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Special Feature Article

Legal and Research Aspects of Physical Restraint in Psychiatry

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Abstract

In psychiatry, the rates of isolation and physical restraint have increased over the past decade, and there are various opinions about factors associated with such increases. Some of these opinions also provide information regarding physical restraint in general medical services and care facilities, or internationally compare the situation. The Japanese legal system only specifies justifiable causes of legality in psychiatry. There are also a number of challenges to be addressed in this area, such as clarifying the difference in the definition of physical restraint between psychiatry and care services. Furthermore, as there is no law specifying justifiable causes of legality in general medical services, it is necessary to determine whether treatment of a general patient was justifiable upon deliberation.

Concerning factors associated with the increasing rate of physical restraint, there have been no studies on this issue since a questionnaire survey, where approximately 70% of all hospitals responded, was conducted in 1999. Although a survey to assess the overall situation was launched in 2003, patient attributes to identify associated factors were not examined. In another survey that started in 2017, information, including patient attributes,

is being collected, but further studies may be required to examine these factors.

Keywords: isolation, physical restraint, Mental Health Act, justifiable causes of legality

Introduction.

There has been an increase in the use of seclusion and physical restraint in psychiatric beds over the past 10 years, and various opinions have been expressed as to the causes of this increase. For example, it may be because of the increase in the number of patients with dementia, or because of the increase in emergency wards, but there is still no data to prove this. In addition, the concept of zero physical restraint in nursing homes and data on dementia are sometimes used, and the debate seems to be mixed. In this paper, we will discuss the peculiarities of the position of seclusion and physical restraint in psychiatric beds in Japan, and describe data on this topic, including surveys we were involved in.

I. Characteristics of Psychiatric Behavioral Restrictions Prescribed by Law

In Japan, Article 220 of the Penal Code stipulates that unlawful arrest or confinement of a person is a crime. Article 208 of the Penal Code also stipulates the crime of "assault" for the

unlawful use of physical force against a person's body. Why, then, do isolation and physical restraint in psychiatry not fall under this category? When we consider seclusion and physical restraint in psychiatry, we must first organize our viewpoints, such as what is happening in general medical care, nursing homes, and overseas.

In criminal law, the word "unlawfully" is used. In other words, if it is not illegal, it does not violate the Penal Code. In addition, Article 35 of the Penal Code stipulates that "justifiable acts" are not punishable if they are committed by law or by legitimate business. For example, a professional wrestling match or a surgery performed by a surgeon under a contract is said to be "legitimate work". The question of who is considered to be a "legitimate business" depends on public opinion and precedent. In the medical field, there are several ways to ensure public trust: approval of surgical procedures by academic societies, review and approval of drugs and medical devices by the Ministry of Health, Labour and Welfare (MHLW), and the consent of the parties concerned.

In addition, surgeries using advanced medical equipment are subject to review and approval by the MHLW for advanced medical treatment. One example of debate as to the legitimacy of a medical procedure has been the case of a series of transplantations of diseased kidneys in Ehime Prefecture in 2006.

In 2007, the Japanese Society for Transplantation Research and other organizations announced their opinion that there was no medical validity 6), and the MHLW also decided in principle that medical treatment other than clinical research was not legitimate, and administrative penalties were imposed on the medical institution that had performed the kidney transplants.

However, this case continued to be debated, and in 2017, the MHLW approved sick kidney transplantation as an advanced medical treatment 2).

Thus, the "legitimate business" in medicine is, by its very act, founded in an unstable environment, but there is another requirement for "legitimate acts" in criminal law, namely, acts by statute. This means that acts under the conditions prescribed by other laws and regulations can be exceptionally prevented from being illegal in criminal law. An example of this is abortion. Article 14 of the Maternal Protection Law states that "Doctors designated by a medical association established in a

prefectural area may perform (abbreviated) abortions". This article prevents the illegality of professional abortion and manslaughter under Article 214 of the Penal Code only for abortions performed by doctors designated under the Maternal Protection Law.

