 years and 48% were diagnosed with psychosis, predominantly schizophrenia. Approxi-

mately half of the sample had a history of substance use (46%)<sup>47</sup>. Positive psychiatric history, including multiple prior hospitalizations and compulsory treatments, was common. Criminological history most often involved homicide and attempted homicide, followed by assault, threats, domestic violence, property crimes, offenses against public officials, stalking, and sexual offenses<sup>48</sup>. A characteristic psychopathological trait of forensic psychiatric patients is both self-directed and outward aggression, with a high propensity for acting out, resulting in frequent verbal, physical, or object-related violence during hospitalization, compulsory treatments, and physical restraint are among the most common adverse events<sup>46</sup>. REMS are typically dual-purpose psychiatric facilities: treating psychopathology while containing dangerousness. As community-based services, they also provide rehabilitative and social reintegration functions. Treatments are therefore integrated, including pharmacological, psychotherapeutic, and technical-rehabilitative interventions. Regarding pharmacotherapy, a 2022 retrospective study of approximately 680 patients receiving antipsychotic therapy showed that about 50% were prescribed two or more antipsychotics, high doses, or first-generation agents. Such prescribing patterns resemble hospital-based rather than community practice and likely reflect the need for containment rather than symptomatic control<sup>48</sup>.

Emerging data highlight specific challenges relevant to risk management. First, the high prevalence of severe, chronic mental disorders associated with substance use and social disadvantage necessitates a community-based approach capable of managing complex cases, integrating mental health, addiction, and social services, and, where necessary, coordinating with units serving individuals with intellectual disabilities. Second, violent behavioral dysfunctions require strategies for monitoring and preventing adverse events to protect patients, other residents, and healthcare personnel. Third, clinical management must include measures to mitigate potential side effects of polypharmacy, ensure evidence-based psychotherapeutic and rehabilitative treatments, and reduce criminal recidivism.

In this context, the reform of the Italian forensic psychiatric system represents a significant challenge for community-based psychiatry. It presupposes that mental health departments possess adequate resources to treat all forensic psychiatric patients, regardless of the level of restrictions imposed based on dangerousness assessments. It also expands the psychiatrist's professional responsibility, extending their position of guarantee to individuals deprived of liberty for public safety reasons. Beyond ordinary medical responsibility, forensic psychiatry requires prognostic evaluation of future patient behavior and what

clinical intervention will elicit, perpetually balancing the duty of care with the need for containment<sup>49</sup>.

Therefore, investment in specialized staff and standardized assessment tools is essential, ensuring each department has a dedicated team and a structured diagnostic, therapeutic, and care pathway for forensic patients. Individualized therapeutic-rehabilitative (PTRI) programs should aim not only at symptoms stabilization and recovery-oriented rehabilitation but also at the periodic assessment of violent recidivism risk. As Ferracuti et al. suggest, departmental teams, in coordination with forensic experts and REMS staff, should move beyond the arbitrary concept of “social dangerousness” toward measurable parameters amenable to critical review<sup>49</sup>.

Currently, literature on treatment outcomes in REMS is limited. Internationally, the cumulative recidivism rate at 12- and 24-months post-discharge from residential forensic care ranges between 13% and 20%<sup>50</sup>. A 2021 Italian study on female patients identified substance use disorder and Axis II diagnoses as risk factors for readmission to REMS. Younger age, shorter length of stay, and absence of post-discharge supervised release also contributed, though to a lesser extent<sup>51</sup>. A male cohort was examined in a pilot study on outcomes 10 years after the closure of the Barcellona Pozzo di Gotto forensic hospital in Sicily. The need for high-control REMS during the first two years post-discharge decreased from 70% at baseline to 12%, reaching 6.7% after 10 years<sup>52</sup>.

Based on the Structured Professional Judgement framework, the HCR-20 V3, correlated with psychopathy assessment via the PCL-R, remains the most widely endorsed instrument for evaluating violent recidivism risk<sup>53</sup>. The DUNDRUM Toolkit V1.0.30.2010 is a structured professional judgment instrument measuring the need for therapeutic security (Toolkits 1 and 2), program completion (Toolkit 3), and recovery (Toolkit 4) in forensic settings; validation of the Italian version is in progress<sup>54</sup>. The Structured Assessment of Protective Factors (SAPROF) is designed to assess protective factors against violent acts, with items classified as internal, motivational, and external. Items 1 and 2 (internal) are static, whereas the remaining 15 are dynamic and likely to change during treatment<sup>55</sup>. Integrating these instruments into regular PTRI evaluations may support the objectives described above, while collaboration with universities should be encouraged to advance research and achieve excellence of forensic care<sup>56</sup>.

### **Informed consent to treatment in community-based psychiatry**

The third, though not least, priority outlined in the PANSM 2025-2030 is the acquisition of informed consent to treatment. In mental health care, the issue of

informed consent encompasses multiple and complex dimensions.

First, the ability to provide consent varies depending on the phase of illness. A person experiencing acute psychopathological decompensation may be unable to make treatment decisions, regaining such capacity only upon resolution of the episode. Furthermore, severe psychiatric disorders can result in cognitive impairments that may partially or completely compromise decisional abilities. A study published in 2025 highlighted that, in schizophrenia spectrum disorders, decisional capacity may be negatively affected by short-term conceptual disorganization and by medium- to long-term cognitive decline. In bipolar disorder, instead, decisional capacity appears to be influenced by symptoms such as somatic concerns and hostility<sup>57</sup>.

