ABSTRACT

The aim of this study was to highlight differences in pharmacist’s perceptions regarding use of pharmacogenetic information in their professional activities based on their practice settings. A survey was electronically administered using the Survey Monkey to 48 practicing pharmacists in the hospitals and non-hospital study groups which include community pharmacy and managed care around the metro Louisville, Kentucky area.

INTRODUCTION

The completion of the Human Genome Project (HGP) has redefined the approach to drugs and dosages. Individualized medicine and tailor-made drugs is the promise that pharmacogenomics holds for patients. Pharmacogenetics testing or testing the variation of drug response based on genetic variation has been approved by the FDA. Although, challenges still exist in translating these pharmacogenetic tests to clinical practice, pharmacists need to be aware of such developments in pharmacotherapy. Very soon, in addition to tracking drug-drug interactions, pharmacists would be required to pay attention to gene product-drug interactions as well.

Managed care pharmacy is also interested in pharmacogenetic information based on the accuracy it will bring to plan coverage and reimbursement decisions. According to an article in the Hospital Pharmacy, pharmacogenetic information can form the basis of drug coverage policy that takes into account the effectiveness of the drug, the dose and duration of use, and length of coverage. In addition, formulary decisions can now be more inclusive and prior authorization programs will have more information than just prescription or claims data.

Barring minor deviations, there was overall homogeneity in our pilot study group’s general knowledge, overall confidence in pharmacogenetics and perceptions about possible impact of this emerging field in their profession, regardless of their professional practice environment. Overall low to moderate levels of pharmacists’ confidence in pharmacogenetics and related areas even a decade after completion of Human Genome Project (HGP) seems to be a matter of concern.

Keywords: Pharmacogenetics, Human Genome Project.
This study highlights differences in pharmacists’ (both in the community and in the hospital) perceptions of use of “Pharmacogenetic information” in their professional activities. In addition, this survey determines the need for educational and training requirements in pharmacogenetics for practicing pharmacists. The purpose of this study was to provide an insight regarding perceptions of practicing pharmacists in the Louisville metro area in integrating the concept of pharmacogenetics in their professional activities, as they are expected to use pharmacogenomics more frequently as they provide “Management Medication Therapy (MTM)” to their patients.

Since its official inception in 2000 (with the completion of HGP), pharmacogenetics has made a robust impact in the pharmaceutical industry and on the process of making drugs. Nearly 25% of the marketed drugs have pharmacogenetic labels in their inserts and many molecular techniques routinely performed in clinical diagnostic laboratories are dependent on this concept. There is a need to access pharmacist’s current level of confidence & knowledge in dealing with the challenging concept of pharmacogenetics and their perceptions about the increased usage of genomic/genetic data in health care as well as the social, moral and legal consequences associated with its use.

OBJECTIVES

In this study tour primary focus was to determine and evaluate the differences in pharmacists’ perceptions in Louisville metro area regarding their use of “Pharmacogenetic information” in their professional activities based on demographic settings. In addition, peripheral objective included determination of the need for further educational and training requirements in pharmacogenetics for practicing pharmacists.

METHODS

An analytical study involving cross-sectional sample population was conducted to assess the study objectives. Figure 1 shows the overview of the study design. In this questionnaire in addition to demographics, differences in pharmacist’s perceptions are being established with reference to the use of PGx knowledge for professionals in a pharmacy setting. Questions were clubbed into three broad categories in the survey. The categories include (a) general knowledge about the topic (b) ideas about pharmacogenetic screening and (c) impact of pharmacogenetics on pharmacists (Refer to Appendices A and B).
Pharmacist pool: Hospital, Community, Managed Care Facilities in Louisville, KY
Surveys sent electronically by Survey Monkey, random sample selection
N*=48; N=32(response rate:: 67%)
Data Analysis By SPSS software

To avoid biased results, no operational definitions were given for the topics. The panel of questions included in the survey was similar to valid questionnaires used in human genome projects with added modifications to suit the purpose of the study. A 5-point Likert scale was used to evaluate this portion of the questionnaire. Participants indicated their level of agreement or disagreement with each of the statements, with 1 indicating “strongly disagree”; 2, “disagree”; 3, “neutral”; 4, “agree”; 5, “strongly agree”. The questionnaire included questions on demographic information such as age, gender, race, educational background and pharmacy practice setting. For determining pharmacists’ overall confidence in pharmacogenetics and related fields, a 4-point modified Likert Scale was used where “high” corresponds to 4 and “no clue” refers to a scaled score of 1.

