

ALCOHOL POLICY INTERVENTIONS TO PREVENT FETAL ALCOHOL SPECTRUM DISORDERS

The First Baltic Conference “Prevention of Fetal Alcohol Spectrum Disorders”
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The National Institutes of Health's Five Priority Areas

- Applying **high throughput technologies** to understand fundamental biology, and to uncover the causes of specific diseases
- **Translating basic science** discoveries into **new and better treatments**
- Putting science to work for the benefit of (U.S.) health care reform
- ***Encouraging a greater focus on global health**
- **Reinvigorating** and **empowering** the biomedical research community



WHAT IS GLOBAL HEALTH?

“... global health is an area for study, research, and practice that places a priority on improving health and achieving equity in health for all people worldwide. Global health emphasizes transnational health issues, determinants, and solutions; involves many disciplines within and beyond the health sciences and promotes interdisciplinary collaboration; and is a synthesis of **population based prevention** with individual-level clinical care.”

Koplan, et al ***Lancet* 2009; 373: 1993–95**





Public Health

- Health of a population or particular country
- Does not require global cooperation
- Prevention at population level

- Health equity at country level

- Multidisciplinary approaches within health sciences and social sciences



International Health

- Health of countries other than one's own, especially low and middle income countries
- Binational cooperation
- Prevention + clinical care
- Helps people of other nations
- Embraces a few disciplines



Global Health

- Health issues that transcend national boundaries
- Global cooperation
- Prevention + clinical care
- Health equity among nations and for all people
- Interdisciplinary and multidisciplinary within and beyond health sciences

NEED FOR DEVELOPMENT OF COLLABORATIVE RESEARCH STRATEGY

United States

National Academies of Science

Institute of Medicine

U.S. Commitment to Global Health
2009

Europe

European Commission

Directorate-General for Research

Drivers of International Collaboration in Research
2009

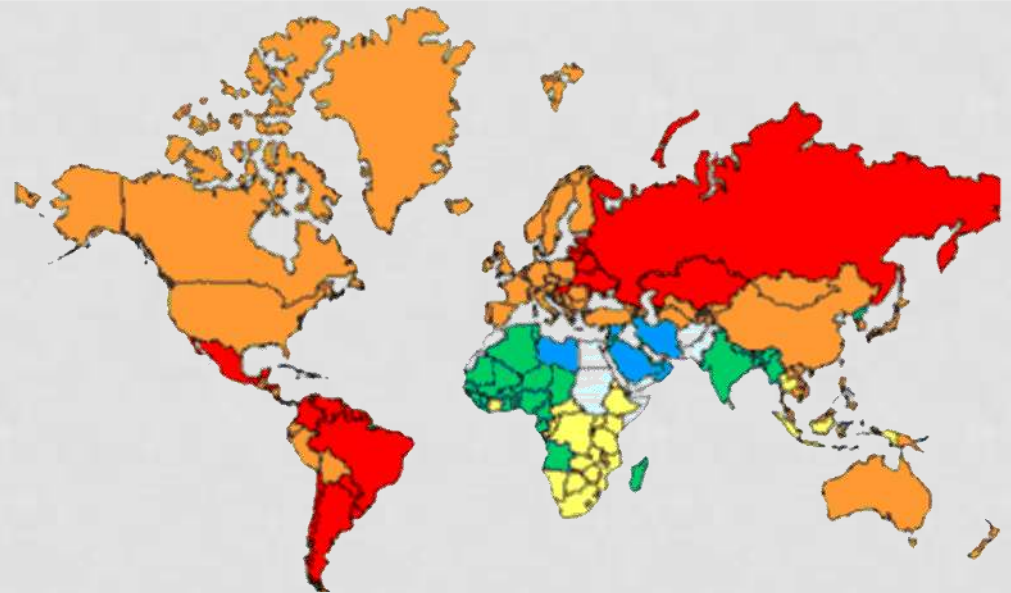
Both reports highlight the rapid growth in policy attention for international research collaboration.

Both reports cite the need for clear goals and well defined outcomes and impacts.

