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Problems Using the Defined Daily Dose (DDD) as a Statistical Basis for Drug Pricing and Reimbursement

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Abstract

The Anatomical Therapeutic Chemical classification and Defined Daily Dose (ATC/DDD) system is used for research purposes to conduct broad scale international drug utilization comparisons. While the system is a good metric for such purposes, it is not appropriate for making pricing and reimbursement decisions. Such misuse is undesirable for a host of reasons, most notably, its ultimately negative impact on patient access to medicines and drug innovation. The World Health Organization (WHO) in its guidance on the appropriate use of the ATC/DDD system specifically warns against such misuse. There is little doubt that the subversion of the ATC/DDD system from a useful utilization metric into an inaccurate pricing lever will eventually leave it completely discredited. For this reason, it is critical to understand why the system was designed, what it was designed for, how it is being manipulated today, and above all, the negative consequences that will result from the system's misuse for pricing/reimbursement.

Introduction

The provision of health care is a global concern and one that impacts people of all nations. However, there is a profound lack of statistical means by which to evaluate the consumption of health care across time, and within and across national boundaries. Traditionally, the statistical system used for evaluating and comparing drug utilization in this fashion has involved the anatomical therapeutic chemical (ATC) classification and its dependant, the defined daily dose (DDD). Each will be detailed in this review.

The History of Anatomical Therapeutic Chemical (ATC) and Defined Daily Dose (DDD) Classifications

From a global perspective, the rise in use of drug utilization studies began in the 1960's. As governments began to understand the importance of identifying and tracking drug consumption and dissemination, they also realized the need for a unified system of comparison. Specifically and formally, at a 1969 symposium entitled *The Consumption of Drugs*, in Oslo, it was determined that an international system of drug consumption measurement was needed. As a result, the Drug Utilization Research Group (DURG) of the Nordic Counsel was established with the goal of creating such a system.¹

In an effort to develop this unified system, the DURG realized that any metric would need to consist of two components; One component addressing the categorization of different medicines used around the world in a single accepted form, and the other providing an accepted unit of measurement to compare a classification. The result was the adoption of the ATC/DDD system, which was built from an earlier system used by the European Pharmaceutical Market Research Association (EPHRA). In successive years, the system was built upon, accepted, and first applied in 1976.²

Since its inception, the ATC/DDD system has experienced continual expansion. The 1981 recommendation from the WHO Regional Office for Europe to use ATC/DDD as an international system and the 1996 establishment of a direct link between the Center for Drug Statistics Methodology and WHO world headquarters are testaments to this expansion. Currently, the stated purpose of the ATC/DDD system is “to serve as a tool for drug utilization in order to improve quality of drug use”.²

How ATC Works

The Anatomical Therapeutic Chemical (ATC) system managed by the WHO Center for Drug Statistics Methodology is responsible for classifying a broad range of drugs into comparable categories. To do this, the system employs information concerning the organ and system on which a drug acts, as well as the drug's chemical, pharmacological, and therapeutic properties. Drugs reviewed by the Center receive an ATC code based on this five-tiered system. The following example illustrates an ATC code for metformin, a drug used to treat type 2 diabetes:

Table 1

ATC Schematic Structure	
Code	Specification
A	Alimentary tract metabolism (1st level, anatomical main group)
A10	Drugs used in diabetes (2nd level, therapeutic subgroup)
A10B	Oral blood glucose lowering drugs (3rd level, pharmacological subgroup)
A10B A	Biguanides (4th level, chemical subgroup)
A10B A02	Metformin (5th level, chemical substance)

Source: WHO Collaborating Center for Drug Statistics Methodology.

As figure 1 demonstrates, all metformin drugs are given the code A10B A02. Importantly, while this code allows the comparison of various metformin drugs, produced by different manufacturers in different nations, it does not equate to bioequivalence. In other words, it does not purport that all drugs with the same code are equally safe and effective or potent.

