

Challenges in Developing Genetic Services in HA

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10 May 2010

Hospital Authority Convention 2010

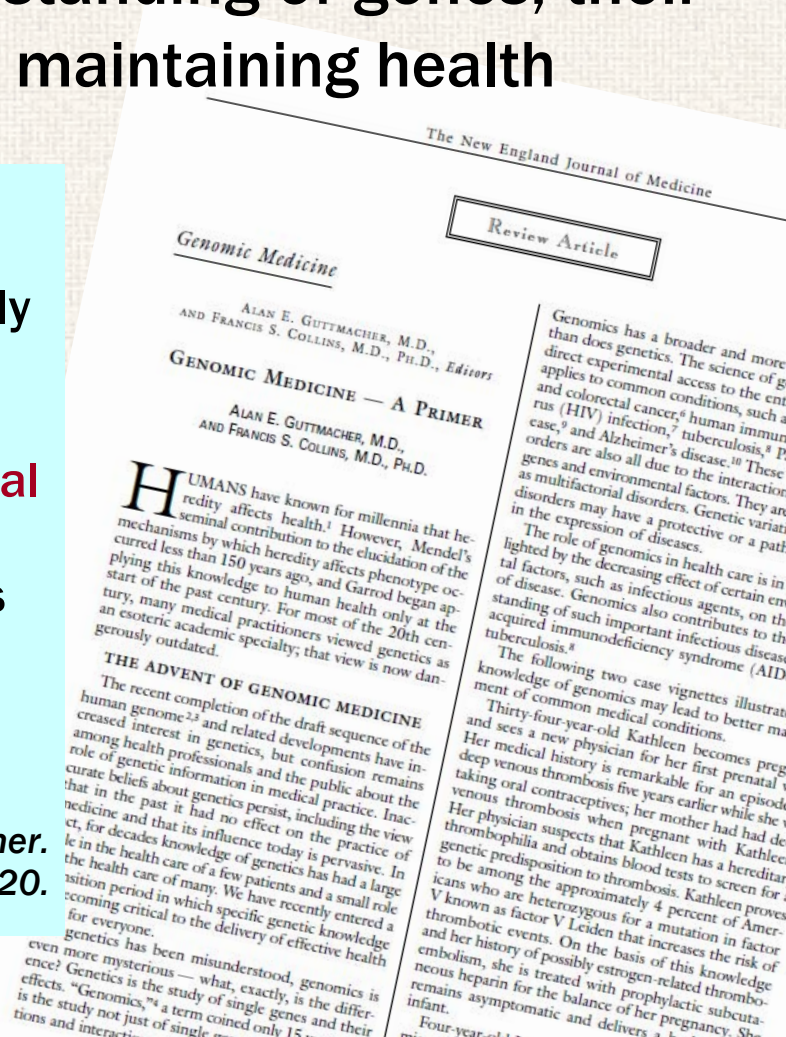
Modern HC is Technology Driven

- Scientific advances in human genetics and genomics have greatly expanded our understanding of genes, their role in disease... and **hopefully** in maintaining health

Medicine's Next Gold Mine?

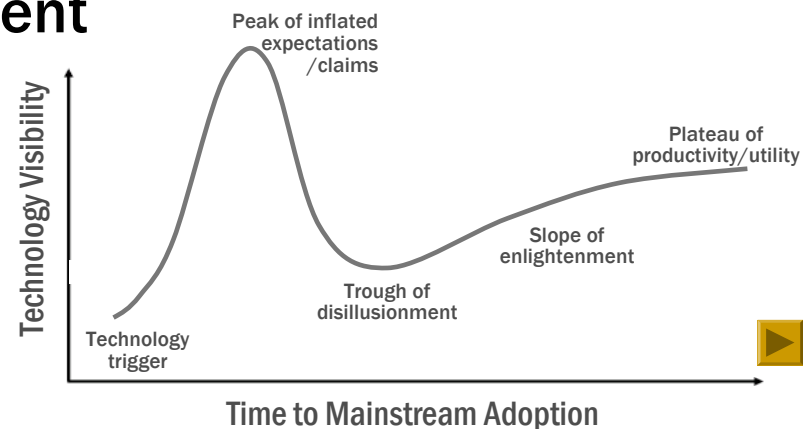
“With the sequencing of the human genome only months from its finish, the practice of medicine **has now entered an era** in which the **individual patient's genome will help determine the optimal approach to care**, whether it is preventive, diagnostic, or therapeutic. Genomics, which has quickly emerged as the **central basic science of biomedical research**, is poised to take **center stage in clinical medicine** as well.”

