MEDICINE SHORTAGES IN A GENERAL COUNTY HOSPITAL: EVALUATION AND ESSENTIAL QUALITY

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Objectives: Medicine shortage in hospitals is defined as insufficient supply from pharmacy, without generic substitution. The particular problem has been reported by both professionals and patients over recent years and acknowledged by the European Medicines Agency and European Commission. The cited causes are multifaceted, ranging from production disruptions, natural disasters, discontinuations to difficulties created by regional conditions. This study aimed to register medicine shortages in a 680-beds general hospital during one year, analyze the causes and correlate them to medicines' ATC and essentiality.

Methods: Medicine shortages were reported daily from 1st August 2017 to 31st July 2018 and analyzed according to 3 causes:

a) Medicine' s Withdrawal (permanent discontinuation of medicine),

b) Manufacturing/Importing problems (e.g. production in/import of small quantities, price policy), and

c) delayed Hospital Pharmacy's Response to stock replacement (HPR) (e.g. delayed order, insufficient orders' follow-up – undelivered orders).

Days to restore availability were recorded and categorized into 2 groups: 1-3 (automated re-stock) and more than 4 days (pharmacists' involvement). A minimum of 3 days from order delivering to receive medicines should be taken into account, due to hospital' s geographical location (all distribution and logistic centres are located in Athens).

Shortage cases were stratified according to Anatomic Therapeutic Category.

All medicines recorded short were classified into 5 classes using a Modified Essentiality List (MEL), based on the WHO model list of essential medicines (20th List, March 2017): 5, 4 and 3 according to WHO model list of essential medicines, 2 attached to medicines excluded from WHO list and OTC local list and 1 attached to OTC local list.
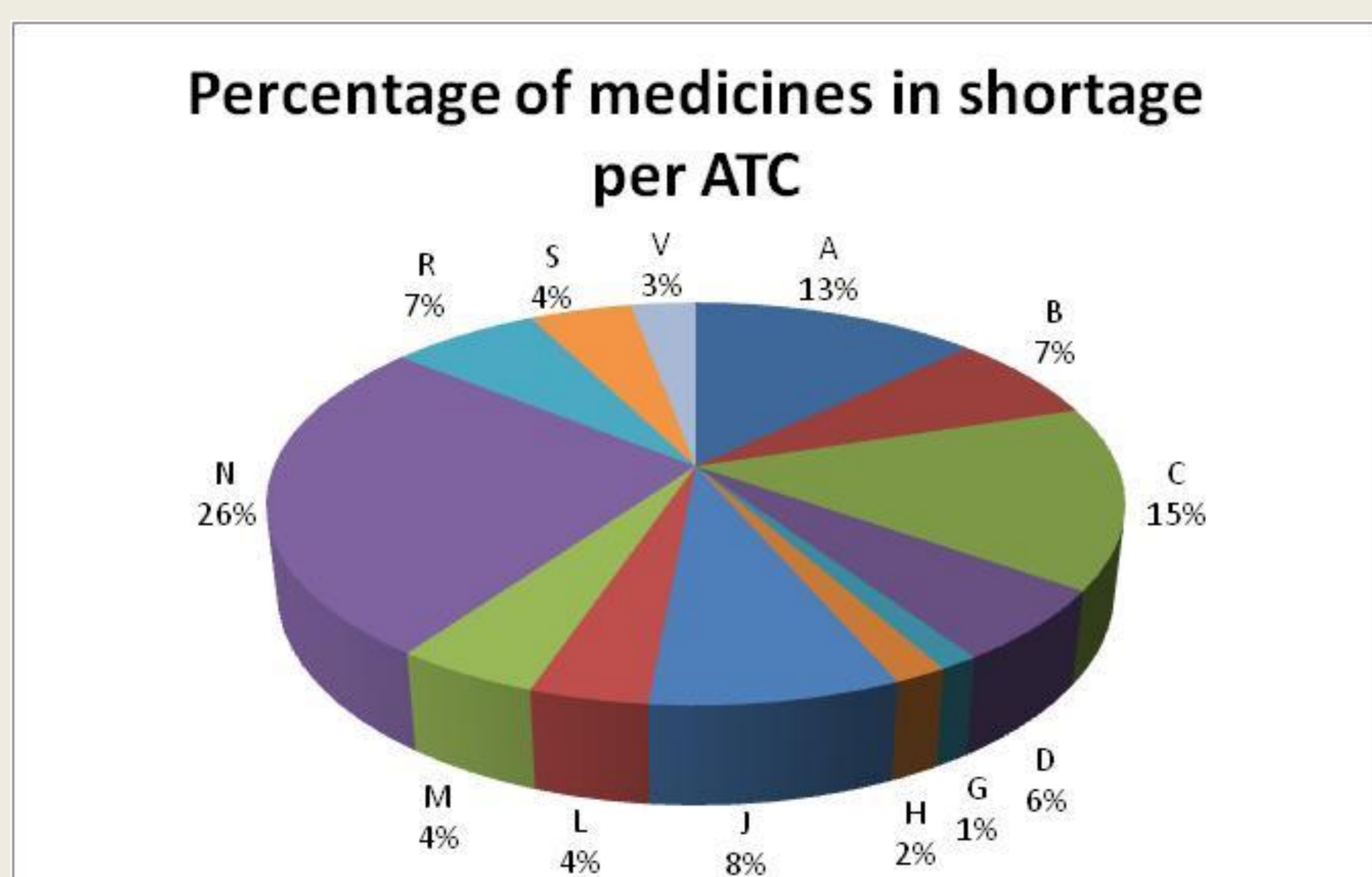
Results: 299 shortage cases were reported concerning 239 medicines. A new shortage case was reported every 1.2 days. 4% concerned Medicine's Withdrawal, 40% Manufacturing/Importing problems and 56% delayed Hospital Pharmacy's Response.