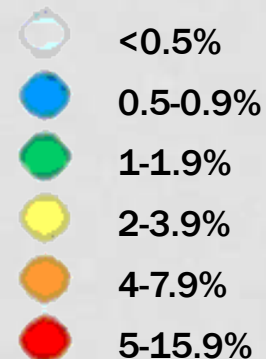
HARMFUL DRINKING - THE PRESENT GLOBAL CHALLENGE

As a percentage of all risk factors that cause ill health, alcohol ranks high in many parts of the world.

Science 16 May 2008:
Vol. 320. no. 5878, pp. 862 - 863



Proportion of DALYs



THE GLOBAL HEALTH RESEARCH AGENDA IS EVOLVING

- **Moving away from an exclusive focus on infectious disease**
- **Maternal and child health has been and continues to be important**
- **Burden of illness should be used as a criterion for global-health priority setting**
- **Risk factors, such as alcohol and tobacco are becoming a priority for prevention**
- **New interest in international collaboration on rare diseases between Europe and the U.S. is resulting in interesting models**

Improving treatment for children with mental illness, like this girl in Somalia, is an urgent priority.



Collins, P., et al.
Nature;475(7354):27-30.

NONCOMMUNICABLE DISEASES (NCDs) KILL MORE THAN 36 MILLION PEOPLE EACH YEAR (WHO 2013)



- Nearly 80% of NCD deaths - 29 million - occur in low- and middle-income countries.
- More than nine million of all deaths attributed to NCDs occur before the age of 60;
- 90% of these "premature" deaths occurred in low- and middle-income countries.
- Cardiovascular diseases account for most NCD deaths, or 17.3 million people annually, followed by cancers (7.6 million), respiratory diseases (4.2 million), and diabetes (1.3 million¹).
- These four groups of diseases account for around 80% of all NCD deaths.
- They share four risk factors: tobacco use, physical inactivity, the **harmful use of alcohol** and unhealthy diets.

THE UNITED NATIONS GENERAL ASSEMBLY ON THE PREVENTION AND CONTROL OF NON-COMMUNICABLE DISEASES POLITICAL DECLARATION



- The first time that all Member States of the United Nations agreed to come together and develop an agenda to reduce the risk of NCD's (UN General Assembly Resolution 66/2, 2011).
- **Reduction in the harmful use of alcohol** has been identified as one of the four behavioral measures countries must focus on as part of the global plan to reduce this risk.

According to the World Health Organization (2012):

- Over 200 million children in developing countries are not reaching their full developmental potential (Grantham-McGregor et al, 2007)
- 10-20% of individuals have learning or developmental difficulties (Durkin et al, 2006)
- Low and middle income countries have higher rates of risk factors that affect child development such as poverty, malnutrition, deficiencies in psychosocial stimulation.

GLOBAL STRATEGY TO REDUCE THE HARMFUL USE OF ALCOHOL

- Represents a unique consensus among Governments of WHO Member States on ways to tackle harmful use of alcohol at all levels
- Sets priority areas for global action
- Contains a portfolio of policy options and measures that could be considered for implementation at national level



Global Strategy to Reduce the Harmful Use of Alcohol: Health Services' Response

...