The study sample was a pool of pharmacists in the Louisville, Kentucky metro area. The participating pharmacists were preceptors of the Sullivan University College of Pharmacy (SUCOP) with their respective affiliated practicing sites whether it is Hospitals or Non-Hospital sites that include community pharmacies and manage care. The survey questionnaire was electronically accessible to all the preceptors and was done through the survey monkey.

Timeline was one (1) month. An electronic reminder was sent twice (2x) every 15 days. Completed surveys were coded using the preceptor’s log in address. The collected responses and information are transmitted to SPSS software 19.0 for data analysis. Descriptive and inferential statistics including Mann Whitney U-test were performed to assess study objectives.

RESULTS

Demographic Features

The response rate to demographic portion of the survey (Refer to Appendix B) was 67% (32 responses). Out of the 13% (16) non-responders; 5 were labeled undeliverable mail; 2 delivered but incomplete responses and 9 delivered but no responses. Results were obtained from the total of 32 completed surveys that were returned. Out of the respondents, 45% were females and 55% were males. The average age of the pharmacists was (44.80±9.60) years. Majority (58%) of the respondents had a PharmD degree, 40% had a BS degree, while the remaining 2% has the above combined degrees. An estimated 63% of the respondents worked in hospital settings while the remaining 37% worked either in community settings or Managed Care Facilities.
Pharmacist’s knowledge of pharmacogenetics

Pharmacists strongly agreed (4.31±0.93)* with the statement that pharmacogenetics is not just a theoretical concept but on the contrary it has manifested its potential in several areas of therapeutics through targeted drugs and pharmacogenetic testing. Furthermore, they strongly concurred (4.03±0.99*) with the idea that drug development process will be accelerated due to recent advances in pharmacogenetics. According to the opinion of respondents, drugs developed due to advances in pharmacogenetics have benefits of being effectively safe (3.61±0.76*), with minimal adverse side reactions (3.58±0.96) and increase patient compliance (3.19±1.03)*. One of the drawbacks however would be its production and manufacturing cost (4.12±1.16)*. It was noted that neither practice settings nor awarded degrees contributed significance to the differences in the opinions of the respondents in this domain. There were no statistical significance differences (P>0.05) in the responses of the hospital pharmacists when compared to that of their colleagues working in the community settings or managed care facilities. A similar insignificant trend was noted in spite of the differences in educational background when PharmD’s were compared to those with BS pharmacists across all practice settings.

Ideas about pharmacogenetic screening

A frequency distribution of the scores showed that most Pharmacists strongly disagreed with the statement that pharmacogenetic screening is ethically wrong (1.80±1.03)*. The study showed that respondents believed that genotyping will reduce health care costs (3.23±0.86)* and would allow pharmacists some form of service reimbursement for genetic counseling (3.77±1.04)*. While everyone strongly agreed that there was a need to include patient’s genetic information in the pharmacy’s database in order to improve drug dispensing; the majority of the participants however, had some reservations regarding health insurers (1.83±1.26)* and employers (1.73±1.26)* gaining free access to a patient’s pharmacogenetic profile. It was further concurred that health insurers (4.33±0.88)* and employers (4.30±0.95)* may discriminate against patients if they have access to their genetic profile.

The plan to have every pregnant woman undergo genetic screening was met with some resistance (2.53±1.33)*. Though favorable, yet there were differing opinions (P<0.05) regarding the pharmacists’ role with regards to the clinical relevance of a PGx screening test based on their educational credentials (Pharm D versus BS). There were no statistical significance differences (P>0.05) in the responses of the hospital pharmacists when compared to that of their colleagues working in the community settings or managed care facilities, for the questions corresponding to this section of the survey.