With so many drugs on the market, perhaps it is unfair to task the Center with an analysis and categorization of all known drugs. Indeed, the Center establishes codes based on requests it receives from the users of the system, such as researchers, pharmaceutical companies, and government entities. As one would expect, drugs used in large quantities by numerous nations are more likely to receive a code than those used by a single country. In addition,

another difficulty arises with the fact that many drugs are used for more than one therapeutic indication and exist in a host of dose variations. While the ATC system generally classifies drugs according to their main indication, it has in certain cases, where a drug is available in different strengths and used for more than one therapeutic indication, assigned more than one ATC code to the drug. While some have requested that the ATC system increase in specificity, it is noted that this could ultimately impede the ATC's capacity to establish classifications to compare trends in utilization.

How DDD Works

The defined daily dose is an *artificially and arbitrarily* created statistical measurement used for research purposes in comparing the utilization of drugs. The formal definition of the DDD is “the *assumed* [emphasis added] average maintenance dose per day for a drug used for its main indication in adults”.¹ DDD's are assigned only to drugs that have already been provided with an ATC code. It is important to note that the DDD is not equivalent to the prescribed daily dose (PDD) or, the average amount of a specific drug prescribed to an adult patient for the drug's main indication per day. In fact, in most cases, the DDD differs greatly from the typical PDD of the drug in question. In some cases, this gap may be exacerbated by the fact that a drug may be prescribed in two vastly different dosages and the DDD represents the average of those outliers.

A DDD is assigned by the WHO Center and may first be reviewed by the International Working Group for Drug Statistics Methodology prior to a final decision by the Center. While the ATC/DDD system has clear limitations, it has been used very successfully for its main purpose, namely research into drug utilization.

Use for Research Purposes

The ATC/DDD system has primarily been used to measure the intensity of consumption of a specific drug product in a single nation or between nations overtime. Ultimately, the DDD results in the numerical identification of the amount of drug product consumed per day, per 1000 residents. The amount of drug product consumed by a specific nation is monitored both from the prescribing end (i.e. IMS) and from the IMS data is not prescribing data in every country amount sold (i.e. pharmacy, wholesaler etc.).³ This information is extremely useful in determining the change in drug use over

time of a particular nation. It is also very useful for comparing consumption across nations to identify overuse, under use and misuse. To clarify this point, table 2 illustrates a hypothetical DDD transnational comparison study where total number of DDDs = the total amount distributed / the defined daily dose.^a

Table 2: Hypothetical DDD Comparison

Country	DDDs/Population * 1,000	DDDs per 1000 Residents per Year
A	1000/100,000 * 1,000	10 DDDs
B	4000/201,000 * 1,000	19.9 DDDs
C	800/90,000 * 1,000	8.88 DDDs
D	790/89,000 * 1,000	8.87 DDDs
E	750/77,000 * 1,000	9.74 DDDs

In this scenario, involving five different nations, it is clear that the average number of DDDs per 1000 residents is about 9. By comparing the data, it is also clear that there is a discrepancy involving country B, which has about twice the number of DDD's per 1000 residents as the other nations suggesting possible overuse. As a result, these findings allow researchers to further examine country B to determine the reason for the difference. It should be noted that the difference could be the result of many different factors including different label restrictions, different reimbursement characteristics and restrictions, different combination products in use, different versions of the WHO dictionary in use, overuse, special population characteristics, or special medical problems. In all cases, additional research is often needed to determine the cause.

The primary goal of conducting ATC/DDD analyses is to improve drug use. The WHO Center has illuminated several specific examples of how this type of analysis can be used to improve overall use²:

- National publications, which provide clinicians, pharmacists and others with a profile of drug consumption in the country (with or without comparisons between countries or between areas within the country).

a) A hypothetical total # DDDs calculation for this scenario might be 2,000kg of product/ 2kg (DDD) = 1,000.