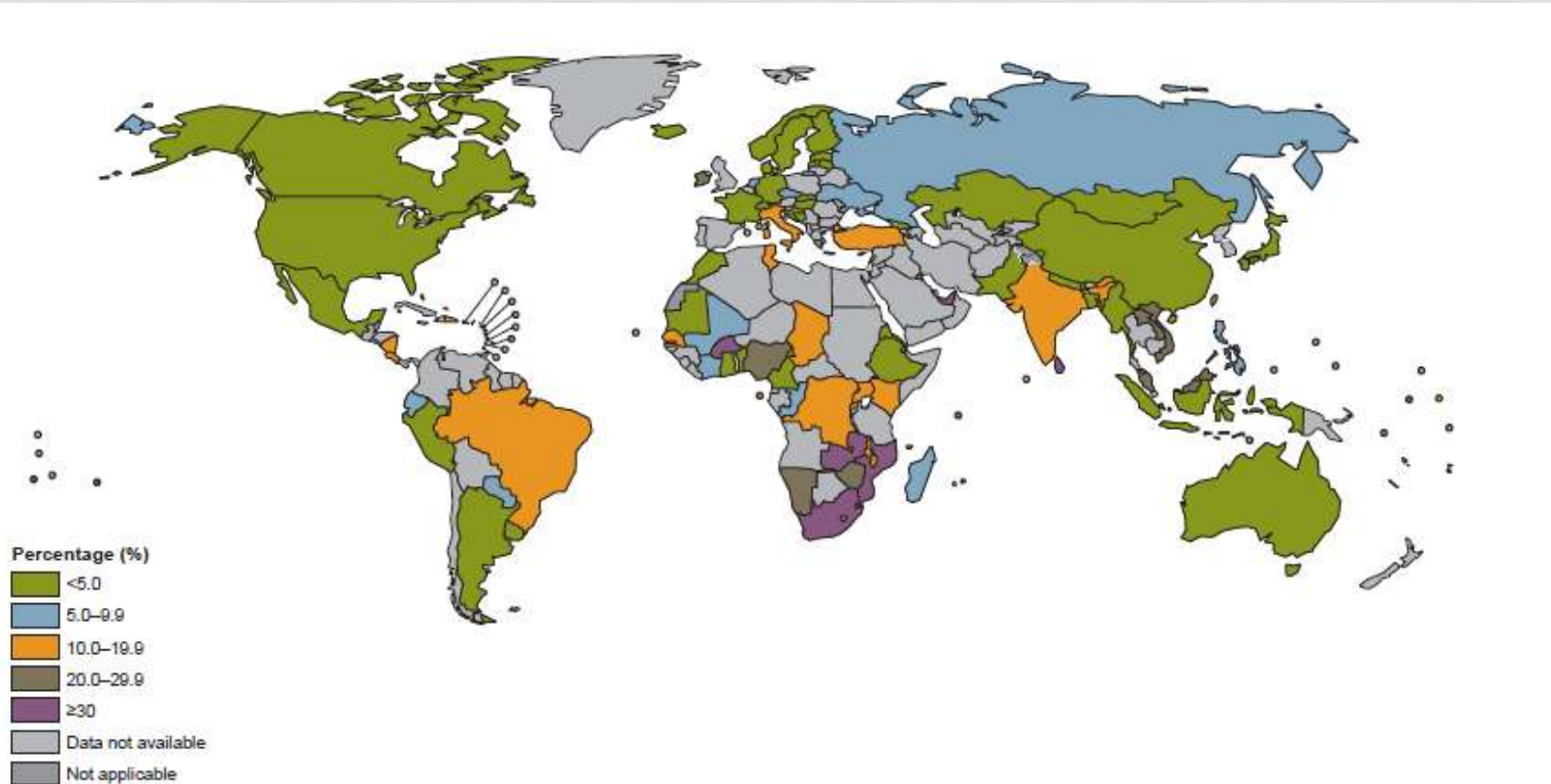
- (b) supporting initiatives for screening and brief interventions for hazardous and harmful drinking at primary health care and other settings; such initiatives should include early identification and management of harmful drinking among pregnant women and women of child-bearing age;
- (c) improving capacity for prevention of, identification of, and interventions for individuals and families living with fetal alcohol syndrome...; ...

Why Should FAS/FASD be Included in the Global Health Policy Agenda?