Impact of pharmacogenetics on pharmacists

Hospital pharmacists and their colleagues in the community settings and managed care facilities agreed that handling of newer drugs will increase the operational cost of pharmacies due to its development through advances in pharmacogenetics. Additionally, in the opinion of both sets of respondents information gathered from these genetic advances may be utilized for future individualized drug dosing and the patient’s therapeutic responses. For the hospital pharmacists, the average response score was 3.37±1.06 while for the non-hospital pharmacists working in community settings or managed facilities, it was 4.18±0.87. Pharmacists in both groups agreed that education and training are highly recommended for all practicing pharmacies and their techs in all types of pharmacy practice settings. It is believed that inclusion of information regarding pharmacogenetics in the curriculum of pharmacy schools (4.48±0.77)* would be one measure of keeping future pharmacists abreast of knowledge regarding future advances in genetic technology. There was a strong support amongst the pharmacists to promote avenues for CE in pharmacogenetics in various pharmacy schools and professional organizations (4.42±0.61)*. Though statistically insignificant, both groups agree that pharmacogenetics will revolutionize the role of pharmacists (3.47±0.91)* and that the pharmacists would require to have the patient’s genetic information in their database for accurate drug dispensing (3.68±0.88)*. Subsequently, advance training on proper handling of genetically developed drugs would give the pharmacists the necessary skills to adjust to the
rapidly changing pharmaceutical way of manufacturing drugs. At the same time, it will provide a venue of providers for trainers to train upcoming practicing pharmacists.

Although most pharmacists would have to spend more time counseling patients on appropriate use of drugs developed as a result of genetiadvances, it is believed that the educational training received by the pharmacists would allow adequate preparation in counseling their respective patients to enhance better patient care. Summary of responses from both groups in this category showed no statistical significant in differences when compared to each other (P>0.05). Though pharmacists’ overall confidence in knowledge in pharmacogenetics, HGP and genetic testing remains LM (low-moderate), yet the difference in summary of responses in this category for pharmacogenetics was statistically significant for hospital pharmacists compared to the non- hospital group (2.70±0.42 versus 1.6±0.20 with P<0.04). However for the other fields, responses between these groups were statistically insignificant (P>0.05).

DISCUSSION

Based on the results, there are no significant differences in perceptions of study group of pharmacists with regards to their overall knowledge on topics related to pharmacogenetics. The use of variables like practice site locations, gender, age, race and educational degree did not provide any statistically significant differences in reference to the group’s respective responses to the questionnaires. There is however a statistically significant difference between the hospital and non-hospital study groups response in reference to confidence of knowledge in advances in pharmacogenetics. Though the confidence level is low for both groups, the hospital pharmacists seemed to be relatively more informed about pharmacogenetics as compared to the non- hospital group. This result seems plausible based on the fact that the hospital group might be more aware about the effect of polymorphic genes on drug disposition probably through a CE program sponsored by the clinical setting or through personal efforts (considered to be a requirement for offering MTM services.

Consistent with our findings were those reported by ERPEG 6, 8 which states that healthcare professionals lack the knowledge and would need to be knowledgeable about genetic testing and other issues related to human genomics. Pharmacists in our study group indicated a low confidence rating that warrants the need for more informative education and training in this field. Although the number of CE programs on pharmacogenomics has shown an increase in the recent years, these programs have concentrated on general issues.7 More pharmacy schools in United States have started incorporating information in pharmacogenomics into their curriculum, however, this is far from a universal stand point. Only limited numbers of schools have placed emphasis on topics pertaining to pharmacogenetics as a stand-alone topic.7,15

A potentially good resource for the current and future pharmacists would be the National Human Genome Research Institute (NCHPEG) which was established in 1996. The organization establishes minimal core competencies in the field of genetics that are essential to sharpen skills and confidence of pharmacists as they provide patient care. Other learning and teaching avenues would include various pharmacy conferences that promote continuing education programs. This would provide opportunities for practicing pharmacists to keep abreast of the current trends. Additionally, CE credits may be achieved through participation in statewide programs, genomic and genetic journal articles, and self-guided study. There is definitely a lot of encouragement for pharmacy organizations and pharmacy schools to include specialized education sessions and workshops to broaden the scope of pharmacy practice as it gears itself for the future of pharmacy care. The next generation of pharmacists could be our current Pharmacy technicians. They should also be made aware of the advances in pharmacogenetics and how this rapidly evolving field could affect their future professional role. Colleges of pharmacy and all pharmacy organizations should recognize the need for CE credit programs and workshops to prepare this group.

