資料５－１

臨床実習の学生諸君へお願い！　　年　　月　　日

本日のレクチャーでお話したことに関する質問です。
小児用医薬品の現状について、以下の問いにお答えください。

１．小児に使用されている医薬品の６～７割が保険診療において適応外（オフラベル）であることを知っていましたか。　（知っていた　　知らなかった）

２．小児用医薬品の開発が遅れている原因として、製薬会社の姿勢、小児の診療にかかわる医師の医薬品に関する無関心、社会的に適応外使用が黙認されている現状（患者様はそのことを知らない）があると思われます。各々、何が問題で、どういった解決法があると考えられますか。簡潔に記入してください。

	問題点	解決法
製薬会社		
医師		
社会		

３．将来、医師として診療に従事するにあたり、治験を担当するなど医薬品開発に取り組んでみたいと考えますか？

（はい　　いいえ　　わからない）

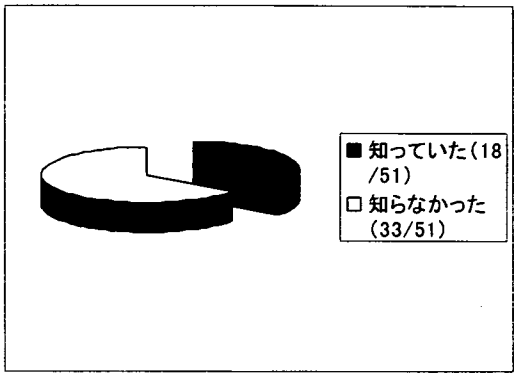
理由を簡単に（１－２行で）書いてください。

資料 5-2

臨床実習の学生諸君へお願い！　　年　　月　　日

本日のレクチャーでお話したことに関する質問です。
小児用医薬品の現状について、以下の問いにお答えください。

1．小児に使用されている医薬品の 6～7 割が保険診療において適応外（オフラベル）であることを知っていましたか。　（知っていた 18　　知らなかった 33）



2．小児用医薬品の開発が遅れている原因として、製薬会社の姿勢、小児の診療にかかわる医師の医薬品に関する無関心、社会的に適応外使用が黙認されている現状（患者様はそのことを知らない）があると思われます。各々、何が問題で、どういった解決法があると考えられますか。簡潔に記入してください。

	問題点	解決法
製薬会社	・ **利益優先　17** ・ 適応外使用の現状の黙認 2 ・ 責任回避している ・ **小児の治験の困難さ 10** ・ **採算性の問題 30** ・ メリットがない 2 ・ 患者の利益を無視 ・ 小児用医薬品開発に積極的でない	・ **小児用医薬品開発に対する国からの補助 35** ・ **製薬企業へのインセンティブを考慮する 23** ・ 小児の治験への法的な整備 4 ・ 小児治験の義務化　5 ・ 治験の活性化への指導 ・ 小児の治験は特別扱いすべき 2 ・ 希少疾病には国際機関を立て、医薬品の開発をする ・ 国が主導で治験をする

		・ 治験プロセスの簡素化 ・ 成人並みの治験をすべき ・ 国立で製薬会社を設立する ・ 患者の会との連携 ・ 医療の向上を優先すような介入が必要 ・
医師	・ **適応外使用に対する認識不足　28** ・ 適応外使用が問題なく行えること　2 ・ 治験に参加しようとしない 4 ・ 薬について学ぶ余裕の欠如 2 ・ 治験についての認識不足 7 ・ 薬の適応に対する関心不足 3 ・ **時間と知識の欠如　10** ・ 学生教育で欠けている ・ 時間的余裕がない　3 ・ 小児の薬物療法の現実が伝えられていない　3 ・ 医師主導治験の活性化がない ・ 家人への説明不足と医師の消極性　2 ・ 両親の説得困難 ・ 国内の治験の遅れに無関心 2 ・ インセンティブの欠如	・ 学会での啓発　2 ・ 適応外使用の認識を変える 6 ・ 勉強すること　2 ・ 世間への発信　4 ・ 治験への参加　3 ・ 治験での業務を減らす　4 ・ 適応外処方を通知する　5 ・ 医薬品の承認と治験の重要性を教育する 7 ・ 医師が国や製薬企業へ働きかける 2 ・ 医学教育で教える　8 ・ 治験専門の外来で教える ・ 専門医の育成 ・ 治験協力の義務化　4 ・ 適応外使用の資料配布や勉強会の実施　8 ・ CRC 専門の人材派遣会社を設立する ・ 薬に対する知識がないと処方できないシステムを作る ・ 学会等の意識の不統一 ・ 治験を正しく認識し、説明を行う 2 ・ 医学部での講義を増やす ・ 医師への継続的啓発　2 ・ インセンティブを与える　2 ・ オンラインを利用してカルテから情報収集を行なう

