#### REVIEW

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# The Danish National Hospital Medication Register: A Resource for Pharmacoepidemiology

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**Background:** The Danish National Hospital Medication Register (DHMR), one of the first nationwide in-hospital medication registries in the world, contains detailed information on medication administration and dispensing.

**Objective:** To provide an overview of the information recorded in the DHMR and to highlight its strengths and limitations as a pharmacoepidemiological research tool.

**Methods:** We reviewed the registry's geographic and clinical specialty coverage and medications recorded according to the main groups of the Anatomical Therapeutic Chemical classification system.

**Results:** From May 2018 through December 2023, the DHMR recorded data on more than 1.9 million unique patients from all approximately 50 public hospitals and associated hospital outpatient clinics, totaling 105.3 million recordings of hospital medication use. The registry records detailed data on the indication for medication, medication type, pharmaceutical form, dosage, and administration time, collected through electronic medical record systems. Although the data quality has not yet been evaluated in a scientific context, some potential limitations are known. These include regional differences in the data collection and a lack of data from certain clinical specialties. Due to its recent establishment in 2018, the registered number of patients treated may still be limited for some rarely used medications.

**Conclusion:** The DHMR is an important new resource for research in Denmark. Combined with the Danish National Prescription Registry, which covers all community pharmacies, it offers access to accurate data on medication exposure in the Danish population. Users should be aware of potential issues with lack of information before 2018.

Keywords: pharmacoepidemiology, hospital medication system, pharmacotherapy, data source, drug databases, registry data, Denmark

## Introduction

Pharmacoepidemiology is the study of medication use and its effects in large populations.<sup>1</sup> A key objective of pharmacoepidemiological research is post-approval detection of adverse effects not identified in phase 3 trials, achieved by examining medication use in populations treated in routine clinical practice.<sup>2</sup> Many medication withdrawals based on phase 4 studies — including early examples such as diethylstilbestrol;<sup>3</sup> publicly well-known cases, such as thalidomide<sup>4</sup> and rofecoxib;<sup>5</sup> and, more recently, ranitidine<sup>6</sup> — have led to increased demand for evidence-based drug safety beyond traditional passive surveillance.<sup>7</sup>

The increased digitization of healthcare has enabled the creation of medical databases containing vast amounts of data over long periods.<sup>8</sup> These extensive databases have provided possibilities for conducting low-cost, large-scale, population-based pharmacoepidemiological research on rare and long-term adverse effects, which were impossible to accomplish decades ago, but few databases include detailed data on medication use from patients treated in hospitals.<sup>9,10</sup> The databases recording in-hospital medication use do not usually capture all segments of a target population because

registration in the databases, except in a few cases,<sup>11–13</sup> is often predicated on qualifying factors such as age; employment or insurance status; or hospital health network affiliation or specialty.<sup>14</sup>

Denmark has established many high-quality health registries over decades.<sup>8</sup> One is the Danish National Prescription Registry,<sup>15</sup> which holds detailed information on prescriptions dispensed at all Danish community pharmacies and is widely used in pharmacoepidemiology. However, the registry does not record data on in-hospital medication use. The recently established Danish National Hospital Medication Register (DHMR) provides detailed data on medication used within all public hospitals in Denmark. This advancement enhances opportunities for research by allowing for in-depth analysis of medication use in the community and during hospital stays.

Several hospital medications, including particularly potent medications such as chemotherapeutic agents<sup>16–18</sup> and reserve antibiotics,<sup>19–21</sup> can have severe adverse effects and long-term consequences. Current research on adherence to chemotherapy protocols and consistency with national chemotherapy guidelines,<sup>22</sup> personalized dosing in decreasing chemotherapy toxicity,<sup>23</sup> reinfection rates after use of broad-spectrum antibiotics, effectiveness and risk of antibiotic de-escalation strategies, or optimal timing for transitioning from intravenous to oral antibiotics<sup>24</sup> has been limited by relatively small sample sizes, reliance on medical record reviews, or a complete lack of studies.

Therefore, the DHMR was established after the Finance Act of 2017 to monitor medication utilization and safety, and enhance research opportunities.<sup>25</sup> This article provides an overview of the data recorded in the DHMR (in Danish; Sygehusmedicinregisteret) and evaluates its strengths and limitations as a research tool, as any epidemiological study should attempt to reduce random and systematic errors.