The same is true for seclusion (over 12 hours) and physical restraint in mental hospital beds. The public notice (Ministry of Health and Welfare Notice No. 129, April 8, 1988) stipulates that these are restrictions on behavior set by the MHLW, as described in Article 36-3 of the Mental Health and Welfare Law. The same article states that these behavioral restrictions "may not be imposed unless deemed necessary by a (mental health) designated physician", which means that the decision to isolate or physically restrain a patient is illegally precluded by the crimes of arrest and confinement under Article 220 and assault under Article 208 of the Penal Code. It is complicated, but it means that acts that would normally violate the Penal Code are exceptionally not illegal under the limited circumstances and conditions stipulated by the Mental Health and Welfare Law. In medical and nursing care, only psychiatric care has a provision that prevents the illegality of behavioral restrictions, and this does not extend to general medical care or nursing care

facilities. Then, what about the illegality of similar behavioral restrictions in general medical care and nursing homes? Since there is no law that prevents illegality, the author thinks that it should be discussed whether it is a legitimate act or not. For example, whether physical restraints to avoid dangerous behavior due to impaired consciousness in life-threatening situations, such as in acute wards of physical medicine, is a legitimate act. The legitimacy of such restraints under various circumstances awaits administrative and judicial discussion.

II. Regulation in other domains

What is the regulation of behavioral restrictions in general medical care and nursing homes, where there is no special law to prevent illegality? When the Long-Term Care Insurance Law came into effect in 2000, the Standards for Personnel, Equipment and Operation of Designated Welfare Facilities for the Elderly (Ministry of Health and Welfare Ordinance No. 39 of 1999) stipulated the prohibition of physical restraint as an operational standard. The following year, 2001, the MHLW's "Zero Physical Restraint Strategy Promotion Council" published "A Guide to Zero Physical Restraint: For All People Involved in Elderly Care" 5). This guide strongly advocates the

prohibition of physical restraint itself, and lists 11 actions that should be prohibited. This includes isolation and mass administration of sedatives in psychiatry, which is defined differently from the Mental Health and Welfare Law or isolation and physical restraint in psychiatry (Table 1). In addition, in long-term care insurance compensation, there is a "subtraction for failure to abolish physical restraint", in which compensation is deducted for all residents due to inadequate recording of physical restraint or failure to take measures to abolish it. In addition, in general medical care, when physical restraint is used on a patient with dementia, the additional points for dementia care in the hospitalization fee will be deducted from the medical fee. Even if the guidance is interpreted to apply to all elderly patients, there is no mechanism for these facility standards or reduction of reimbursement for general medical care inpatients who are not elderly patients.

In other words, in Japan, there are no legal standards for the use of seclusion and physical restraint outside of psychiatric beds, and they are regulated only by so-called rules and initiatives, such as facility standards, medical and nursing care fees, and guidance. Therefore, although there are rules and initiatives, no one denies the illegality of physical restraint, and this is a

dangerous situation in which seclusion and physical restraint are performed as "legitimate business" in general medical care.

III. Current and future understanding of behavioral restrictions in psychiatry

In psychiatric beds, which are required by law, how much seclusion and physical restraint are practiced? In 1999, a nationwide survey on seclusion and physical restraints in psychiatric beds in Japan was conducted for the first time by the Health and Welfare Science Research Institute 1). The survey covered 1,548 hospitals in Japan with mental health beds, and responses were received from 1,090 hospitals. Among 246,616 beds, 5,643 (2.3%) were secluded and 4,667 (1.9%) were physically restrained as of the survey date. The data were disaggregated by hospital establishment, ward admission rate, diagnosis, and duration of behavioral restriction, as well as by location, reason, and interruption. Following this survey, it was recommended that a committee for minimizing behavioral restrictions be established. Although similar surveys have not been conducted since then, "the number of patients in seclusion rooms" was surveyed in the 630 Survey in 2002 3), "the number of patients in isolation rooms" and "the number of patients being physically restrained"

were surveyed by hospital type from 2003 to 2016, and since 2008, the number of patients by type of hospitalization has been added to these surveys 3).

Since the 630 Survey is an almost exhaustive survey in which more than 90% of hospitals with psychiatric beds responded, it is not possible to make a simple comparison between these figures and those of the 1999 survey.

In addition, the 2002 survey was based on the "number of people using the protection room" on the day of the survey, and it is not clear whether this was isolation or not.

Therefore, the data that can be compared over time are the aggregate data for all psychiatric beds without any attributes such as diagnosis or age, out of the 630 Survey conducted since 2003. This transition and the results of the 2017 and 2018 surveys are shown in the figure.

