

# **Implementation of a Personalized Medicine (Pharmacogenomics) Service in a Community Pharmacy**

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## **OBJECTIVE**

To determine the feasibility of pharmacogenomics testing in a community pharmacy using clopidogrel as an example.

## **METHODS**

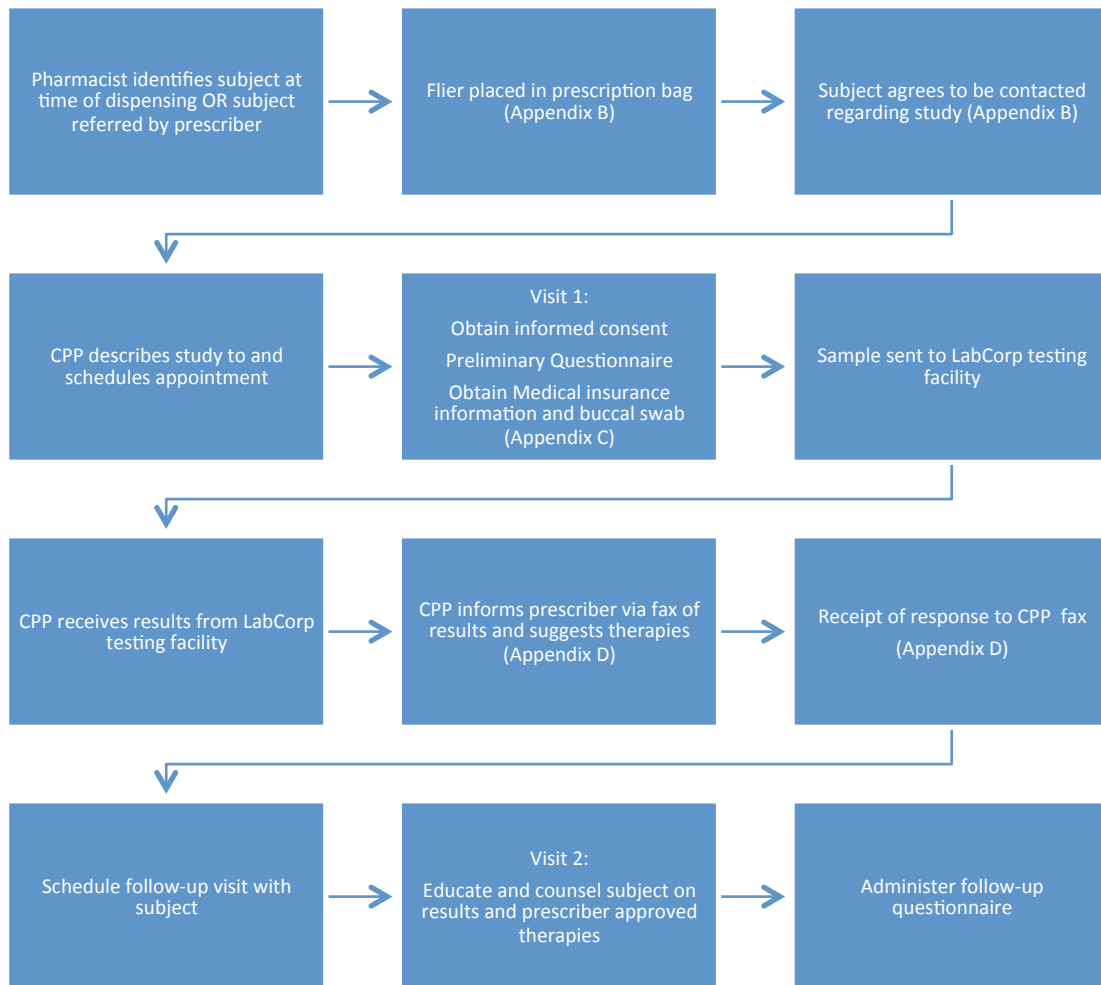
Patients at Kerr Drug in Chapel Hill, North Carolina who are taking clopidogrel or newly started on clopidogrel during the study period were presented with a flier to explain the study. This study only included subjects who have been prescribed clopidogrel by their prescriber and it did not determine subject's need for clopidogrel as this assessment has already been performed by the prescriber. Patients were included in the study if they were 18 years of age or older, currently taking clopidogrel for ACS, recent PCI with stent, or history of TIA or stroke. Patients were excluded if they were unable to complete study materials (surveys) with or without assistance, non-English speaking patients, taking clopidogrel for another indication, pregnant or breastfeeding, or had an allergy to aspirin. Pregnant or nursing women must be excluded from this study because there are no clear studies that clopidogrel or prasugrel are safe in human subjects who are pregnant. Women who were breastfeeding must be excluded because prasugrel is excreted in breast milk. Subjects with an allergy to aspirin were also excluded as these subjects may not be eligible for the alternative therapy suggested in this study.