#### Setting

Denmark's healthcare system provides a foundation for understanding the management of in-hospital medications. This system is universal, tax-funded, and governed by five regions managing healthcare services;<sup>26</sup> the Capital Region of Denmark (~1.9 million inhabitants), Region Zealand (~0.8 million inhabitants), the Region of Southern Denmark (~1.2 million inhabitants), the Central Denmark Region (~1.4 million inhabitants), and the North Denmark Region (~0.6 million inhabitants).<sup>27</sup> Out-of-pocket expenditures are limited mainly to primary care and outpatient clinic medication and are often partially reimbursed.<sup>28</sup> Depending on the setting and the type of medication order, prescription medications can be acquired from community pharmacies, dispensed through hospital outpatient clinics, or administered during hospital admission.<sup>29</sup>

In 2022, 2.9 million<sup>30</sup> of Denmark's then 5.8 million inhabitants experienced 792,000 hospital admissions lasting longer than 12 hours and had 12.2 million hospital outpatient clinic visits.<sup>31</sup> Approximately 1.8% of these contacts were handled in the private sector.<sup>32</sup> Medications used at public hospitals and hospital outpatient clinics accounted for 5.7% of all defined daily doses in Denmark, amounting to 206 million daily doses, compared with 3,614 million daily doses sold at community pharmacies.<sup>33,34</sup> This uneven distribution is likely driven by many hospital medications not having defined daily doses, whereas the majority of medications sold at community pharmacies do. The expenses for medications used in hospitals and those sold at pharmacies were more similar. Costs for medication used at public hospitals totaled 1,234 million DKK (165 million EUR), half of which was dispensed through hospital outpatient clinics. In comparison, community pharmacies sold medication for 1,390 million DKK (186 million EUR).<sup>33,35</sup>

In Denmark, in-hospital medication use is documented in a two-step process through electronic medication management systems. These systems, integrated into electronic medical record systems, are used for both medication orders and to document medication administration. First, a physician makes a medication order, with details including the medication type, dosage, administration route, and dosing frequency and duration. Subsequently, when the medication is administered or dispensed, often by a nurse, the time of administration is recorded, and other information is verified or adjusted according to actual administration.

Two electronic medical record systems have been used in Denmark in all public hospitals since 2022: (1) Columna CIS (Systematic A/S, Aarhus, Denmark) in the North Denmark Region, Central Denmark Region, and Region of Southern Denmark, and (2) Epic (Epic Systems Corporation, Verona, WI, USA) in Region Zealand and the Capital Region of Denmark. The processes and systems described above lay the foundation for data recorded in the DHMR.

# **Content of the Registry**

## Geographic, Clinical Specialty, and Medication Coverage

Since its establishment in May 2018, the DHMR has recorded data on medication administration and dispensing across all approximately 50 public hospitals and associated hospital outpatient clinics. Electronic medication management systems, the primary data sources for data recorded in the DHMR, have not been fully implemented in all types of departments and differ among regions. In some regions, entire clinical specialties, such as radiology, anesthesiology, ophthalmology, and subdivisions of oncology and hematology care, and departments such as neonatal and intensive care units, have been allowed only to use these medication management systems for certain types of medication administration, or have been exempt from implementing them altogether. Therefore, data on medications delivered mostly in these settings, such as cytostatic agents, biological therapies, and anesthetics, are currently not recorded completely in all five regions. However, in the next several years, the Danish Health Data Authority intends to record all medications used in all hospital-related settings in the DHMR.<sup>36</sup> A region-based overview of the departments and types of medications currently not reported to the DHMR is presented in Table 1.

Only data from public hospitals, including emergency departments and hospital outpatient clinics, should be reported by the five regions to the DHMR. Therefore, the regions use the National Catalogue of Health Organisations (in Danish; Sundhedsvæsenets Organisationsregister) codes to exclude data from entities outside public hospitals, such as hospices and the few private hospitals, as defined by the Danish Ministry of Health, as well as medications administered in the prehospital setting.

