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Editorial

I am happy to share with you that our journal, International Journal of Community Pharmacy (IJCP) is now one of the online indexed journals. IJCP is now officially indexed in Budapest Open Access Initiative and Directory of Open Access Journals. Hence we are happy that our journal will be accessed and will reach globally to professionals across the world.

Further, I am happy to announce the 62 Indian Pharmaceutical congress will be held at Manipal University during 17-19 December 2010. The focus of the 62 IPC will be on Hospital Pharmacy, Clinical Pharmacy and Community Pharmacy. Although India has established leadership in Pharmaceutical Industry, there is a need to reengineer the profession in the areas of patient safety and pharmaceutical care. There is need to popularize the fields like pharmacoeconomics and pharmacoepidemiology.

The Association community Pharmacists of India has completed its two years and is able to establish itself as a leader in promotion of patient care. It has given encouragement for many young pharmacists to realize the importance of community pharmacist in health care.

In years to come the ACPI will be able to motivate the pharmacists to indulge in patient related services, which are presently not available in India.

Prof N Udupa

Editor In Chief, IJCP

MESSAGE FROM ACPI

Dear colleagues members,

The patient safety is not only ignored but remain un addressed in the current health care practice in India. There are numerous incidents and causes leading to drug accidents, failure in out comes and injuries to the patient, which are avoidable which if, addressed in a systematic manner. As there is no documentation in clinical practice what would have gone remains a mystery. There are also poor redresses regarding medical negligence despite of medical services being covered under consumer protection act in the country. As it is unfunded reward less, it seems it is convenient to pretend ignorant and attend in case of being detected or caught.

The pharmaceutical illiteracy and lack of appreciation for pharmaceutical care has led to the vulnerability of patients to many avoidable drug accidents make it all the important to give attention.

The practice of pharmaceutical care would bring the much-needed identity for the pharmacists, who at present are obscure in health care. This would make the health care accountable for outcomes, by identifying what would have been gone wrong in disease management. The pharmaceutical care could assist and strengthen the existing health care system

It is high time for the entire community pharmacist to stand up for the cause of patient safety and ethical practice in community pharmacy services.

I am very much happy to announce you that association has completed annual Audit 2009-2010, which is available for your comments,

With regards,

President, ACPI

REVIEW ARTICLE

EMERGING TRENDS OF RFID IN ANTI-COUNTERFEITING

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Abstract

RFID technology plays an important role in the pharmaceutical industry by reduction of the counterfeit drugs in the market. Radio frequency Identification (RFID) is a technique through which any product can be tagged which stores all the static information about it. When the product moves along the supply chain, the product being tagged at every stage of the movement helps in updating the database of the drug product. An emerging infrastructure in anti-counterfeiting is the EPC network, which can be used to provide pedigree information of the drug products and makes plausible checks possible. But the cost of technology, immaturity and lack of standards restrict the adoption of this technology in India.

Introduction

Counterfeit drugs are defined as those containing no active ingredient, an incorrect amount of active ingredients, incorrect ingredient, and/or unapproved labeling and packaging. Product counterfeiting is an ever increasing problem that affects trademark and brand owners, governments, as well as consumers. Though some aspects of the problem are often considered relatively harmless by the public, the intellectual property rights and investments of licit businesses must be protected [1] [2]. Furthermore, in more dangerous forms of product counterfeiting, the fake products are injected into the licit distribution channel and sold as genuine articles. While potentially risking the health and safety of consumers, in this way the counterfeiters can sell their articles in higher price for higher profits. As a result, the licit supply chains need to be protected from counterfeit products. Traditionally, the problem of counterfeit pharmaceuticals has been limited to developing nations in Asia and Africa. Now, drug counterfeiting is rapidly becoming a worldwide concern, and counterfeit drugs are reaching the U.S. market. The International Chamber of Commerce estimated that seven percent of the world trade is in counterfeit goods, with the counterfeit market being worth 500 billion USD in 2004. US pharmaceutical market annual sale revenue is approximately $200 billion but the US pharmaceutical industry loses approximately $2 billion to counterfeiting annually. In addition to loss of sales, counterfeiting tarnishes the reputation of a trusted brand. Pfizer confirmed three cases of fake Viagra being sold in pharmacies in California[3]. Radio-frequency identification (RFID**)** is a technique through which a product, animal, or person is identified with the help of certain objects known as RFID tags. In 1946 an espionage tool was invented for the Soviet Union by León Theremin which had capability of retransmitting incident radio waves with audio information. Sound waves vibrate a diaphragm which slightly alters the shape of the resonator, resulting in modulation of the reflected radio frequency. The device was considered as a

predecessor of RFID technology and the first U.S. patent associated with the abbreviation of RFID was granted to Charles Walton in 1983.

How The Technology Works?

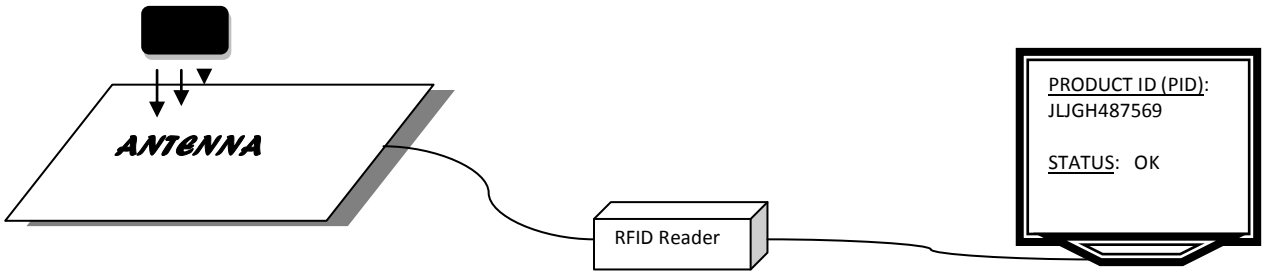
The RFID technology can effectively thwart counterfeiting in pharmaceutical manufacturing. These RFID tags are applied to or incorporated into a product and the emitting radio waves are tracked. Some RFID tags can be read from several meters away and beyond the line of sight of the reader [4]. Most RFID tags are made up of two parts. One is an **integrated circuit** and the other is an **antenna**. Integrated circuit is used for storing and processing information, modulating and demodulating a radio-frequency (RF) signal, and for other specialized functions .The antenna (Fig.1) is used for receiving and transmitting the signals [5].

There are generally three types of RFID tags:

- ✓ **Active RFID tags**: They contain a battery and can transmit signals autonomously.
- ✓ **Passive RFID tags**: They have no battery and require an external source to provoke signal transmission.
- ✓ **Battery assisted passive (BAP) RFID tags**: They require an external source to wake up but have significant higher forward link capability providing great read range.

