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Working Papers

Title
Concept Papers of the 5 Subgroups

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Author
UC-México Health Working Group

Publication Date
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Concept papers of the 5 subgroups
UC-México Initiative
Health Working Group
Summary of Concept Papers

VIOLENCE.............................................................................................................1
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HEALTH LEADERSHIP AND MANAGEMENT ..................................................4
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Health Working Group (HWG)
Summary of Accomplishments

- 5 groups established: diabetes, violence, maternal/neonatal health, health leadership, regulatory sciences
- 60 high profile faculties from the 10 UCs and 15 Mexican institutions participate in these subgroups
- Resources from UCOP, UNAM and CONACYT distributed to each subgroup to accomplish their scopes of work

As a result:
- 3 research proposals written
- 9 Potential funders in MX and CA approached
- Curricula for the 2 certificates almost completed. Online platforms and marketing strategies in negotiations
- One in-person meeting at each country
  - UCSF: 53 attendees: 10 UCs & 12 MX Institutions
  - UNAM: 56 from 5 UCs and 13 Mexican institutions
- XI Summer Institute on Migration and Global Health (70 attendees) collaboratively organized
- UNAM/ UCB evaluating Cerro Prieto Geothermal plant in Mexico, 10 researchers collaborating
- Website created for the HWG.

Subgroup key accomplishment

- A primary preventive experimental study, including a multi-phase intervention/trial of Metformin/Poly-Pill to delay onset of type 2 diabetes
- A position paper about the importance of binational collaboration drafted
- Founding obtained to conduct biomarker analysis in Mexico National Health Survey and proposal submitted to foundations: Rio Arronte and to the Robert W. Johnson
- USAID and CONACYT contacted to sponsor 6 proposed interventions to reduce youth violence in the US-Mexico border
- Panel presentations at the 2016 Consortium of Universities in Global Health Conference
- A collaborative paper will be published in “Migration and Health” (CONAPO/ UC.)
- Research-interventions to decrease adolescent's pregnancy & cesarean sections in both countries submitted to foundations
- A grant from the Research Program on Migration and Health (PIMSA) secured
- A collaborative paper accepted for publication in "Migration and Health" (CONAPO / UC.

Projection of Progress

2016
- 3rd binational conference in Bay Area
- Dissemination of collaborative research in academic publications
- Final proposal/concept papers prepared by each subgroup

2017
- Outside funding received by all subgroups
- Implementation of various binational projects
- Project evaluations commence

2018
- Demonstration of decrease in youth violence in the US-MX border
- Decrease of adolescent pregnancy in Mexico and Fresno, California
- Public Policy Implementation
- Binational Network for Research fully established

• Curricula for the certificates developed
• Faculty from UC and Mexican Universities contacted to teach both certificate programs
• Potential clients to offer certificates approached

Maternal & Neonatal

Online Certificates

Maternal & Neonatal

Online Certificates
Making large-scale change to prevent youth violence across borders.

A CONCEPT PAPER FROM THE YOUTH VIOLENCE PREVENTION SUBGROUP OF THE HEALTH WORKING GROUP OF THE UC-MÉXICO INITIATIVE
Youth violence is a highly visible global health problem that is persistent and pervasive in México and in the United States and has been jointly identified as a priority issue by both governments. Throughout North America, youth violence is a complicated, interrelated social phenomenon where complex networks of transnational actors (migration, social disintegration, poverty and others) are interlinked across borders, placing youth and other vulnerable civilians at highest risk (Howarth, 2016).

In México, homicide is the leading cause of death among young men aged 15 to 29 years (de la Portilla, 2015; Lozano R, 2014). In the United States, youth violence is currently the third leading cause of death of young people, with Black and Latino minorities disproportionately affected (CDC, 2016).

Yet, youth violence is not just about homicide. It is driven by adverse environments and includes types of violence that range from bullying to the most serious form, homicide. In our preliminary research, we have compiled and assessed published data to understand the causes of youth violence, along with barriers and successes in keeping youth (aged 12 – 25 years) safe and free from violent actions whether as a perpetrator or victim. We have gathered baseline data on prevalence and risk factors of violence, mental and physical health outcomes related to migration and violence, especially as found in California and México. We have also identified established youth violence prevention programs on the primary, secondary and tertiary levels. Understanding that social cohesion can play a role in protecting communities, our systematic review of the literature and case study analyses on social cohesion in Latin America will guide our proposed work as we incorporate community strengths through social cohesion strategies in programming and planning (Ramos et al, in preparation).

Youth violence and the associated impacts (homicide, emotional and physical abuse, etc.) demand comprehensive intervention strategies that target the highest at-risk groups. There is a strong need to identify programming along the prevention continuum that reduces the social and economic burden of injury and morbidity from youth violence. A binational public health approach is an innovative strategy for meeting these needs in this transnational region. To that end, researchers from the University of California statewide system and the National Institute of Psychiatry in México have formed a collaborative partnership to address and prevent these burgeoning problems through prevention programming with promising outcomes.
This partnership will support the establishment of the Binational Network for Research, Implementation and Evaluation of Youth Violence Prevention in México and California. We will create the network and its infrastructure to build on our preliminary research and our proposed programs; we have convened a strong cadre of established researchers whose work will be showcased through the network. The resulting network will become a key resource for all researchers and community programmers in youth violence prevention in both México and California.

Throughout the Network, we will employ several frameworks and theoretical models in our proposed programming. For example, some of our proposed programs will be built on the dimensions of community social cohesion by convening and promoting participation in community networks. These will include representation from stakeholders including federal, state and municipal governments, business, civil society, community and institutions, education, justice, health and, most importantly, youth. These interventions will work to create a shared sense of common purpose and a sense of belonging to the place (Langa et al, 2016). Many of our activities will take into consideration the three pillars of social cohesion: social relations, connectedness and a focus on the common good. (Figure 1) In addition, our projects will rely on a socioecological theory and take into account real-life experiences of low-income and public housing residents (e.g., trauma-informed community building). We will place community individuals as a central driver for change.

We will conduct qualitative / quantitative diagnosis in selected communities to assess not only the magnitude of youth violence but also factors (environmental, social, structural, etc.) that affect risk and protective factors, including community social cohesion.

This Binational Network will be headquartered within the offices of the co-chairs of the proposed initiative: one office within the National Institute of Psychiatry in México and the Universidad Nacional Autónoma de México under the guidance of Maria Elena Medina-Mora, PhD and one office within the UCLA Blum Center on Poverty and Health in Latin America under the guidance of Michael A. Rodriguez, MD, MPH.
The overarching aim of the proposed project is to reduce youth violence. We will work toward this aim on many levels: through research (to identify underlying causes, risk and protective factors) that will inform the subsequent design, development, implementation and evaluation of multi-level interventions addressing cross-cutting issues including migration, gender, and other special vulnerabilities and conditions. Our proposed interventions will seek to modify the environment (e.g., create safe meeting places), strengthen community ties, promote activities directed at the use of leisure time and incorporate other protective factors to prevent youth from engaging in violent or illegal activities. (Figure 2)

Figure 2. Binational Network: Programming grounded in social cohesion strategies to prevent violence among youth in México and in California.

Abbreviations: Futuros = Futuros, Youth-Led Community Mobilization and Educational Savings to Reduce Partner Violence among Adolescence; TICB = Trauma Informed Community Building; Treating Violent Youth = Treatment of Aggressive and/or Dissocial Behavior in First Offenders with Psychiatric Disorders
Target Populations and Communities

Through the work of this UC-México partnership, we will engage multiple communities in both California and México to include: Tijuana, Central México and southern México border communities, Chihuahua, San Diego, Los Angeles and others to be identified during Phase 1. In all, we will focus on youth aged 6 – 25 years although each project will target specific age groups and categories of youth. For example, for the social cohesion interventions, we will focus on young people in two age groups: aged 12-17 years and aged 18-25 years. Within these age groups, we will include young people who fall into one of three categories: 1) those who neither work nor study; 2) those who only work; and 3) those who only study. Other populations to be targeted through our proposed interventions include: 1200 9th graders in Tijuana; college students in Tijuana and two other sites in Central and South México; young people who inject drugs; parents of children aged 6-12 in Mexico; former youth gang members; youth who have been incarcerated; Latina mothers of youth aged 7-12; and teens in housing communities.