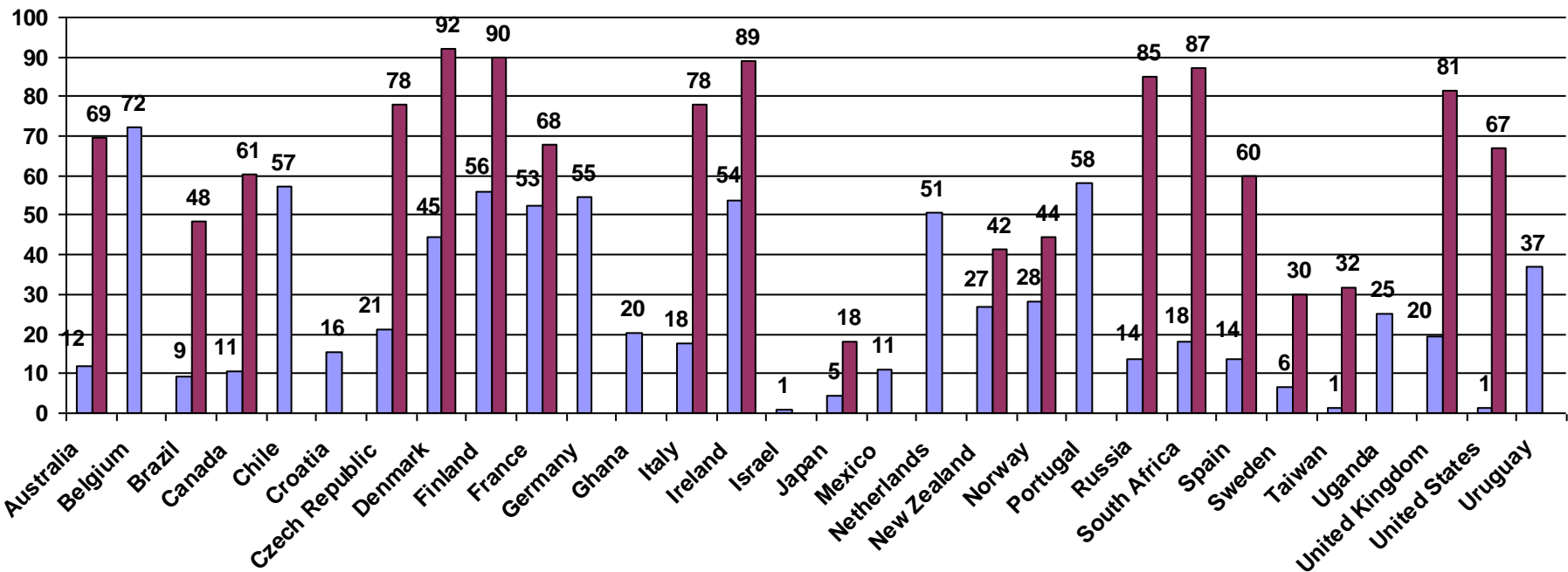
Photo Courtesy of Theresa Kellerman

PREVALENCE OF HEAVY EPISODIC DRINKING AMONG PAST-YEAR FEMALE DRINKERS FOR 2004 (WHO, 2011)



* Best estimates for 2004 based on surveys carried out within the time period 1997–2009.

MATERNAL ALCOHOL USE DURING PREGNANCY BY COUNTRY



The ranges are inclusive of any amount of alcohol consumed and at any point during pregnancy

The upper estimate $\geq 85\%$: Denmark (92%); Finland (90%); Ireland (89%); SA (87%); Russia (85%)

The lower estimate: $< 5\%$ Israel (1.1%); Taiwan and the US (1.4%); Japan (4.6%)

FASD

- **Alcohol use during pregnancy is a substantial public health concern worldwide**
- **Alcohol consumption during pregnancy is an established cause of FASD and is theoretically, largely preventable**
- **However, FASD and other negative health consequences may increase in the near future since:**
 - 1) the rates of alcohol use, binge drinking and drinking during pregnancy appear to be increasing in young women in a number of countries**
 - 2) a majority of pregnancies in both developing and developed countries are unplanned**

FASD IS AN INTERNATIONAL PROBLEM

Update: Of 3490 Articles in a Pubmed search for “Fetal Alcohol Syndrome,” 433 were in a language other than English

- Russian
- German
- French
- Spanish
- Japanese
- Italian
- Finish
- Danish
- Czech
- Chinese
- Norwegian
- Polish
- Dutch
- Swedish
- Hebrew
- Portuguese
- Bulgarian
- Croatian
- Romanian
- Hungarian
- Greek

EPIDEMIOLOGY: PREVALENCE OF FETAL ALCOHOL SYNDROME (FAS)
AND PARTIAL FETAL ALCOHOL SYNDROME (PFAS) IN SCHOOL ENTRY
STUDENTS