Basically, **EPC** (Electronic Product Code) network is designed to ensure global interoperability along the supply chain from manufacturer to distributor to retailer and then to stores. EPC Information Services are individual companies' databases that contain the details related to a product .Every company host a publicly accessible EPC IS that would contain the Manufacturer ID, Object class, SKU number, description, size, weight, packaging and various other data that are appropriate to share with supply-chain partners. Additionally, the EPC IS maintains a record of each EPC status change for that site i.e. shipment to customer, receipt from supplier, etc., and communicates that status change to the EPC Discovery Service.

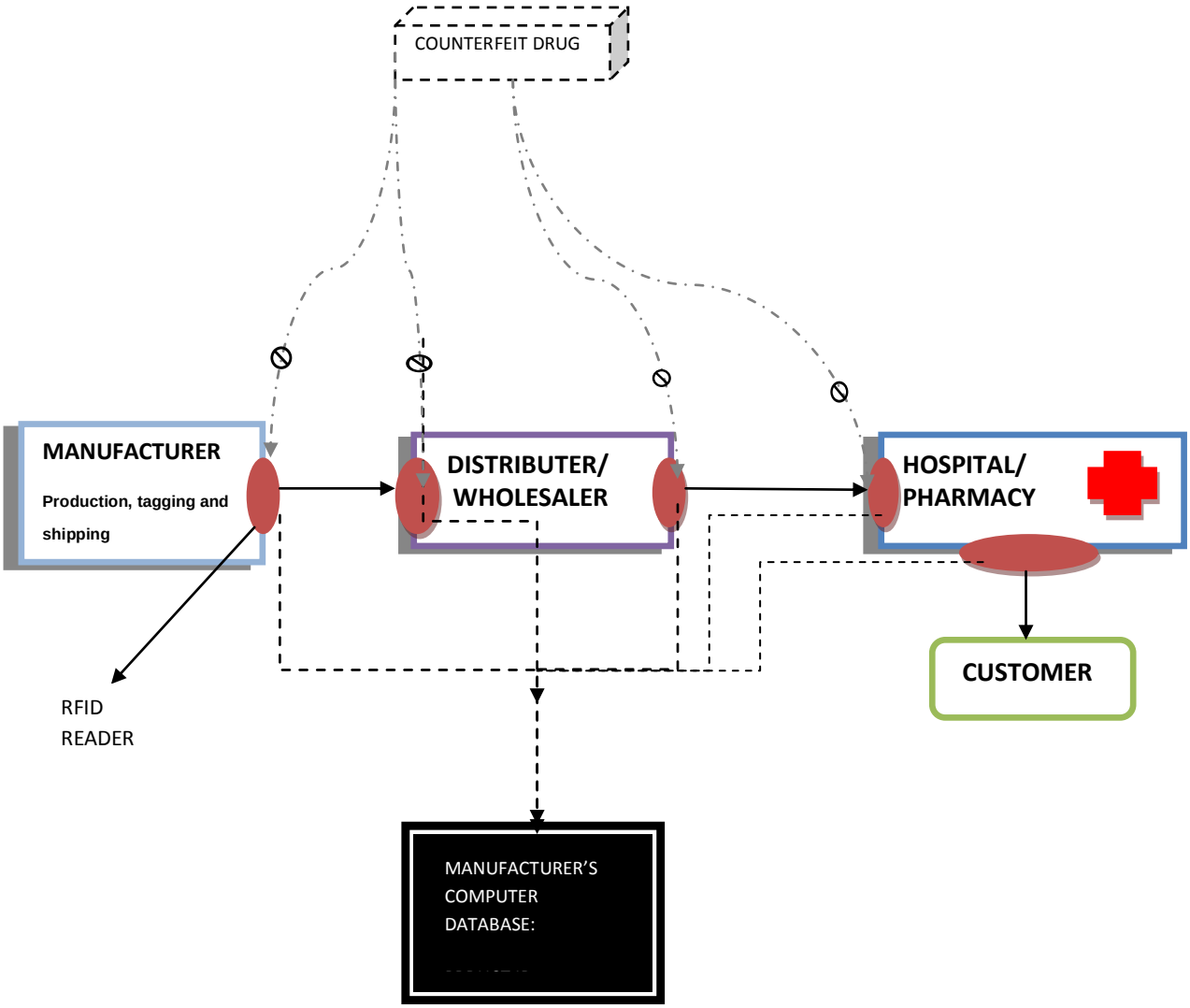
The EPC Discovery Service is essentially an electronic chain of custody (or pedigree for pharmaceuticals) for EPC tags. As an EPC tag is encoded and attached to an item, that data are transmitted to the manufacturer's EPC IS. The data, in turn, are communicated to the EPC Discovery Service as well. The EPC Discovery Service interacts with Information Services throughout the life of the product and maintains a history of each status change for the EPC tag. [5]



(Fig .1) Antenna for receiving and transmitting signals

When the manufacturer puts an RFID tag on the product, it stores all the static information about the product such as lot number and expiry in the database, and links this information to the COMPANY. When the product moves across the supply chain, from the manufacturer to the wholesaler (Fig.2), this observation is updated in the database holding the initial information. This happens at all phases of the movement of drugs, from the wholesalers to the distributors, to the pharmacies and then to the hospitals.

(Fig.2) Supply chain of information through RFID reader



The electronic pedigree is an ever-growing chain of custody, detailing the path of the drug through the supply chain. If the drugs inspector wants to check for the authenticity of the drug, he scans the RFID tag on the drug and then looks up in the database that hosts information about it. RFID is fast, reliable, and does not require physical sight or contact between a reader and scanner, eliminating the problems mentioned for barcodes. RFID allows participants in the supply chain to know where a particular product began its life, its current location and where it has been[5].

Emerging trends in Indian market

RFID Association of India formed in 2004

The RFID Association of India (RFIDAI) has been formed as a not-for-profit society under the Companies Act to promote the adoption of RFID technology, standards and applications across industry, government and academia. The association's goals include positioning India as a country of pre-eminence in RFID technology applications and use across industry and fight against increasing counterfeiting in India .It will encourage Indian industry to establish a leadership position in the emerging global RFID[6] market, and will collaborate with like-minded international associations.

OTA training offers RFID expertise at INTERPHEX India

When INTERPHEX made his debut in India on October 2007, it hosted an educational program with the collaboration of OTA Training, LLC. Based in Dallas, Texas, OTA offers RFID training courses worldwide. The educational sessions were meant to serve the burgeoning pharmaceutical industry in India, the most in-depth and relevant RFID education content available today.