		・医師同士の連携 ・小児科医の増員
社会	・情報提供の不足 4 ・**適応外使用の現状が知らされていない 29** ・適応外使用の黙認 2 ・実際に困っている人が少ない ・小児用医薬品開発や適応外使用に無関心（無知）8 ・マスコミの過剰な反応を危惧 ・治験に対する誤解があり、受け入れにくい 5 ・治験を受け入れにくい環境 2 ・治験の重要性についての認識不足 7 ・人体実験的イメージ 2 ・小児用医薬品開発の遅れに無関心 ・治験の知識不足 4 ・治験への参加意思がない ・行政の無策 ・医薬品の承認が大変すぎる	・**マスメディアへの情報提供 14** ・治験参加の重要性を訴える 6 ・適応外使用を自己負担として問題提起する ・医師に責任を負わせないための法整備 ・オフラベル使用のデータを収集し、承認への資料とする ・**ジェネリック同様、マスコミを利用して知ってもらう 10** ・小児用医薬品の多くが未承認であることを広く訴える 4 ・被験者のインセンティブを上げる 2 ・啓発活動を行なう 7 ・治験に参加する患者や家族の負担軽減 ・患者への情報提供を勧める 2 ・義務教育で医薬品の意識を高める 2 ・治験参加で現在の治療レベル同等の治療を保証する ・世論を高める ・治験協力のパンフレットを作成 2 ・実施中の治験の情報公開 ・マスメディアによる適応外使用の積極的な報道 3 ・治験無しで医薬品は使えないことを教育する 3 ・オフラベル使用に対し明確に線引きし再考しなおす ・開発の遅れを明らかにし、治験の悪いイメージを払拭する 2

		・ 行政がシステムを作る ・ 適応外使用を社会の共通問題として認識させる　2 ・ 医薬品の承認を早くするようシステムを整える

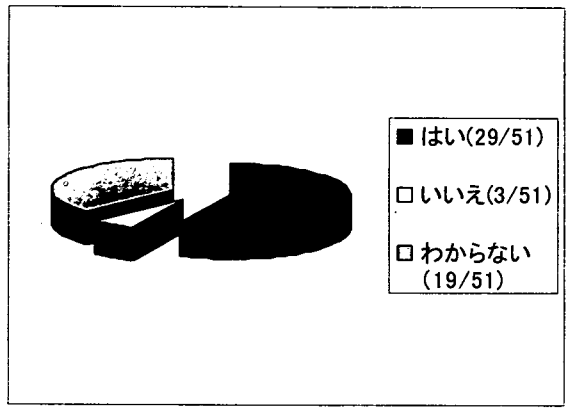
3．小児の治療における適応外使用の現状を解決するにあたり、医学部教育や小児科医の活動で不足しているものは何と思いますか？

・ 世間への公表と啓発　5
・ 適応外使用により患者と医師にかかるリスクを訴える　3
・ 製薬企業へ小児用医薬品開発の責任を追及する
・ オフラベルの原因が国全体にあることを訴える。国民が声を上げないと国も製薬企業も動かない　2
・ 適応外使用の多さを公表する　5
・ 医師や医学生、一般の国民に対する啓発活動 3
・ 医学部教育での講義を徹底することと小児科医の適応外使用に対する世間への啓発活動　5
・ 医学部教育で正しい医薬品の使用法を教える　4
・ 時間と人材　2
・ 関係者の理解を得ること
・ 時間
・ 医学教育で医薬品に対する講義数が少ない 7
・ 適応外使用の多さを認識する機会が少ない　4
・ 小児の薬物療法の現状、治験、製薬会社の立場等を教えるべき
・ 国への働きかけ
・ 医師主導治験の不徹底と実施のために必要なものが理解されていない
・ 小児科医の数を増やし、臨床研究に携わる人材を育成する
・ 適応外使用や医薬品開発遅れを解決しようとする意思統一の不足
・ 小児治験への積極的な参加
・ 医薬品全般について教えられる先生がいること
・ 適応外使用の具体例を教える機会が少ない
・ 治験の重要性と推進の講義を徹底する
・ 小児科医自身による現状把握と問題意識を持つこと　2
・ 治験に対する正しい知識

・ 小児治験実施の国民の理解と予算化
・ 無回答
・ 適応外使用の現状をデータとしてフィードバックするシステムの構築
・ 現在の問題点を政府や国民にもっとアピールし、国のレベルで解決に取り組むべき
・ 医療の現状を大学では教えない
・ 多くの情報の中で、新しく正しい情報を吟味し取捨選択する。自分自身の問題として取り組むこと