VIA **ACTIVE CASE ASCERTAINMENT**

Location (Reference Year)	Population	Socioeconomic Status	FAS* (FAS+pFAS) Rate per 1000
United States: Mid-Western Medium Size City (May et al. 2009)	75% white; 25% AI, Af. A, and Asian	Middle SES with full range -low to Upper	6 – 11 (14 – 25)
Italy; Lazio Region (May and Ceccanti, 2007)	Predominantly white	Middle SES	4 – 9 (27 – 55)
South Africa: Western Cape (2007)	85% Mixed Ancestry, 15% European White	Low Middle SES White: Middle – Upper SES	51 – 67 (68 – 90)
South Africa: Northern Cape (Urban et al. 2008)	64% Mixed Ancestry 36% Native Black	Low & Middle SES	67 (75 – 119)

*IOM 1996 prevalence estimated in U.S. for FAS at **0.5 – 2 /1000**

WHO Global Alcohol Initiatives

- WHO International Collaborative Research Project on Child Development and Prenatal Risk Factors with a Focus on Fetal Alcohol Spectrum Disorders
 - In collaboration with CAMH (Canada) and NIAAA (USA)
- WHO International Collaborative Research Project on the Harm to Others From Drinking
 - In collaboration with ThaiHealth Foundation (Thailand)
- WHO International Collaborative Research Project on Alcohol and Infectious Diseases (HIV, TB)
 - In the process of development

WHO Global Prevalence Study on FASD: Objectives

- Generate new knowledge on prevalence of FASD among children of 7-9 years old and prevalence of prenatal risk factor exposure (focus on alcohol)
 - First wave of data collection in Canada, Namibia, Poland, Ukraine, Republic of Belarus, Republic of Moldova and 1-2 other countries in Africa (to be determined in April 2013)
- Raise awareness of FASD and strengthen capacity for prevention and identification of FASD and promote treatment and support of affected individuals and families
- Support international collaboration, networking and partnerships for advancing FASD-related research globally.

alcohol

Global strategy to
reduce the harmful
use of alcohol



World Health
Organization

WHO Prevalence Study

April 2013 Second discussion of the protocol and training in assessment and diagnosis took place in sub-Saharan Africa.

- Countries who sent experts in pregnancy and child development included the following:

Kenya (3)

Ghana (2)

Ethiopia (1)

Tanzania (1)

Rawanda (1)

Seychelles (3)

Namibia (20)



TRAINING IN WINDHOEK , NAMIBIA (NIAAAA/WHO, 2013)



WHO Prevalence Study

- Countries who have funded or are funding their own prevalence studies (some regional) that are compatible with this design and could be included in some data analysis and country comparisons:
 - United States (May et al and Chambers et al)
 - Canada
 - Poland (PARPA)
 - South Africa (May et al)
 - Italy (May and Ceccanti et al)



Prevention of FAS/D can be broken down into the following components ...

- Reducing alcohol consumption in general
- Reducing at – risk drinking in women of child bearing age
- Reducing alcohol consumption in sexually active women not using contraception
- Stopping alcohol consumption in women who are pregnant or trying to become pregnant
- Treatment of alcohol use disorders in pregnant women

WHO Guidelines on Identification and Management of Substance Use and SUD in Pregnancy

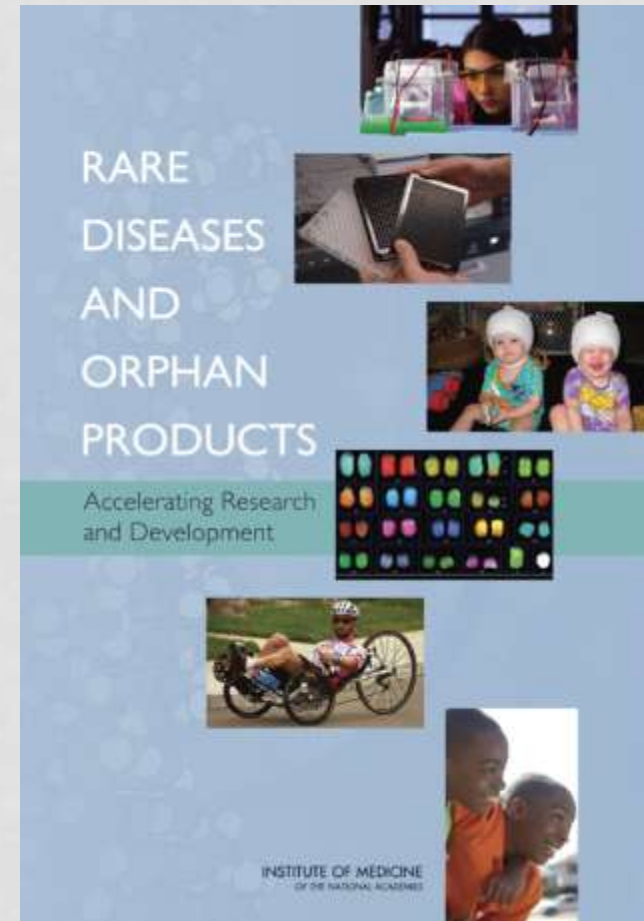
- Covering use of alcohol and major classes of illicit drugs in pregnancy
- Development in parallel to WHO guidelines on identification and management of tobacco use in pregnancy
- In collaboration with UNODC and other partners
- First meeting of the Guidelines Development Group took place 28 February – 1 March 2013 in Washington D.C.
- Publication released June 2014.