As new discoveries are made and applications developed as a result of advances in pharmacogenetics, understanding how it may affect our professional responsibilities will be critical. Likewise, advances in this field are expected to lead to the development of a number of new products that may requirespecial storage and dispensing
requirements as well as special delivery systems. Pharmacists would have to apply the knowledge gained through education and training to ensure effective delivery of these products. Besides the new drugs being developed, pharmacists will also have to keep up with the current pharmacogenetic technology and understand its applications. The high possibility of rapid conversion of many genetic discoveries into clinical applications could have prompted the pharmacists in our study to believe that they required training on the proper handling of upcoming and new drugs.

With such advances in pharmacogenomics, the pharmacists will have to spend more time counseling patients and answering complex questions from physicians. This will usher in the era of tailor-made drugs; drugs that will carry profiles for a genetically specific person.9, 10, 11, 12 Statistically significant responses were obtained from our study group with regards to genetic screening. It was strongly agreed that there is “nothing ethically wrong” for advocating genetic screening. However, subjecting all pregnant women to genetic screening was not at all favorable. Further more, genetic profile accessibility should be limited to avoid discrepancy in treatment and patient rapport due to genetically induced discrimination from the employers, insurers and health care professionals. With confidence and strong conviction, the group believes that the advent of genotyping would greatly impact healthcare cost (reduction in cost) while subsequently opening gateways for reimbursement of pharmacy counseling services. Any information gathered from pharmacogenetic studies and experiences would be beneficial as pharmacists may apply this knowledge to customized drug dosing and identify a number of patients most likely to respond to drug therapy. Moreover, this would help enhance patient counseling for specific products. Several medical centers have been using genetics as guides to some therapy. It is now being used for warfarin and tamoxifen therapy. Large and national level laboratories are currently offering pharmacogenetic testing.13 Everyone in the US has access to pharmacogenetic tests not because every drug should be tested but rather for drugs with narrow therapeutic indexes or for those drugs with significant risks of adverse reactions.13 According to McLeod2008, this will potentially make difficult drugs more manageable.

LIMITATIONS

Certain limitations are adherent to the current study. Consideration should be taken into stride for accurate interpretation of the study’s significance in the perception of the pharmacists’ knowledge in reference to the rapidly advancing application of PGx in pharmacy practice. The responses to the variables were subjective and hence open to different interpretations. Questionnaires may be perceived differently by the subjects due to insufficient information and clinical exposure to this new field in their practice. The observed outcomes from this would be inadequate and a less meaningful insight to the subject’s responses. Consequently, a differing opinion may occur as pharmacists are given more time to gain knowledge on the topics. The subjects were recruited using a convenient method of selection by using the preceptors affiliated to SUCOP rather than a random selection process. The small sample size was limited to a specific group of pharmacists thus the results may not represent the general perspective of the pharmacists at large. Moreover, the study was limited to the metro Louisville hospitals, community and managed care areas. The time line for completion of the questionnaire may be too short to accommodate the busy schedules of the participants thereby resulting in two incomplete and 11 no-response survey results. This further reduced the number of study population.