4．将来、医師として診療に従事するにあたり、治験を担当するなど医薬品開発に取り組んでみたいと考えますか？

（はい　29　　いいえ 3　　わからない　19）



理由を簡単に（１－２行で）書いてください。

はい

・ 適応外使用に対する危機　2
・ 副作用に苦しむ子供を減らしたい
・ 医薬品開発に取り組むことが患者さんの利益となる　4
・ 医薬品開発に取り組みたい
・ 小児科希望なので、医薬品開発をしていきたい
・ 一つの医薬品開発で救える人は多いので、また、治療法がない疾患も治癒できるかもしれない　2
・ 医療の進歩につながる　3
・ 良い医薬品を必要とする患者さんは多いと思う
・ 医師である以上多くの人に適切で安全な治療を行ないたいので　2
・ 医師にとっても患者にとっても有益となる　2
・ 必要だから　2
・ 新しい治療法の開発は重要で、医師としてやりがいがある
・ 適応外使用が多い現状を解決したい

・ 必要な医薬品開発に取り組むことは医師の業務の一つだと思う　2
・ 医学の発展を実践できないのは残念だから
・ とりあえず治験は大切と考えるので
・ できる範囲で社会に貢献したい
・ 日本で治験を受けられないという状況を改善していきたいので
・ 適応外使用の多さと矛盾を改善していきたい
・ 医師の裁量権だけで処方するのは恐ろしいし、小児にもエビデンスに基づいた処方がなされるべきだと思う
・ 医学の進歩の一翼を担えるのはすばらしい

いいえ
・ 医薬品開発の重要性は認識できるが、具体的なイメージがない
・ そのようなオプションを考えたことがない

わからない
・ 興味はあるが、責任が大きすぎて怖い 2
・ 小児用医薬品開発の重要性は理解できるが、治験を担当することの具体的な内容や仕事量がわからない
・ 将来のことがわからない（未定）
・ 医薬品そのものについて理解できていない
・ 診療を始めてみないとなんとも言えない
・ 時間的余裕がないかもしれない
・ 無回答　5
・ 煩雑すぎて医師業務と両立できるかわからない　2
・ 取り組むべきと考えているが、治験を嫌がる患者さんに説得して行動できるかわからない
・ 基礎研究をしてみたい
・ 具体的にどうすればいいかわからない

資料 6

UNIVERSITY of TORONTO
FACULTY OF MEDICINE

University of Toronto

Comprehensive Research Experience for Medical Students (CREMS)

The Comprehensive Research Experience for Medical Students (CREMS) is a student program for undergraduate medical students that has recently been created with the stated purpose of providing an enhanced summer and core curriculum experience for medical students in the fundamentals of research. This program will have linkages with graduate supervisors from across the full spectrum of departments, including biomedical, health outcomes, and international health research. Initial funding from the CREMS Program has already been used to provide additional support to the Summer Medical Scholarship programs. Indeed, the CREMS program is not meant to replace, but to complement, the Summer Medical Scholarship and other research programs within the Faculty of Medicine. Further developments this year have included hiring of a Director, Dr. Donald R. Branch, Associate Professor of Medicine, the organization of an advisory committee of representative faculty and medical students to decide on the format of a structured 12-month longitudinal program of research experience that will include a summer seminar series and the opportunity to present research experiences at a Research Day.

- **crems.med.utoronto.ca**

UNIVERSITY of TORONTO
FACULTY OF MEDICINE

University of Toror

Overall Curriculum Schedule

	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May
YEAR 1	**Structure and Function 20 weeks** Sept. 4, 2007 to Jan. 31, 2008 <-ORIENTATION Aug 27, 2007 to Aug 31, 2007					**Metabolism and Nutrition 8 weeks** Feb. 4, 2008 to Apr. 7, 2008		**Brain and Behaviour 8 weeks** Apr. 8, 2008 to May 30, 2008	
	Art and Science of Clinical Medicine 1 (ASCM-1) - Hospital (4 hours/week) Sept. 14, 2007 to May 23, 2008								
	Determinants of Community Health 1 (DOCH-1) - MSB/Community (4 hours/week)Sept. 6, 2007 to May 26, 2008								

	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May
YEAR 2	**Pathobiology of Disease 14 weeks** Sept. 4, 2007 to Dec. 7, 2007				**Foundations of Medical Practice 21 weeks** Dec. 10, 2007 to May 30, 2008				
	Art and Science of Clinical Medicine 2 (ASCM-2) - Academy/Hospital (4 hours/week) Sept. 6, 2007 to May 28, 2008								
	Determinants of Community Health 2 (DOCH-2) - Community (4 hours/week) Sept. 4, 2007 to May 20, 2008								