Revision of International Classification of Diseases (ICD-10)

- To be finalized by 2015
- 2012-2014: Review and field testing following the WHO protocol(s)
- Neurodevelopmental Disorder *Due to Prenatal Alcohol Exposure* – recommended for inclusion in the section "Neurodevelopmental Disorders".
 - Includes Fetal Alcohol Syndrome and Partial FAS
 - May have qualifiers at 4th digit.

USING MODELS DEVELOPED FOR RESEARCH ON RARE DISEASE COULD BE USEFUL FOR INTERNATIONAL COLLABORATIONS IN FAS/FASD RESEARCH

- FAS/FASD is still a relatively rare disease and presents the same challenges for research, diagnosis, and care:
 - Attracting public and commercial funding
 - Recruitment of sufficient numbers for research
 - Designing sound clinical trial strategies for small populations
 - Assessing safety and efficacy of products before they are marketed



MODEL INCLUDES:

- **Active involvement and collaboration by a wide range of public and private interests**
- **Timely application of advances in science and technology**
- **Appropriate use and further development of trial design and analytic methods tailored to research on small populations**
- **Creative strategies for sharing research resources and infrastructure to make good and efficient use of scarce funding, expertise, data, biological specimens and study subjects**
- **Mechanisms for weighing priorities for research and product development, establishing collaborative as well as organization-specific goals and assessing progress**

IRDIRC: INTERNATIONAL RARE DISEASES RESEARCH CONSORTIUM

- Launched in April 2011
- Joint effort of the European Commission and the U.S. National Institutes of Health