In the 630 Survey up to 2016, we surveyed "those isolated for more than 12 hours" and "those under physical restraint" on June 30, the day of the survey. However, we did not know how to treat those who were suspended (e.g., under open observation), as was the case in the 1999 survey, and we did not count those who were isolated for less than 12 hours on the order of a doctor other than a designated mental health physician. From the standpoint of the

patient, a situation in which isolation is ordered, but the patient is under open observation, is simply a situation in which isolation is postponed, and there is no change to the isolation even for a short time. Beginning with the 630 Survey in 2017, the definition for inclusion was strictly defined as "those with an order for seclusion or physical restraint at midnight". At the same time, the following attributes are now available in aggregate for different hospital locations: principal diagnosis, gender, length of stay, type of hospitalization, age, hospitalization fees for hospital wards, prefecture, and patient residence 4). Therefore, please note that the definitions of the graphs in the figure differ between 2016 and 2017. Table 2, Table 3, and Table 4 show the total number of persons with orders for seclusion and physical restraint by principal diagnosis, age, and ward admission fee in 2018. While the overall rate of seclusion orders was 4.4% and the rate of physical restraint orders was 4.0%, by principal diagnosis, the number of seclusion orders for schizophrenia and intellectual and developmental disabilities, as well as the number of physical restraint orders for dementia, was high. By age group, the number of seclusion orders for patients aged 40 to 65 years and the number of physical restraint orders for patients aged 75 years and older was

high. By ward admission rate, the percentage of instructions in acute care wards was high, but in dementia treatment wards, 1.3% of instructions were for seclusion and 5.7% were for physical restraint.

The figure shows that the number of people in seclusion and physical restraint has increased, but it has not been possible to determine which attribute is responsible for this increase. Since the aggregate values for the above attributes have only been available since 2017, it is necessary to look at the aggregate values for at least the next few years in order to discuss the identification of the attributes that have increased. In addition, the period of time, existence of interruptions, and reasons for interruptions, which were collected in the 1999 survey, were not investigated in the 630 Survey, which will be an issue for future research.

Conclusion.

In Japan, there is a special legal framework for seclusion and physical restraint in psychiatric beds, which makes it difficult to make simple comparisons with general medical care or long-term care facilities, or to discuss them in the same category. Therefore, any discussion must be based on an understanding of these issues. In addition, conventional studies have only revealed an increase in the use of

seclusion and physical restraints. In order to empirically explore the factors behind the increase, it is necessary to conduct a series of surveys that include attributes, time periods, and reasons. Although attributes became available in the 630 Survey from 2017, at least a few years of data accumulation is required.

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表1 介護保険における身体的拘束の項目

■禁止の対象となる具体的な行為

介護保険指定基準において禁止の対象となっている行為は、「身体的拘束その他入所者（利用者）の行動を制限する行為」である。具体的には次のような行為が挙げられる。

- ①徘徊しないように、車いすやいす、ベッドに体幹や四肢をひも等で縛る。
- ②転落しないように、ベッドに体幹や四肢をひも等で縛る。
- ③自分で降りられないように、ベッドを柵（サイドレール）で囲む。
- ④点滴・経管栄養等のチューブを抜かないように、四肢をひも等で縛る。
- ⑤点滴・経管栄養等のチューブを抜かないように、または皮膚をかきむしらないように、手指の機能を制限するミトン型の手袋等をつける。
- ⑥車いすやいすからずり落ちたり、立ち上がったたりしないように、Y字型抑制帯や腰ベルト、車いすテーブルをつける。
- ⑦立ち上がる能力のある人の立ち上がりを妨げるようないすを使用する。
- ⑧脱衣やおむつはずしを制限するために、介護衣（つなぎ服）を着せる。
- ⑨他人への迷惑行為を防ぐために、ベッドなどに体幹や四肢をひも等で縛る。
- ⑩行動を落ち着かせるために、向精神薬を過剰に服用させる。
- ⑪自分の意思で開けることのできない居室等に隔離する。

（文献5より引用）

Table 1: Items of physical restraint in long-term care insurance

Specific acts subject to prohibition

The acts subject to prohibition under the designated standards for long-term care insurance are “physical restraint and other acts that restrict the behavior of residents (users)”. Specifically, the following acts are listed.