- Publications providing feedback within health services to individual health facilities, groups of health care providers, or individual health providers.
- Use of drug utilization statistics by national health systems, universities, drug information centers, and others to identify possible overuse, under use or misuse of individual drugs or therapeutic groups. Depending on the situation this information can then be used to initiate specific studies or specific educational interventions. Educational interventions may include articles in drug bulletins, articles in scientific journals, letters to clinicians, etc.

ATC/DDD Misuse

Clearly, the ATC/DDD system is useful for comparing drug consumption between nations and over time on a macro-level. However, increasing pressure to reduce overall health care costs has prompted some governments to consider and use the ATC/DDD system as a basis for making pricing and reimbursement decisions.

On a broad scale, governments (typically those with a national health care scheme) can use price comparisons as leverage for forcing manufacturers to reduce prices. For example, a regulating body, in comparing the price per DDD of two similar ATC coded drugs, can opt to add the cheaper of the two to its formulary, thereby providing reimbursement for the cheapest drugs. While slightly effective in reducing short-term costs, utilizing this policy may eventually lead to elevated health problems and increased overall costs.⁴ The cheapest drug is not always the best drug. As we will see, this process is dangerous because a price per DDD calculation places a premium on cost savings but not on optimal therapeutic outcome. Furthermore, this process may ultimately discourage new research, as this approach does not reward new medicines or therapeutic improvements to already marketed drugs.

Physician Influence

In addition to misusing ATC/DDD for pricing and reimbursement purposes on the patient side, some governments have also begun to apply the system to the regulation of physician practice. Increasingly, physicians' prescribing habits may be monitored and regulated in terms of the artificially established DDD, the original purpose of which is for research and not for therapeutic prescribing. In this subverted use of the ATC/DDD system, physician compensation from the health insurance provider is adjusted according to the physician's proximity to the DDD for particular drugs. In other words, if the physician is prescribing medicine in higher quantities than

the internationally recognized DDD, s/he will receive a reduced remuneration from the provider. As a result of this practice, physicians are forced to alter their prescribing patterns to accommodate a metric that has no applicability in terms of providing appropriate treatment. With the system used in this subverted manner, the physician is no longer making prescribing decisions based on experience or patients' needs but on an artificially calculated metric.

Why Can't ATC/DDD be used for Pricing and Reimbursement Decisions?

It is widely understood that decisions concerning reimbursement and prices ultimately impact patient health. What follows is a description of why the ATC/DDD system is inappropriate for such decision-making:

A DDD is an “Assumed” Daily Dosage: A given DDD represents an international compromise on an artificial number because the system is intended for research purposes, not decisions that will have an immediate impact on patient health and welfare. A given DDD does not take account of outcomes and efficacy or duration of treatment.

For most drugs there is no single dose but rather multiple variations prescribed depending on the severity of the patient's condition or the level of tolerance. Moreover, prescribing practice and medical customs differ from country to country. As a result, an international compromise must be made that often has little to no relevance to actual prescribing practice from one country to another.

Drugs Are Not Classified in Terms of Therapeutic Outcome: It is important to understand that an ATC classification does not take into consideration the therapeutic profile of individual drugs. It assumes that all drugs within the same ATC code have exactly the same efficacy and ultimate health outcome. This is a faulty assumption because the ATC system was designed to be broad enough for research purposes to make useful macro-comparisons between nations using different drugs. Individual drugs classified in the same ATC level cannot be considered pharmacotherapeutically equivalent since their mode of action, therapeutic effect, drug interactions and adverse drug reaction profile may and more likely than not, do differ.

ATC/DDD Does Not Account for Drug Improvements: Because the ATC/DDD system is designed to support general macro level research, it inherently must classify widely diverse but similar drugs under single ATC codes. As a result of this necessity, new drugs, specifically those that are improvements on older drugs, often do not receive new codes as they are essentially similar to older classifications. The net effect when applied to pricing/reimbursement is that a P&T Committee can ignore improvements in drug treatment and reimburse the cheapest drug in an ATC classification, regardless of the improvements made for a specific drug.