	Sept	Oct	Nov	Dec*	Jan	Feb	Mar	Apr	May	June	July*
YEAR 3	Sept. 4 to 28 Passport to Clerkship -DOCH 3	**Phase I Clerkship 42 weeks** Oct. 1, 2007 to Aug. 3, 2008 Medicine Surgery Obs/Gyn Elective Psychiatry Family Medicine & Ophthal & Paediatrics									

Academy Sessions -Themes	6 wks	6 wks	6 wks	6 wks	6 wks	ENT 6 wks	6 wks

	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May
YEAR 4	**Phase II Clerkship 35 weeks** Aug. 13, 2007 to Apr. 27, 2008									
	Medicine	Elective	Emergency & Anaesthesia		Elective	CaRMS		DOCH4 & ACE & Derm	Surgery	
	5 or 6 wks	6 wks	5 or 6 wks		5 wks	3 wks		5 or 6 wks	5 or 6 wks	

NB: Clerkship rotations are shown diagrammatically; the various rotations are actually offered simultaneously.
* = 2 weeks vacation (6 weeks in all during Clerkship Phases I and II).

UNIVERSITY of TORONTO
FACULTY OF MEDICINE

University of Toronto

Undergraduate Applicants

Minimum requirements:

- at least 3 years of study towards a Canadian university bachelor's degree in any discipline
- minimum GPA of 3.6 / 4.0 on the OMSAS scale
- minimum MCAT scores of 9 in each section and N on the Writing Sample
- applicants educated outside of Canada must complete the equivalent of a Canadian four-year university bachelor's degree (please see the section for International Applicants)

Prerequisites:

- two full-course equivalents (FCE) in any life science
- one FCE in any of social sciences, humanities, or a language

General Information

Students attending a Canadian university taking programs leading to degrees in any discipline (e.g., Arts, Engineering, Pharmacy, Science, etc.) may apply for admission during the third or higher years of university study provided they have fulfilled the prerequisite course requirements.

Undergraduate academic achievement is assessed through MCAT scores and GPA. The coherence and rigour of the program of study, and the relative standing of the applicant in that program will be assessed in the interpretation of GPA. Prospective applicants are encouraged to pursue challenging and rigourous courses of study, as this will not jeopardize their chance of successful application. Applicants are expected to have taken courses at a level corresponding with the year of their program. For example, a student who applies for admission while registered in the third year of undergraduate work should have at least three third-year or higher courses in his/her program. Applicants in the fourth year of their program should be enrolled in a majority of courses at the third- and fourth-year levels.

The calculated grade point average used to fulfill the academic requirement will not include the candidate's current year of study, as this information is not available to us during the application period.

All applicants are asked to explain their choice of undergraduate study in their personal statement. Applicants who are not following a prescribed program are required to submit an explanation and focus of their chosen

program. Applicants registered in cooperative programs are advised to submit a separate letter detailing the schedule of their academic and work terms, if this information is not clear from their transcript.

Students applying in the final year of a three- or four-year degree program must complete the degree requirements and provide proof of completion prior to the date of enrolment. Students applying in the third year of a four-year degree program must provide proof that they have completed the requirements of that year of their degree prior to the date of enrolment in the medical program.