Specific Aims and Objectives

To reach our overarching goal to reduce youth violence, we will work toward these specific aims:

Organizational Aims

1. Establish a binational research network to showcase current research, both theoretical and implementation science.
2. Build upon and sustain academic-community collaborations in México and California.

Program Aims

3. Finalize research (surveying, secondary data analysis, etc.) that provides specific baseline data to form a diagnostic tool to measure program success (or not) in the communities selected for program implementation.
4. To implement and evaluate youth-focused violence prevention program across the prevention continuum (primary, secondary and tertiary) and identify programming that shows promise as best practices for reducing youth violence in the targeted communities.

Objectives

To reach each of these four aims, we will achieve these objectives:

1. Formalize the structure and organization of the Research Network to include: governance, goals, objectives and procedures, virtual or land-based location(s), staffing, recruitment of contributing research faculty, website and research archive portal, to name a few steps.
2. Finalize surveillance in selected communities to define magnitude, scope, characteristics and consequences of youth violence through the collection of data from existing sources and surveys (e.g., security within neighborhoods, typology of violent behavior, arrests, etc.).

3. Identify actors that contribute to social cohesion in the community, formation of a network to prevent youth violence, and collaboratively develop and implement best practices.

4. Develop cooperative agreements with organizations of civil society, private sector, academia and the government to promote the sustainability of the project.

5. Develop and implement proposed interventions (see Table 2).

6. Set baseline and follow-up studies to evaluate implementation, impact, and cost-effectiveness.

7. Scale up effective programs and policies to prevent youth violence.

8. Sustain and advance cross-border partnerships through ongoing meetings via conference calls, in-person meetings, email, web portals, and other methods of communications.

Across Borders and the Prevention Continuum

The newly established Binational Research Network will plan and implement nine programs in both México (blue) and California (green) across the prevention continuum: primary, secondary, tertiary (Table 1). As the Network is launched, our nine proposed interventions across the prevention spectrum will have programming in all three levels of prevention programming.

<table>
<thead>
<tr>
<th>Table 1. Prevention Programming across the Prevention Continuum</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Prevention</strong></td>
</tr>
<tr>
<td>Social Cohesion and Reduction of Youth Violence: A Community Intervention</td>
</tr>
<tr>
<td>Futuros, a Youth-led Community Mobilization and Educational Savings Program to Reduce Violence among Adolescents</td>
</tr>
<tr>
<td>PUERTAS, a University Project for Healthy Students</td>
</tr>
<tr>
<td>Madres á Madres</td>
</tr>
</tbody>
</table>

Proposed Interventions

Each of the proposed interventions will work toward reaching the overarching aim to reduce youth violence and, in sum, will leverage dimensions of social cohesion to help address the effects of violence risk factors, including lack of work, quality education, and other adverse environmental and individual factors that impact lifestyle choices of youth. Proposed interventions are briefly described in Table 2.
<table>
<thead>
<tr>
<th>Program</th>
<th>Descriptor</th>
<th>Target Group / Location</th>
<th>Aim(s)</th>
<th>PI, Collaborators</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>México-based Interventions</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social Cohesion and Reduction of Youth Violence: A Community Intervention</td>
<td>Research, development and evaluation of interventions with multiple components that combine situational and social strategies to promote social cohesion in youth and reduce the level of violence.</td>
<td>Male / females in 2 groups: aged 12-17 years and aged 18-25 years in a community with high rates of youth violence in Tijuana</td>
<td>To develop and test a multiple interventions strategy designed to increase youth social cohesion.</td>
<td>Luciana Ramos Lira, INPRF Collaborators: Adriana Sereno, Karla Flores, María Elena Medina-Mora</td>
</tr>
<tr>
<td>PUERTAS, University Project for Healthy Students</td>
<td>A longitudinal study of University-level students to assess impact of early detection of behavioral problems and referral for minimizing effects of violence and improving student outcomes.</td>
<td>College students in Tijuana and two other sites (TBD) located in Central México and in the southern border</td>
<td>1. To develop and test a method for screening for risk factors; 2. To examine the student engagement in available resources; 3. To determine the impact of violence and other behaviors on academic achievement and school termination.</td>
<td>Corina Benjet Instituto Nacional de Psiquiatría Ramón de la Fuente Muñiz, México</td>
</tr>
<tr>
<td>Parent Management Training – Oregon Model</td>
<td>This program, proven effective in México City, will be adapted to local sites to train parents in practices related to behavior problems of children aged 6-11 years.</td>
<td>Tijuana and two other sites located in Central México and in the southern border (TBD)</td>
<td>To evaluate the effectiveness of the PMTO™ program in diverse settings in México for modifying parenting practices and diminishing behavior problems in children aged 6 to 11 years.</td>
<td>Nancy Amador Universidad Autónoma de México</td>
</tr>
<tr>
<td>Preventing Violence among Young People Who Inject Drugs</td>
<td>An analysis of changes in youth risk behaviors before and after involuntary drug treatment.</td>
<td>Tijuana young people who inject drugs and who were involuntarily sent to residential drug centers in Tijuana, México</td>
<td>1. To gain an understanding of young people who inject drugs, the conditions in rehab centers, their discharge and relapse into drug use; 2. To assess how these past experiences affect subsequent voluntary treatment seeking.</td>
<td>Claudia Rafful Instituto Nacional de Psiquiatría Ramón de la Fuente Muñiz, México</td>
</tr>
<tr>
<td>Treatment of Aggressive and/or Dissocial Behavior in First Offenders with Psychiatric Disorders</td>
<td>Program will test the efficacy of psychotherapeutic and psychopharmacological treatment regimens for young offenders after first stay in prison.</td>
<td>Young persons in prisons in México: Tijuana and two sites located in Central México and southern border (TBD)</td>
<td>To develop guidelines, provide treatment of persons with violent and/or antisocial behaviors in the first imprisonment and evaluate the impact over violent behavior.</td>
<td>Nicolás Martínez Instituto Nacional de Psiquiatría Ramón de la Fuente Muñiz, México</td>
</tr>
<tr>
<td><strong>US-based Interventions in both California and México</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Futuros, Youth-led Community Mobilization and Educational Savings to Reduce Partner Violence among Adolescence</td>
<td>Interest-earning commitment savings program with subsidies to promote educational savings for adolescents</td>
<td>Adolescents in low-income migrant communities in Tijuana, México; 1200 9th grade students in 16 middle schools</td>
<td>1. To incorporate a parent-led one-year commitment savings program, engaging adolescents’ parents/guardians to set aside educational savings for adolescents; 2. To pilot test Futuros with a small-scale two-armed cluster randomized controlled trial</td>
<td>Elizabeth Reed UC-San Diego Department of Medicine Los Ninos de Baja California</td>
</tr>
</tbody>
</table>
### Table 2. Proposed Programs for the Binational Network for Research, Implementation and Evaluation of Youth Prevention

<table>
<thead>
<tr>
<th>Program</th>
<th>Descriptor</th>
<th>Target Group / Location</th>
<th>Aim(s)</th>
<th>PI, Collaborators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trauma-Informed Community Building for Youth in Los Angeles</td>
<td>A program built on the Trauma-Informed Community Building model to strengthen sense of community among youth in trauma-affected neighborhoods</td>
<td>Young persons in targeted housing community in Los Angeles, California</td>
<td>1. To de-escalate chaos and stress; 2. To foster resiliency; 3. To strengthen social connections</td>
<td>PI: Irene Yen UC-San Francisco</td>
</tr>
<tr>
<td>Homeboy Industries</td>
<td>A longitudinal scientific evaluation to examine whether Homeboy is successful in providing meaningful wrap-around services to reduce recidivism.</td>
<td>Gang youth in Los Angeles who have either been incarcerated or have engaged in harmful gang activity</td>
<td>1. To determine characteristics and positive behaviors associated with decreases in misconduct and recidivism; 2. To determine Homeboy components most effective in increasing positive behaviors</td>
<td>PI: Jorja Leap, PhD UCLA Luskin School of Public Affairs</td>
</tr>
<tr>
<td>Madres á Madres</td>
<td>A community-based parent training program using Promotoras to deliver programming through home education.</td>
<td>Latina mothers of children aged 7-12 years in Chihuahua, México and Santa Ana, California</td>
<td>1. To improve mothers’ parenting skills 2. To improve broad family functioning with fewer increases in child internalizing and externalizing behaviors relative to violence.</td>
<td>PI: Nancy Guerra UC-Irvine</td>
</tr>
</tbody>
</table>