Ranbaxy Pharmaceuticals chose RFID solution

Ranbaxy Pharmaceuticals India's largest pharmaceutical company, has chosen **Acsis** to implement a radio frequency identification tracking system to meet Wal-Mart's RFID mandate for its class 2 pharmaceutical suppliers like addictive painkillers and other prescription narcotics.[7]

Verayo and Bartronics Team Up to Deliver "Unclonable" RFID Tags to Indian Market

Verayo, a security and authentication solutions provider, on September 1 2009 announced it has partnered with Bartronics India Limited (Bartronics), one of India's largest bar code and RFID technology companies, to provide cost-effective RFID offerings to the Indian market. The strategic partnership not only strengthens the long-term cooperation between the two companies, but also addresses the need for differentiated solutions targeting anti-counterfeiting and low-cost authentication. [8]

Applications

Though, RFID techniques are potentially used for replacing barcodes ,telemetry ,identification of patients and hospital staff ,regulations and standardization ,commercialization, problems and concerns ,global standardization ,security concerns ,exploits ,passports ,shielding ,controversies ,privacy and human implantation[11] yet the RFID technology has a very wide application in the pharmaceutical industry generally to overcome the increasing problem of counterfeit drugs in the market[1][16].

- Pfizer, the world's biggest drug company, has spent $5 million to RFID-tag Viagra, a treatment for sexual dysfunction in men that totaled $1.6 billion in 2005 sales [9]. A recent Google search on the words "buy cheap Viagra" resulted in more than 18 million hits.

- Purdue Pharma, the privately held maker of OxyContin, has RFID-tagged the painkiller, a narcotic that can cause physical dependency. The British drug maker GlaxoSmithKline has RFID-tagged its HIV treatment Trizivir. HIV drugs are often sold at reduced prices to poverty-stricken populations in sub-Saharan Africa where the killer virus is most prevalent, which makes the drugs ripe subjects for theft and illegal reimportation to Europe at an inflated price.

The major companies to implement the RFID technologies for these pharma giants are IBM, Symbol Technologies, Alien Technology and Tagsys.

Limitations

Cost, technology immaturity and lack of standards have been some of the factors for poor adoption in the country. This has hindered the solution providers based in India to get business. The pharmaceuticals mandate will give the right impetus to the RFID solution providers waiting for the right moment to unleash their potential. Newcomers are reluctant to invest in RFID especially in developing countries like India because it's hard to tell whether it's cost-effective in protecting the products[10][12].

Conclusion

RFID is a promising approach and is increasing prevalent as the price of the technology decreases and certain big pharma giants have started adopting the technology for preventing the increasing scenario of counterfeiting using e-pedigree to prevent attacks on their brand names. Hence based on its wide applications against counterfeit medicines, it should be made cost effective so as to maintain the standards across the country.

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REVIEW ARTICLE

COMBINATION PRODUCT, CO-PACKAGED FORMULATION, FIXED DOSE COMBINATION, POLY PILL – SIMILARITIES AND DIFFERENCES

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Combination product, Co-packaged Formulation, Fixed Dose Combination and Poly Pill are widely used terminologies in various journals, periodicals and scientific discussions. There exists confusion of these terminologies among the Students, researchers, medical practitioners and other health care professionals. Some times these terminologies can be wrongly inferred for one another.

Combination Products

Office of Combination products, USFDA had defined combination product in 21 CFR § 3.2(e) [1]. It includes the combination of drug device, biologic device, drug biologic or drug device biologic. The definition given by USFDA avoids the confusion with regard to which product would be considered as combination product and has been of great help for all pharmaceutical manufacturers to understand their product would fall under such category.

The term combination product includes:

(1) A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity;

(2) Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;

(3) A drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or

(4) Any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug,

device, or biological product where both are required to achieve the intended use, indication, or effect.

Examples

Neupro Patch for treatment of Parkinson's disease by Schwarz Bioscience, Daytrana for treating Attention Deficit Hyperactivity Disorder (ADHD) in children six to 12 years of age is manufactured for Shire US. Inc., by Noven Pharmaceuticals Inc, Emsam for treating depression by Somerset Pharmaceuticals, Inc are some recent examples of combination products which have been approved by USFDA. A few examples according to the category are mentioned in the Table 1 [2].

Table 1: Examples of the Combination Products

Combination Products	Examples

Combination products where the components are physically, chemically or otherwise combined	• Monoclonal antibody combined with a therapeutic drug
	• Device coated or impregnated with a drug or biologic
	  • Drug-eluting stent; pacing lead with steroid-coated tip; catheter with antimicrobial coating; condom with spermicide
	  • Skin substitutes with cellular components; orthopedic implant with growth factors
	• Prefilled syringes, insulin injector pens, metered dose inhalers, transdermal patches

Combination products where the components are packaged together	• Drug or biological product packaged with a delivery device • Surgical tray with surgical instruments, drapes, and lidocaine or alcohol swabs
Combination products where the components are separately provided but labeled for use together	• Photosensitizing drug and activating laser/light source • Iontophoretic drug delivery patch and controller

Co-packaged formulations

Co-packaged formulation includes two are more separate single drug pharmaceutical products in their final dosage form that are packaged together and recommended to be consumed

simultaneously[3]. This is very useful where active ingredients cannot be combined because of the chemical or physical incompatibilities.

Examples

Examples of Co-packaged formulations include antituberculosis kits like Zucox-3 by GSK, CX-4 by Zydus Cadila and kits for the treatment of *Helicobacter Pylori* like Pylokit by Cipla, Helikit by Zydus Cadila and Zovanta Kit by Dr. Reddy's [4].

Fixed Dose Combinations

Two are more active ingredients combined in a single dosage form (Solid Dosage form), each active ingredient available in certain fixed dose is referred to as fixed dose combination (FDC). This is possible only when the active ingredients are chemically and physically compatible with each other. Fixed Dose Combination Finished Pharmaceutical Product (FDC-FPP) a synonym is a finished pharmaceutical product that contains two or more actives. Finished Pharmaceutical Product is a product that has undergone all stages of production, including packaging in its final container and labeling. FDCs have advantages when there is an identifiable patient population for whom treatment with a particular combination of actives in a fixed ratio of doses has been shown to be safe and effective and when all of the actives contribute to the overall therapeutic effect. Also there can be real clinical benefits in the form of increased efficacy and/or a reduced incidence of adverse effects, but should have sufficient evidence to prove the same. Additional advantage of FDCs includes lower costs of manufacturing compared to the costs of producing separate products but administered concurrently. Simpler logistics of distribution, improved patient adherence and reduced development of resistance in the case of antimicrobials are a few other distinct advantages of FDCs [5].

Examples

Examples of fixed dose combinations include antidiabetic drug brands like Amaryl-M by Sanofi Aventis, Bigonyl by Indoco Remidies and also many antihypertensive drugs.

Poly Pill

Poly pill, nearly similar to fixed dose combination, refers to FDC containing three or more drugs in single pill; here pill restricts to tablet formulation where as fixed dose combination may be in a tablet or capsule formulation. Poly pill came into popularity after an article published in British Medical Journal on June 28, 2003 by Wald and Law [6]. They proposed a poly pill consisting of six active ingredients and triggered the debate among the scientists, researchers and healthcare professionals.

Although Combination Product, Co-packaged formulation, Fixed Dose Combination, Poly Pill sound nearly similar but they are essentially different. They give a room for confusion to the readers of journals and periodicals. It is essential to understand the similarities and differences to avoid wrong use of the terminologies in the scientific discussions.