CONCLUSIONS

Hospital pharmacists and their colleagues in non-hospital settings have similar perceptions with observed minor deviations in reference to the overall influence of pharmacogenetics in their profession. The study establishes the fact that the overall confidence in knowledge of the pharmacists in pharmacogenetics and associated fields can be best described as low-moderate (LM). This clearly indicates that there exists an insufficient and inadequate learning resource tools for the pharmacists. Moreover, factual data points out that educational institutes or pharmacy professional organizations are lacking in their responsibility to educate their colleagues in genomics, which is worrisome, given its increasing importance in MTM in the coming years. In spite of some recent advances, a greater awareness for a more in-depth approach to pharmacogenetics curricula within colleges and
pharmacy schools of the United States is urgently needed. The leadership role of future pharmacists calls for a more structured, formalized manner of teaching this importantly challenging scientific field. Pharmacogenomics and pharmacogenetics may be far from being a routine part of clinical and community pharmacy practice for some time, however, the field presents vast opportunities for involvement in personalized medicine, pharmacogenomics research, better drug and treatment selection guidelines and dosing techniques based on genetic information. All of the above leads to improvement in overall patient care. As drug experts, pharmacists offer unique perspectives on appropriate use and disposition of medications in the body and therefore are a natural fit for helping to define the eventual role of pharmacogenetics in pharmacotherapy.

APPENDIX A

Highlighting Differences In Pharmacists’ Perceptions Regarding Use of Pharmacogenetic Information in their Profession

This advanced survey is aimed at evaluating the perception of practicing pharmacists in incorporating the concept of “Pharmacogenomics/Pharmacogenetics” in their professional activities. Since its inception in 2001 (with the completion of Human Genome Project), Pharmacogenomics has made a tremendous impact in the pharmaceutical industry and on the process of making drugs. Nearly 25% of the marketed drugs have Pharmacogenomic labels in their inserts and many molecular techniques routinely performed in clinical diagnostic laboratories are dependent on “Pharmacogenomics.” Thus, it is absolutely vital that practicing pharmacists grasp the basic knowledge of “Pharmacogenomics”, since they will be required to frequently counsel patients on genomic information as they deliver “Medication Therapy Management”.

Note: Please put a tick mark in the circles 1,2,3,4 or 5 to indicate your assessment (1 = “strongly disagree”; 2=“disagree”; 3 =“neutral”; 4=“agree”; 5=“strongly agree” ;)

GENERAL KNOWLEDGE OF PHARMACOGENETICS:

A. I believe that “Pharmacogenomics/Pharmacogenetics” studies identifying which gene predispose to a disease, do allow the scientists to understand crucial biologic pathways that can then be directly or indirectly targeted with drugs.

1. O

2. O

3. O

4. O

5. O
D. Drugs developed due to advances in “Pharmacogenomics/Pharmacogenetics” will have less adverse drug reactions.

1. O  
2. O  
3. O  
4. O  
5. O

B. Genotyping a patient is a reliable method to identify or eliminate risk of developing congenital diseases.

1. O  
2. O  
3. O  
4. O  
5. O

E. Drugs developed due to advances in “Pharmacogenomics/Pharmacogenetics” will be safer and more efficacious.

1. O  
2. O  
3. O  
4. O  
5. O

C. To be clinically relevant a “Pharmacogenomics/Pharmacogenetics” screening test must predict the outcome of drug treatment as accurately as possible.

1. O  
2. O  
3. O  
4. O  
5. O

F. Drugs developed due to advances in “Pharmacogenomics/Pharmacogenetics” will favor patient compliance.

1. O  
2. O  
3. O  
4. O  
5. O

D. Genotyping could be made cost effective if a prescriber selects a specific protocol in the clinical settings based on the following parameters: initial set up costs, fixed cost per marker and consumable costs proportional to usage.

1. O  
2. O  
3. O  
4. O  
5. O

G. Drugs developed due to advances in “Pharmacogenomics/Pharmacogenetics” will improve health outcomes.

1. O  
2. O  
3. O  
4. O  
5. O

E. I believe that “Pharmacogenetic” screening is morally and ethically wrong if that information is used for making health care decisions.