### Expected Results and Outcomes

- Development of a Binational Network for Research, Implementation and Evaluation of Youth Violence Prevention in México and California
- Increased resources for researchers and community programmers working to prevent youth violence in México and California
- Increased community social cohesion through research-based community interventions using a social cohesion approach
- For youth in localities where programs will be implemented:
  - Decreased youth violence, including intimate partner violence
  - Decreased unintended pregnancy
  - Decreased substance use
  - Decreased involvement in illegal income generation
  - Increased education and employment opportunities
  - Ongoing protection against violence, including partner violence
  - Diminished behavior problems in early childhood and improved parental wellbeing
- Evidence-based guidelines for the treatment of young offenders
- Encouragement of a human rights approach to public policies related to young people who inject drugs
- Making large-scale change to prevent youth violence and by establishing conditions for long-term community and individual change.
México Co-Chair: **Maria Elena Medina-Mora, PhD** is the general director of the Instituto Nacional de Psiquiatría “Ramón de la Fuente Muñiz” (INPRF, México). She received her PhD in Social Psychology from the National Autonomous University of México where she is a member of the Board of Directors and teaches in the schools of Psychology and Medicine. Dr. Medina-Mora’s areas of interest are methodological, psychosocial and epidemiological issues as they relate to addictions and mental health; she has published more than 210 peer-reviewed articles, 187 book chapters and 7 books.

California Co-Chair: **Michael A. Rodriguez, MD, MPH** is professor and vice chair in the Department of Family Medicine at the David Geffen School of Medicine at UCLA, founding director of the UCLA Blum Center on Poverty and Health in Latin America, and chair of the UCLA Minor in Global Health. His research activities focus on health equity and social determinants of health. He is a leading researcher and policy expert on the health of underserved populations and the strengthening of health systems to improve health care provided to Latinos in the United States and Latin America.

Jennifer Ahern, PhD MPH, Division of Epidemiology, UC Berkeley

Héctor Cárdenas, Goldman School of Public Policy, UC Berkeley;

Xochitl Castaneda, California-México Health Initiative

Tommi L. Gaines, DrPH; Division of Global Public Health, UC San Diego

Rafael Lozano, MSc, MD; Institute for Health Metrics and Evaluation, University of Washington

Richard Matthew, PhD, School of Social Ecology, UC, Irvine

Sidra Goldman-Mellor, PhD, School of Social Sciences, Humanities and Arts, University of California, Merced

**Maria Gudelia Rangel Gomez, PhD**, Comprehensive Strategy for Migrant Health, México Ministry of Health

**Bryan L. Sykes, PhD**, Center for Demographic and Social Analysis, UC, Irvine
To reach our goals and objectives, we will work through a three-phase approach to establish the Binational Network for Research, Implementation and Evaluation of Youth Violence Prevention in México and in California.

Phase I: Program Design, 12 months
During this program design phase, we will flesh out the vision, mission, goals, priority areas and decide core operational structures of the Network, including hiring of key administrative, scientific and other staff, website development and other functions of the emerging Network. The nine proposed programs will be supported by research from Network faculty and will be prepared to launch by the end of Phase 1.

Phase 2: Program Development, 12 months
Phase 2 will advance the development of the Network and priority research, implementation and evaluation areas of work. Collaborators from institutions in México and the University of California will be identified and recruited to become members of the Network. Phase 2 will see the ongoing work of the nine proposed programs and the fleshing out of resources on youth violence prevention programming.

Phase 3: Sustainability, 12 months During this phase, the Network will move into sustaining operations, with a focus on continuous improvement within its programming. We will work toward the development of a permanent funding model, which will include a diverse stream of revenue that might include member dues, registration fees for Network-supported events, corporate funders; private donors and federal/local grants.

| Binational Network for Research, Implementation and Evaluation of Youth Violence Prevention in Mexico and in California |
|---|---|---|---|---|
| | Phase 1 | Phase 2 | Phase 3 |
| | Months 1-6 | Months 7-12 | Months 13-18 | Months 19-24 | Months 25-30 | Months 31-36 |
| Program Design | | | | | | |
| Network vision, mission statements | | | | | | |
| Network core operations established | | | | | | |
| Design for all interventions completed | | | | | | |
| Recruitment for interventions | | | | | | |
| Gathering baseline data for interventions | | | | | | |
| Program Development | | | | | | |
| Network research hub established | | | | | | |
| Six interventions deployed | | | | | | |
| Network website launched | | | | | | |
| Sustainability | | | | | | |
| Seven interventions continue | | | | | | |
| Evaluation of all interventions | | | | | | |
| Funding efforts to support Network | | | | | | |

Preliminary Budget Estimates

<table>
<thead>
<tr>
<th></th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>TOTALS, per activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core Operations: Network</td>
<td>$625,000</td>
<td>$662,500</td>
<td>$702,250</td>
<td>$1,989,750</td>
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<td>Interventions</td>
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<tr>
<td>Futuros</td>
<td>$534,000</td>
<td>$566,040</td>
<td>$600,002</td>
<td>$1,700,042</td>
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<td>PUERTAS</td>
<td>$100,000</td>
<td>$106,000</td>
<td>$112,360</td>
<td>$318,360</td>
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<td>Social cohesion and reduction of youth violence</td>
<td>$408,100</td>
<td>$500,500</td>
<td>$364,760</td>
<td>$1,273,360</td>
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<td>Parent management training</td>
<td>$325,000</td>
<td>$344,500</td>
<td>$365,170</td>
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<td>Homeboy Industries</td>
<td>$350,000</td>
<td>$371,000</td>
<td>$393,260</td>
<td>$1,273,360</td>
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<td>Treating anti-social behaviors among violent youth</td>
<td>$350,000</td>
<td>$300,000</td>
<td>$150,000</td>
<td>$590,000</td>
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<tr>
<td>Preventing violence among young people who inject drugs</td>
<td>$405,000</td>
<td>$429,300</td>
<td>$455,058</td>
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<td>Trauma-informed community building for youth in LA</td>
<td>$485,000</td>
<td>$514,100</td>
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<td>Madres a Madres</td>
<td>$525,000</td>
<td>$556,500</td>
<td>$589,890</td>
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<td>TOTALS, per yr</td>
<td>$4,107,100</td>
<td>$4,350,440</td>
<td>$4,277,696</td>
<td>$12,735,236</td>
</tr>
</tbody>
</table>

3-YEAR TOTAL
REFERENCES


Our goal is to prevent new cases of Type 2 diabetes and develop interventions to help those suffering from diabetes better manage their condition and prevent further complications. Our underlying principles include collaborative team-work, focusing on the most vulnerable populations, prioritizing cost-effective interventions, ensuring that our interventions are scalable and have a strong impact and that are independent from (diabetes- and nutrition-related) industry.
**THE OPPORTUNITY**

**Statement of Need**

Mexico and the United States are among the top 10 countries in the Organization for Economic Cooperation and Development (OECD) with the highest prevalence of diabetes (T2D). In the United States, California is a particularly important state given that a high proportion of inhabitants are of Mexican-origin. At the same time, Mexican and Mexican-Americans are disproportionately affected by diabetes and its complications. In Mexico, 14.1% of the adult population has diabetes, and in the US, over 23% of Mexican-Americans have diabetes, more than double the rate of non-Hispanic whites, and an additional 38% of Mexicans on either side of the border have prediabetes. In California, nearly 1% of Mexican-Americans teens have diabetes.