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RESEARCH ARTICLE

ASSESSMENT OF BASIC CLINICAL KNOWLEDGE AND UNDERSTANDING OF H1N1 INFLUENZA AMONG COMMUNITY PHARMACISTS.

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Abstract

BACKGROUND: Pharmacists role as health care provider is expanding from traditional product-oriented function of dispensing, distributing medicines and health supplies to patient focused cognitive, administrative and public health functions. OBJECTIVE: An attempt has been made to assess extent of local pharmacist's preparedness for counseling and information need services in community regarding medication use in H1N1 pandemic, in order to be in a position to counsel and allay fears and anxieties of patients and self-protection. METHODOLOGY: A set of related questions in local language were used to record the understanding and knowledge of community pharmacists. RESULTS: Among the 61 pharmacists responded, 73.7% were of opinion that virus caused the H1N1, while 26.2% regarded pig is the reason flu is on rise. 65.5% agreed that infection is amenable to treatment, 31.1% considered treatment for H1N1 is unavailable and 3.2% did not know anything about the medicine for H1N1.9.8% agreed that use of medicine prevent the disease, if taken before appearance of symptoms, 65.5% expressed view that drugs cannot prevent onset of flu and 24.59 were undecided. CONCLUSION: The basic clinical knowledge of community pharmacist appears to be good in some aspects of self-care and understanding of symptoms. Pharmacists need to improve in certain aspects of self care such as contact with sick and eye, nose and mouth, alcohol based hand wash. The safe and reliable information needs of patient can only be met, if pharmacist is wary of facts and resources relating to H1N1.

Introduction

Pharmacist should be no stranger to public health planning and emergency preparedness. Recent events of SARS, disasters (flood, earth quake, bomb blasts), bioterrorism (anthrax) mandates pharmacist to be sensitive to emerging unforeseen perils. Swiftness in acting against a challenge determines the outcome in emergency and critical situations, where acquiring information about the event becomes crucial in shaping the outcome

Pharmacists can be a reliable and readily accessible source of health and medication information. Pharmacist's unique expertise can benefit many functions of public health [1]. The collaborative approaches by health care team in public work force-health education, disease prevention and health promotion, public health advocacy, and health quality will aid in achieving optimal public health outcomes[2]

Through shared responsibility, the pharmacist is equipped to strengthen the existing public health system[3].Community pharmacist can act as an information resources on lifestyle changes for effective health outcomes [4,5] .

Objective

A study was undertaken to assess the extent of local pharmacist's preparedness for counseling and information need services in community regarding medication and public health issues in H1N1 related pandemic. WHO has already declared pandemic alert of phase 6, necessitating strict monitoring [6] on the part of health care team to be in a position to counsel and allay fears and anxieties of patients and self-protection

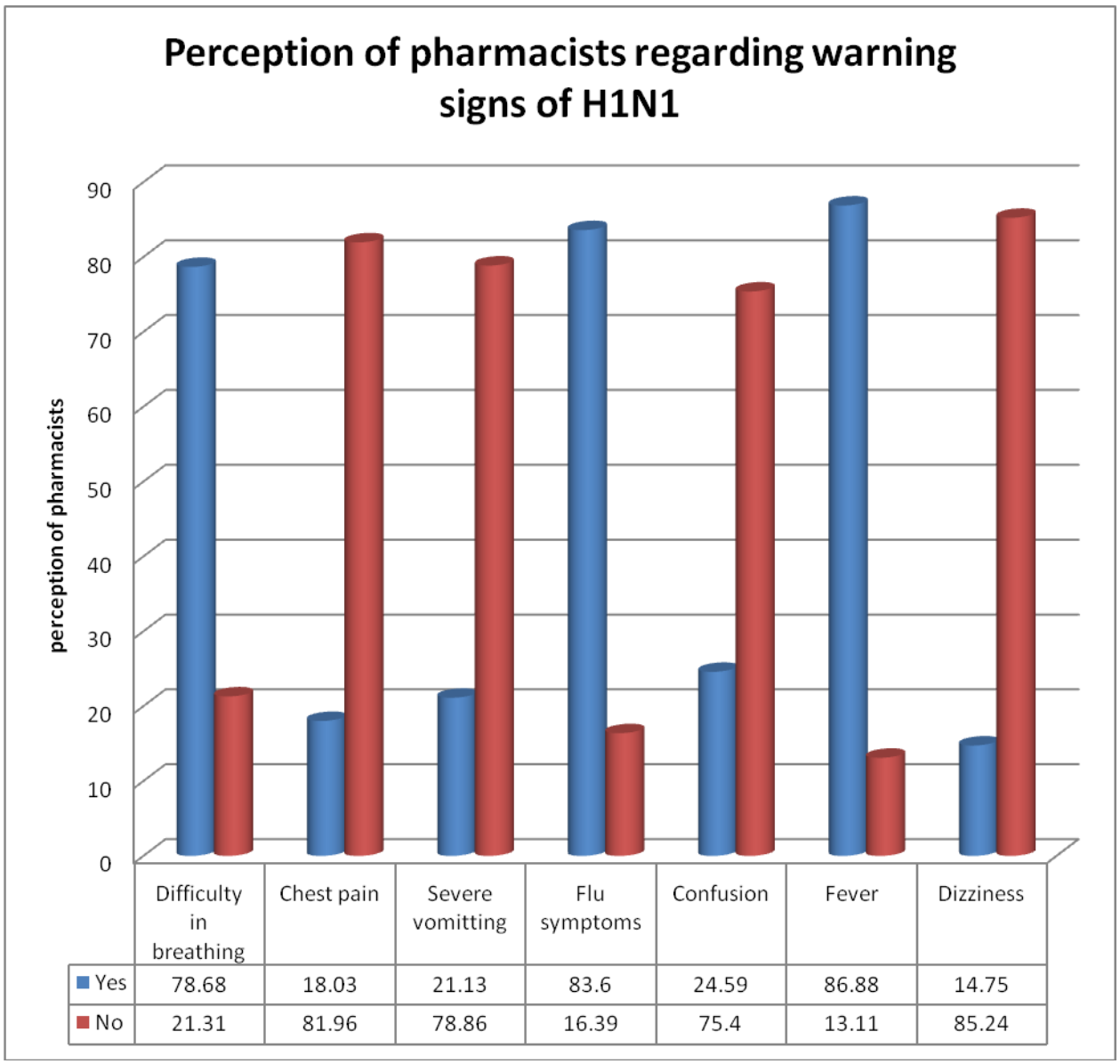
Method and subjects

A set of questions in local language was drafted to collect the required basic clinical knowledge and understanding of community pharmacists regarding this seven month old pandemic of H1N1 influenza in India. The questionnaire was provided to 67 randomly selected pharmacists in community and the responses were analyzed to interpret the data.