Denmark uses a national online solution to improve medication reconciliation processes ensuring that prescribed medications are reviewed and aligned with what patients are actually taking. This system, the Shared Medication Record (in Danish; Fælles Medicinkort), enables healthcare providers to share and update patient medication information across healthcare sectors.<sup>37</sup> In the DHMR, updates to medications prescribed before a hospital admission are not recorded if hospital personnel only review or adjust prescriptions, or if patients bring medications to the hospital for self-administration. In addition, if a hospital medication order extends into a prescription and is redeemed at a community pharmacy, it is only recorded in the Danish National Prescription Registry.<sup>15</sup>

All data in the DHMR are collected by the regions and provided to the registry by daily data transfers, and each region is responsible for timely reporting and data validity while the Danish Health Data Authority manages the registry.

# Information in the Registry

The registry contains 34 variables, most directly associated with the detailed recording of medication type, order, administration, and dispensing. The registry records administrative patient data, including civil registration numbers

	Capital Region of Denmark	Region Zealand	North Denmark Region	Central Denmark Region	Region of Southern Denmark
Department type					
Outpatient clinics			(-)		
Ophthalmology departments	-	-	-		-
Medication during anesthesia <sup>a</sup>			-	-	-
Medication type					
Cytostatic agents			(-)	(-)	-
Biological drugs			(-)		-
Clinical trial drugs	-	-	(-)	-	-
Antibiotics					(–) <sup>b</sup>
Insulin					(–) <sup>b</sup>
Medication for home treatment	-	-	(-)	(-)	(-)

**Table I** Overview of Current Reporting Limitations, by Department and Medication Type, to the Danish National HospitalMedication Register Across Danish Administrative Regions

**Notes**: Lack of reporting in an area is denoted by "--" for complete absence of data and "(-)" for partial absence of data. This table is a modified version of a table in the registers official data documentation from June 20th, 2023, provided by the Danish Health Data Authority. <sup>a</sup>Including intrahospital transport and post anesthesia care units. <sup>b</sup>Some departments in the region report these data.

and other unique identification codes, enabling accurate record linkage at the individual level for a specific hospital contact and treatment course. The Anatomical Therapeutic Chemical (ATC) classification system is used to specify the medications' active substances and therapeutic uses.<sup>38</sup> Additionally, a six-digit product number, mandatory on all pharmaceutical packaging sold in Denmark, provides package-related information, such as price, pharmaceutical form, strength, and quantity. The Danish Health Data Authority provides a continually updated variable list with detailed descriptions of each variable. A summary of current variables available for research in the DHMR is provided in Table 2.

From its establishment through December 2023, the DHMR recorded data on more than 1.9 million unique patients with one or more inpatient or hospital outpatient clinic medication administrations or dispensing, amounting to 105.3 million recordings. Table 3 shows the medications most frequently recorded in 2023, according to the number of unique patients with at least one administration or dispensing, and includes the corresponding total administrations,

Administrative data		
CPR number	Unique national personal identifier assigned at birth or immigration	
Region	Administrative region where the medication management occurred	
Department, primary	Department responsible for the patient at the time of administration	
Contact ID	Unique identifier for the patient contact in administrative systems	
Treatment course	Unique identifier for the treatment course in administrative systems	
Medication order		
Start date	Start date and time indicating when the medication could be given	
End date	End date and time after which no further medication should be given	
Туре	Medication orders type "single-dose", "multi-dose", or "PRN/as-needed"	
Indication	Underlying condition(s) for which the medication was ordered (code/text)	
Administration		
Treating department	Department that administered the medication	
Date	Date and time of medication administration	
Туре	Type of administration, either "administered" or "dispensed"	
Route	Route of administration, eg, "per os", "intravenous", or "injection"	
Dose	Numerical dose of the administered medication	
Dose unit	Unit of the administered dose, eg, "mg", "ml", or "pieces"	
Medication		
Name	Product name of the medication	
Drug ID	Key identifier of the medication	
ltem number	Item number used in ApoVision and medicinpriser.dk pharmacy systems <sup>a</sup>	
ATC code	Code specifying the substance and its main therapeutic use	
Form	Pharmaceutical form of the medication, eg, "tablet" or "injection"	
Strength	Numerical strength of the medication per unit	
Strength unit	Units of medication strength, eg, "mg" or "mmol"	
Package size	Number of units per package	
Package size unit	Units of package size, eg, "ml" or "pieces"	
Cost	Estimated cost of the medication based on purchase price	
Cost date	Date on which the estimated cost of the medication was calculated	
Other		
Creation date	Date and time of datapoint creation in the medicine module	
Modification date	Date and time of datapoint modification in the medicine module	
Deletion	Indicates a deletion of a medication administration in the medicine module	
Keys <sup>b</sup>	Unique keys for each medication order, administration, and subcomponent;	
	keys are unique only in combination with region ID	
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Table 2 Summary of Variables in the Danish National Hospital Medication Register