**The Current Opportunity**

There are unique research opportunities for the study of T2D in Mexicans living in Mexico and California. The uniqueness of the population and their environment may be used to generate new local and global knowledge in the field. For instance, Mexicans have a large proportion of Amerindian heritage (30-70%), a group that has not been sufficiently represented in the genetic consortia. This ethnic group also develops diabetes at an earlier age and at lower body mass indices compared to Caucasians. In addition, the study of their increased susceptibility for having microvascular complications (especially diabetic nephropathy and retinopathy) may offer new insights about the pathogenesis and treatments of the diabetes related chronic complications. Finally, the ways in which poverty, food insecurity and migrational forces all interact to generate Type 2 diabetes is of utmost interest, as is the ways in which poor access to care and suboptimal quality of care lead to unnecessary complications. In summary, a strategic research plan is required to understand the interaction of multiple factors that contribute to the increased prevalence of diabetes and its complications, and to develop robust interventions that address both the clinical and socio-ecological dimensions of this epidemic.
Proposal Summary

The UC-Mexico Health Initiative Nutrition & Diabetes subgroup is seeking funding to support collaborative efforts. The Diabetes & Nutrition subgroup will provide an action-research platform in which the best medical research and public health institutions in California and Mexico can unite forces and implement bi-national efforts to prevent new cases of this disease, reduce the increasing health burden on society, help those suffering from T2D better manage their condition, as well as prevent complications.
The Nutrition & Diabetes subgroup of the UC Mexico Health Initiative is taking a methodical approach to address the diabetes epidemic among the Mexican-origin populations in Mexico and California. Three sequential yet overlapping phases are being rolled. The first phase started in late 2015 with the creation of the subgroup, identification of its co-chairs and teams, development of its mission, objectives and goals and creation of essential descriptive studies. Phase II will begin in mid-2016 and is primarily focusing on the discovery of new knowledge by carrying out population-based surveys and collection of biometric data and synthesizing the promise of current and future diabetes prevention and control policy efforts. Phase III will initiate in 2017 and will primarily involve large-scale interventions to make a significant impact on the diabetes epidemic as well as to improve the health of patients suffering from diabetes.
PROPOSED APPROACH

Phase I: Descriptive Studies

**Deliverables**
- Identify important collaborators in California and Mexico and design an interactive, comprehensive and catalyzing matrix
- Write a position paper about purpose of our group and importance of collaboration
- Write a descriptive article of relevant binational public health interventions and policies

Phase II: Discovery

**Deliverables**
- Conduct ENSANUT Medio Camino 2016 and CHIS analyses (secondary data)
- Conduct secondary analyses using IMSS and CA health system data
- Conduct cost-effectiveness modeling studies of diabetes prevention interventions
- Write policy briefs on different diabetes interventions related to diabetes prevention and control
- Develop a proposal to a foundation on Retinopathy/Nephropathy, such as harnessing Information Technology for retinopathy identification and treatment
- Advance diabetes prevention and control communication campaign collaborations and seek funding to support these efforts

Phase III: Large-Scale Interventions

**Deliverables**
- Pursue foundation funding for an Initiative to detect and reduce Retinopathy/Nephropathy
- Pursue foundation funding and implement communication campaign collaborations
- Design intervention to harness the “Social Safety Nets” to prevent diabetes (e.g. food banks in US, PROGRESA in Mexico)
- Pursue extramural funding to implement and evaluate large interventions/trials
  - PROSPERA Social Safety Net Trial for Diabetes Prevention/Feeding America Food Bank Diabetes Prevention Intervention
### PROPOSED APPROACH

- Metformin Quasi Experimental Study for Chronic Disease Prevention or Poly-Pill for prevention and control

<table>
<thead>
<tr>
<th>Team Formation</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>Beyond</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identify co-chairs and collaborators</td>
<td></td>
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<th>2017</th>
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<td>Retinopathy/Nephropathy proposal development</td>
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<td>Advance communication campaign collaborations</td>
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OUR TEAM

University of California

- **Marc Schenker, MD, MPH** is a distinguished professor of Epidemiology at UC Davis who specializes in environmental and occupational risk factors for respiratory disease and lung cancer, occupational and health issues of migrant populations.

- **Dean Schillinger, MD** is a professor of Medicine at UCSF, Chief of the UCSF Division of General Internal Medicine at San Francisco General Hospital, founder of the UCSF Center for Vulnerable Populations and current Director of Health Communications Research Program, and National Resource Director for the UCSF/Kaiser NIDDK Center for Type 2 Diabetes Translational Research. Dr. Schillinger served as Chief of the Diabetes Prevention and Control Program for the California Department of Public Health from 2008-2013. Dr. Schillinger carries out research related to healthcare for vulnerable populations, and is an internationally recognized expert in health communication science.

- **Alicia Fernandez, MD** is a Professor of Clinical Medicine at UCSF and an attending physician in the General Medical Clinic and the Medical Wards at San Francisco General Hospital. Her research focuses on health and disparities, with a particular interest in diabetes, Latino health, immigrant health, and language barriers.

- **Margaret Handley, PhD, MPH** is a Professor in the Departments of Epidemiology and Biostatistics and Medicine, at UCSF. She is involved in the Clinical and Translational Science Institute (CTSI) program, as core faculty in both the Community Engagement Program and Associate Director of the Training Program in Implementation and Dissemination Sciences, which focus on the art and science of translating evidence into practice, policy and public health. She has done seminal work in promoting health literacy in Latinos is ESL (English as a Second Language) settings, and currently serves as PI for an NIH-funded project to prevent incident diabetes in post-partum women with a history of gestational diabetes.

- **Kirsten Bibbins-Domingo, MD, PhD, MAS** is the Lee Goldman, MD Endowed Chair in Medicine and Professor of Medicine and of Epidemiology and Biostatistics. She directs the UCSF Center for Vulnerable Populations at Zuckerberg San Francisco General Hospital, a research center focused on discovery, innovation, policy, advocacy, and community engagement for communities at risk for poor health and inadequate healthcare. Dr. Bibbins-Domingo has expertise in cardiovascular disease, diabetes, and chronic kidney disease with a particular interest in the development of chronic disease in young adults.
OUR TEAM

• **Luis A. Rodriguez, MPH, RD**, is a doctoral student in Epidemiology at UCSF. He’s a pediatric clinical dietitian with expertise in the prevention and treatment of pediatric cardiometabolic dysfunction, type 2 diabetes, and obesity. His research focuses on identifying and implementing population level interventions for the prevention of non-communicable chronic diseases.

**National Institute of Medical Sciences and Nutrition (INCMNSZ)**

• **Carlos Aguilar Salinas, MD, PhD** is Deputy Head of the Department of Endocrinology and Metabolism of the Instituto Nacional de Ciencias Medicas y Nutricion, Mexico City, and a specialist in internal medicine and endocrinology. His main research line is in the epidemiology, pathophysiology, and treatment of dyslipidemia, diabetes, and components of the metabolic syndrome.

• **Martha Kaufer, PhD** is a Medical Sciences Investigator. Her research focuses on obesity from various perspectives, including body composition, nutritional treatment programs, migration, dietary guidance to patients and population.

**National Institute of Public Health, Mexico (INSP)**

• **Simon Barquera, MD, PhD, MS** is President of the Nutrition Board of Professors at the Mexican School of Public Health and Director of the Nutrition Policy and Program Research Division at the National Institute of Public Health (INSP-Mexico), where he is also leader of the obesity, diabetes and cardio-vascular disease research line.

• **Juan A. Rivera, PhD** is founding Director of the Center for Research in Nutrition and Health at the National Institute of Public Health, a Professor of Nutrition at the School of Public Health of Mexico and an adjunct professor at the Rollins School of Public Health in Emory University in Atlanta, GA. His research interests include the epidemiology of malnutrition (undernutrition and obesity), the short and long-term effects of undernutrition during early childhood, the nutritional status and dietary intake of the Mexican population and the evaluation of programs and policies to improve the nutritional status of populations.