Results

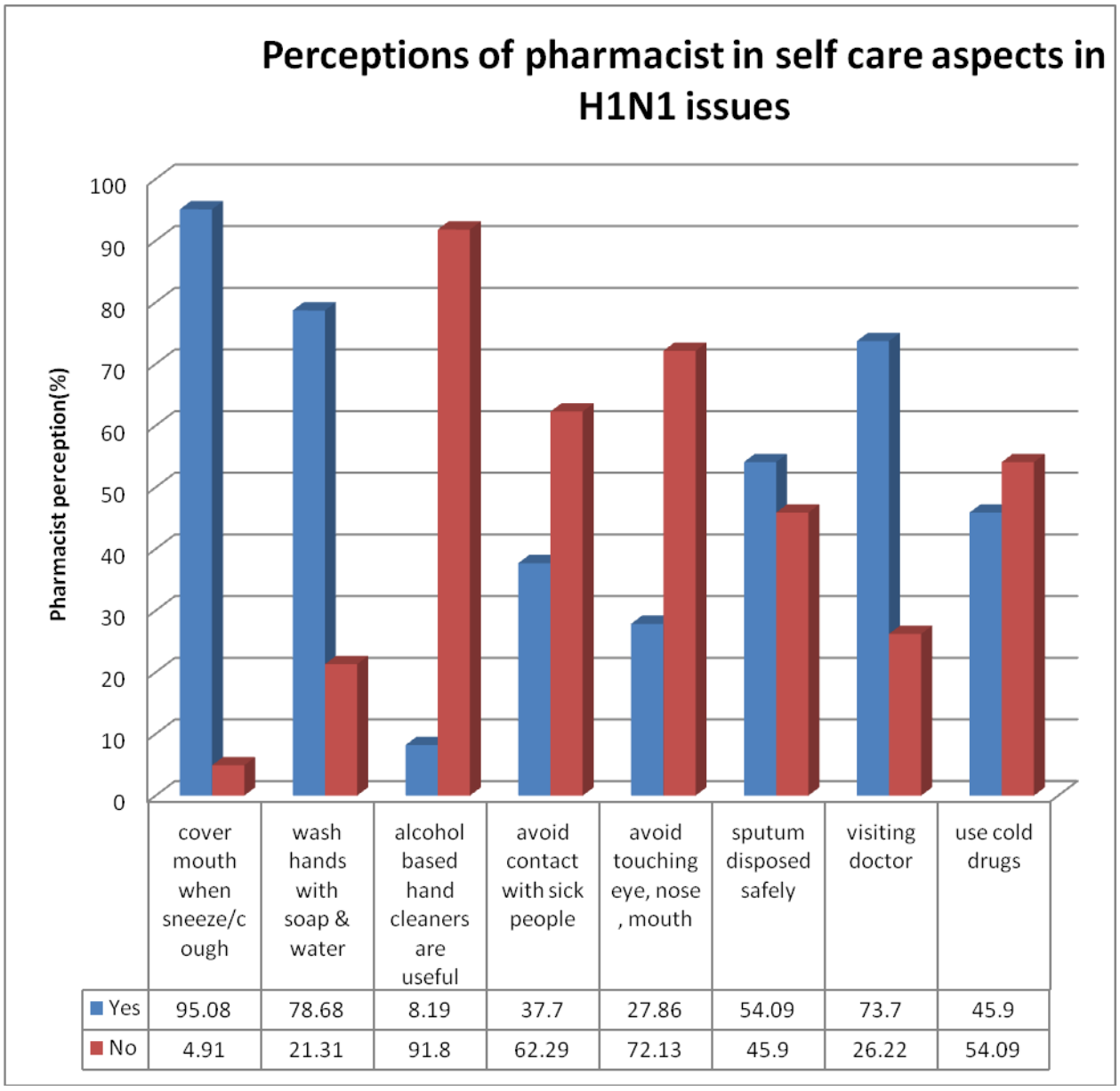
Among the 67 pharmacists approached 6 declined to comment, while 61 pharmacists responded. Out of 61 respondents, 73.7% were of opinion that virus caused the H1N1, while 26.2% regarded pig is the reason flu is on rise. On the availability of medicines to treat H1N1 65.5% agreed that infection is amenable to treatment, 31.1% considered treatment for H1N1 is unavailable and 3.2% were unaware of the medicines for H1N1.9.8% agreed that use of medicines prevented the disease, if taken before appearance of symptoms, 65.5% expressed view that drugs cannot prevent onset of flu and 24.59 were undecided. 68.5% reported eating pig meat is safe, whereas 1.6% disagreed and 29.5% were doubtful. 21.3% (graph-1) rejected difficulty of breathing as not a symptom in H1N1.75.4% and 85.24% respectively did not accept confusion and dizziness as a symptom of H1N1.With relation to self-protection practices, as in (graph-2) 62.2% and 72.1% respectively did not view contact with sick and touching eye, nose and mouth amounted to unsafe practice.54% disregarded common cold drug for self-care. Only few (8.19) believed it's effective to wash hands with alcohol-based cleansers. There were few (22.6%) who opined visiting doctor is not necessary.

Graph-1: Distribution of pharmacist perception regarding warning signs and symptoms of H1N1



	Difficulty in breathing	Chest pain	Severe vomitting	Flu symptoms	Confusion	Fever	Dizziness
Yes	78.68	18.03	21.13	83.6	24.59	86.88	14.75
No	21.31	81.96	78.86	16.39	75.4	13.11	85.24

Graph-2: Distribution of pharmacist perception with regard to self-care aspects in H1N1 related issues



	cover mouth when sneeze/cough	wash hands with soap & water	alcohol based hand cleaners are useful	avoid contact with sick people	avoid touching eye, nose, mouth	sputum disposed safely	visiting doctor	use cold drugs
Yes	95.08	78.68	8.19	37.7	27.86	54.09	73.7	45.9
No	4.91	21.31	91.8	62.29	72.13	45.9	26.22	54.09

Discussion

Knowledge and understanding of practicing pharmacist with respect to medicine along with health promotion public health functions takes a predominant role in community settings, where access is easy. In special situations like disaster the patient education by pharmacist, being a member of health care team influences the care delivery and patient outcome. Common symptoms like confusion, dizziness, chest pain, dyspnea, and flu like symptoms, including the source should be known and made readily available for consultation. Patients present to pharmacists with vague symptoms like malaise, vomiting, fever, if pharmacists are aware of common symptoms and signs he would be in good position to guide patient to doctoras overlap between symptoms of respiratory tract infections are possible. Epidemics outbreaks can be prevented by following precautionary measures such as washing hands and covering mouth while coughing, such measures can save many lives, including pharmacists who come in contact with infected cases frequently. As H1N1 is communicable, the informations pertaining to safe health practices both by the pharmacist and patients family alike requires consideration particularly at a stage when WHO has alerted phase 6 pandemic where monitoring plays a key role.