Guttmacher and Collins. *Genomic Medicine – A Primer*. *NEJM*. 2002; 347: 1512–20.

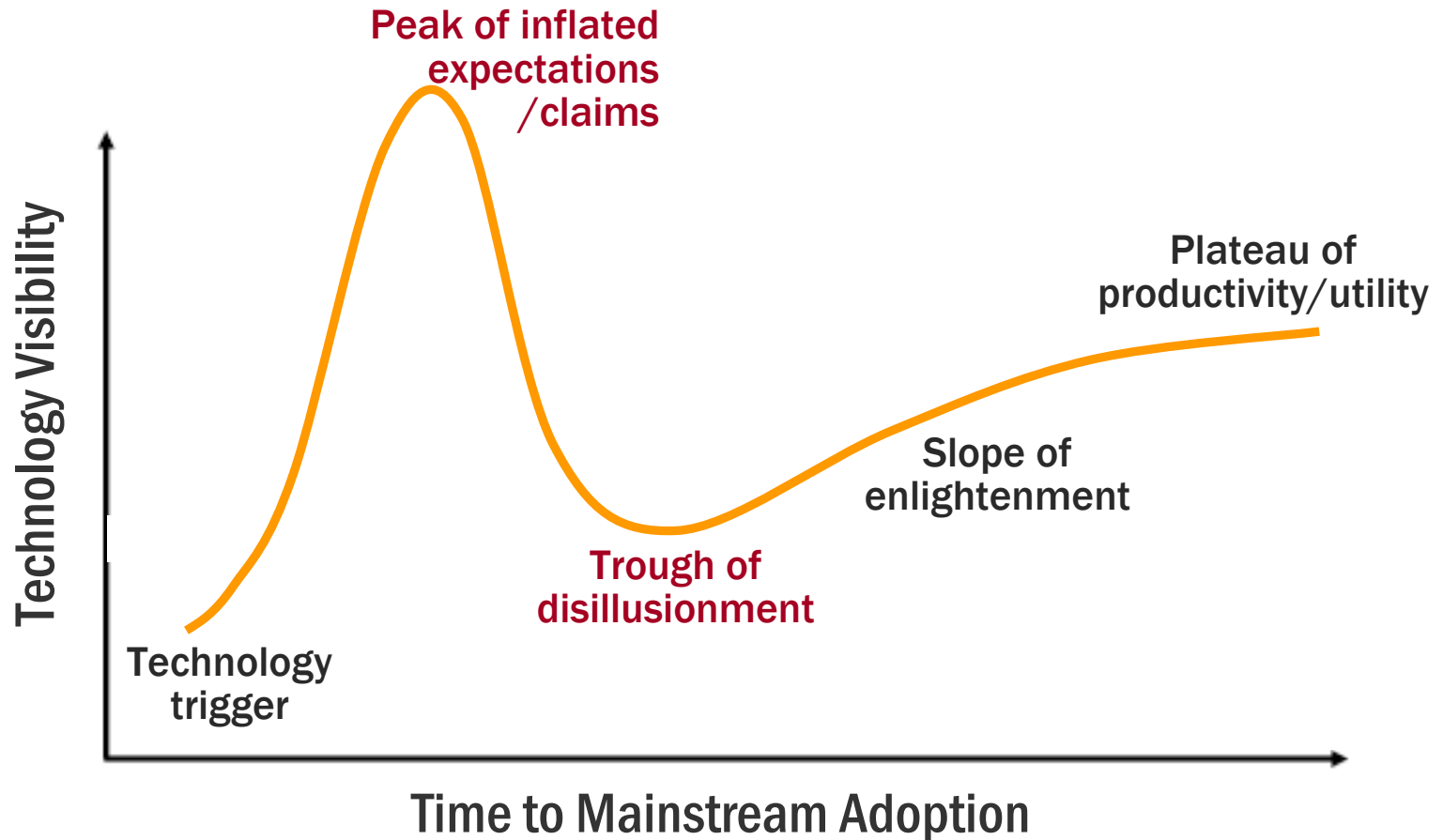


New Genetic and Genomic Technologies

- A wide range of genetic tests previously available to research are now developing into novel tests for clinical use
 - Advances in clinical genetics
 - Diagnostics for bacterial, viral and neoplastic disease
 - Genotyping to predict response to cancer chemoRx
 - Pharmacogenetic/pharmacogenomic studies
 - DNA-based vaccine development
 - ...



Beware of Hype... *Where Are We Now?*



ETHICS WATCH

Genetics services and market forces

For years, commentators have been speculating on the adverse implications of market forces on the use of genetic services. Although the use of genetic services is both necessary and desirable for many reasons, the use of genetic technologies, the associated with...

DISCUSSION AND DEBATE

The Helix in the Labyrinth: Do We Need Genetic Health Services and Policy Research?

Le labyrinthe de la spirale : la recherche sur les politiques et les services de santé touchant à la génétique est-elle nécessaire?



BY FIONA ALICE MALLEY, Associate Professor, Department of Health Policy, University of Toronto, Toronto, Ontario

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REVIEW ARTICLE

GENOMIC MEDICINE

Alan E. Guttmacher, M.D., and Francis S. Collins, M.D., Ph.D., Editors

Ethical, Legal, and Social Implications of Genomic Medicine

Ellen Wright Clayton, M.D., J.D.

OTHER ARTICLES IN THE GENOMIC MEDICINE SERIES, already to our understanding of the molecular ba... ing extent, to the development of effec... ever, are concerned about the ef... tual persons and groups... tress the ethical,

Community Genetics

Commentary

Community Genet 2001;4:12-17

Current Challenges to Appropriate Clinical Use of New Genetic Knowledge in Different Countries

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Key Words

Genetics - Genetic services

Abstract