Therapeutic Effects: Different drugs with the same ATC code are often formulated differently and therefore, vary in quality and potency. Neither equipotency nor the route of administration are incorporated within an ATC/DDD measurement. Clearly, different dosage forms will have different levels of efficacy. For example, as one researcher puts it, “an intravenous dose is usually more potent than an oral dose of equal strength”.⁵

Multiple Indications and Combination Drugs: The ATC/DDD system classifies drugs according to their main indication while most drugs are used for more than one indication. For example, diazepam, according to its ATC code is found under the central nervous system, subgroup tranquilizers (N05BA) and not antiepileptic or anesthetics, whereas the WHO’s essential drugs list has a separate code for diazepam under each condition.⁵ Drugs which treat multiple indications offer a therapeutic advantage, which is not reflected in the ATC/DDD system.

Duration of Treatment: The ATC/DDD system does not factor the duration of treatment of individual drugs. One could assume that a drug with a shorter treatment time would offer a greater likelihood of patient compliance and thus would improve therapeutic outcome. Additionally, a drug that costs more but works better and requires a shorter duration of treatment is ultimately more cost effective than a drug that is cheaper but requires a longer treatment scheme.

Clearly, the ATC/DDD system is riddled with flaws when viewed from the point of view of pricing/reimbursement. This, however, does not equate to an attack on the system itself but only on the manipulation of its use. The creators of the system are fully aware of its limitations, most of which stem from the general nature of classifications. Policy and healthcare decision makers must realize that the ATC/DDD system generalizes because it must

allow for broad drug utilization comparisons across widely different health care arenas. Understanding the disastrous effects of the misuse of the system, the WHO has repeatedly, while not always clearly, discouraged the use of ATC/DDD for pricing/reimbursement decisions.

The WHO View

Since 1996, the WHO Collaborating Center for Drug Statistics Methodology has been the primary body deliberating on the use of ATC/DDD at the international level. From its creation to today the Center has basically maintained that using ATC/DDD for pricing and reimbursement decisions is a misuse of the system. As we will see, however, the Center's guidelines have been modified over the years, in some cases, to accommodate governments already using the system inappropriately. Each year, the Center's working group meets to discuss the use of ATC/DDD and update its guidelines. Viewing these guidelines, with respect to their discussion of pricing, shows how the WHO, as recently as 2004, has been manipulated by member states to adjust its stance on ATC/DDD use. (See table 3)

Table 3: Selected Guidelines from the WHO’s Center for Drug Statistics Methodology Concerning ATC/DDD use for Pricing

Year	Guideline
1996	<p>“Basing Reimbursement decisions indiscriminately on certain ATC groups is not recommended, since the indications for use of drugs often differ widely between countries, and the ATC code is decided according to what is considered to be the main international use. The grouping of pharmacotherapeutically equivalent drugs should always be based on review by national clinical experts. It is important to emphasize that the main purpose of the ATC/DDD system is to be a tool for presenting drug consumption figures. This will influence the basis for assignment of both ATC codes and DDDs and may make it less suitable for other purposes.”⁶</p>
2000	<p>“Drug Utilization data have a central role in the quality of care cycle, and are essential to manage policy related to drug supply, pricing, cost and use. The ATC and DDD methodologies can be helpful in following and comparing trends in cost, but need to be used with caution. Basing detailed reimbursement, therapeutic group reference pricing and other specific pricing decisions on the ATC and DDD assignments is a misuse of the system.”⁷</p>
2001	<p>“Basing reimbursement, therapeutic reference pricing and other pricing decisions on the ATC/DDD classifications is a misuse of the system. Defined Daily Doses are not designed necessarily to reflect therapeutically equivalent doses.”⁸</p>
2003	<p>“Basing reimbursement, therapeutic reference pricing and other decisions on ATC/DDD classifications is a misuse of the system. Defined Daily Doses are not designed necessarily to reflect therapeutically equivalent doses.”⁹</p>
2004	<p>“Drug utilization data have a central role in the quality of care cycle, and are essential to manage policy related drug supply, pricing, cost and use. The ATC and DDD methodologies can be helpful in following and comparing trends in cost, but need to be used with caution. Basing detailed reimbursements, therapeutic group reference pricing and other specific decisions on the ATC and DDD assignments is a misuse of the system.”¹⁰</p>