- (1) Tie a resident's trunk or limbs to a wheelchair, chair, or bed with strings to prevent wandering.
- (2) Tie the trunk and limbs to the bed with strings to prevent the patient from falling.
- (3) Surround the bed with a fence (side rail) to prevent the patient from getting out by themselves.
- (4) Tie the patient's limbs to the bed with strings so that the patient cannot pull out the intravenous drip tube or tube feeding tube.
- (5) Wear mitten-type gloves that restrict the functions of the fingers so that the patient cannot pull out the IV tube or tube feeding tube, or scratch the skin.
- (6) A Y-shaped restraint belt, waist belt, or wheelchair table should be worn to prevent the patient from slipping out of the wheelchair or chair or from standing up.
- (7) Use a chair that prevents a person with the ability to stand from getting up.
- (8) Dressing the patient in nursing clothes to limit undressing and diaper removal.
- (9) Tie the patient's trunk and limbs to the bed with strings to prevent disturbance to others.

- (10) Excessive use of psychotropic drugs to calm behavior.
 (11) Isolate the patient in a room that the patient cannot open at will.
 (cited from Reference 5)

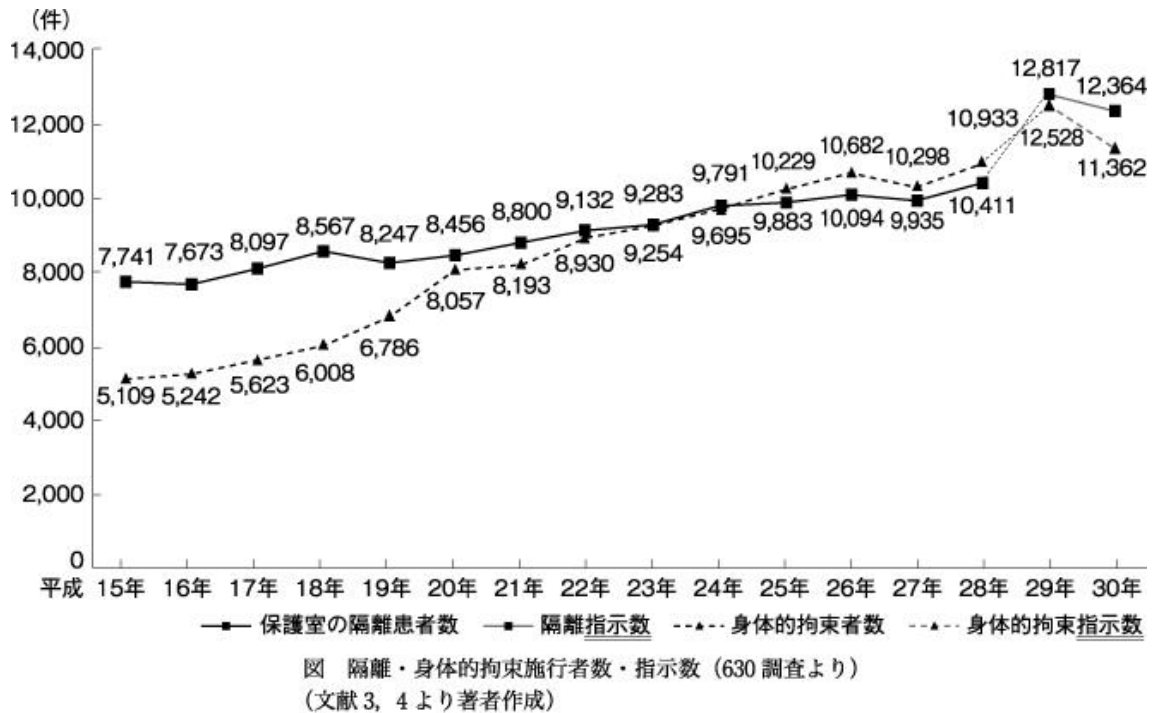


Figure Number of persons subjected to seclusion and physical restraint, and number of instructions (from the 630 Survey)

(Prepared by the author from References 3 and 4)