Objective: To describe the challenges facing countries all over the world regarding the appropriate clinical use of genetics in their health care systems. Methods and Results: Aspects of the economic and social context in different countries which are of particular relevance to the existing challenges are discussed. Issues which are relevant (but of different prominence) in all countries in providing genetic services are discussed. Conclusions: The challenges facing the provision of appropriate genetic services differ markedly in four major groups of countries. These challenges range from controlling inappropriate commercialization and the over-use of genetic approaches to putting in place even minimal basic community genetics services in countries where the infant mortality rate has fallen to a range where genetic and congenital disorders contribute substantially to ongoing handicap and early mortality.

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Introduction and Context

The utilization of new genetic knowledge in clinical practice could be viewed very broadly to include uses of DNA-based information to develop diagnostics for bacterial, viral and neoplastic disease. DNA-based vaccine development, genotyping to predict responses to cancer chemotherapy and tailoring the use of pharmaceuticals to drug metabolism and tailoring new genetic knowledge on current challenges to utilizing new genetic knowledge in the practice of clinical genetics.

To date, recognized, 'traditional' genetic services have largely concentrated on single-gene and chromosomal disorders and severe birth defects. When offered with informed consent and adequate resources, they have been well accepted and brought benefit. A mainstay of such services has been to offer prenatal diagnosis of individuals who will have serious early-onset illness, with the option being available for parents to have a termination [1]. There has not been major commercial interest in the past in genetic testing and services for these relatively uncommon disorders; there has been relatively little 'market push'. In fact, in many health systems, the problem has been to obtain sufficient resources, the problem beneficial screening and genetic services to offer.