The Italian Case

The Italian use of ATC/DDD provides the best example of how member states can influence WHO to change guidelines legitimizing their already subverted use of the system. Looking for ways to curb health care costs, the Italian Ministry of Health, in 2002, “requested WHO’s advice on the use of Defined Daily Doses (DDDs) in its review of the list of reimbursed pharmaceuticals”.¹¹ The WHO’s response was that using DDDs to review reimbursed pharmaceuticals could be a complementary element to guide the CUF (Commissione Unica del Farmaco) as long as they were aware of the inevitable limitations, that all concerned parties were involved in the pre-implementation discussion phase, and that the whole system be open to permanent review”. Beyond this, it was reported that WHO staff were involved in the Italian government’s use of ATC/DDD to develop a national cost-containment policy.¹² As of 2003, the Italian government’s use of ATC/DDD has been “crucial to define the new National Pharmaceutical Formulary”.¹³

Because the Italian Ministry of Health was already using ATC/DDD to make pricing/reimbursement decisions in 2003, it was highly interested in petitioning the WHO Center for Drug Statistics Methodology to change its guidelines regarding the systems use. Specifically, the Director General of Italy’s Ministry of Health asked the WHO Center to “modify the statement regarding the use of the ATC/DDD methodology in reimbursement procedures.”¹³ The seeming result of this intervention can be seen in the Center’s adjusted guidelines as of 2004 concerning pricing/reimbursement, which is much less critical of ATC/DDDs use for this purpose (see table 3).

This scenario is objectionable in several ways. First, the WHO should not allow individual member states to influence its stance on critical global health policy issues such as ATC/DDD. Second, WHO staff should not be involved in aiding governments to use the ATC/DDD system for pricing/reimbursement when an expert group authorized by the WHO has affirmed that such action constitutes misuse. Third, neither physicians nor patients were consulted on the implications such changes might have for the state of public health and the integrity of the ATC/DDD methodology in a rules based system.

Why do they do it?

In examining the realities of the way the ATC/DDD is increasingly misused in various countries, one is left confused as to why any nation would apply a system to the important issue of deciding drug reimbursement. The answer lies in the increased pressure on governments to reduce health care expenditures by whatever means possible. Stated bluntly, the ATC/DDD system allows individual governments to validate their selection of the cheapest drugs for reimbursement because they can claim that these selections are based on an internationally recognized system of drug comparison. Governments use ATC/DDD for pricing and reimbursement decisions because it shields them from owning up to the reality of their decisions. They use it as an excuse to select the cheapest drugs on the market, potentially at the expense of the public's health, without having to come out and say what they are really doing, selecting the cheapest drugs available. According to the Italian Ministry of Health, "the CUF identified a cut-off (based on the DDD system) within each therapeutic category and required pharmaceutical companies to adjust the price of their products if they wanted their drugs to continue to be admitted to reimbursement. This readjustment, at no cost for the patients, produced a saving of around 2% of the total drug prices reimbursed by NHS."¹³ But there are some fundamental issues that the Italian government neglected in its confident assertion of savings. What about the cost borne by patients who can no longer receive the best available medicines for their conditions? What about the additional medical care and associated expenditures needed to counterbalance the absence of the highest quality drugs? Why is there no attempt to measure the reduced quality of life that inevitably accompanies ATC/DDD misuse? What is the anticipated impact of declining physician autonomy in deciding what drug and dosage level is best for patients?