**Notes:** <sup>a</sup>ApoVision is the national hospital pharmacies' inventory management system, and medicinepriser.dk is a public website providing updated information on medication pricing. <sup>b</sup>This covers five keys, which is why this table contains 30 variables and not 34, as described in the main text.

Abbreviations: ATC, Anatomical Therapeutic Chemical; CPR, Civil Personal Register (number); ID, identification; PRN, pro re nata.

Generic name	ATC code	Count (percentage)				
		Unique patients	Administrations or dispensing			
		Total Inpatient		Inpatient	Outpatient	
Acetaminophen	N02BE01	497,384(57.6)	2,301,930(7.1)	1,980,916(86.1)	184,012(8.0)	
Electrolytes solutions	B05BB01	263,371(30.5)	756,928(2.3)	567,103(74.9)	160,781(21.2)	
Ondansetron	A04AA01	224,802(26.0)	418,483(1.3)	298,568(71.3)	86,280(20.6)	
Morphine	N02AA01	220,979(25.6)	877,904(2.7)	756,723(86.2)	58,959(6.7)	
Ibuprofen	M01AE01	182,546(21.1)	398,615(1.2)	311,327(78.1)	60,733(15.2)	
Dexamethasone	H02AB02	169,316(19.6)	243,979(0.8)	148,722(61.0)	75,863(31.1)	
Pantoprazole	A02BC02	126,201(14.6)	980,648(3.0)	931,916(95.0)	16,438(1.7)	
Fentanyl	N01AH01	117,216(13.6)	143,055(0.4)	76,553(53.5)	61,260(42.8)	
Midazolam	N05CD08	114,146(13.2)	161,084(0.5)	66,952(41.6)	90,073(55.9)	
Propofol	N0IAXI0	111,658(12.9)	143,528(0.4)	103,111(71.8)	39,591(27.6)	
Potassium Chloride	AI2BA0I	104,573(12.1)	773,372(2.4)	735,983(95.2)	10,644(1.4)	
Cefuroxime	J01DC02	103,428(12.0)	235,845(0.7)	201,305(85.4)	24,287(10.3)	
Piperacillin/tazobactam	J01CR05	100,172(11.6)	577,361(1.8)	535,895(92.8)	22,333(3.9)	
Furosemide	C03CA01	84,314(9.8)	671,505(2.1)	637,033(94.9)	11,040(1.6)	
Dalteparin	B01AB04	77,899(9.0)	528,111(1.6)	442,454(83.8)	65,492(12.4)	
Total recorded in 2023		863,666 (100)	32,324,645(100)	28,068,479(86.8)	2,969,259(9.2)	

**Table 3** Fifteen Most Frequent Medications by Number of Unique Patients, Total Administrations, andAdministrations According to Inpatient or Outpatient Setting Labels Recorded in the Danish NationalHospital Medication Register in 2023

**Notes:** "Unique patients" represents the count of all patients with at least one administration or dispensing recorded in the registry in 2023. Percentages are the proportions of all 863,666 unique patients and all 32.3 million administrations or dispensing in 2023, respectively. Percentages of inpatient and outpatient administrations or dispensing are proportions of the 2023 total for that medication; these values do not add to 100% because of missing data in the patient type variable.

Abbreviations: ATC, Anatomical Therapeutic Chemical.

and their distribution by inpatient or outpatient clinic setting. That year, 863,666 unique hospital patients had a combined 32.3 million administrations and dispensing recorded in the DHMR. Similar numbers have been recorded each year since the establishment of the registry in 2018.

Table 4 presents the annual distribution of medications used among unique patients, categorized according to the main anatomical groups of the ATC system. The distribution across ATC main groups was similar throughout the period. Annually, the approximate percentages of patients receiving at least one administration or dispensing of medications classified under the three largest ATC main groups were as follows: 21%, "nervous system"; 14%, "blood and blood forming organs"; and 13%, "alimentary tract and metabolism".