With the Human Genome Project, the ability to detect genotypes and

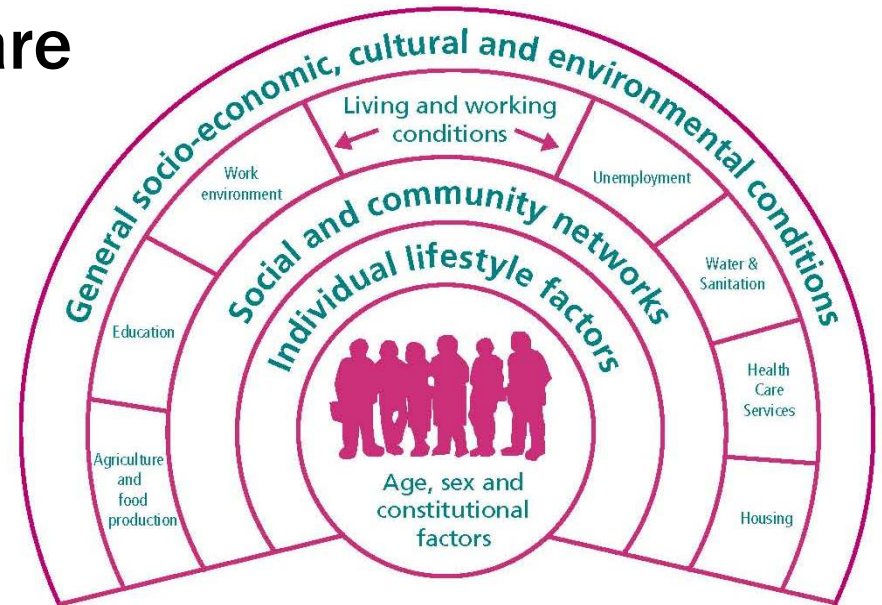
Not everyone is so optimistic

The Path from Research Discoveries in Genetics and Genomics to Improved Health Services... is Not a Straight One

- There are uncertainties over its implication in health services
 - Unbalanced investment between biomedical and health services policy research
 - The **clinical utility gap** remains large
 - Consensus is lacking as to which are the most important challenges
- **Risk of medicalization and commercialism** ▶

New assays continue to emerge in the pipeline, their sophistication and scope don't stand still

- Commercial interests will promote the impression that genes (and medicinal products) are the key to avoiding disease outcomes
- From a population health perspective...
Determinants of health are multiple



Whitehead M. & Dahlgren G. What can we do about inequalities in health? Lancet, 1991, 338: 1059-1063

Health status $\approx \Sigma$ interactions between all determinants over time

Back to Basics:

Technology Does Not Exist in a Vacuum

- **HC systems are always confronted by challenges...**
from epidemiological transition, technological advances, changing public expectations/demands, resource limitations and the rising cost of health care
 - **Measure of Value: health gains** (*individually and population based*)
 - **Consideration: appropriate and cost-effective use of health technologies** *in the local context*
-