Average days to restore availability for Manufacturing/Importing problems and delayed Hospital Pharmacy's Response was 52 and 11, respectively. For Manufacturing/Importing cause, 114 shortage cases (94.21%) needed more than 4 days to restore, while for delayed Hospital Pharmacy's Response cause 97 cases (58.43%).

Neurological and cardiovascular regiments' shortages were first (26%) and second (15%) categories respectively, regardless cause. For Manufacturing/Importing cause, neurological regiments' shortages were first (21%) and medicines for alimentary track and metabolism second (13%) categories.

Modified Essential List class 5 comprised 53 cases (18%), including Lithium (ATC N05AN01), Nitroglycerine (ATC C01DA02), Verapamil (ATC C08DA01), Loperamide (ATC A07DA03) and Tuberculin (ATC V04CF01). Modified Essential List class 2 comprised 152 (51%) cases.

Levels of Modified Essential List of 20th WHO model list of essential medicines	Shortage cases	Medicines in shortage
5 Core List of WHO model list with high level priority	53	23
4 Core List of WHO model list with high level priority but also with clinically similar solutions	44	34
3 Complementary List of WHO model list	13	12
2 Medicines excluded from WHO model list and OTC local list	152	126
1 Medicines of OTC local list	37	23

Percentage of medicines in shortage per ATC

Shortage Cause	Shortage cases	Percentage
Medicine's Withdrawal (MW)	12	4%
Manufacturing/Importing problems (M/I)	121	40%
Delayed Hospital Pharmacy's Response to stock replacement (HPR)	166	56%

	Time to re-stock			Average time to re-stock
	Shortage cases (% percentage)			days
	1-3 days	4-8 days	>8 days	
Manufacturing/Importing problems (M/I)	7 (5.79)	27 (22.31)	87 (71.90)	52
Delayed Hospital Pharmacy's Response to stock replacement (HPR)	69 (41.57)	50 (30.12)	47 (28.31)	11