Selected examples illustrating the extent of patients' exposure to medications used in hospital settings, associated with high costs, or having potential for severe adverse effects are highlighted in Table 5.

## Data Quality

The medication data recorded in the DHMR are generated during clinical care, and data recorded in such contexts often have high validity. However, some medication administrations may not be recorded, which could reduce the sensitivity of assessing medication exposure.

One study evaluating a regional hospital medication registry covering hospital medication use in the Capital Region of Denmark has demonstrated that a high proportion, 100% (95% confidence interval, 98.4%–100%), of 227 medication administrations in the electronic medical record system was also recorded in the registry. For clinical observations, 98.3% (95% confidence interval, 95.1%–99.6%) of 176 medication administrations recorded by investigators observing registered nurses during dayshifts were later found in the regional registry.<sup>39</sup> However, the specific electronic medication management systems in use, when data were recorded for that registry, were replaced before the initiation of the DHMR.

AT	C main group, alphabetically	Patients, count (percentage)					
		2018	2019	2020	2021	2022	2023
А	Alimentary tract and metabolism	261,780(13.3)	399,047(13.0)	390,854(13.2)	394,312(13.3)	418,460(13.5)	437,934(13.7)
В	Blood and blood forming organs	286,770(14.5)	437,524(14.3)	420,362(14.2)	414,505(14.0)	423,003(13.6)	428,942(13.4)
С	Cardiovascular system	186,612(9.5)	285,413(9.3)	280,173(9.5)	282,240(9.5)	293,398(9.4)	299,256(9.3)
D	Dermatologicals <sup>a</sup>	8,451(0.4)	13,291(0.4)	13,430(0.5)	13,120(0.4)	12,895(0.4)	12,729(0.4)
G	Genito-urinary system and sex hormones	29,307(1.5)	45,141(1.5)	46,269(1.6)	47,748(1.6)	48,337(1.6)	49,149(1.5)
Н	Systemic hormonal preparations, excluding sex hormones and insulins	154,680(7.8)	253,665(8.3)	250,454(8.5)	256,178(8.6)	283,891(9.1)	302,292(9.4)
J	Anti-infectives for systemic use	213,349(10.8)	332,396(10.9)	315,897(10.7)	314,577(10.6)	322,177(10.4)	333,632(10.4)
L	Antineoplastic and immunomodulating agents	34,230(1.7)	48,651(1.6)	51,209(1.7)	55,719(1.9)	67,282(2.2)	71,641(2.2)
М	Musculo-skeletal system	200,556(10.2)	321,229(10.5)	303,707(10.3)	296,892(10.0)	311,296(10.0)	328,366(10.2)
Ν	Nervous system	427,054(21.6)	654,263(21.4)	615,922(20.9)	616,657(20.8)	640,139(20.6)	655,548(20.4)
Ρ	Antiparasitic products, insecticides, and repellents	15,036(0.8)	21,791(0.7)	20,120(0.7)	18,091(0.6)	17,070(0.5)	15,961(0.5)
R	Respiratory system	75,451(3.8)	119,869(3.9)	112,024(3.8)	115,329(3.9)	117,320(3.8)	119,855(3.7)
S	Sensory organs	18,585(0.9)	30,809(1.0)	32,380(1.1)	39,004(1.3)	41,051(1.3)	40,705(1.3)
۷	Various	62,207(3.2)	94,816(3.1)	97,783(3.3)	106,030(3.6)	108,665(3.5)	109,972(3.4)
Tot	al	197,406(100)	305,790(100)	295,058(100)	297,040(100)	310,498(100)	320,598(100)

 Table 4 Annual Distribution of Patients in the Danish National Hospital Medication Register by Count, According to ATC Main

 Groups

Note: A patient is defined as someone with at least one administration or dispensing in a given ATC group in any hospital setting covered by the registry. Percentages do not add to 100% vertically because a patient may be counted in more than one ATC group within the same year. <sup>a</sup>Because of limitations in our data, we did not include the following ATC codes from this category D01\*-D05\* and D08\*-D11\*.

Abbreviations: ATC, Anatomical Therapeutic Chemical.