表2 2018（平成30）年の全国の主診断ごとの隔離・身体的拘束指示の状況

主診断	総数 (A+B+D-C)	隔離・拘束指示			
		隔離あり (A)	拘束あり (B)	隔離かつ拘束 (C)	隔離・拘束指示 なし (D)
F0 症状性を含む器質性精神障害	70,932	1,571	4,632	293	65,022
F00 アルツハイマー病型認知症	38,661	756	2,600	128	35,433
F01 血管性認知症	7,949	92	487	14	7,384
F02-09 上記以外の症状性を含む器質性精神障害	24,322	723	1,545	151	22,205
F1 精神作用物質による精神及び行動の障害	12,104	327	279	34	11,532
F10 アルコール使用による精神及び行動の障害	10,665	238	240	25	10,212
覚せい剤による精神及び行動の障害	598	40	17	6	547
アルコール、覚せい剤を除く精神作用物質使用による精神及び行動の障害	841	49	22	3	773
F2 統合失調症、統合失調型障害及び妄想性障害	149,972	7,995	4,795	814	137,996
F3 気分（感情）障害	26,756	990	727	159	25,198
F30-31 躁病エピソード・双極性感情障害（躁うつ病）	14,411	676	412	91	13,414
F32-39 その他の気分障害	12,345	314	315	68	11,784
F4 神経症性障害、ストレス関連障害及び身体表現性障害	5,220	193	98	24	4,953
F5 生理的障害及び身体的要因に関連した行動症候群	695	42	36	13	630
F6 成人のパーソナリティ及び行動の障害	1,014	74	39	13	914
F7 精神遅滞（知的障害）	5,791	569	395	56	4,883
F8 心理的発達障害	1,952	327	71	26	1,580
F9 小児期及び青年期に通常発症する行動及び情緒の障害及び特定不能の精神障害	660	63	21	6	582
てんかん（F0に属さないものを計上する）	2,197	78	82	8	2,045
その他	3,278	131	185	20	2,982
不明	244	4	2	0	238
合計*	280,815	12,364	11,362	1,466	258,555

*大項目の総和を算出。
(文献4より引用)

Table 2: Seclusion and physical restraint instructions by main diagnosis nationwide in 2018

Main diagnosis, Total number (A+B+D-C), Seclusion/restraint instructions
With seclusion (A), With restraint, (B) Seclusion and restraint, (C) None (D)

F0 Organic mental disorder, including symptomatic 70,932 1,571 4,632 293 65,022

F00 Alzheimer's disease dementia 38,661 756 2,600 128 35,433

F01 Vascular dementia 7,949 92 487 14 7,384

F02-09 Organic mental disorders, including symptomatic, other than the above
24,322 723 1,545 151 22,205

F1 Mental and behavioral disorders due to psychoactive substances 12,104 327 279
34 11,532

F10 Mental and behavioral disorders due to alcohol use 10,665 238 240 25 10,212

Mental and behavioral disorders due to stimulants 598 40 17 6 547

Mental and behavioral disorders due to use of psychoactive substances other than
alcohol and stimulants 841 49 22 3 773

F2 Schizophrenia, schizotypal disorder, and delusional disorder 149,972 7,995 4,795
814 137,996

F3 Mood (affective) disorders 26,756 990 727 159 25,198

F30-31 Manic episodes and bipolar affective disorder (manic depression) 14,411
676 412 91 13,414

F32-39 Other mood disorders 12,345 314 315 68 11,784

F4 Neurotic disorders, stress-related disorders, and somatoform disorders 5,220 193
98 24 4,953

F5 Behavioral syndromes related to physiological disorders and physical factors 695
42 36 13 630

F6 Personality and behavioral disorders in adults 1,014 74 39 13 914

F7 Mental retardation (intellectual disability) 5,791 569 395 56 4,883

F8 Disorders of psychological development 1,952 327 71 26 1,580

F9 Behavioral and emotional disorders and unspecified mental disorders of normal
onset in childhood and adolescence 660 63 21 6 582

Epilepsy (to record those not belonging to F0) 2,197 78 82 8 2,045

Other 3,278 131 185 20 2,982

Unknown 244 4 2 2 0 238

Total* 280,815 12,364 11,362 1,466 258,555

*The sum of the major items is calculated.

(Cited from Reference 4)

表3 2018（平成30）年の全国の年代ごとの隔離・身体的拘束指示の状況

年齢	総数 (A+B+D-C)	隔離・拘束指示			
		隔離あり (A)	拘束あり (B)	隔離かつ拘束 (C)	隔離・拘束指示 なし (D)
20歳未満	2,377	299	74	37	2,041
20歳以上40歳未満	18,498	2,476	669	248	15,601
40歳以上65歳未満	92,691	6,117	3,114	637	84,097
65歳以上75歳未満	71,633	2,010	2,671	269	67,221
75歳以上	95,319	1,447	4,831	274	89,315
不明	297	15	3	1	280
合計	280,815	12,364	11,362	1,466	258,555

(文献4より引用)