Shortage essentiality based on MEL
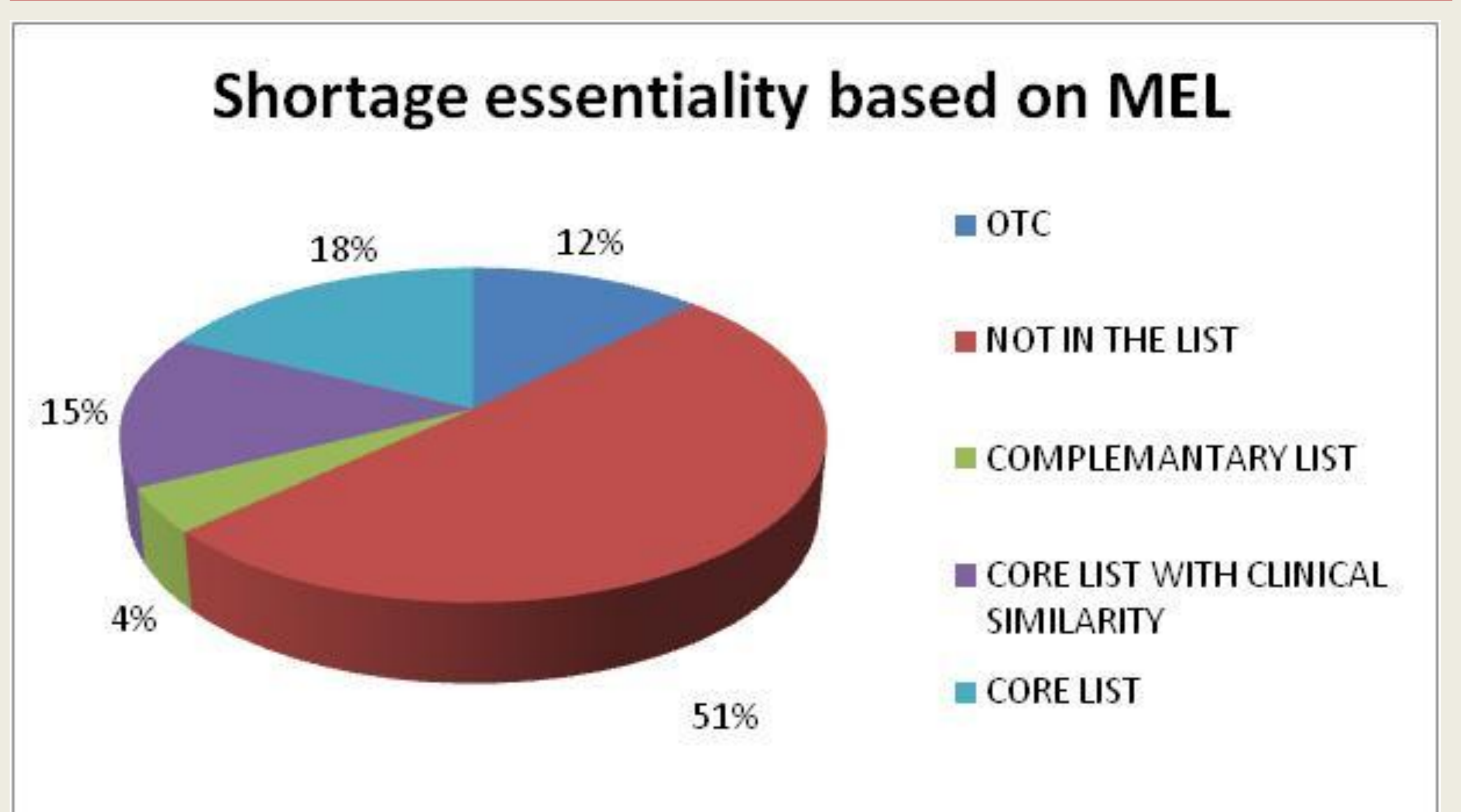
Discussion:

• The frequency of shortage reporting is quiet high (0.81/day).

• For shortage cases reported, delayed Hospital Pharmacy's Response is responsible for more than half of the cases (56%). In practice, this is due to pharmacy's difficulty to predict hospital's needs and subsequently to place an order timely to suppliers, due to failure to communicate with the supplier (via fax or e-mail), due to limited stock of medicines in hospital pharmacy, or due to special circumstances that prevent the product from being transported on time (weather, strikes etc).

• When delayed Hospital Pharmacy's Response is the cause, time to restore availability is reduced: average time to re-stock is 11 days compared to 52 days, being the average time to re-stock when a shortage is due to Manufacturing/Importing problems. In both cases, hospital pharmacists' involvement is important factor for time to re-stock or to find alternative solutions.

• Neurological and cardiovascular medicines were the two more frequent ATC categories to be found in shortage.

• The use of Modified Essential List of WHO (WHO essential list extended with non-essential according to WHO and ATC medicines), permitted stratification of shortages according to essentiality and available clinically equivalent solutions.

• 18% of shortages are classified as class 5, high level priority medicines, meaning that no clinically equivalent substitution was automatically available.

• Shortages classified as class 1 and 2 represented 66%; in these cases the crucial cost for dealing with shortages is not the clinical one (impact on patient) but the one related to time of hospital pharmacists needed to find an appropriate solution, in collaboration with other healthcare professionals.

Conclusions:

➢ Shortage cases are very often reported in hospital pharmacy.

➢ Delayed Hospital Pharmacy Response is the more frequent reason for a shortage case, the quicklier to resolve, but demands strong pharmacists' involvement.

➢ For the Manufacturing/Importing problems as cause of shortage, there is a much longer restoration time.

➢ The re-ordering model of our pharmacy is being reviewed and orders' follow up is now more frequent.

➢ Use of Modified Essential List classification sets the priority for an efficacious response especially if combined to local distribution conditions. Our aim is to combine Modified Essential List classification with duration of shortage to safely conclude shortages' importance and act accordingly.

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