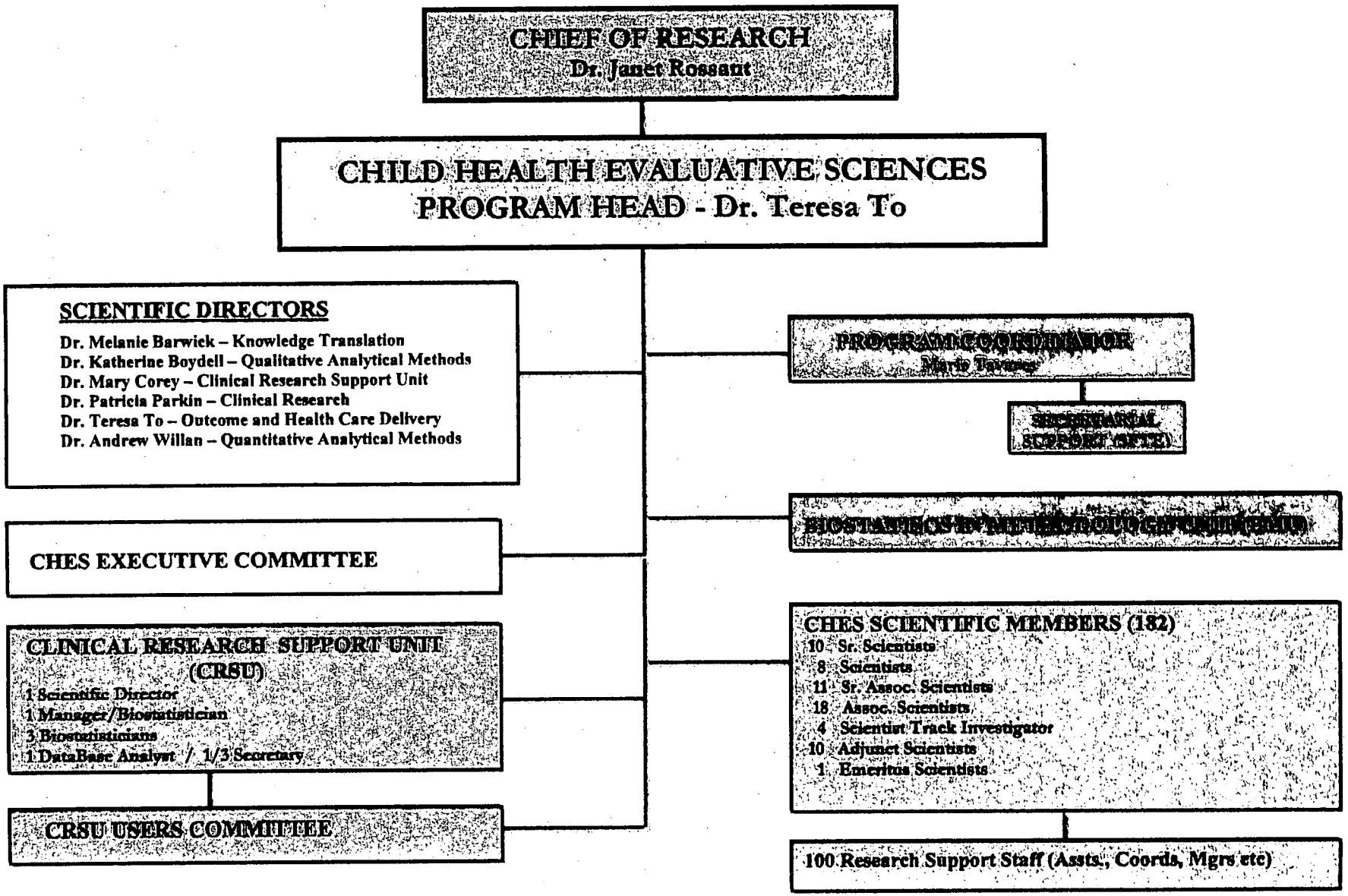
NOTE: Applicants accepted from the third year of a four-year degree program will not be considered for deferred admission. The decision whether or not to first complete one's undergraduate degree should be carefully considered before application to medical school is made.