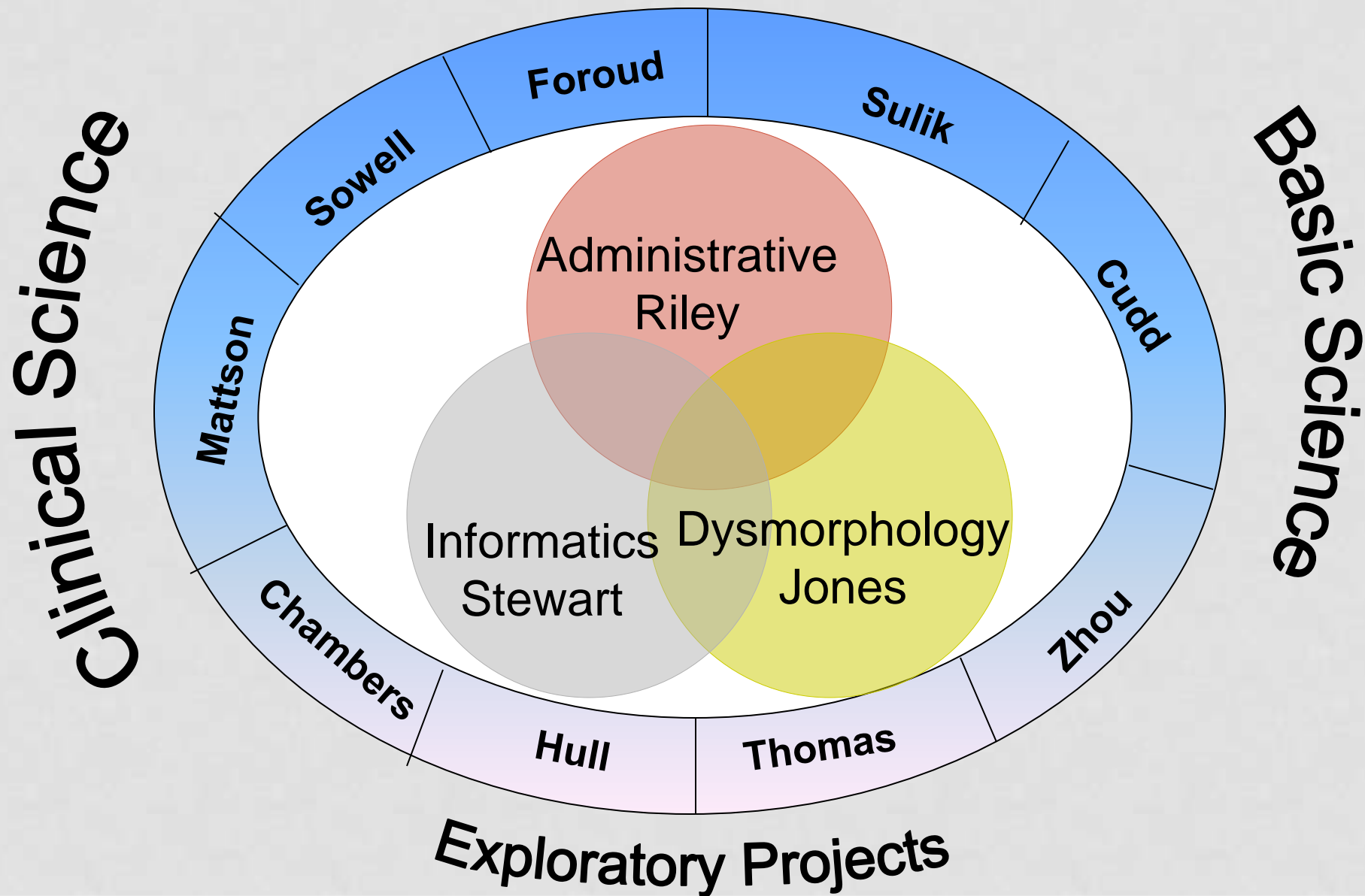


- Working to maximize resources and coordinate research efforts

RECOMMENDATIONS INCLUDE:

- **Standard Terms of Reference**
- **Common ontologies**
- **Patient registries**
- **Tissue repository**
- **Research databases**
- **Disease information networks**
- **Access to specialized social services**
- **Access to orphan drugs/incentives for orphan drug development**
- **Improved diagnosis**
- **Improved recognition**
- **Production of good practice guidelines**
- **E-health**
- **Primary prevention**
- **Cross-border collaboration and cooperation**
- **National and regional centers of expertise**
- **Empowerment and involvement of patients and patient organizations**

Collaborative Initiative on Fetal Alcohol Spectrum Disorders (CIFASD)



3-D APPROACH

“LARGE MULTI-POINT ANALYSIS”

- Developed by Peter Hammond (**University College, London**)
- Procedure involves morphing large number of facial points to derive an average multi-dimensional face for FAS and controls.
- The approach was applied to FAS and control individuals from a **prospective FAS study in South Africa** (*Drs. Joseph and Sandra Jacobson from the United States*)
- Subjects were approximately 9 years of age at time of 3-D image: 21 FAS cases; 68 non-alcohol exposed healthy controls



National Organization on Fetal Alcohol Syndrome
The Leading Voice and Resource of the Fetal Alcohol Spectrum Disorders Community

mencap
NOFAS·UK

National Organisation for
Foetal Alcohol Syndrome UK





- Linking European professionals concerned with alcohol and pregnancy

FASworld.com

FASworld Toronto

FASD shall be recognized as Canada's most common, most expensive, yet most preventable mental disorder.

farr

Foundation for Alcohol Related Research

Since 1997, FARR has been dedicated to building positive futures in South African communities by significantly reducing birth defects and mental disabilities caused by alcohol consumption during pregnancy.

It is time for these and other organizations to work together to lay out a comprehensive and cohesive global health policy agenda on prevention of FASD.



Labai ačiū