**Mexican Social Security Institute/UNAM**

• **Jorge Salmeron, MD, PhD** is Head of Epidemiological Research Unit and Health Services of the IMSS regional hospital in Cuernavaca, Mexico. His medical research focuses on the influence of diet and carbohydrate metabolism and dietary patterns impact on the risk of developing diabetes mellitus.
### Table 1: Investment requirements for UCSF and UC Davis, 2016-2017

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<th>Category</th>
<th>Description</th>
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<td>• Rodriguez (PhD Student) 15% =</td>
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<td>• Program Director 100%</td>
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<td><strong>Total</strong></td>
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MATERNAL AND NEONATAL HEALTH IN MEXICO AND IN CALIFORNIA

Making large-scale change to improve the health of mothers and their children across borders.

A CONCEPT PAPER FROM THE MATERNAL AND NEONATAL HEALTH SUBGROUP OF THE HEALTH WORKING GROUP OF THE UC-MEXICO INITIATIVE
ADOLESCENT PREGNANCY

The adolescent birth rate in Mexico remains one of the highest in the region and the world with 68 births per 1000 females 15–19 years old (Sedgh, Finer, Bankole, Eilers, & Singh, 2015). Women with lower educational levels, living in rural areas, and from indigenous groups are much more likely to give birth (Tuiran, Partida, Mojarro, & Zúñiga, 2002). Although 97% of female adolescents ages 15–19 report knowing of at least one contraceptive method and the Mexican government offers free family planning services, lack of youth-friendly services and inadequate sex education continue to act as barriers to access (Juárez, Palma, Singh, & Bankole, 2010). In Guanajuato, 37% of married females and 20% of sexually active, unmarried females ages 15–24 report using a modern form of contraception, significantly lower than the national rates (Juárez et al., 2010). One study found that the unmet need for contraception increased from 23% in 1997 to 31% in 2006 among females ages 15–24, which may be partially explained by a higher number of women starting their sexual debut prior to marriage and barriers to contraceptive access (Juárez et al., 2010).

Although the adolescent birth rate in California is much lower than in Mexico, there is considerable variability across counties and between different racial/ethnic groups. The birth rate among all California adolescents ages 15–19 is 23.2 per 1,000 females, but among Latina adolescents, it is 34.9. This represents 74% of all births in the state (California Department of Public Health, 2015). In Fresno County, the adolescent birth rate is 42.9 per 1,000 females, much higher than the state average (California Department of Public Health, 2015). There is also evidence that adolescent Latino immigrants face greater challenges in accessing sexual and reproductive health services and are at increased risk for an unintended pregnancy, particularly in rural communities (Lara, Decker, & Brindis, In press).

GESTATIONAL DIABETES/OBESITY

Gestational diabetes is present in 3–14% of all pregnancies in Mexico and Guanajuato is one of ten states with the highest incidence; cases have increased substantially in the last few years (SUIVE/DGE/Secretaria de Salud de Mexico, 2015). While there is little research on the rates of gestational diabetes among Mexican adolescents, the rates of obesity have increased considerably in this group. One study found that the prevalence of overweight and obese female adolescents increased from 11% to 36% from 1988–2012 (Barquera, Campos, & Rivera, 2013). Nationally, around 69% of Mexican women are either overweight or obese, an important risk factor for developing gestational diabetes and diabetes mellitus. This is particularly concerning
since diabetes mellitus is currently the leading cause of death among Mexican women (Perichart-Perera et al., 2009).

In California, Latino youth have disproportionally higher rates of obesity (40%) compared to White youth (21%), with rates increasing among youth of Mexican origin (Wolstein, Babey, & Diamant, 2015). One study found that first generation Mexican-origin youth had a significantly higher prevalence of obesity compared to White youth, and similar rates of obesity to second and third generation Mexican American youth, complicating the “healthy immigrant” theory (Buttenheim, Pebley, Hsih, Chung, & Goldman, 2013). In California, the prevalence of gestational diabetes is second highest among Latinas (6%) and is increasing among all age groups, but especially among younger women (Center for Vulnerable Populations, 2013). A study looking at the age-adjusted prevalence of gestational diabetes in California by country of birth found that the risk for gestational diabetes for women born in Mexico was 35% higher compared to all women born in the US (Hedderson, Darbinian, & Ferrara, 2010).

**CESAREAN SECTIONS**

Mexico has one of the highest rates of C-sections and non-medically indicated C-sections in the world at 37.8 C-sections per 1,000 females (Gibbons et al., 2010). From 2006–2012, 47% of births were planned or emergency C-sections, with higher rates among women who deliver in the private sector (Heredia-Pi, Servan-Mori, Wirtz, Avila-Burgos, & Lozano, 2014; Suárez-López et al., 2013). Mexico also has observed a 50% increase in use of C-sections nationally between 2000–2012 (Suárez-López et al., 2013). The rate of C-sections is increasing among adolescents, with one study noting the prevalence as high as 36% in this age group (McDonald, Mojarro, Sutton, & Ventura, 2015). Although younger age tends to be a protective factor against C-sections, when observing the association between age and parity, primiparous women ages 12–19 have six times the risk of undergoing a C-section compared to women ages 20–34 (Suárez-López et al., 2013). Factors associated with having a C-section during adolescence include failed labor induction, BMI greater or equal to 26, low socioeconomic background, and birth weight greater than 7.7 lbs. (Gonzalez-Perez, Vega-Lopez, & Cabrera-Pivaral, 2011).

In contrast, first birth C-section rates in California are lowest among Latinas (26%) compared to all other races/ethnicities (Let's Get Healthy California, 2013). However, C-section rates are increasing in California among all races and ethnicities with the greatest increases seen in women under 25 years of age (Main et al., 2011).
Teen pregnancy is a serious public health problem, in Mexico there are 22.4 million adolescents between the age of 10 and 19 years old; they represent 20% of the Mexican population, 49.3% of which are women. In 2014, 44,372 of the 2.4 million births in Mexico were women between 15 and 19 years old. This represents 1225 births per day and 50 woman every hour become part of the complex national problems of being an adolescent mothers. Besides this, it is highly likely that the mother’s partner is also an adolescent. These figures place Mexico as the leading country in Teenage pregnancy within the member countries of the Organization for Economic Co-operation and Development (OECD). According to the Mexican National Survey of Demographic Dynamics (ENADID, for its Spanish acronym) the fertility rate in this age group has increased from 69.5 / 1000 in 2009 to 77/1000 in 2014.

While adolescent birth rates in the United States and California have declined overall, substantial disparities based on race, ethnicity, socioeconomic status, and geographic location still exist. Unstably housed and homeless youth, lesbian, gay, bisexual, transgender, queer/questioning (LGBTQ) youth, and youth of color are disproportionately affected by unplanned pregnancy and sexually transmitted infections (STIs). Fresno County, California, has some of the highest rates of adolescent births and STIs in the state, as well as elevated rates of poverty, unemployment, and high school dropouts. These outcomes in part are a result of a lack of comprehensive sexual education and limited access to sexual reproductive health information and services, especially for highly mobile youth and other marginalized populations.

The Maternal and Neonatal Working Group sought to identify and evaluate promising interventions to address adolescent pregnancy, obesity and gestational diabetes, and cesarean sections in Mexico and California. While our initial goal was to submit a joint research proposal, we opted to pursue research projects and funding streams that best responded to the unique environment for Mexican adolescents living in the Mexico and the U.S. For this reason, our group did not submit one large-scale, integrated proposal, but rather two parallel proposals to funders in Mexico and the United States as well as one joint proposal. In California, The Digital Initiative for Youth (DIY) overall goal is to provide the necessary and timely skills, information, and resources to improve the reproductive health and overall well-being of adolescents living in Fresno County, California.