Back to Basics: *Do Not Oversimplify*

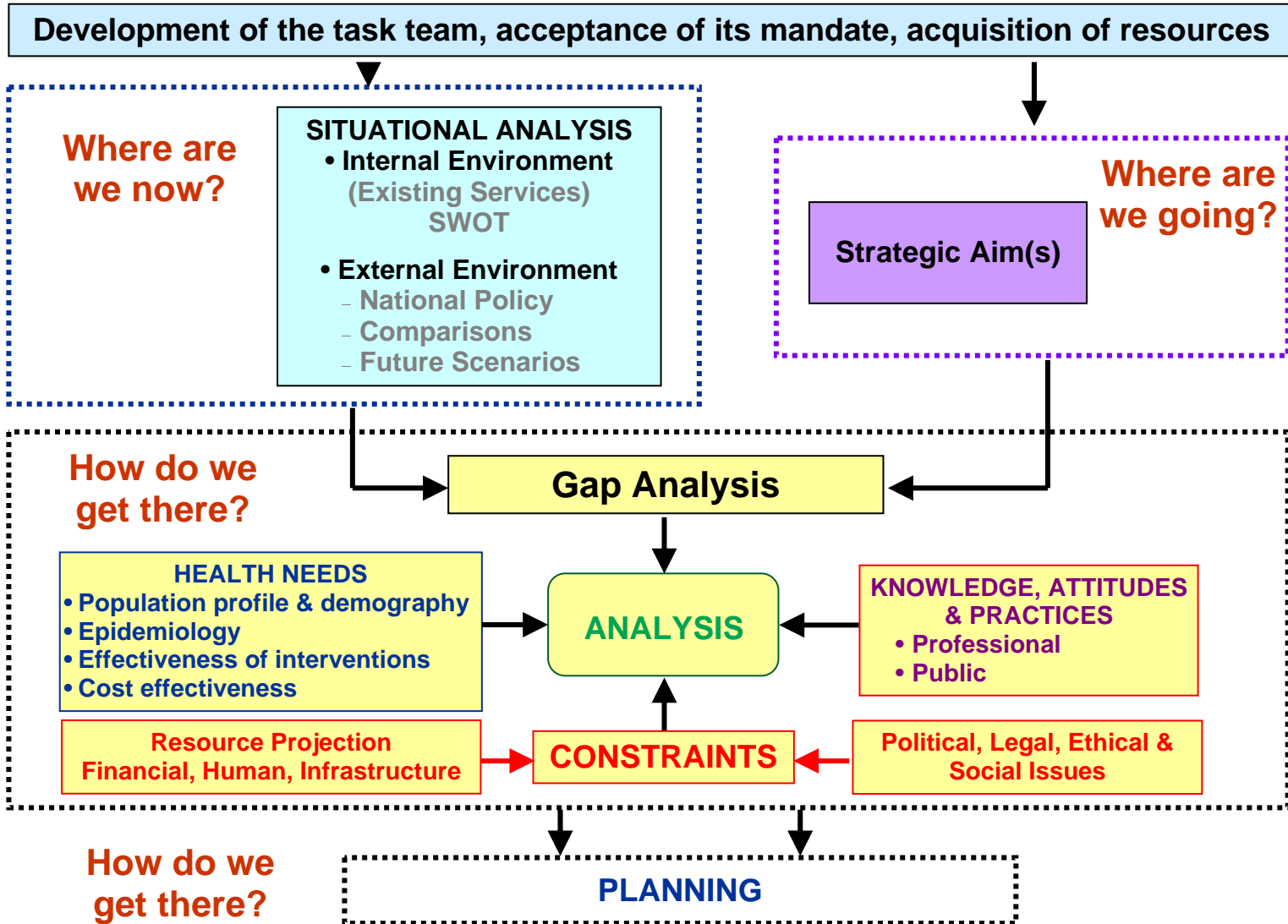
- **Clinical utility vs. personal utility vs. public utility vs. economic value**

What if we have good genetic susceptibility markers for tobacco-related...

- **Ethical, social, legal and political concerns**

- How do different stakeholders define the value, and risks, of genetic and genomic technologies?
 - How do stakeholders evaluate the weight of one kind of value in relation to another?
 - How do people assess relative values to make health care decisions?
 - How do these types of value relate, or not relate, to the monetary cost of the technologies?
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Back to Basics: *What to Aim For and Plan For*



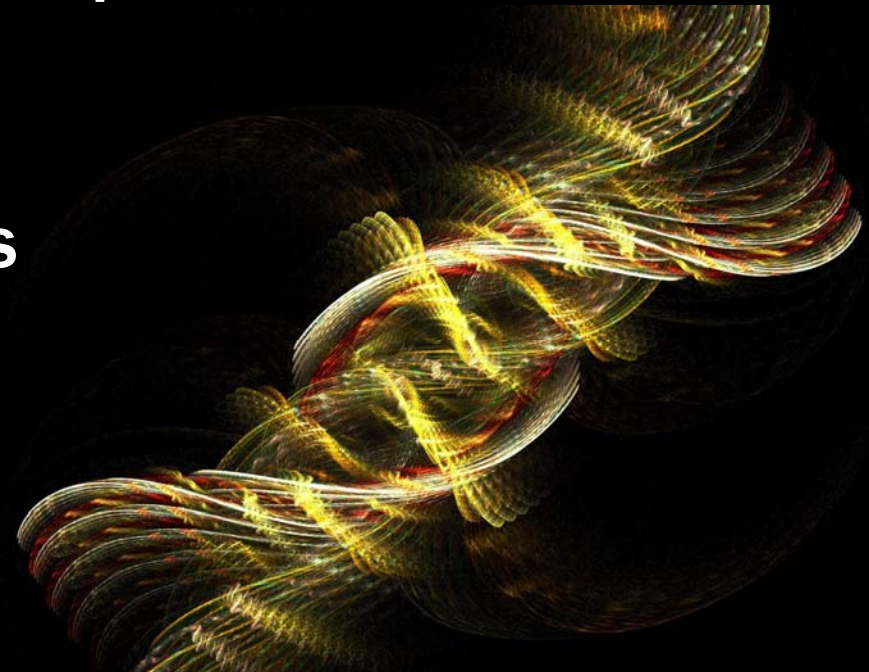
Source: *Health Needs Assessment for Medical Genetic Services in Middle- and Low-Income Nations*. CAPABILITY Consortium