The Hospital for Sick Children
Research Institute

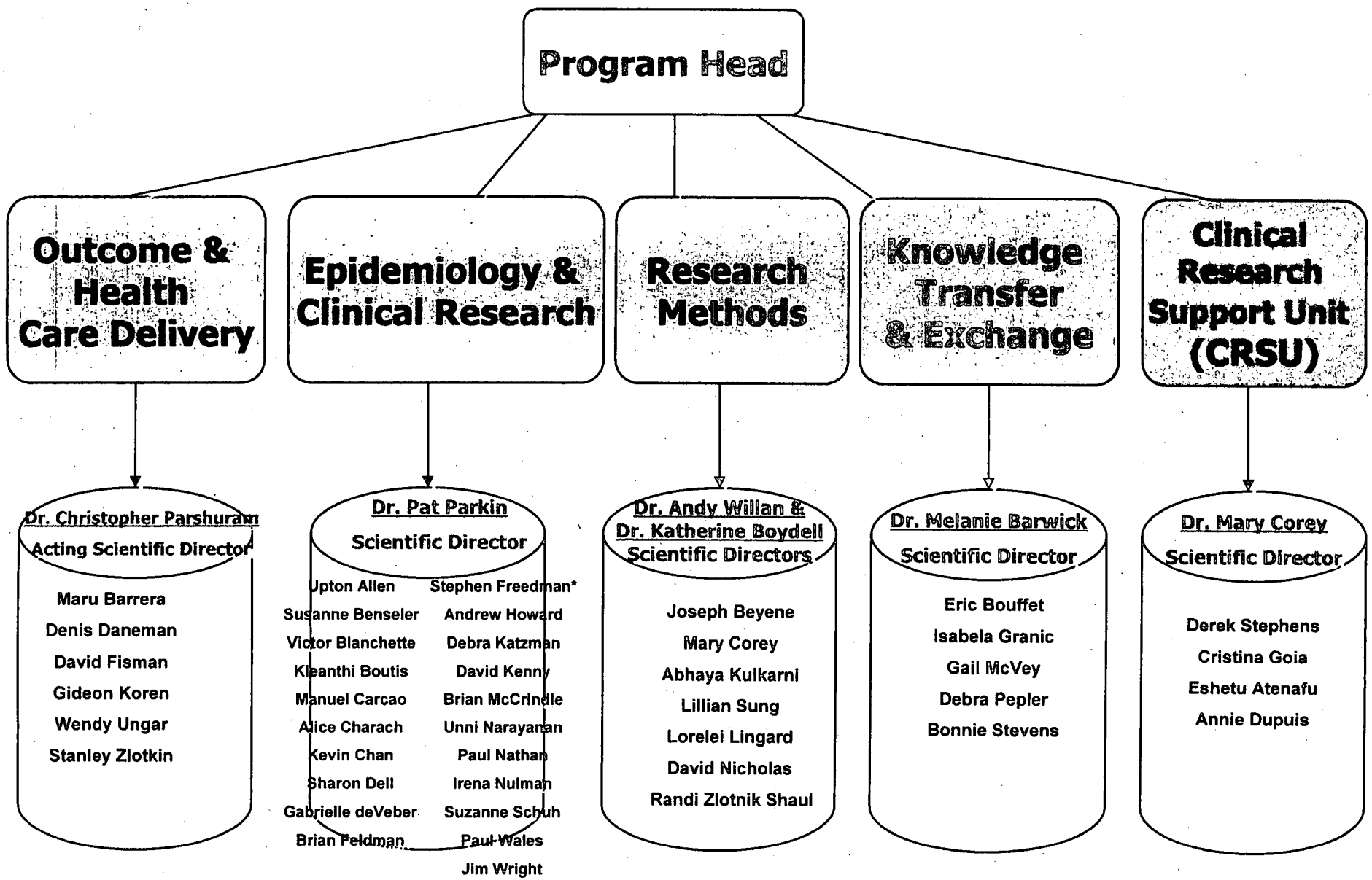
September 2007

Child Health Evaluation Sciences (CHES) Program

The current organizational structure of CHES depicted below facilitates efficient internal communication between the Program Head and CHES scientific and administrative staff as well as "external" communication with the Chief of Research at the Research Institute.



The Hospital for Sick Children
Research Institute
Child Health Evaluative Sciences Program (CHES)



Revised: September 2007

PART II:

STUDENT PROJECT

The key element of the second year DOCH experience is the student project. Each student negotiates a placement in a pivotal agency in the community and carries out a project to describe the interaction of a health problem and a related determinant of health. The project should result in some recommendations, which could be utilized by the pivotal agency.

Objectives:
There are three main objectives for the DOCH Year 2 project. These are:

- Students should be able to apply the research methodology learned in Part I of this course to an applied project in Part II of the course;
- Students are to gain experience in a community setting working with a pivotal agency;
- Students will have an opportunity to work on a project of their choosing and be able to explore an area of interest in greater detail.

The Project:

As stated in the first objective, the DOCH Year 2 project is intended to be an application of the principles learned in Part I. This may not be easy since there is often a real tension between doing a project that is of "research quality" that is suitable for publication and doing something that is applied and useful to the agency. The course strives to achieve a balance between these two highly desirable goals. On the one hand, students will be expected to apply research methodology to their project but on the other hand, this will be kept to within reasonable time limits and the course recognizes practical limitations.