In Mexico the aim is to impact three different levels of adolescent health: 1) Preventing first pregnancies, 2) ensuring the right to a healthy pregnancy, and 3) preventing rapid repeat births. While the Maternal-Neonatal Working Group was not able to submit a joint research proposal at the scale originally envisioned by the UC-Mexico initiative during the planning phase, we were able to secure funding to conduct a brief UC-Mexico bi-national project in Fresno, CA and Guanajuato, Mexico. The goal of the study is to determine if there are differences in perinatal care between obese adolescents of Mexican origin in Guanajuato and Fresno. Despite the
differences in studies, all three proposals have an overarching goal of addressing adolescent pregnancy, obesity and gestational diabetes, and cesarean sections in Mexico and California

The target population for each study will vary according to their needs. In Fresno, California the intervention will be geared towards youth aged 13–19. The intervention will specifically focus on the needs of and outreach to homeless and unstably housed youth, youth of color, LGBTQ youth, and Native American youth, where the population is primarily Mexican immigrants and Mexican-American.

In Mexico City, geographic areas that will particularly benefit from intervention will be identified using data from the Secretariat of Health census.

For the joint California-Mexico project, adolescents 15–20 years old who were diagnosed with obesity and/or gestational diabetes during pregnancy will be recruited. Participants will be recruited from clinics and non-profit organizations and clinics that provide services to adolescents and migrants in Fresno and Guanajuato. We will conduct half of the focus groups with adolescents who had a vaginal delivery and half with adolescents who had a C-section. Furthermore, we will interview approximately two nurses, one social worker, one nutritionist, and one physician in order to gather information about the protocols of attention that they follow with adolescents with obesity and/or gestational diabetes.

Target Populations and Communities
To reach our overarching goal of addressing adolescent pregnancy, obesity and gestational diabetes, and cesarean sections in Mexico and California, we will work toward these specific objectives:

**CALIFORNIA**

1. Increase use of condoms and contraceptives, among those who are sexually active.
2. Improve awareness about healthy relationships and decrease the incidence of sexual, physical, and emotional violence among youth.
3. Improve educational and career skill development and attainment.
4. Develop healthy life skills including goal setting and stress management.
5. Increase access to healthcare and other services through referrals and information.

**MEXICO**

1. Prevention of first pregnancies
2. Ensuring the right to a healthy pregnancy
3. Prevention of rapid repeat births

**JOINT EFFORTS**

1. To compare experiences in prenatal care and delivery services—in Fresno and Guanajuato—between two groups of adolescents with obesity and/or gestational diabetes based on their delivery method (C-section and vaginal)
2. To explore the differences between the two groups of adolescents—in Fresno and Guanajuato—in their opinions about programs, activities or information that help them to reduce the risks of a C-section and/or gestational diabetes
3. To explore specific barriers to access contraception among adolescents with obesity and/or diabetes—in Fresno and Guanajuato—as well as their attitudes and experiences obtaining contraception after childbirth.

Each of the proposed interventions will work toward reaching the overarching aim to address adolescent pregnancy, obesity and gestational diabetes, and cesarean sections in Mexico and California.
CALIFORNIA

The Digital Initiative for Youth (DIY) combines existing, in-person, group-based, comprehensive sexual health education with wraparound digital technologies. This enables reinforcement of key messages and skills as well as provides real-time information and referrals for local services and resources. DIY is built on three strategies: positive youth development, youth-centered design, and wraparound technologies. It will focus on four main areas: sexual health and contraceptive use, healthy relationships, educational and career development, and life skills.

MEXICO

The proposed clinical-based project aims to impact three different levels of adolescent health: 1) Preventing first pregnancies, 2) ensuring the right to a healthy pregnancy, and 3) preventing rapid repeat births. The intervention consists of enhanced collaboration and integration of different clinical departments and is coordinated by the Research Unit for Adolescent Medicine. The intervention is multi-faceted and includes the following components:

- Implementation of “Adolescent Reproductive and Sexual Health” Clinic.
- Offer information and services regarding: contraception, STI’s, Adolescent sexuality and rights, prevention of sexual and gender violence, and evaluation and prevention of common adolescent gynecological problems.
- Implementation of “Adolescent Maternal and Child” Clinic.
- Implementation of “School for Adolescent parents” program.
- Educational outreach regarding secondary prevention of pregnancy in adolescent patients by raising awareness on the use of family planning methods.

JOINT EFFORTS

The qualitative study will compare data from Guanajuato, Mexico (a traditional point of origin for migrants to California) and Fresno, California (a primary point of arrival). In each location, we will conduct focus groups and interviews with female youth who had gestational diabetes and/or obesity during a past recent pregnancy as well as in-depth interviews with health providers.

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<td>In-depth interviews with health providers</td>
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Binational Network

Network Leadership

Co-Chair: Dr. Arturo Cardona Pérez, INPer

Co-Chair: Dr. Claire D. Brindis, UCSF

Principal Investigators

INPER TEAM

Guadalupe Estrada-Gutierrez, PhD

Josefina Lira, MD

Ivan Pantic, PhD

Mario Guzman-Huerta, MD

Enrique Reyes-Muñoz, MD

Otilia Perichart-Perera, PhD

UCSF TEAM

Mara Decker, DrPH

Abigail Gutmann-Gonzalez, MPH

Diana Lara, MD, MS

UCB

Sylvia Guendelman

Project Timeline
### MEXICO

#### PHASE I
Prevention of First Pregnancies

#### PHASE II
Ensuring the right to a healthy pregnancy

#### PHASE III
Prevention of rapid, repeat births

### JOINT EFFORTS

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</table>
References


Gibbons, Luz, José M Belizán, Jeremy A Lauer, Ana P Betrán, Mario Merialdi, and Fernando Althabe. 2010. The global numbers and costs of additionally needed and unnecessary caesarean sections performed per year: overuse as a barrier to universal coverage. In World Health Report.


In Mexico, the most frequently promoted personnel to management positions overseeing complex institutions are medical professionals who require skill sets beyond their original training. The Initiative has capacity in this area to contribute to certificate content in collaboration with faculty of UC and Mexican institutions. The healthcare industry is one of the fastest-growing industries in both Mexico and the U.S. Future healthcare leaders with strong health and hospital management skills will be in high demand in the near future.

This binational online certificate will be elaborated by Mexico and the University of California to serve the development of health care leaders in both countries. The Mexican National Institute of Public Health (INSP for its Spanish Acronym) and the National Autonomous University of Mexico (UNAM for its Spanish Acronym) have strongly expressed their commitment to support the technical requirements for the online platform. Coordination roles have been defined for each participating institution; UNAM will lead academic development, UC will lead operational details, and INSP will lead production of the Health Leadership and Management Certificate (HLMC).

To develop, implement, and evaluate a self-sustaining health care leadership training program that enables physician leaders and administrators to improve their leadership skills to more effectively manage organizational change. The Certificate aims to fill an important gap in health care leadership and management training for new leaders of Mexican health care organizations. The innovative training program aspires to accelerate and drive improved performance of Mexican health care organizations, to enhance political influence of health care leaders, and to foster the application of new leadership skills in real-time.
The HLMC proposes a 160-hour, 9 month; primarily online certificate program will be tailored to fit the demands of healthcare executives and emerging leaders, with the purpose of elevating their management capacity and skills. It will focus on data-driven management of performance to maximize quality and efficiency. The initial structural phase of the HLMC is completed, including the 11 modules students will take based on 6 themes: Mexican Reality; Leadership; Quality Improvement; Human Resources, Finance, and IT Tools and Systems. There is also an additional 10 hour pre-requisite module deemed essential to understand how the Mexican Health System works to lead into and set the tone for the rest of the modules. The team’s approach to creating case studies for the curriculum has been refined and is in the initial stages of development. INSP and UNAM alongside UC are committed to developing the content of the modules, the pedagogic strategy, and the online platform for the certificate. Professors from both countries have been approached to participate in this innovative training effort with the goal of augmenting and broadening the skills and knowledge necessary for efficient management of, and effective leadership in Health Services.

