

Cancer patient acceptance, understanding, and willingness to pay for pharmacogenetic testing (PGT).

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Background: PGT offers the potential to improve cancer therapy through the use of specialized tests that can predict the level of efficacy and/or toxicity of specific treatments in an individual. However, there is currently little knowledge concerning cancer patient attitudes towards such testing in the clinical setting.

Methods: We interviewed a broad cross-section of 278 cancer patients (20% lung, 19% breast, 20% colorectal, 40% other) using hypothetical time, efficacy, toxicity and willingness-to-pay trade-off PGT scenarios.

Results: 153 potentially curable patients and 125 incurable patients received a separate series of trade-off scenarios. For curative patients, 70% accepted chemo that had a 5% absolute improvement in cure rate and <5% of severe toxicity. Of these, 99% wanted PGT where the test identifies a subset of patients benefiting from chemo; the same individuals were willing to pay a median \$2,000 (range: \$0-25,000) for PGT and would accept a median wait time for PGT results of 21 days (0-90). Patient preferences were insensitive to variation of fractions of individuals carrying the genetics associated with lack of benefit. In the incurable scenario, 90% of patients accepted palliative chemo with an 80% response rate and a severe side effect rate of 5%. Of these, 98% wanted PGT, where the test identifies individuals at highest risk of severe toxicity; the same individuals were willing to pay a median \$1,000 (\$0-15,000) for PGT, and would accept PGT turnaround times of 14 days (1-90). Patient preferences were insensitive to variation of fractions of individuals carrying the genetics associated with severe toxicity. The majority of patients (76% adjuvant; 87% metastatic) wanted to be involved in decision making regarding PGT; however, one in five patients (20% adjuvant; 22% metastatic) admitted that they lacked a basic understanding of what PGT means and its clinical implications.

Conclusions: Among cancer patients willing to undergo chemo, almost all wanted PGT and were willing to pay for it, waiting several weeks for results. While patients had a strong desire to be involved in decision making for PGT, a considerable proportion lacked the necessary knowledge to make informed choices.



Princess Margaret Hospital
University Health Network

March 28th, 2012

Dear Members of the NOYCIA awards committee,

Re: Dr Sinead Cuffe's Application for a NOYCIA Award.

It is with great pleasure that I nominate Dr. Sinead Cuffe for consideration of an award in recognition of her senior authorship of the abstract "Cancer patients' acceptance, understanding, and willingness to pay for pharmacogenetic testing (PGT)" which has been accepted as an oral presentation at the 2012 ASCO annual meeting this year. This is an unusual situation whereby Dr. Cuffe had two abstracts eligible for ASCO, and so was listed as a senior author on this particular abstract (she was listed as first author of the other abstract). As explained below, she certainly meets the criteria for co-senior author / first author, based on her work on this project.

Dr. Cuffe is a medical oncology clinical and research fellow from Ireland who has been working under my supervision as a clinical fellow in Princess Margaret Hospital. In her first two years of the fellowship, she was primarily supervised by Dr. Shepherd. In this past year, she has been primarily supervised by myself. During the course of her fellowship, Dr Cuffe has proven herself to be a mature and capable clinical researcher. Quite, unassuming, and humble by nature, I had not realized the extent of her capabilities until I started to work with her on several research ideas. Within a short time, Dr.Cuffe wrote full proposals with minimal guidance from me. Her writing skills are excellent – logical, clean, and to the point.

She has successfully completed several research projects in thoracic oncology and pharmacogenomics which have led to a growing number of publications. A further five manuscripts are under preparation or recently submitted, including the two associated with ASCO abstracts for 2012. These projects include: (i) Patient preferences for pharmacoepidemiologic testing using trade-off scenarios (the current study); (ii) Pharmacogenetic analysis of polymorphisms as prognostic factors in advanced non-small cell lung cancer treated with cisplatin (another ASCO abstract); (iii) Patient and physician preferences for pharmacogenomic testing using conjoint analysis and scenario comparisons; (iv) Patient acceptance of and preferences for completing epidemiologic surveys incorporated into the clinical trial setting (co-supervised by Wendy Parulekar); and (v) Plasma biomarkers associated with disease tracking and prognosis in Malignant Mesothelioma. To say that Dr. Cuffe is talented

young investigator with a knack of developing research ideas into full-blown studies may well be an understatement.

