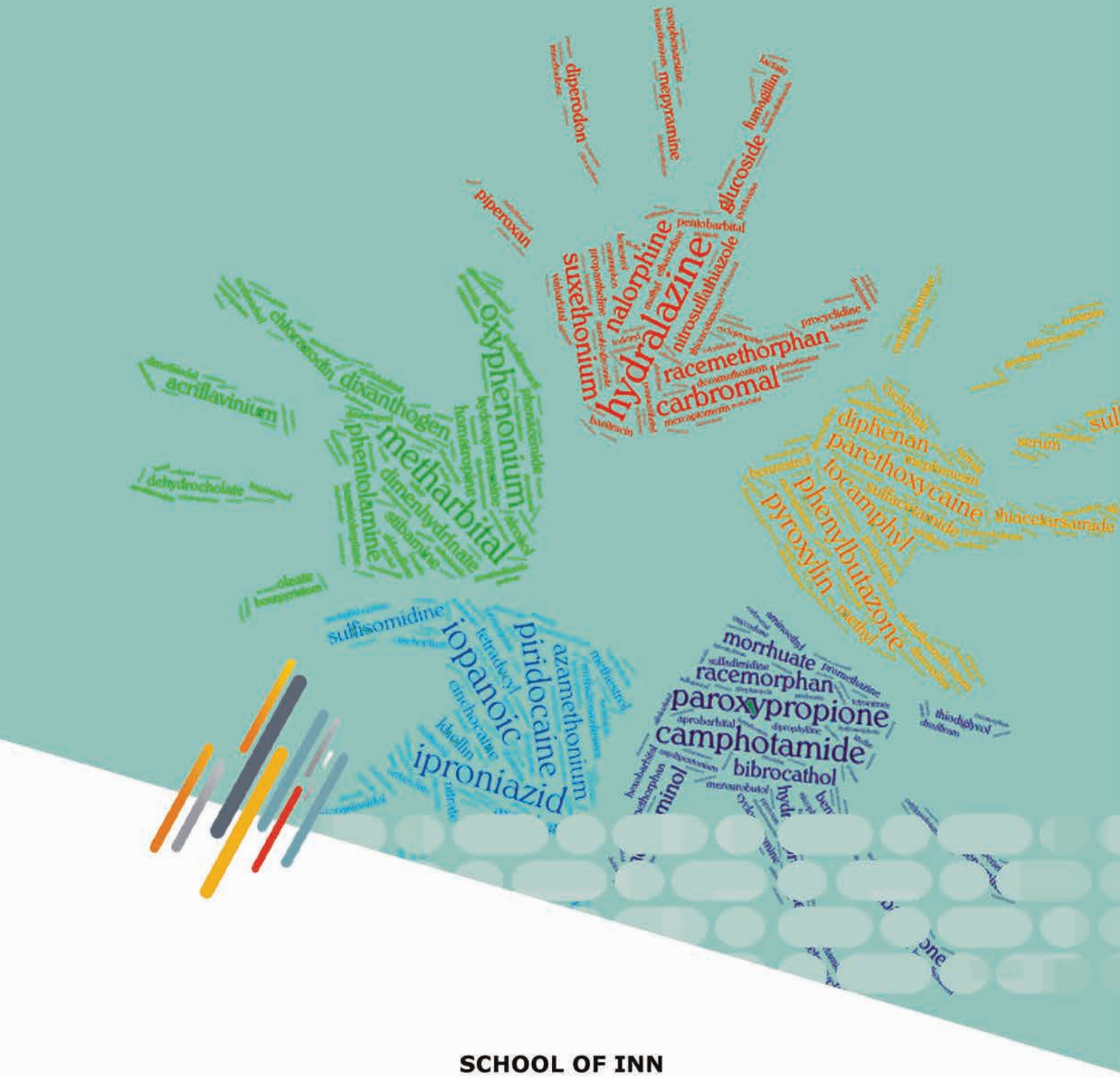

SCHOOL OF INN

Learning clinical pharmacology with the use of INNs and their stems

World Health Organization

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TABLES

Any student who studies pharmacology and therapeutics will tell you that remembering the names of drug substances and their mechanisms of action is one of the most challenging tasks. Healthcare professionals also find it demanding to keep up with the names of new therapeutic agents. Knowing how to classify medicines in a systematic way and assisting healthcare professionals to select the most appropriate medicines for their patients is of utmost importance in ensuring efficacy and safety. Names of medicines come in different formats; there are chemical names, generic names and brand names. They are derived from different approaches and some are more practical than others in the clinic; but they all are intended to identify the active pharmaceutical ingredient. Patients, who are not technical experts of medicines, can find names confusing and may encounter risks, particularly in self-medication. For example, as the same active pharmaceutical ingredient can appear in different brands of a medicine, unknowingly the patient may consume the same active ingredient from different brands thus leading to drug overdose or toxicity. Therefore, protection of the patient against potential health risks is central to medicine nomenclature.