The HLMC has promising prospects to becoming a highly demanded certificate in both Mexico and in other Latin American countries. The target audience will be high level professionals that are or will be in top directive positions in Mexico as well as students wanting to complete foundational requirements for a master’s degree at one of University of California’s health care leadership/management programs, including UC Berkeley, UCLA, and UCSD.
<table>
<thead>
<tr>
<th>Learning Outcomes of each Module:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>.01 Pre-requisite</strong></td>
</tr>
<tr>
<td>• Gain functional knowledge of the Mexican Health system - the interdependency, integration and competition among healthcare institutions and sectors, including financing and payment mechanisms</td>
</tr>
<tr>
<td><strong>1. The Mexican Reality</strong></td>
</tr>
<tr>
<td>• Understand how the generic material in each module relates to the Mexican Health System and the most important institutions providing healthcare services in Mexico</td>
</tr>
<tr>
<td>• Understand the legal and normative frameworks of the Mexican Health System</td>
</tr>
<tr>
<td>• Map out the regulators (national and regional) of the Mexican Health System</td>
</tr>
<tr>
<td><strong>2. Leadership</strong></td>
</tr>
<tr>
<td>• Develop professionalism and work ethics in the healthcare sector</td>
</tr>
<tr>
<td>• Identify and apply leadership techniques</td>
</tr>
<tr>
<td>• Develop a peer senior management and executive multinational alumni network</td>
</tr>
<tr>
<td>• Build &amp; manage efficient and trans-disciplinary teams</td>
</tr>
<tr>
<td>• Understand and apply theory and process of effective negotiation</td>
</tr>
<tr>
<td>• Identify and apply conflict resolution strategies</td>
</tr>
<tr>
<td><strong>3. Quality Improvement</strong></td>
</tr>
<tr>
<td>• Identify and apply the PDSA model for improvement</td>
</tr>
<tr>
<td>• Measuring improvement: be able to collect, display and interpret data and the value of aggregate data for decision making at the local, regional and national level</td>
</tr>
<tr>
<td>• Develop an understand how to complete a cost-benefit analysis</td>
</tr>
<tr>
<td>• Understand change management and the role of leadership in relation to societal, epidemiological and economical trends</td>
</tr>
<tr>
<td>• Know the internal and external environment in which Mexican (or other) healthcare organizations function</td>
</tr>
<tr>
<td>• Principles of strategic management and its application to innovation in healthcare organizations</td>
</tr>
<tr>
<td><strong>4. Human Resources</strong></td>
</tr>
<tr>
<td>• Learn and apply talent management and develop practical communication skills</td>
</tr>
<tr>
<td>• Learn the principles of Hospital Operations, Process Design, and Systems; and apply knowledge for optimal performance</td>
</tr>
<tr>
<td><strong>5. Finance &amp; Accountability</strong></td>
</tr>
<tr>
<td>• Analysis of Financial Statements: Manage and respond effectively to financial valuation and analysis</td>
</tr>
<tr>
<td>• Understand the justifications and consequences of funding and mechanisms of the Mexican (or other)</td>
</tr>
<tr>
<td>• Principles and strategies of Accountability</td>
</tr>
<tr>
<td>• Learn and Apply an analytic framework for accountability in health service delivery systems</td>
</tr>
<tr>
<td><strong>6. IT Tools and Systems</strong></td>
</tr>
<tr>
<td>• Effectively use and manage information and information technologies</td>
</tr>
<tr>
<td>• Develop the IT tools for adequate Project Management</td>
</tr>
<tr>
<td>• Develop practical skills to work with IT tools in financial and accounting activities</td>
</tr>
<tr>
<td>• Use technology to enhance downward and upward accountability (reporting)</td>
</tr>
</tbody>
</table>
Structure of the Certificate

- Pre-requisite
  - Mexican Health System: Organization and Financing Structure
  - Applied Knowledge and Decision Making
  - Healthcare Regulators and Regulations
  - Healthcare Leadership and Strategic Vision
  - Conflict Resolution, Negotiation and Team Building
  - Healthcare Outcomes and Quality Improvement
  - Innovation Management
  - Human Resources and Process Management & Improvement
  - Financial Accounting and Analysis
  - Accountability in Healthcare
  - Using and Managing Technology in Healthcare Services
  - IT tools for Managers

- The Mexican Reality
- Leadership
- Quality Improvement
- Human Resources
- Finance & Accountability
- IT tools and Systems
## PROJECTED BUDGET

<table>
<thead>
<tr>
<th>UCOP Budget Categories</th>
<th>Project Period 1</th>
<th>Project Period 2</th>
<th>Total Expenditures</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>UCB</td>
<td>INSP</td>
<td>UCB</td>
</tr>
<tr>
<td>Administrative Support</td>
<td>8,817</td>
<td>-</td>
<td>14,004</td>
</tr>
<tr>
<td>Faculty Support (to oversee various modules)</td>
<td>-</td>
<td>-</td>
<td>72,000</td>
</tr>
<tr>
<td>Production Costs (i.e. graphic design and interphase design)</td>
<td>-</td>
<td>-</td>
<td>6,000</td>
</tr>
<tr>
<td>Lesson Design &amp; Development</td>
<td>-</td>
<td>-</td>
<td>10,000</td>
</tr>
<tr>
<td>Project Management</td>
<td>-</td>
<td>-</td>
<td>7,500</td>
</tr>
<tr>
<td>Training</td>
<td></td>
<td></td>
<td>5,000</td>
</tr>
<tr>
<td>Maintenance Expenses</td>
<td></td>
<td></td>
<td>15,530</td>
</tr>
<tr>
<td>Travel Expenses (Project Related)</td>
<td>900</td>
<td>-</td>
<td>1,475</td>
</tr>
<tr>
<td><strong>Total Direct Costs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### PROJECT TIMELINE

<table>
<thead>
<tr>
<th>Phase 1</th>
<th>Elaborate the completed curriculum for the certificate</th>
</tr>
</thead>
</table>
| Phase 2 (1-2 months) | - Determine final faculty for online certificate  
  - Final revisions of curriculum with faculty  
  - Pre-production of media  
  - Finalize student base core:  
    - Approach interested parties and relevant stakeholders, including those at the Ministry of Health in Mexico, Social Security Institutes in Mexico, and other health service providers  
    - Secure financial means to develop certificate |
| Phase 3 (3-6 months) | - Coordinate with relevant stakeholders (faculty members, institutions, media studios, LMS, Adaptive Platform) in the production of media (videos, interactive sections, games, simulations, info graphs, etc.)  
  - Production of certificate content with relevant stakeholders, and delivery to technology coordinator (INSP)  
  - Develop modules in learning management system  
    - To be coordinated by INSP  
    - Addition of adaptive platform for specific modules  
  - Coordinate with INSP Online Education team so all relevant parties resolve questions in order to avoid bottlenecks in development  
  - Complete formal/final QA 1 month before certificate opens for students  
  - Coordinate with INSP in order to provide training anytime during the phase |
| Phase 4 (9 months) | - Coordinate and plan certificate launching and graduation  
  - Coordinate certificate delivery  
    - Coordinate with and ensure expert interviewee participation  
  - Coordinate with UC-MX stakeholders  
  - Act as representative for UC-MX in disseminating results and certificate impact  
  - Coordinate with INSP to ensure provision of tech support and synchronous delivery support  
  - Coordinate deployment of student evaluations with INSP: adjust content and platform as necessary and feasible |
| Phase 5 (continuous) | - Develop evaluation methodology to evaluate certificate impact  
  - Gather student evaluations  
  - Meet faculty and stakeholders to debrief and review student and instructor feedback  
  - Gather requirements for next generation |
| Phase 6 (continuous) | - Coordinate creation of and maintenance of Web-Portal  
  - Coordinate regular academic and professional alumni activities |
A BINATIONAL ONLINE COURSE ON REGULATORY SCIENCES IN MEXICO AND IN CALIFORNIA

A CONCEPT PAPER FROM THE REGULATORY SCIENCES ONLINE COURSE SUBGROUP OF THE HEALTH WORKING GROUP OF THE UC-MEXICO INITIATIVE
México is a rich and complex country, with an economy that depends heavily on trade. Globalization has made necessary for countries like México to strengthen their regulatory frameworks in order to ensure the health of its citizens and visitors. The analysis of this framework, with an international and global perspective, is necessary for Mexican regulatory agencies and professionals to understand its strengths and deficiencies in accordance to international standards and best practices. Mexico has the 2nd biggest pharmaceutical market in Latin America and 11th biggest worldwide with a steady annual growth rate 2005-2011 of 4.8%, according to COFEPRIS (Guaia, 2013). Also, about 10 percent of Mexico's GDP, 92 billion dollars, is allocated to the health regulation authorities (Guaia, 2013). According to María de Jesús Medina Arellano, an attorney from the Autonomous University of Nayarit, the pharmaceutical's significant impact can be seen through the large medical tourism industry in Mexico which major consumers are from the United States (Stem Cell Therapies: Opportunities for Ensuring the Quality and Safety of Clinical Offerings: Summary of a Joint Workshop: Comparative Regulatory and Legal Frameworks, 2014).