Conclusion

The basic clinical knowledge of community pharmacist appears to be satisfactory in some aspects of self-care and understanding of symptoms, though there is want of information in areas least stressed such as symptoms of confusion, dizziness. Pharmacists need to improve in certain areas of self care such as contact with sick and eye, nose and mouth, alcohol based hand wash. If this is the case of community pharmacist's infectious diseases like SARS, swine flu is bound to raise as education of public plays an important role in prevention. The safe and reliable information needs of patient can only be met, if pharmacist is wary of facts and resources relating to H1N1.

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RESEARCH ARTICLE

A PRELIMINARY STUDY ON PATIENT REPORTED AND PHARMACIST OBSERVABLE SIGNS AND SYMPTOMS IN DOT TB PATIENTS

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Abstract

Tuberculosis is one of the most infective disease as per WHO, among the 2 billion infected cases of TB in the world, 3.4 million are reported in India making it the most prevalent country for the TB patients in the world. DOTS (directly observed treatment, short course) programme run by RNTCP (revised national tuberculosis control programme) is the second largest and fastest growing in the world. A survey of TB patients was done on 45 patients for adverse effects of anti – TB drugs, in which 25 (55.5%) were male and 20 (45.5%) were female. The mean age of male and female were 35.54 ± 3.289 n=24 and 32.52 ± 3.316 n=21, p=0.64 respectively, is insignificant. In category – I patients the patient reported signs include side effects requiring immediate reporting to provider are dark urine(90.91%) which was seen in maximum number of patients,81.82% of patients reported of hearing problems. dark urination, malaise and hearing related problems were more common in category II than III. Jaundice, Anorexia, visual changes fever, abdominal pain and jaundice were reported very less while, rashes, vestibular changes and marked clinical rashes were not observed in any patient. In category – III patients dark urination, malaise and vomiting were seen as major symptoms. In this direction apart from other functions pharmacist can play his role in monitoring the adverse reactions and counsel the patients as the recognition of the adverse effects.

Keywords: Tuberculosis, DOTS, adverse drug reactions

Introduction

Globally India has the highest TB burden country with one fifth of the global incidence. Indian population is nearly 40% infected with the TB bacillus. Annually 1.9 million new cases of TB occur in the country, of which about 0.8 million are infectious new smear positive pulmonary TB cases[1]. Every day, more than 5,000 people develop TB disease, and nearly 1,000 people die of TB, i.e. 2 deaths every 3 minutes, despite availability of curative chemotherapy with greater efficacy and reasonable toxicity potential in most countries[2]. Administration of drug combinations for prolonged periods of time is likely to potentiate the adverse reactions of one drug with companion drugs used[3, 4]. Defaulters of regimen could occur as adverse reaction is one of the major cause[4]. It's essential to have good insight of pattern of adverse drug reactions of various regimens to avoid or mitigate the adverse outcomes[5]. Anti-TB agents observed symptoms are still debatable with chemotherapy regimens differing in frequency and severity[6]. Pharmacist role in anti-TB therapy monitoring is less documented in India unlike foreign pharmacists[7-8] and unless a joint concrete effort is made TB burden is bound to increase. An

effort has been made to quantify the adverse effects of anti-TB therapy regimens by registered pharmacist.

Material and Methods

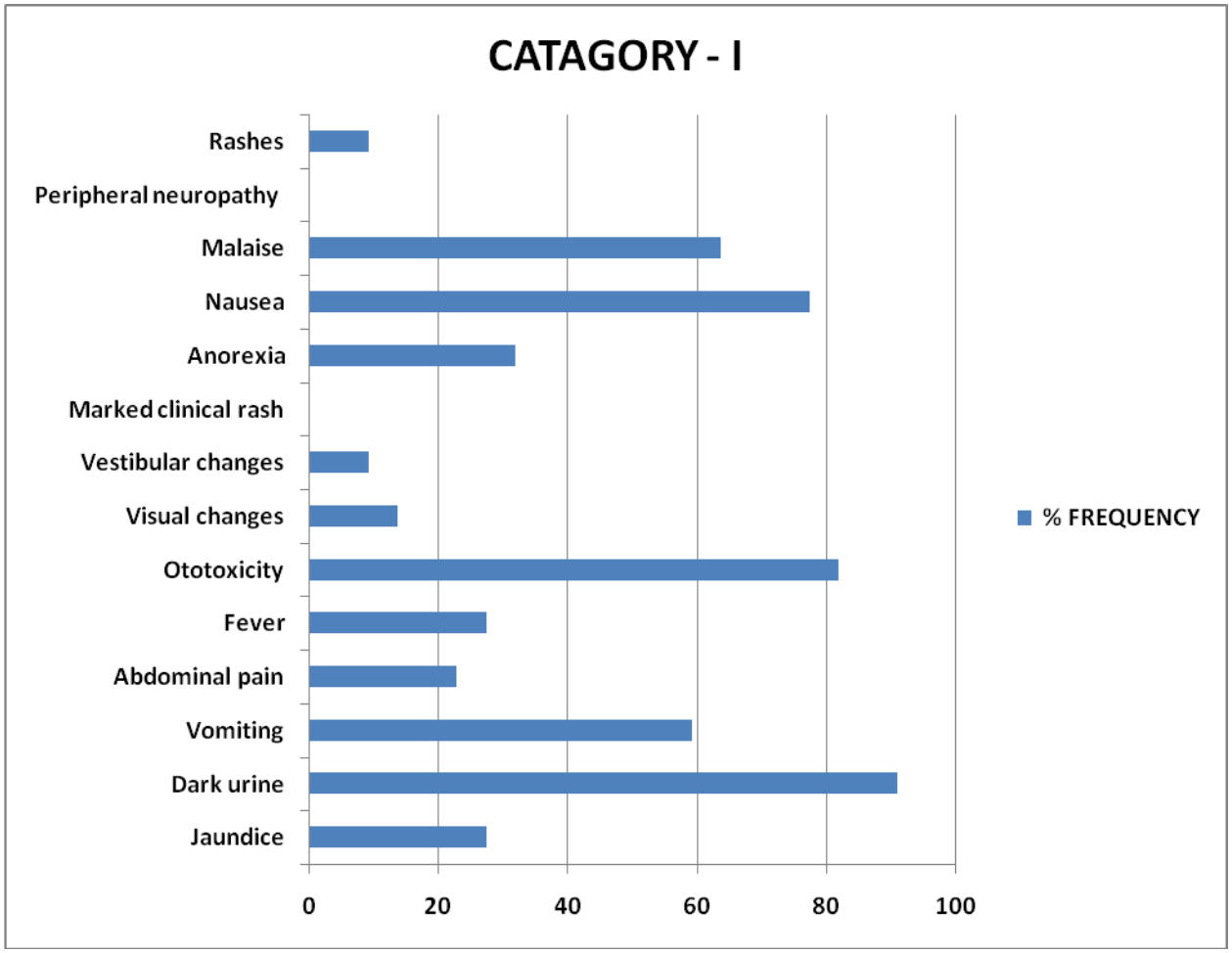
A cross-sectional prospective observational study was carried out by registered pharmacist on patient population of Mehsana district, Gujarat who were screened and enrolled for RNTCP-DOT (direct observation therapy) based on diagnosis of three sputum examinations and classified into three categories. The anti- tuberculosis regimens used for category I, II, and III patients were 2H3R3Z3E3/4H3R3, 2H3R3Z3E3S3/1H3R3Z3E3/5H3R3E3 and 2H3R3Z3/4H3R3, respectively. (H= Isoniazid; R= Rifampicin; Z= Pyrazinamide; E= Ethambutol; S= Streptomycin. Numbers before the letters indicate the duration of the treatment phase in months and numbers in subscript indicate the number of times the drug is given each week). All the patients of either sex, pulmonary tuberculosis, aged above 12, and who showed signs of ADRs were included in the study and the patients of category IV, with history of hepatitis, hepatic or renal impairment and pregnant women were excluded. In total 45 patients were included in this study, of which 22 had received category I, 4 anti-TB drugs that include rifampicin, isoniazid, ethambutol, pyrazinamide. Another 15 patients received category II: 5 anti-TB drugs that included rifampicin, isoniazid, ethambutol, pyrazinamide and streptomycin. All the patients received the drugs under direct observation therapy short-course (DOTS)-treatment program.