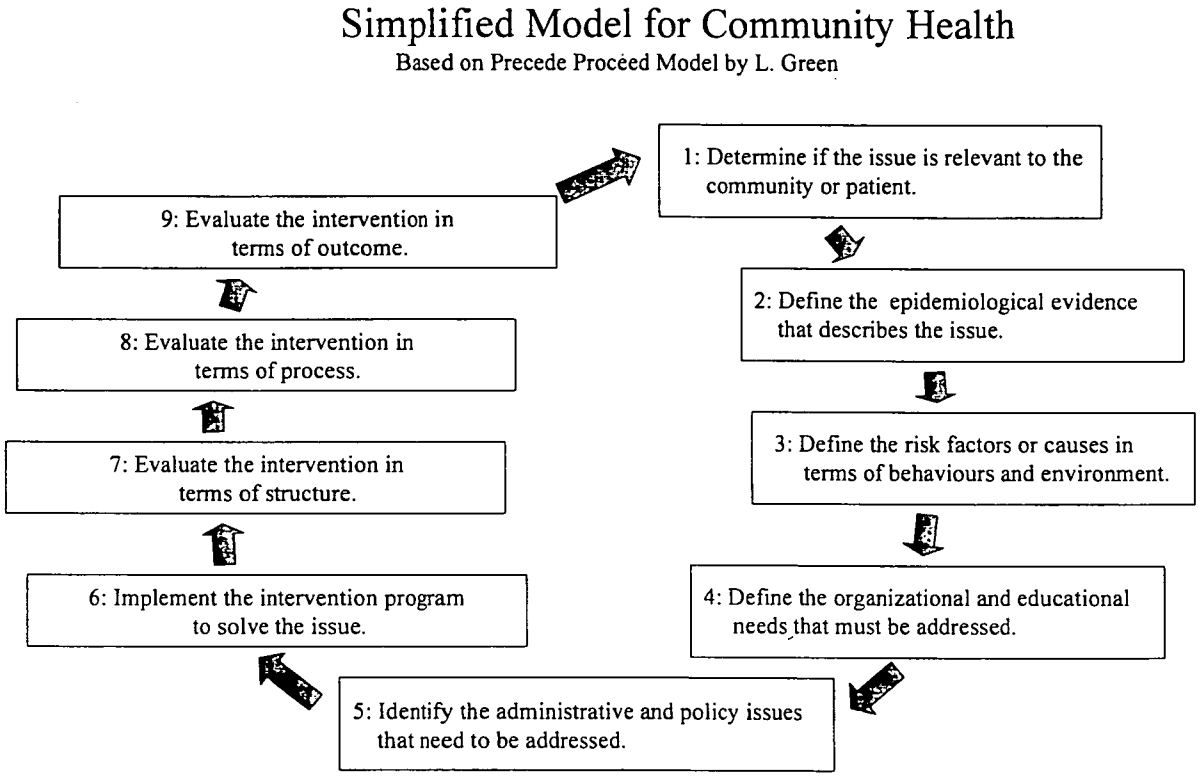
Size of the project: most students over estimate how much they can accomplish. Please note that in full time equivalents, you have approximately 3 weeks of full time work. Sample sizes of 10-15 participants are fine. Pilot projects are also acceptable. Full surveys with sample sizes of over 30 are rare and usually involve previously collected data. Be sure to keep your project small. If you want large sample sizes, you may perfect the methodology and continue to collect data over the summer.

Balance of research versus service: In past academic years, a few students became overly concerned with the research aspect of this course and missed the community experience. An example is a student who wanted to achieve a sample size of 100 so the student spent all her time doing chart reviews and not seeing the program that was being provided. In the end she had difficulty with her presentation since she did not fully understand the context of the research. Students are expected to do both: To have a community experience and to do some research. Be sure you maintain a healthy balance. Again, small sample sizes are acceptable for

this course. A student who spends equal time on research and learning about the agency and its clients will likely get a higher mark since that person can interpret their data so much better.

Role of Precede Proceed Model

For research to be optimally effective, it should be completed within an overall planning model. For this course, the overall planning model is the PRECEDE-PROCEED model, as described in year 1 (see figure below). This model has been previously described.



The purpose of the planning model is to provide a context for the research and indicate the next steps in using the derived information in order to improve the programs and services. Within the model, students are encouraged to take on one of four major types of research.

- **Research Component:** Looking at the elements in greater detail, the application of community health research involves the students developing the research question and developing the individual learning plan (ILP) to address the question. The main part of the year will be spent in fulfilling the ILP. These activities include, but are not limited to, completing a literature review, completion of ethics approval as required, collection and analysis of relevant data, and interpretation of findings so the community agency

understands the results. Students will also be providing a final report to the agency and making a presentation to their classmates.

- **Community Component:** The project is to be community-based. This means that the project should ideally involve a community agency. If the project is hospital-based, it must have a strong community focus and a direct linkage to a community agency must be established.
- **Determinant of Health:** The project should begin with a determinant of health from the Jakarta Declaration. These are the following:

  Physical Environment

  - Shelter
  - Stable Ecosystem
  - Peace
  - Sustainable Resource

  Social Environment

  - Income
  - Education
  - Social Security
  - Social Relations
  - Equity
  - Social Justice and Respect for Human Rights
  - Access to health care services

  Biological and behavioural determinants of health

  - Genetic factors such as ethnicity
  - Lifestyle factors such as immigration, smoking, etc.

  Please note that using the health care system as a determinant of health is not acceptable for the project. Projects such as the organization of outpatient clinics will not be accepted.

  Be sure to choose a determinant of health wisely. In the past, many projects received low marks because the determinant of health was poorly defined.