The International Non-proprietary Name (INN) Programme

The World Health Organization (WHO) has recognised and supported the importance of safety among users of medicines regardless of whether they are manufacturers, health professionals, patients or consumers. Therefore, WHO established The Programme on the International Nonproprietary Name (INN) for pharmaceutical substances in 1950 through resolution WHA3.11 of the World Health Assembly. This programme has been active since 1953. The main objective of setting up the INN Programme was to provide a unique single name for a pharmaceutical substance that is accepted globally. The INNs are intended to be used as public property without restraint. Since its inception, WHO has also taken the initiative in collaborating with national nomenclature organisations, pharmacopoeial commissions and regulatory agencies to harmonize the usage of the developed INNs. Recently, the INN Programme also opened its doors to frequent dialogue with the inventors and manufacturers of pharmaceutical substances while feedback from health professional organizations, patient advocates and consumer organizations are valued and considered in the naming process. All this is done in an effort to raise more awareness of the INN system as well as to strengthen the advocacy of ensuring patient safety.

The Science of Drug Nomenclature

The development of INN has evolved with time; new approaches and additional guidelines are continuously being included in the process of creating unique names for pharmaceutical substances. The naming of medicines is an evidence-based process and indeed it is part and parcel of evidence-based medicine. The science behind drug nomenclature has advanced over the years with the advent of better analytical techniques for identification and purity verification. With the introduction of biotechnological methods that are used in the manufacture of biologics and other biomedical treatments, the characterization of biologicals has become more precise and unambiguous. All these new advancements have underpinned the development of more sophisticated chemical and biological therapeutics and with this advances, the naming of new pharmaceutical substance candidates has become more complex and challenging.

In the early years of the INN Programme, modification of the chemical name was an acceptable approach to create the INN. As more pharmaceutical substances were being discovered and many of them shared similar chemical structures, although the mode of actions could be different, this approach eventually was superseded by other methods. Moreover, structural information was less informative or useful for the prescribers and dispensers. Gradually, with the discovery of more targets and with new medicines continuously being designed and used clinically, a move to using the mode of action to name the newer pharmaceutical substances became more prevalent. This mode of action became linked to a specific 'stem'.

What is a stem?

An INN typically begins with a random prefix, possibly followed by one or more infixes/substems and terminates with a suffix/stem. INN can also consist of more than one word. The stem, that usually coincides with the suffix, could also in principle be a different part of the word. A stem is a syllable (or 2-3 syllables) to indicate the pharmacological relationship and is developed based on three criteria, the mode of action, and/or the clinical use, and the structure. The purpose of the stem is to group medicines that have similar therapeutic use or clinical action, this minimises the co-use of similar medicines which would increase adverse reactions, and facilitates the use of an alternative medicines when one becomes ineffective. Stems usually coincide with the suffix but can in principle appear in a different part of the word. Every two years the INN Programme publishes a document containing extensive information about the INN stem system and the complete WHO stem book: "The use of stems in the Selection of International Nonproprietary Names for Pharmaceutical Substances", which is complemented twice a year, after each INN Consultation, by an Addendum.

Thus the stem in the INN is a guide towards the mode of action or pharmacological class and defines the pharmacologically related group to which the INN belongs. Stems and their definitions have been selected by WHO experts and are used when selecting new INNs. As the nomenclature process is on-going and constantly under revision, the definitions of older stems are modified as and when newer information becomes available. Whenever possible, an INN should include an established stem expressing the pharmacologically-related group to which the substance belongs. Names that are likely to convey an anatomical, physiological, pathological or therapeutic suggestion are avoided. It should be highlighted that INNs are issued before a drug is marketed and typically even before it has completed its clinical development. It may therefore occur, in particular instances, that the INN reflects the knowledge at the time of its issuance, but which may have been surpassed when the drug arrives on the market.

For each stem, INNs in the WHO stem book are classified as (a), (b) or (c) where:

a. INNs in which the preferred stem has been used in accordance with its definition;
b. INNs in which the preferred stem has been used, but not in accordance with its definition;
c. INNs which belong to the same group of pharmaceutical substances but in which the preferred stem has not been used. (This part of the list is not exhaustive).

Sometimes sub-stems are established to differentiate between different related groups of substances.

Layout of information