A set of signs and symptoms categorized as severe requiring immediate attention and less severe requiring consultation with in 24 hours, according to CDHS (California Department of Health Services) /CTCA (California Tuberculosis Controllers Association) JOINT GUIDELINES- TB Case Management - Core Components-These guidelines are official State Recommendations and have been endorsed by the California Tuberculosis Controllers Association[9].

Results

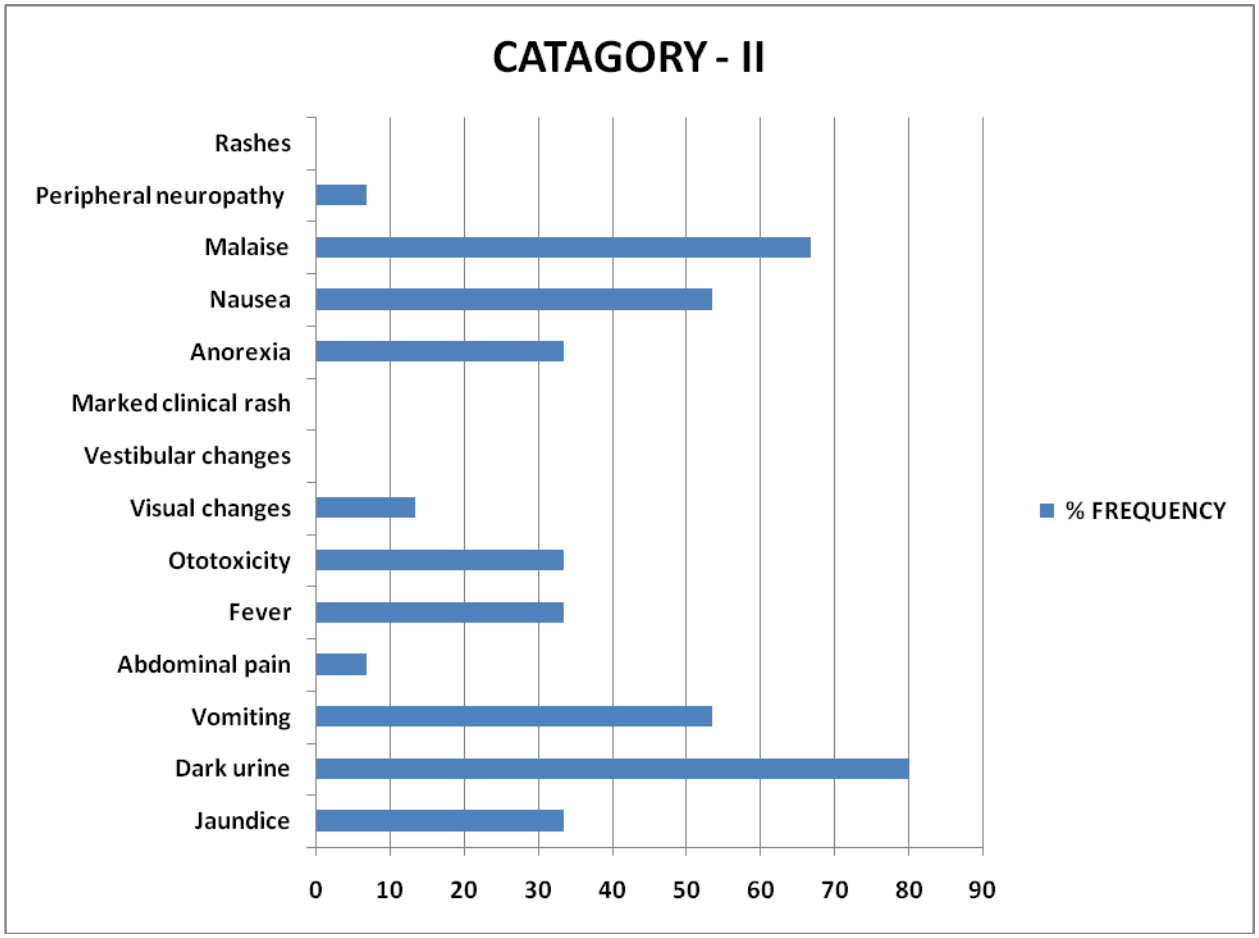
Among the patients observed in this study, 25 (55.5%) were male and 20 (45.5%) were female. In category I group 13 male and 9 female accommodated, 7 males and 8 females in category II, and 4 male and 4 female equally in category III. The mean age of male and female were 35.54 ± 3.289 n=24 and 32.52 ± 3.316 n=21, p=0.64 respectively, is insignificant.