The Way Forward *(down to earth)*

- 1. Build infrastructure to address current and emerging demands on integrating genetics into mainstream healthcare**
- 2. Evidence-based evaluation of new genetic technologies that can be incorporated into health services within the local ethical, legal and social framework**
- 3. Prioritize against competing needs**

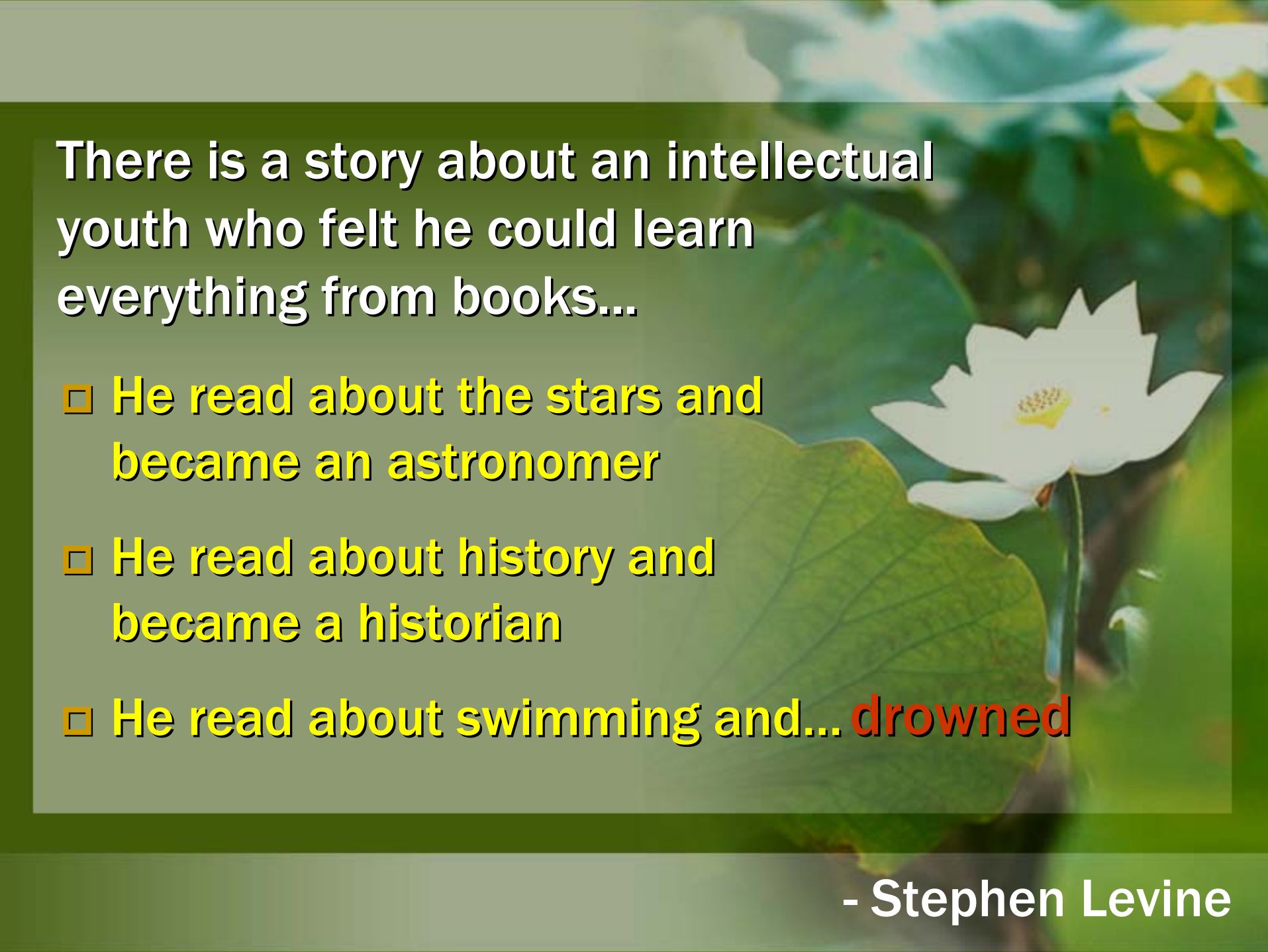


4. Assuring quality of genetic services
5. Improve coordination and efficiency of genetic service delivery... *not just within HA*
6. Provide and promote relevant education and training programs for professionals and the public
7. Making genetic services reasonably accessible to persons in need of them





*“Knowledge is soon changed, then lost in the mist,
an echo half-heard.”* - Gene Wolfe



There is a story about an intellectual youth who felt he could learn everything from books...

- ❑ He read about the stars and became an astronomer
- ❑ He read about history and became a historian
- ❑ He read about swimming and... **drowned**

- Stephen Levine



Life happens at a level of events not of words or concepts... Don't get carried away by them

Idea ≠ Action ≠ Outcome... *as desired*

- Knowing why (it is important) ≠ knowing what (is needed) ≠ knowing how (to get it) ≠ good at the knowhow (in getting it) ≠ timing is right or circumstance is favorable
- What you want vs. what others want
- What is needed vs. what is affordable
- Outcome is contingent upon complex interactions amongst multiple factors... and chance

Justifying a need does not entitle you to it

To What Extent Do You Understand/Accept?

- There will never be sufficient resources to allow all possible means of improving health to be provided to all people who might benefit from them... ►