The study in question is of clinical relevance given the emerging role of pharmacogenomics and personalized medicine in cancer care. The results of this study are the first, to our knowledge, to conclusively show that a broad spectrum of cancer patients overwhelmingly accept, and are willing to pay substantial amounts of money to receive pharmacogenetic testing in the clinical setting. Further, up to 20% of patients require additional help in understanding the concept of pharmacogenomic testing. This knowledge will greatly assist in promoting the diffusion of appropriately validated pharmacogenetic testing into routine clinical practice in oncology. Already, several OICR and CCO colleagues have requested presentations and data from the current analysis, as they plan on using this data to help further their agenda in Ontario.

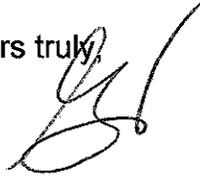
Furthermore, by identifying significant deficiencies in cancer patients' understanding of pharmacogenomics, that could potentially negate their strong desire to be involved in decision making regarding pharmacogenetic testing, we highlight the urgent need for improved patient education in this regard. One follow-up project that Dr. Cuffe is working on with another clinical fellow is a collaboration with Jodie Jenkinson of the Department of Biomedical Communications at the University of Toronto Faculty of Medicine, where the concept of pharmacogenomic testing is converted into a set of visual aids, including the use of Flash or Javascript or HTML animations, and simple flip-charts. In the summer of 2012, Dr. Cuffe and colleagues plan on testing the incorporation of these tools (some of which will be administered using i-Pads), to determine whether patient understanding of these pharmacogenomic concepts improve. Thus, Dr. Cuffe has the capability to carry forward follow-up studies, based on her prior research, signs of creativity, dedication, ambition, and drive. She is also able to follow through from clinical research to knowledge translation into the clinical setting.

Dr. Cuffe was instrumental to the success of this study which qualified her for senior authorship of this abstract. The original nidus of a concept came from me, as well as funding support (through my research chair). However, Dr. Cuffe performed the background research, developed the study design and protocol (from start to finish), developed the trade-off survey tool, identified and fostered internal and external collaborations necessary to complete this research, supervised four summer medical students and a full-time junior clinical research coordinator (A Masters of Engineering graduate in his first clinical research coordination position, who was listed as the first author of the abstract, and was directly supervised by Dr. Cuffe) in the data collection and conduct of survey, interacted directly with our two statisticians, interpreted the data, and prepared

the manuscripts. I and other colleagues have provided advice on the interpretation and analysis, but Dr. Cuffe had final word on all elements of the analysis and interpretation. Her level of involvement in this project clearly meets the definition of principal investigator (I only supplied the funding and germ of the original idea).

As such, I strongly believe that she would be a worthy recipient for a NOYCIA award in recognition of this work and sincerely hope that you look favourably on this application.

Yours truly,

A handwritten signature in black ink, appearing to be 'G. Liu', written over the text 'Yours truly,'.

Geoffrey Liu MD, MSc, FRCPC
Medical Oncologist and Clinician Scientist, Princess Margaret Hospital
Associate Professor of Medicine, Epidemiology, and Medical Biophysics
University of Toronto and Dalla Lana School of Public Health

SINEAD CUFFE

The original concept for this study was proposed by my supervisor, Dr Geoffrey Liu. Furthering on his original idea, I developed the study design after completing the necessary background research. Using knowledge gained from an extensive literature review, I designed the trade-off survey tool and questionnaire which were used in this study. I wrote the study protocol and obtained the necessary approval from the hospitals' research ethics board. I trained and supervised four summer medical students, and one clinical research coordinator in administering the survey and collecting study data. I personally extracted additional health status and treatment data from the electronic medical records of each of the 278 patients participating in this study, which was linked to the study data. I was involved in planning and overseeing the statistical analyses of this study which was conducted by two statisticians within our department. I was responsible for interpreting the study results and have completed the manuscript. Finally, I initiated two follow up studies based on this research project. The first study also evaluated patient preferences for pharmacogenetic testing but employed conjoint analysis as an alternative form of trade off testing. 264 patients were enrolled in this study, while 64 physicians were also surveyed regarding their opinions on pharmacogenetic testing. This study will be presented at the International Society for Pharmacoepidemiology annual meeting in August 2012. The second study is being conducted in collaboration with the Department of Medical Communications in the University of Toronto's Faculty of Medicine and will explore the use of visual aids in improving patients understanding of the concept of pharmacogenetic testing.

Contribution percentage:

70%