1. O  
2. O  
3. O  
4. O  
5. O

IDEAS ABOUT “PHARMACOGENETIC” SCREENING:

A. Drug development will be faster due to advances in “Pharmacogenomics/Pharmacogenetics” screening techniques.

1. O  
2. O
F. Every pregnant woman should undergo “Pharmacogenomics/Pharmacogenetics” screening.

1. O  
2. O  
3. O  
4. O  
5. O

G. Genotyping will reduce cost associated with health care.

1. O  
2. O  
3. O  
4. O  
5. O

H. Health insurers should have access to a complete “Pharmacogenetic” profile for insured members.

1. O  
2. O  
3. O  
4. O  
5. O

I. Employers should have access to a complete “Pharmacogenetic” profile for their employees.

1. O  
2. O  
3. O  
4. O  
5. O

J. Employers having access to genetic information may discriminate against present and potential employees.

1. O  
2. O  
3. O  
4. O  
5. O

K. Health insurers having access to genetic information will discriminate against present and potential patients.

1. O  
2. O  
3. O  
4. O  
5. O

L. Pharmacists should be considered providers of genetic testing services to patients and should be reimbursed for their services.

1. O  
2. O  
3. O  
4. O  
5. O

“PHARMACOGENETICS” AND ITS IMPACTS ON PHARMACISTS:

A. The advent of “Pharmacogenomics/Pharmacogenetics” will revolutionize the role of pharmacists.

1. O  
2. O  
3. O  
4. O  
5. O

B. Pharmacy schools should include information on “Pharmacogenomics/Pharmacogenetics” in their curricula.

1. O  
2. O  
3. O  
4. O  
5. O
C. Professional Pharmacy Organizations/Pharmacy schools should provide continuous education on “Pharmacogenomics/Pharmacogenetics” for pharmacists.
   1. O
   2. O
   3. O
   4. O
   5. O

D. “Pharmacogenomic/Pharmacogenetic” information on a patient could directly or indirectly improve formulary management decisions in a managed care pharmacy.
   1. O
   2. O
   3. O
   4. O
   5. O

E. “Pharmacogenomics/Pharmacogenetics” information available for individual patients could potentially make Drug Utilization Review (DUR) evaluations and communications more robust between the physicians and pharmacists in either hospital or managed care settings.
   1. O
   2. O
   3. O
   4. O
   5. O

F. Pharmacists will need patients’ genetic information in their database to improve drug dispensing.
   1. O
   2. O
   3. O
   4. O
   5. O

G. Pharmacists as well as pharmacy technicians will require additional training on the proper handling, storing and dispensing of new drugs being developed due to advances in “Pharmacogenomics/Pharmacogenetics.”
   1. O
   2. O
   3. O
   4. O
   5. O

H. Drugs being developed due to advances in “Pharmacogenomics/Pharmacogenetics” will require special storage instructions before dispensing.
   1. O
   2. O
   3. O
   4. O
   5. O

I. Handling of so called “Pharmacogenomics/Pharmacogenetics” drugs will increase the operational costs of a pharmacy.
   1. O
   2. O
   3. O
   4. O
   5. O

J. Pharmacists’ workload will increase as they will have to spend more time in counseling the patients on the appropriate use of “Pharmacogenomics/Pharmacogenetic” drugs.
   1. O
   2. O
   3. O
   4. O
   5. O
K. How do you rate your overall confidence in knowledge for "Pharmacogenomics/Pharmogenetics"?

  High
  Moderate
  Low
  Not a clue

L. How do you rate your overall confidence in knowledge for "Human Genome Project"?

  High
  Moderate
  Low
  Not a clue

M. How do you rate your overall confidence in knowledge for "Genetic Testing"?

  High
  Moderate
  Low
  Not a clue

C. Please indicate all the professional degrees (mentioned below) earned?

  1. BS
  2. PharmD
  3. Others (specify)

D. In which year did you graduate from the Pharmacy School?

E. In which year were you registered as a pharmacist?

F. How many years you have been practicing?

G. What is your ethnicity?

  1. White, Non Hispanic
  2. African American
  3. Hispanic
  4. Asian
  5. Others (specify)

H. Please indicate your practice settings.

  1. Chain Pharmacy
  2. Independent Pharmacy
  3. Hospitals
  4. Others (specify)

I. Which one best describes your principal activity at your practice settings?

  1. Pharmacy Directors/Managers
  2. Clinical Pharmacist
  3. Staff Pharmacist
  4. Others (Specify)

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