- There has to be a process for setting service priority

- Informed decision making

*What you want vs.
What others want
What is needed vs.
What is affordable*

- Optimize limited resources

*to provide the maximum
benefit to the greatest
number of people* ►

How much do you know?

■ Sources of funding

- ❑ Annual growth funding (OLV/recurrent)
- ❑ Govt. designated RAE (project based)
- ❑ CBV (medical equipment > 150K)
- ❑ SH8100MX (minor improvement work)
- ❑ ITBV (IT funding)
- ❑ Income (patient fee, ASOI)
- ❑ CWRF (special projects)
- ❑ 'Productivity gain'/'Redistribute internal resources'

No more than a few percent of the budget can contribute to annual plan

98% of the budget is allocated to clusters. Service development is a very pluralistic process

- Note also system and workforce constraints, market condition, and individual hospital's fiscal condition



Problem of Utilitarianism

- “... *to provide the maximum benefit to the greatest number of people.*”
 - But it will be to the advantage of some and the disadvantage of others
 - The risk is... **it would allow any degree of subordination (to some) provided the benefit was considered (by those in power to decide) to be great enough**
-

Utilitarianism in Action

- The question is...
 - “Can one be truly impartial? Can you eliminate turf and gaming?”
 - Not unless we are innocent... *the so-called “Original Position” where bias and self-interest are eliminated by a “veil of ignorance” (John Rawls. A Theory of Justice)*
 - The real question is...
 - **“What is the best pragmatic approach?”**... *How can one offer more effectively to HC planning and execution?*
-

How can one offer more effectively



to

healthcare planning and execution?