Graph – 1: Characteristic adverse effects observed in category –I patients



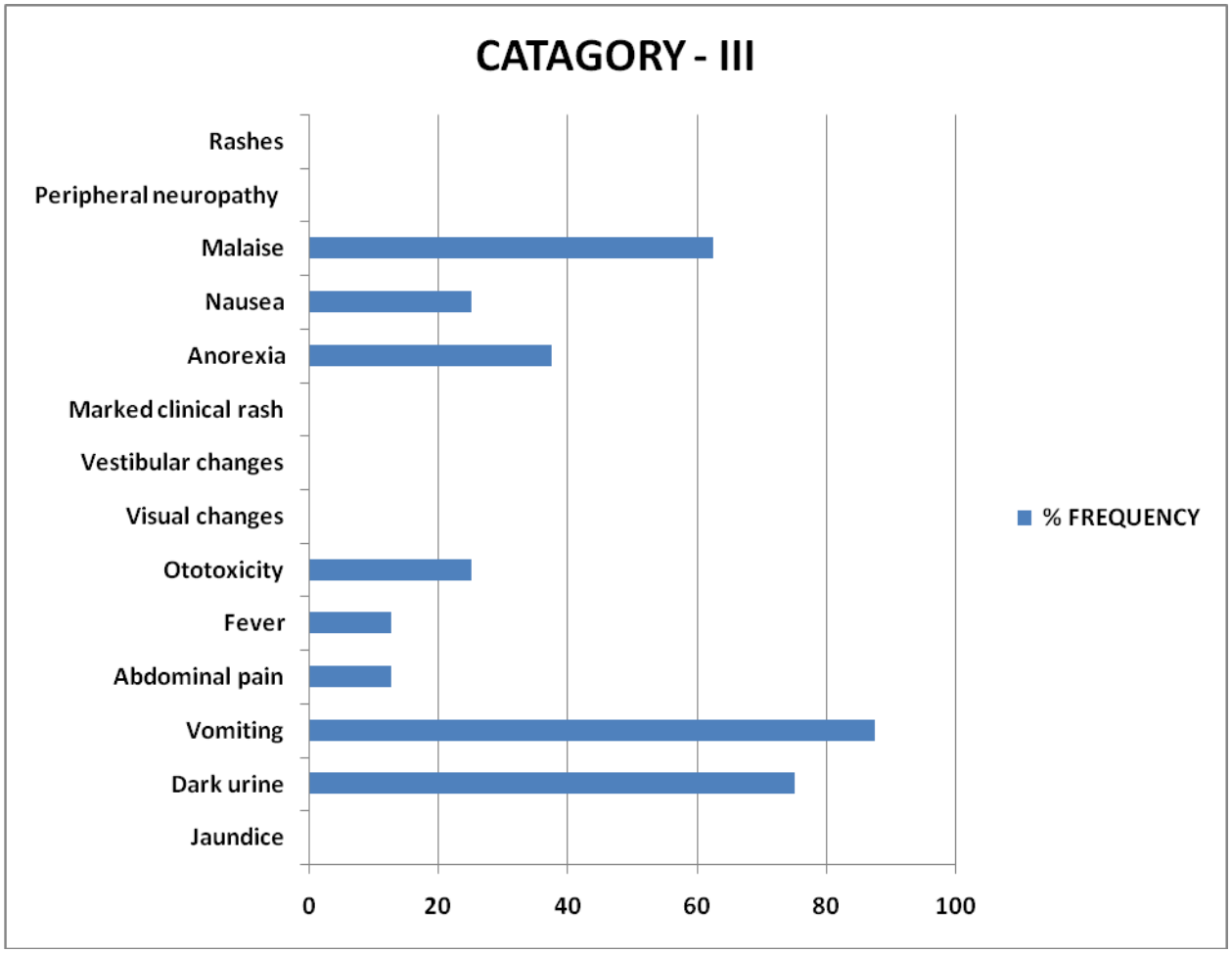
In category – I patients the patient reported and signs include side effects requiring immediate reporting to provider are dark urine(90.91%) which was seen in maximum number of patients,81.82% of patients reported of hearing problems. Malaise (63.64%) and Nausea was reported in 77.27%, anorexia (31.82%) patients require to be reported in 24 hrs to the care provider. Rashes, vestibular changes, visual changes, fever, abdominal pain and jaundice were reported very less while, peripheral neuropathy and marked clinical rashes were not observed in any patient.

Graph– 2: Characteristic adverse effects observed in category-II patients



Patient reported dark urination was same in both categories of II (80%) and III (75%) cases which was almost similar. Hearing related problems were more common in category II than III. Malaise was common feature in category II than III. Nausea and Vomiting were equally seen as major symptoms in 53.33% of patients of category II. Jaundice related signs were observed in category I (27.27%)and II(33.33%) only. Peripheral neuropathy (6.66%) was experienced only in category II patients, anorexia, visual changes fever, abdominal pain and jaundice were reported very less while, rashes, vestibular changes and marked clinical rashes were not observed in any patient.

Graph – 3: Characteristic adverse effects observed in category-III patients



In category – III Patients Dark urination, Malaise and Vomiting were seen as major symptoms. Ototoxicity, Nausea, anorexia, fever and abdominal pain were reported very less while, Rashes, Peripheral neuropathy, vestibular marked clinical rashes changes visual changes and jaundice were not observed in any patient.

Discussion

Pharmacists play an important role in ADE surveillance activities, and his part in monitoring the therapy is under-utilized. His role as educator and counselor regarding drug and its adverse reactions can prevent non-compliance and improve therapeutic outcome[10]. Therapeutic success with anti-TB medications depends on compliance. DOTS and fixed dose combination (FDC are effective means to achieve compliance[11]. The drugs used in the regimen have been well tolerated by patients[12]. This study of cross-sectional prospective design attempted to quantify the patient reported adverse reactions and observable signs on patients undergoing DOTS and signs and symptoms were categorized according to categories I, II and III. As predisposing risk factors for adverse effects we observed age, sex. According to WHO monitoring of adverse effects are key for detection and management[13]. The guidelines of WHO states that patients experiencing serious adverse effects require review and change in therapy or hospitalization. Reduction or symptomatic treatment required if minor adverse effects develop, the responsible drug should stop if major side effects develop[13].

The frequency and severity of symptoms of TB when undergoing chemotherapy is still debatable. The obstacles include the frequency of complications as it is difficult to quantify as many patients are treated with a range of different drugs. Among the factors for failure of TB therapy has been side-effects. Further as combination of drugs prevents measurement of effectiveness or toxicity of a specific drug. It's the responsibility of the health care team members involved with provision of therapy encompasses appropriate regimen, adherence to the regimen and drug monitoring, including the side-effects of drugs until completion of treatment[14]. Hence, side-effects of anti-TB chemotherapy need not necessarily adversely affect outcomes. One concern when considering side-effects is whether they prevent patients from taking medication and, hence, influence the outcomes of anti-TB treatment. No antitubercular drug is devoid of adverse drug reactions[6] and may cause ADRs involving almost all systems in the body, including the gastrointestinal tract, liver, skin, nervous system, oto-vestibular apparatus and the eyes[15]. Probability of 15% chance of adverse effect prevails when multiple antitubercular drug regimens instituted [16]. Pharmacists both in community and hospital setting can contribute by monitoring adverse reactions which might be an important cause of default and referring the patients early can prevent the withdrawal of therapy and preserve the confidence of the patient in treatment programme[17, 18].

Conclusion

New cases of Tuberculosis, a potentially curable infection is on rise, unless collaborative efforts of health care team members (including pharmacist) is made, it's unlikely to be controlled. In this direction apart from other functions pharmacist can play his role in monitoring the adverse reactions and counsel the patients as the recognition of the adverse effects if it does not occur on time and managed properly they can lead to treatment interruption resulting in appearance of resistance and therapeutic failures or can even can be life threatening. It's essential that monitoring has to be carried out during the whole treatment course, including patient education, clinical examination, laboratory tests.

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