## **Procedures (please see chart below for study procedures)**

All patients at Kerr Drug Chapel Hill taking clopidogrel will be assessed for inclusion in the study. Pharmacy staff can also identify any new patients starting clopidogrel at the time of dispensing. All patients who do not immediately meet exclusion criteria will be contacted via a flier given at time of dispensing to determine interest in participation. Participants may opt out of contact by checking the corresponding box on the flier and submitting to pharmacy personnel. Interested patients will be followed up via phone by study personnel. The phone call will detail the plan for the study and expected outcomes for the patients. Patients who express interest in participation in the study will be asked to come to the pharmacy; at this interview they will be asked to provide consent to participate in the study. Subjects who provide consent will be asked to provide a complete list of medications, complete a pre-study questionnaire, provide a copy of their medical insurance card, and have a buccal swab. The swab will be sent to Laboratory Corporation of America (LabCorp) for genotypic testing of CYP2C19. The physician co-investigator will serve as supervising physician for all ordered genetic testing via a Clinical Pharmacy Practitioner (CPP) agreement, and the CPP will have oversight of lab ordering and interpretation under this agreement as per the approved collaborative practice protocol (similar to Nurse Practitioners and Physician Assistants). Upon receipt of the results of the CYP2C19 genotype

results, the prescriber will be informed via fax and the CPP will propose an intervention to the prescriber based on the patient's indication for clopidogrel and the identification of certain genetic variations at CYP2C19. The indication for therapy and presence of genetic variation will signal implementation of a change in therapy. If no pertinent genetic variations exist, the CPP will inform the prescriber that this patient has no relevant genetic variations at CYP2C19. All patients will be asked to return to the pharmacy for explanation of the results and implementation of any changes approved by the prescriber and to complete a follow-up questionnaire. After the visit to explain the results of testing, the patient's insurance will be billed electronically for a medication therapy management (MTM) visit using pharmacist-specific CPT codes (not genetic-specific) to the patient's medical insurance. Patients may opt out of billing to insurance at any time by informing study personnel or checking the corresponding box on the informed consent during the first visit. Regardless of reimbursement rate from insurance, the patient will not be charged for participation in this study. The pharmacy already has a method in place to bill medical claims electronically for immunizations that the pharmacist administers. This same billing platform was created for this study but to bill for the pharmacist's time using the CPT codes specific for MTM. The billing of insurance is included to determine the rate of reimbursement for the clinic visit associated with a pharmacogenomics visit to a community pharmacist, which is vital to determining the feasibility of the service.

## Flow Chart: Study Procedure



## Study Endpoints

- Determine the percentage of eligible patients that consent to a pharmacogenomics test conducted by a community pharmacist
- Determine the percentage of prescribers that accept the pharmacist's suggested intervention
- Determine how much time it takes for the pharmacist to perform pharmacogenomics testing
- Determine the pharmacist reimbursement for interpretation of and counseling regarding pharmacogenomic testing
- Assess patient satisfaction of pharmacogenomic testing

## RESULTS

### Patients

A total of 58 patients, aged 18 years or older, were identified as taking clopidogrel. A retrospective data pull of prescription fills between the dates of May 1, 2011 and October 26, 2011 yielded 53 patients with at least one fill of clopidogrel. Subsequently, during the recruitment period of December 12, 2011

through May 8, 2012, five additional patients were identified at the time of dispensing by the pharmacy staff as having a new prescription for clopidogrel.

Of the 53 patients from the data pull, nine were no longer taking clopidogrel during the study enrollment period, three received prescription deliveries and were not interested in or able to be contacted regarding the study, and one was identified as being admitted to nursing home care and was not able to be contacted. Thus, a total of 40 patients from the data pull were identified for study participation. With the addition of the 5 patients identified during the enrollment period, a total of 45 patients could be targeted for study participation. Forty-three of the 45 (95.5%) patients were presented with the opportunity to participate in the research study via presentation of the recruitment flier at the point of dispensing.

Of the 43 patients presented the opportunity for participation, 33 agreed to a follow-up via phone call. During follow-up by phone call, two patients were excluded due to unidentified aspirin allergies and 13 opted out due to lack of transportation or similar previous genetic testing. A final sum of 18 out of 43 patients (41.9%) were enrolled in the study.

The average age of participating patients was 77 years old (range: 61-92 years old) and 72.2% were male. The indication for taking clopidogrel was cardiovascular in origin for 72.2% and cerebrovascular for 27.8% of participants.