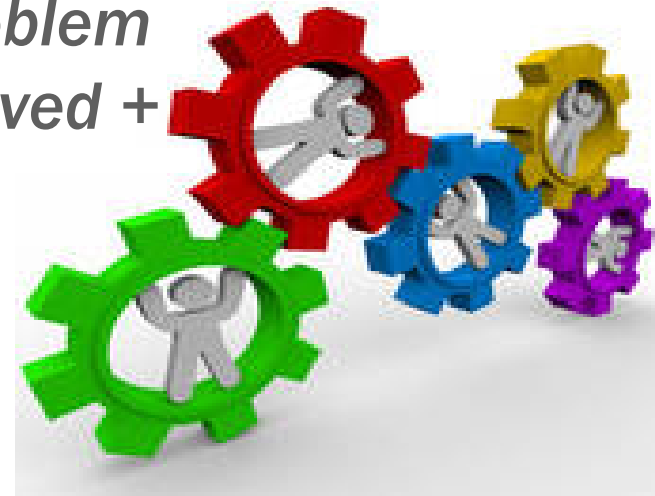
“We can't solve problems by using the same kind of thinking we used when we created them.” Albert Einstein

Seek to Understand


1. *Others...* You are neither the only stakeholder nor the sole resource

2. No solution can be perfect/final

- *All solutions have downsides: problem + solution = problem partially solved + 'new' problems...*



Managing change is primarily a political process

A silhouette of a person in a suit, pointing towards a bright, glowing light source. The background is a fiery, orange and yellow gradient, suggesting a fire or a bright light. The person is in the foreground, and the light is in the background.

In the end, outcome depends on...

ACTION

Innovation isn't hard, implementation is

- **Implementation requires a very different mindset and skill mix...** *more an attitude to serve than to lead*
 - ❑ Ability to connect and mobilize... *help others to see outcomes of alternatives in ways they understand*
 - ❑ Dedication of time and resources... *acquire mandate and resources, mediate competing interests, build infrastructure, orchestrate changes and follow through*
 - ❑ Shoulder responsibilities/blames
 - ❑ Be strategically mindful

Over ambitious objective, mismatched strategy or over commitment pave the way for failure ▶

Over-commitment is a Serious Risk



Toyota was once the global gold standard for manufacturing quality. Ironically, its success and emphasis on expansion backfired to a massive quality failure and credibility crisis

- 
- CMS III revamp
 - eHR
 - Filmless HA
 - In-Patient Medication Order Entry
 - Upcoming HC & HC financing reform
 - System risks revealed through incidents, e.g. drug risk, IT risk, workforce risk (shortage, competency, supervision)
 - Accessibility to care... long waiting times (SOPC referral, imaging, elective surgery, cancer Rx)
 - Utilization and efficiency of CT, MR, LINEAC, OT, etc.
 - Re-engineer cancer care
 - Mental health service gaps
 - Need to develop family medicine & train FM specialists for primary care
 - Workforce condition... overload, long work hours, legal claim for OT and on-call duty
 - Funding for expensive drugs and medical devices
 - Health technology management and scale of provision among hospitals
 - Quality gaps revealed through hospital accreditation
 - Aseptic dispensing facility and the new PIC/S Guide to Good Manufacturing Practice for Medicinal Products
 - Compliance to law: fire safety, OS&H, personal data privacy
 - HA faces many burning needs

These and other projects are competing for the same pool of resources (funding and workforce – frontline, supporting) within the HA

Where Are We Now ?

Technocrat
(Agent)



Agenda Setting

Pioneers (in
& outside HA)

- **Opportunistic development**
- **Pockets of expertise but...**
 - uncoordinated
 - not aligned
 - no long term plan

- Yet to draw the attention of policy makers
- Yet to build a case for a territory-wide policy
- Yet to convinced them to invest (... not just financially but also in human resource)
- In the process of engaging stakeholders and exploring governance internally
- Plan to stock take... still a long way to go for gap and needs assessment
- Yet to align understanding, expectation and strategy
- **Just formed a CC (Genetic Services) in 2010**

How do we
get there?



What to Do Next?

“Think of a car driving through the night. The headlights only go a hundred to two hundred feet forward, and you can make it all the way from California to New York driving through the dark, because **all you have to see is the next two hundred feet. And that's how life tends to unfold before us.** If we just trust that the next two hundred feet will unfold after that, and the next two hundred feet will unfold after that, your life will keep unfolding. And it will eventually get you to the destination of whatever it is you truly want.”

Jack Canfield

An ounce of practice is worth a pound of theory