Table 3: Seclusion and physical restraint instructions by age group in Japan in 2018 (Heisei 30)

Age, Total number (A+B+D-C), Seclusion/restraint instructions
 With seclusion (A), With restraint (B), Seclusion and restraint (C), None (D)
 Under 20 years old 2,377 299 74 37 2,041
 20 to less than 40 years old 18,498 2,476 669 248 15,601
 40 to less than 65 years old 92,691 6,117 3,114 637 84,097
 65 to less than 75 years 71,633 2,010 2,671 269 67,221
 75 years old and over 95,319 1,447 4,831 274 89,315
 Unknown 297 15 3 1 280
 Total 280,815 12,364 11,362 1,466 258,555
 (Cited from Reference 4)

表4 2018 (平成30) 年の全国の病棟入院料ごとの隔離・身体的拘束指示の状況

病棟入院料	総数 (A+B+D-C)	隔離・拘束指示			
		隔離あり (A)	拘束あり (B)	隔離かつ拘束 (C)	隔離・拘束指示 なし (D)
精神科救急入院料	9,051	1,612	349	233	7,323
精神科救急・合併症入院料	373	35	69	12	281
精神科急性期治療病棟入院料	14,639	1,412	498	177	12,906
精神療養病棟入院料	87,082	2,480	2,459	282	82,425
認知症治療病棟入院料	32,905	431	1,885	68	30,657
特殊疾患病棟入院料	4,528	35	280	13	4,226
児童・思春期精神科入院医療管理料	793	92	11	6	696
医療観察法	750	13	1	0	736
地域移行機能強化病棟入院料	1,998	68	57	10	1,883
10対1入院基本料	742	39	114	20	609
13対1入院基本料	3,643	256	237	37	3,187
15対1入院基本料	113,293	5,542	4,705	552	103,598
18対1入院基本料	3,747	93	123	5	3,536
20対1入院基本料	1,290	30	18	0	1,242
特別入院基本料	1,650	61	84	4	1,509
特定機能病院入院基本料 (7対1)	344	22	27	8	303
特定機能病院入院基本料 (10対1)	355	28	27	9	309
特定機能病院入院基本料 (13対1)	948	71	61	17	833
特定機能病院入院基本料 (15対1)	200	16	18	7	173
その他	2,484	28	339	6	2,123
不明	0	0	0	0	0
合計	280,815	12,364	11,362	1,466	258,555

(文献4より引用)

Table 4: Seclusion and physical restraint instructions for hospital ward admission fees in Japan in 2018 (Heisei 30)

Inpatient ward admission fee, Total number (A+B+D-C), Seclusion/restraint instructions

With seclusion (A), With restraint (B), Seclusion and restraint (C), None (D)

Inpatient psychiatric emergency 9,051 1,612 349 233 7,323

Inpatient psychiatric emergency and complications 373 35 69 12 281

Inpatient psychiatric acute care unit 14,639 1,412 498 177 12,906

Inpatient psychiatric care unit 87,082 2,480 2,459 282 82,425

Inpatient dementia treatment ward 32,905 431 1,885 68 30,657

Hospitalization for special diseases 4,528 35 280 13 4,226

Child and adolescent psychiatric inpatient care management 793 92 11 6 696
 Medical observation law 750 13 1 0 736
 Inpatient ward with enhanced community transition function 1,998 68 57 10 1,883
 Basic admission (patients: nurses=10 : 1) 742 39 114 20 609
 Basic admission (patients: nurses=13 :1) 3,643 256 237 37 3,187
 Basic admission (patients: nurses=15 : 1) 113,293 5,542 4,705 552 103,598
 Basic admission (patients: nurses=18 : 1) 3,747 93 123 5 3,536
 Basic admission (patients: nurses=20 :1) 1,290 30 18 0 1,242
 Special basic admissions 1,650 61 84 4 1,509
 Basic admission to a specific functional hospital (patients: nurses=7 : 1) 344 22 27 8
 303
 Basic admission to a specific functional hospital patients: nurses= (10 : 1) 355 28 27
 9 309
 Basic admission to a specific functional hospital (patients: nurses= 13:1) 948 71 61
 17 833
 Basic admissions to a specific functional hospital (patients: nurses=15:1) 200 16 18
 7 173
 Other 2,484 28 339 6 2,123
 Unknown 0 0 0 0 0
 Total 280,815 12,364 11,362 1,466 258,555
 (Cited from Reference 4)