- **Health Component:** The project will address a relevant health issue that is of concern to the population and is linked to the determinant of health. The health issue will be of interest to the agency and the student.

In order to achieve this balance, there are four main types of projects that students can complete. These are described below.

Types of projects

➢ Needs assessment:

- **Description of project type:** In this type of research, students will assess the need of a community group with respect to a particular health and its related determinant of health. Students will assess the literature, develop a clear question, collect suitable data (for example, using a survey or qualitative method), interpret the results, and write a formal report for use by the community agency. If the community needs are determined to be present, the student will recommend methods of addressing them.
- **Where it fits in the planning cycle**: Needs assessment link to the planning model (figure 1) by being phases 1, 2, 3 and/or 4 of the PRECEDE PROCEED Model. Examples of projects include: perceived and documented health needs of persons with diabetes (Phase 1 and 2 of model), or an assessment of the use of services by diabetic homeless men in Toronto (Phase 3 and 4 of model).

➢ Barrier assessment:

- In this type of research, students will assess the presence and possibly the cause of a barrier faced by a community group as it relates to a particular health and social issue. These projects are similar to the ones on needs assessment but focus on barriers. Students will assess the presence and importance of a perceived barrier (for example, using survey or a qualitative method) and write a formal report for use by the community agency on the presence or absence of the barrier. If present, students will recommend ways to remove or address the barrier by the agency.

➢ Instrument and/or resource development:

- **Description of project type**: In this type of research, students will develop a formal assessment instrument (e.g. survey questionnaire) or a resource for use by the agency. This type of project must have three components. The first is a systematic review of the literature that justifies the intervention as being effective in doing what it is proposed to do. The second is the documentation of the

resource or instrument. The third component is the development of a proposal to evaluate the resource or instrument so that the pivotal agency can complete it. The final report will contain the revised instrument or resource that is suitable for use by the agency. Should students decide to develop a specific resource for the agency, e.g. a website or brochure, the content of the brochure must be evaluated as to its effectiveness (based on a systematic review of the literature) and an evaluation proposed. For example, if a student were to develop a brochure for promoting school breakfast programs for inner city school children, a literature review on the effectiveness of school breakfast programs would have to be included.

- **Where it fits in the planning cycle:** Instrument development fits with both the planning and evaluation phases of the planning model. Examples can range from development of an instrument to assess the specific needs of a group in the community (Phases 1, 2, 3 and 4), the development of a specific resource (Phases 5 and 6), or the development of an evaluation tool (phases 7 through 10). Despite this flexibility, students will be expected to articulate clearly how the results of the project would fit into the planning of programs for the agency.

➢ Evaluation:

- **Description of project type:** This is a very broad category and includes evaluation of a program or an intervention by the pivotal agency that is being done at the community level. Interventions to be included in this type of project can be based in a hospital but must have a community focus and one community-based agency must be involved. The final report will contain an evaluation of the intervention including the acquisition of new data to justify the conclusion.
- **Where it fits in the planning cycle:** Evaluation fits within phases 7 through 10 of the PRECEDE PROCEED model. Examples include an evaluation of the needle exchange program for IV drug users, evaluation of the public health surveillance system, and evaluation of the effect of removing lead from gasoline.

PLEASE NOTE:

It is important to undertake projects that are manageable and do not interfere with your other academic work. You are expected to demonstrate an understanding of the interaction between a health problem and a determinant of health in your final report. There is a very broad range of approaches to achieving this goal.

You should be able to manage your project in approximately four hours per week. If your project is too ambitious and is taking more than the suggested four hours you should seek assistance in

paring it down. If you feel in need of advice or assistance, please consult your Academy Coordinator and/or research advisors.

Please find below several suggestions, which may help to ensure that your placement at the pivotal agency is successful and enjoyable.

1. Take time to consider the advantages and disadvantages of each pivotal agency in terms of your interests and career goals. Remember you will be with this agency and its network for a good part of the academic year.

2. The working relationship you have with the pivotal agency supervisor will be a key factor in your placement's success. You may want to establish or define your expectations of the pivotal agency supervisor as well as that person's expectations of you.

3. Consider arranging regular meetings with your pivotal agency supervisor, which can be used to monitor progress, answer questions, seek guidance and coordinate your activities.

4. Do seek advice from the research advisors (see page 36) and academy based research directors as well as the DOCH website. These people are responsible for providing academic guidance, while they may not know the answer to all of your questions, they will help you to find someone with the answers.

5. Your friends and colleagues at other agencies are a valuable source of information. You may wish to allow time to speak with them regarding their experiences and the guidance they have received.