### **Genetics, Recommendations, and Prescriber Approval**

Each of the 18 patients enrolled in the study underwent pharmacogenomic testing for CYP2C19 alleles. Nine of the eighteen (50%) were homozygous wild-type (\*1/\*1) with the remaining nine having some type of genetic variation. Two patients had a loss-of-function allele (\*1/\*2), thus it was recommended to the prescribers to replace clopidogrel with an alternative antiplatelet agent. Both prescribers agreed to substituting clopidogrel with an alternative medication, one with Aggrenox, one with aspirin. Five of the eighteen patients carried at least one increased function allele (\*17). Four of the five prescribers agreed to the recommendation of increased monitoring for bleeding. The other patient was determined to no longer need clopidogrel therapy per the treatment guidelines, and the prescriber agreed to the recommendation to discontinue clopidogrel. Two of the 18 patients carried one loss-of-function and one increased-function allele (\*2/\*17). The recommendation to continue clopidogrel therapy was agreed to by both prescribers. None of the patients were homozygous for a loss-of-function allele (\*2/\*2).

### **Pharmacist Time**

The average time spent by the CPP with each patient was 76.6 minutes. This included the average time of 10 minutes to describe the research flier at the time of dispensing and the follow-up phone call, 40 minutes for the first patient visit, approximately 20 minutes for the second visit, and a few minutes for the CPP to schedule patient appointments. It took about one week to get test results from LabCorp, while securing prescriber approval for recommendations took about two weeks. Six prescribers

responded after the first facsimile, five after a second fax, and seven had to be called. The average time to complete the study per patient was 30.1 days.

### **Reimbursement**

Seventeen of the 18 patients consented to allowing the pharmacy to attempt to bill their medical insurance for the pharmacogenomic testing and pharmacist consultation services using CPT codes specific for MTM. Thirteen patients had Medicare Part B coverage as their primary medical insurance. Two patients had Blue Cross and Blue Shield of North Carolina as primary medical insurance. For two patients insurance could not be billed electronically through the pharmacy dispensing system as one had NC Medicaid and one had a Medicare Advantage plan. A clearing house was used for billing the insurance claims. The clearing house was able to submit medical claims on behalf of the pharmacy. However, the clearing house was unable to get any of the claims to be recognized by the medical insurance and thus was not able to collect reimbursement for any of these claims. Of the 18 patients, six patients had a Medicare Part D plan which could be billed for MTM services through a statewide MTM program for all patients with Medicare Part D.\*

### **Patient Satisfaction**

Forty-one percent of patients said they would pay \$50 or more for this kind of personalized medication test while 42% would pay but less than \$50 and 17% said they would not pay for the service. Sixteen of 18 patients noted the service was a “valuable use” of their time. The remaining two patients did not respond to the question. Sixteen of 18 patients said the service was “valuable” to have at a community pharmacy.

Perception of pharmacists’ abilities was not documented to have increased post study however; confidence in this ability was already documented as high on the pre-study questionnaire. Sixty-five percent of patients said they were “very sure” of a pharmacist’s ability to perform personalized testing pre-intervention. This can be compared with 71% of patients who said they were “very sure” of a prescriber’s ability to perform personalized testing pre-intervention. Following the intervention, the perception of the ability of both pharmacists and prescribers was rated equally by 71% of patients.

### **CONCLUSION**

The investigators were able to show that a pharmacogenomics service is viable in community pharmacy. Our findings reveal that nearly half of the patients who qualified were interested in participating in the study. Physician response to pharmacist testing and recommendation was entirely positive, with no suggestion by the CPP being rejected by the prescriber. Overall time spent by the pharmacist per patient slightly exceeded one hour. The majority of the time was spent during the first visit with the patient when administrative duties and the buccal swab were performed. Approximately one month passed between initial patient contact and prescriber response. While about one week was needed to obtain results from LabCorp and two weeks for a response from the prescriber. Facsimile was the primary

\*Post-submission note: The Part D information was observational and after the fact. Since we were not able to determine if we could bill medical insurance we decided to look at what we could bill, which was Part D MTM. We thought this information might be helpful to anyone that tries to create this type of service and how they might be able to get reimbursed for their time. Although, we did not bill for the service during the study.

method used to contact the prescriber. This study was not designed to determine which method of prescriber contact is most efficient, however, such information would be critical to the operation of such a service. Medical insurance claims were submitted for 15 of the 18 participating patients; however, reimbursement was not collected for these claims. Since six of the 18 patients had Medicare Part D, MTM services would have been covered by a statewide MTM program. Future studies to determine economic feasibility of pharmacogenomic services in community pharmacy would be needed. However, a pharmacogenomics service can be an extension of MTM services already offered in a community pharmacy and patients and prescribers were receptive to pharmacists conducting the testing.