As a result, psychiatric practice unfolds across a wide spectrum of interventions, ranging from compulsory treatments to individualized, recovery-oriented therapeutic projects, and ultimately to a clinical relationship fully comparable to that applied in any other medical setting. Psychiatrists are required to act within the limits defined by law, yet their professional responsibility extends further: they are expected to provide prognostic judgments on patient behavior and to uphold a duty of care not only toward patients but also toward third parties<sup>49</sup>.

Within this framework, certain populations – such as migrants, offenders, and individuals with cognitive disabilities – pose additional challenges. In the case of migrants, for instance, it is notable that first-generation immigrants who have been in Italy for less than two years are at greater risk of compulsory admission compared with Italian nationals<sup>58</sup>. Beyond general barriers to health care access, immigrants often face obstacles to information accessibility, particularly due to language barriers and difficulties navigating social and health systems in a foreign country. In the forensic context, legal obligations to impose restrictions do not correspond to mandatory treatment obligations. Moreover, the legal concept of criminal insanity does not overlap with the medical notion of decisional incapacity. Consequently, patients placed under security measures are nonetheless required to provide their consent to treatment, as they cannot be compelled to accept care solely on the grounds of social dangerousness – an element not included among the legal criteria for compulsory admission in Italy<sup>48</sup>. Finally, individuals with cognitive disabilities represent a particularly vulnerable group, whose protection must be tailored according to the actual degree of incapacity, and for whom both the health and social care systems bear responsibility.

Within the Italian context, the protection of patient self-determination in healthcare processes is ensured by Law n. 219/2017 on informed consent. This legislation has placed the patient’s will and per-

sonal conception of dignity at the centre of the therapeutic relationship. However, its practical implementation in psychiatry remains controversial<sup>59</sup>. In particular, is reported that shared care planning may serve as a valuable tool to safeguard patients' preferences regarding the type of treatment, the management of critical phases of illness, and various aspects of daily life. It also allows for the appointment of a representative and the expression of the patient's value framework, which should guide future medical decisions in unforeseen circumstances<sup>60</sup>.

In this respect, community-based psychiatry appears to have a dual duty: to conduct periodic assessments of decisional capacity and to involve patients as much as possible in designing their individualized treatment plans.

Once again, the literature reviewed is consistent in indicating that clinical judgment alone – though widely used – is inadequate to reliably determine whether a person is capable of providing informed consent. Instead, the use of standardized assessment tools is recommended. Mental health departments should therefore be equipped with both trained staff and appropriate instruments for decisional capacity assessment, such as the MacArthur Competence Assessment Tool for Treatment (MacCAT-T) and the Evaluation of Informed Consent to Treatment (EICT)<sup>61</sup>. Routinely adopting such practices would not only safeguard patients' right to self-determination but would also provide objective parameters for initiating legal procedures for the appointment of guardians or legal representatives.

The dissemination of a culture of informed consent must also be supported by the promotion of Shared Decision Making (SDM) in the drafting of individualized therapeutic recovery plans (PTRI). Recovery is defined as «a personal process of changing one's attitudes, values, feelings, goals, skills, and/or roles. It involves the development of new meaning and purpose and a satisfying, hopeful, and contributing life as the person grows beyond the effects of psychiatric disability». Given this definition, it is difficult to understand why SDM remains poorly implemented in psychiatry. A performance-driven health system, rather than one oriented toward the recognition of personal value, likely discourages professionals from practicing SDM<sup>37</sup>. Even less frequently shared are processes related to risk assessment and management, in which psychiatrists' conviction of acting in the “best interest” of the patient and their heightened sense of professional responsibility may hinder dialogue with service users<sup>17</sup>.

Nevertheless, evidence shows that actively involving patients reduces the rate of unmet needs<sup>62</sup>, strengthens therapeutic alliance and adherence to treatment – including pharmacological interventions – and mitigates negative experiences related

to antipsychotic use<sup>63</sup>. Shared risk management further reinforces patients' perception of being heard and enables the creation of more effective support networks, including peers, relatives, and friends<sup>64</sup>. In conclusion, positive associations have been reported between SDM, guideline concordance, satisfaction with care, and medication adherence<sup>65</sup>. Implementing SDM practices within mental health departments would enhance the quality of care, reduce the stigma associated with mental illness, and empower patients to become informed participants in their own treatment.

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### Study limitations and future perspectives

We move now to present this study's limitations: it is a non-systematic review, characterized by heterogeneous sources and a scarcity of empirical data on risk management in community-based mental health services. These constraints imply that the results provide a general, though not exhaustive, overview of the main areas of risk and management strategies. Future research should focus on trigger validation, the implementation of Structured Professional Judgment (SPJ), the assessment of Shared Decision-Making (SDM) outcomes, and the monitoring of indicators outlined in the National Action Plan for Mental Health (PANSM).

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### Conclusions

Literature review suggests that risk management represents a key process for improving the quality of mental health care. Psychiatry in general – and community-based psychiatry in particular – may see key improvements in bridging the persistent gap in this field. It appears to be moreover urgent that mental health departments be equipped with trained staff and standardized tools for reporting and monitoring adverse events, and that they promote evidence-based practices to achieve high standards in fostering the well-being and safety of mental health professionals, in managing forensic psychiatric patients, and in promoting a culture of informed consent.

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