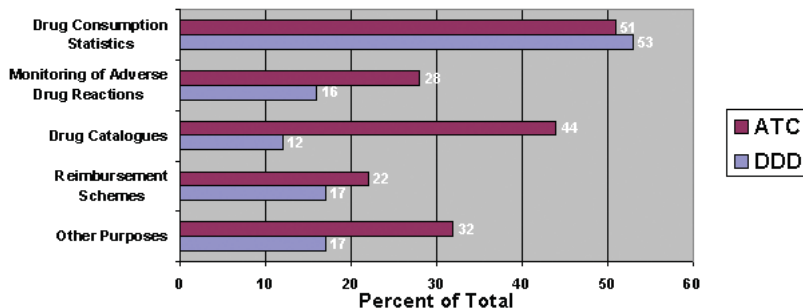
The Effect of Misuse

In the most immediate sense, the use of ATC/DDD for pricing and reimbursement leads to a decrease in the quality of healthcare that patients receive. This occurs because patients can be denied access, through lack of reimbursement, to the best medicines available. Unfortunately, while there is no current data on the long-term added health costs of the misuse of ATC/DDD, it can be expected that these costs, will far outweigh any minimal short-term savings.

Beyond this initial concern lies the pejorative effect that ATC/DDD misuse will have on the system itself. Ultimately, as health care costs do not significantly decrease as a result of ATC/DDD's subverted use, and patients' become aware that they are no longer receiving the best possible treatment for their conditions, the good name of the ATC/DDD system will be tarnished. Additionally, as WHO member states are highly involved in the deliberations that determine the DDD values, once it is converted to a pricing tool, those values are sure to become reflections not of actual drug use but of the need for governments to reduce drug costs. In other words, it is possible to envision a scenario where government representatives to WHO intentionally lower DDD values with the hope of securing overall lower DDD values relating to decreased reimbursement levels. Clearly, by allowing individual governments to manipulate the system for their own monetary interests, the metric will be further transformed from a useful utilization tool to an inaccurate pricing lever.

Figure 1

Results from an International Survey in 1995 Concerning the Use of ATC and DDD



Source: Adapted from Hanne Strom. Different Uses of the ATC/DDD Methodology. WHO Collaborating Center for Drug Statistics Methodology. Oslo, September 9-10, 2004.

Conclusion

In order to curb rising health care costs across the globe, pharmaceutical regulators are searching for the winning formula that is equal to the task. Clearly, the ATC/DDD system, while useful for making broad scale drug utilization comparisons, is not such a formula. Many experts, including the authors of this review, are concerned that the use of ATC/DDD for pricing and reimbursement decisions will not only lead to a bad name for a good metric, but ultimately to decreased health care quality and reduced incentive for new medicines innovation. While it is easy to use a readily available but inaccurate system for determining reimbursement and pricing schedules, it is hard to justify the negative impacts that those measurements will have on patients' health.

In conclusion, when dealing with classification systems and taxonomy, it is essential to keep in mind four core principles. First, public health depends on the quality as well as the quantity of pharmaceuticals consumed¹⁴. Second, there is no single drug classification system today that fits all of the diverse needs of drug utilization research, and no drug utilizations system should be used unless validated for its intended purpose. Third, use of a drug classification system for a purpose for which it was not created, such as the

misuse of the WHO ATC DDD system for pricing and reimbursement purposes, diverts public health policy development away from a focus on the patient. Four, new approaches, such as the development of new tools and integrating existing ones, are needed for drug utilization research to measure how new medicines impact the patient and public health - such as looking at access to drugs by disease area or by “vintage” of the drugs available to patients.

Further collaboration and research in the field of drug utilisation is needed to facilitate the development of patient focused public health policy.

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