Table 5 Total Counts and Percentages of Patients Receiving Selected					
Medications, Recorded in the Danish	National Hospital Medication				
Register Among 863,666 Unique Patients in 2023					

Generic name	ATC code	Count	Percentage
Heparins <sup>a</sup>	BOIAB	138,994	16.1
Tranexamic acid	B02AA02	63,807	7.4
Amiodarone	C01BD01	8,917	1.0
Adrenergic and dopaminergic agents <sup>a</sup>	C01CA	92,014	10.7
Gentamicin <sup>b</sup>	J01GB03	30,545	3.5
Vancomycin <sup>b</sup>	J01XA01	6,276	0.7
Capecitabine	L01BC06	727	<0.1
Nivolumab	LOIFFOI	795	<0.1
Cisplatin	L01XA01	1,162	0.1
Clozapine	N05AH02	1,622	0.2

**Note**: The medications were selected as examples of those currently available in the registry, considering their predominant administration in hospital settings, high cost, or potential for severe adverse effects. Percentages indicate the proportions of the total patient population in the registry in 2023. <sup>a</sup>For these categories, the 3rd level of ATC is used to include similar medications otherwise divided at the 5th level of the ATC system such as heparin and low-molecular-weight heparin. <sup>b</sup>Only including antiinfectives for systemic use. **Abbreviations**: ATC, Anatomical Therapeutic Chemical.

During electronic medication ordering, most fields in these systems require mandatory filling and are designed to focus on detailed data for clinical documentation. Therefore, data entry errors are likely to be minimized, data loss is avoided, and standardization in coding is enhanced.

## **Record Linkage to Other Registries**

All individuals residing in Denmark for more than three months are assigned a unique civil registration number,<sup>40</sup> which is registered every time an individual is in contact with the healthcare sector. This enables the use of national registries as sampling frames for creating cohorts according to the identification of events such as exposures, clinical outcomes, and other variables. Examples of frequently used registries for record linkage in pharmacoepidemiology include the Danish National Patient Registry,<sup>41</sup> the Danish Psychiatric Central Research Register,<sup>42</sup> and the Danish Cancer Register,<sup>43</sup> as well as administrative registries containing information such as socioeconomic characteristics, eg, the DREAM database with data on social benefits,<sup>44</sup> and the Danish Integrated Database for Labour Market Research which records data on labor market participation.<sup>45</sup>

The application of data privacy protocols, including pseudonymization and encryption of personal data before linkage, is integral to data linkage. The Danish Health Data Authority ensures that data shared across databases remain de-identified.

# **Strengths and Limitations**

### Strengths

A major strength of the DHMR is its potential to achieve full coverage of nearly all medication administrations in all public hospitals in Denmark, particularly in the future when all regions fully report data across all departments and medication types.

With the possibility of record linkage to other health registries and clinical quality registries and the opportunity for nearly complete follow-up on death and emigration through the Danish Civil Registration System, the DHMR opens new possibilities in pharmacoepidemiology for studying effects and safety monitoring of treatments used in hospitals. Combined with the Danish National Prescription Registry, researchers can create a complete overview of patients' overall medication use across general practitioners and hospitals. The DHMR also provides new opportunities to examine off-label medication use and guideline compliance.

Double-counting and misrepresentation of medication sources are limited by documentation of only medication orders with subsequent administration or dispensing by hospital staff. Another strength of the DHMR is the fact that actual administration to inpatients can be tracked, thereby eliminating concerns regarding missing data regarding adherence.

Finally, the registry is updated daily, including information on whether earlier reported data have been changed or deleted. Two regions have assessed the proportion of medication administrations linkable to contacts in the Danish National Patient Registry, and both found a linkage in approximately 95% of cases.<sup>36</sup> This linkage allows for accurate assessment of the context of medication administration, including detailed disease and patient trajectories.

## Limitations

The registry's recent establishment in May 2018 may cause, in rare cases, a risk of patients' medication history being left truncated for selected treatments because some patients will have already experienced an adverse event or medication exposure before the data collection began.<sup>8,46</sup> This may be addressed by including only incident patients.

Also, studies on small sample sizes of patients treated with rarely used medications may be affected by low precision of the risk. Additionally, the registry does not record data from the private sector, which often involves less complex cases. More than half of the referrals to private hospitals are for brief diagnostic visits, and prolonged inpatient care is almost non-existent. However, the private sector accounts for less than 1.5% of Danish healthcare expenses.

As summarized in Table 1, not all hospital departments use electronic medication management systems, but some departments, including oncology and hematology, partly use these systems and, therefore, only report certain medications as administrations, some as procedures, or both. Another limitation is that not all variables have been collected from the start of the registry, thereby increasing the risk of incomplete longitudinal data.

Because medication packages are scanned in connection with medication administration only in the Capital Region of Denmark and in Region Zealand, the validity of medication documentation and cost assessments might differ between

regions. Over time, however, it will be mandatory to report all administrations and new data documentation for the DHMR is scheduled for early 2025.<sup>36</sup> It aims to provide a better and more updated overview of the registry's content. A limitation regarding dispensing is that, as with most prescription registries, the period for which medications are dispensed is often unknown.

Finally, because no studies have yet directly evaluated the data validity of individual variables in the DHMR, some concerns may be raised regarding how accurately the DHMR reflects clinical records and whether the data in the electronic medication management systems accurately represent the medications actually administered to patients.<sup>47</sup>

## **Data Access**

Access to the DHMR is facilitated through the Danish Health Data Authority's Research Service<sup>48</sup> (Danish, Forskermaskinen), which provides secure remote access to data on its servers. To gain access, researchers must work at or collaborate with a Danish institution authorized by the Danish Health Data Authority because only Danish institutions can take on data responsibility for Danish health data.

Accessing DHMR data involves an application process specifying the population and variables needed and requires prior permission from the Danish Data Protection Agency. This permission ensures safety precautions for data processing and defines cancellation deadlines. Researchers working with register-based data in Denmark must comply with the European Data Protection Directive (2016/679)<sup>49</sup> and the Danish Data Protection Act (Act No. 502),<sup>50</sup> which governs access to individually identifiable health data for research while protecting privacy rights and promoting quality research.

## **Perspectives**

Establishing the DHMR represents an important advancement in pharmacoepidemiological research, not only in Denmark but also globally. As the DHMR continues to expand to include all departments and clinical specialties across Denmark, the registry has the potential to provide new insights into the safety and effectiveness of hospital medication use across a nationwide cohort. This is further enhanced by linking data to the Danish Civil Registration System, which enables accurate record linkage and provides data on events such as emigration or death, enabling near-complete follow-up.

In Denmark, access to registry data on hospital medication use not explicitly collected for research<sup>47</sup> has previously been limited to the Danish National Patient Registry or clinical quality registries. Although valuable, these sources record basic and often incomplete data, and often only regarding specialized treatments in selected patient groups, thus highlighting the need for a more comprehensive data source with broad coverage, such as the DHMR. In addition, the DHMR might aid in post-approval monitoring of medications by providing real-world evidence of their effectiveness and safety. The insights gained from data on treatment adherence, patient outcomes, and side effects, including data from comparative effectiveness studies, can provide evidence of a medication's effectiveness in everyday clinical practice.

Further, with increasing hospital medication costs and limited opportunities for conducting health economic studies, the detailed data available through the DHMR can support health economics analyses used for prioritizing resources effectively within the healthcare system and supporting the advancement of personalized medicine.

The DHMR may provide medication data regarding cross-sectoral healthcare utilization and medication errors across care transitions, which was previously unavailable when patients transferred between sectors. Moreover, as similar registries may be established in other countries in the coming years, international collaboration may strengthen in-hospital and hospital outpatient clinic pharmacoepidemiological research on conditions with small numbers of patients, such as new medications for rare conditions. As the DHMR evolves, the registry is likely to have the potential to become an integral part of pharmacoepidemiological research in Denmark.

## **Ethics Statement**

The project was registered in the data processing inventory of Aarhus University (2016-051-000001, record number 812) and The Danish Data Protection Agency (2015-57-0002). Danish law does not require further approval or informed consent for register-based studies using administrative data.

## Disclosure

The authors report no conflicts of interest. The Department of Clinical Epidemiology, Aarhus University and Aarhus University Hospital, receives funding from various companies in the form of research grants to (and administered by) Aarhus University. None of these grants are related to the present study.

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