Regulation of health sciences in Mexico is needed for the safety of the Mexican citizens and of every person that travels or goes to México.

In addition, there is a lack of regulatory health sciences educational programs in México. The development of this program will be a step forward for the consolidation of regulatory health sciences in the academic arena.

This partnership will support the establishment of the binational course of Regulatory Sciences in Mexico and California. The team will be composed of leading experts in various subjects from binational institutions including the University of California Berkeley, Autonomous Technological Institute of Mexico, Center for Economic Research and Teaching, the National Autonomous University of Mexico Legal Research Institute, National Institute of Public Health, and the National Autonomous University of Mexico.

The aim of the Regulatory Sciences Online Course is to provide students with information needed to understand the most important health regulations issues in Mexico and abroad.
Description of the Online Course

The Regulatory Sciences online course will be offered with the Mexican National Institute of Public Health online platform and will be made up of a total of 42 credit hours. The course is composed of 5 general modules, each one divided into two units. The first will be a general unit where the regulatory themes specific to the modules will be described theoretically focusing on international law and best practices. The second will be a specific unit of Mexican regulation, where the most important contents of the specific field will be as well as the challenges that national regulation faces in the particular Mexican context. In addition, each unit is divided into general subunits that may be reviewed independently by the student based on their personal preferences. That is, if a student wants to review only the general units they may revise those sub units without studying the Mexican ones. This allows the subunits to be shared and obtained independently between the different programs offered by the participating institutions and allows specialists in the field to provide such subunits according to their area of expertise.

Target Populations and Communities

Health care is one of the fastest-growing industries at the moment due to advances in medical technology and changing federal regulations. The Regulatory Science certificate will be tailored to health care executives, regulators, academics, and emerging leaders, with the purpose of elevating their capacity and skills to respond to increasing market pressures, and constant change within the health regulatory environment. As the biomedical industry continues to rapidly grow, the demand for professionals in the regulatory sciences does so as well, nationally, binationally and globally.
Description of the Modules

Description of the five modules:

Introduction

• The general part of the module will include the basics of health regulation, regulatory theory, and ethical principles applied to health regulation.
• The Mexican part of the module is intended for the student to comprehend the organizational structure of the government bodies responsible of health regulation. In addition, the norms and regulations hierarchy will be described as well as their area of application.

Public Health Regulation

• The general part of this module will revise the role of international treaties, soft law, as well as, the best regulatory practices in public health. The main tenets of regulation in global public health will be also analyzed. The unit will focus on environmental, food, work and legal and illegal substances regulation.
• In the Mexican part of the module Mexican laws and standards will be reviewed in the context of: environmental, food, work and legal and illegal substances regulation. Furthermore, the challenges that these regulations face and the role of the various state departments and regulatory agencies in their implementation will be explained.

Regulation of medical facilities and medical practice

• The general part of the module will discuss the market of medical facilities and medical practice. An introduction to patient rights, obligations of medical practitioners, medical malpractice, and the best international practices on these matters will be discussed.
• The Mexican side of the module, will revise the role of different state agencies and bodies responsible for the regulation of medical facilities and medical practice. In addition, the main laws and regulations governing the certification and authorizations in the matter will be reviewed. Similarly, laws and regulations applicable to medical professionals and malpractice, and the role of the National Medical Arbitration Commission and the National Commission of Human Rights will be outlined. Students will be invited to reflect on the challenges of this type of regulations.

Regulation of research and bioinformatics

• In the general part of the module the main principles of the ethics of research and development will be reviewed, as well as intellectual property standards. In this module it is intended that the students understand the life cycle of a product, the ethical dilemmas of research, different types of existing research and innovations in the field.
• On the Mexican side of the module, Mexican laws and regulations in research and development will be studied as well as the intellectual property of health products. The challenges posed to Mexican laws and rules regulating genetic material and emerging innovations in this area will be considered. The effects that the Treaty of the Trans-Pacific Partnership has on the patent protections for Mexico and Latin America will be reviewed. Finally, students will be able to describe how the intellectual property rights may affect access to medicines.

Regulation of Health Products

• In the general section the common characteristics of health products and the way they should affect regulatory frameworks will be reviewed. The products that will be reviewed are: pharmaceuticals, vaccines, biological products, diagnostics, and generics and biosimilars. Similarly, the challenges of regulating medical innovations, such as stem cell therapy treatments are reviewed.
• In the Mexican section Mexican laws and regulations of pharmaceuticals, vaccines, biological products, diagnostic products, generics and biosimilars will be studied, as well as innovative treatments.
1. Introduction
   - General
   - Health Regulation
   - Human Rights
   - Revision of the Mexican health system and laws and regulations on health.
   - International Public Health Laws

2. Public Health Regulations
   - General
   - Environmental regulation
   - Food regulation
   - Occupational regulations
   - Legal and illegal substances regulation
   - Environmental regulation
   - Food regulation
   - Occupational regulations
   - Legal and illegal substances regulation

3. Regulation of medical facilities and medical practice
   - General
   - Regulation of medical facilities
   - Regulation of medical practice
   - Mexican regulations on medical facilities
   - Mexican regulations on medical practices
   - Research and development regulation
   - Regulation on intellectual property
   - Mexican regulation on research and development
   - Mexican regulation on intellectual property

4. Regulation of research and bioinformatics
   - General
   - Regulation on medical innovations
   - Mexican regulation on research and development
   - Mexican regulation on intellectual property
   - Regulation on pharmaceuticals and biomedicine

5. Regulation of Health Products
   - General
   - Regulation on medical innovations
   - Mexican regulations on pharmaceuticals and biomedicine
   - Mexican regulation on medical innovations
### Table 1. Proposed Programs for the Binational Network for Research, Implementation and Evaluation of Youth Prevention

<table>
<thead>
<tr>
<th>Subunit</th>
<th>Themes</th>
<th>Lesson</th>
<th>Assessment</th>
<th>Faulty</th>
</tr>
</thead>
</table>
| Health regulation | - Regulatory rationales of health regulation applied to global and local contexts  
- Science based regulation compared and contrasted to regulation based on other factors or principles  
- Identify how the development of health regulations impact the access to health or the progressive relation of the right to health of the population.  
- Describe different approaches to science based regulation such as the precautionary principle and the demonstrated harm principle and be able to give reasons why each would or would not be appropriate to case study examples of public health regulations. | 1. Three questions will be formulated in the online forum:  
a. Students will be able to post their responses and comments to each of the responses in order to develop a discussion  
b. Tutor will be able to read and respond to contributions formulated by the students  
2. Problems sets by tutor and generate discussions and create new questions for deeper analysis of the issues raised by the class | 1. Summary of the papers including a critical personal opinion  
2. Create a glossary of key concepts in healthcare regulation  
3. Create a hypothetical case study taking into consideration the issues raised in class discussion.  
4. Presentation by students of their created case study | UC Berkeley |
| Human Rights | 1. Three questions will be formulated in the online forum:  
| -Basic concepts of human rights and the human right to health  
| -History and future trends of health regulation  
| -Relationship between health public policies and health regulations  
| -Human rights and the public's health  
| -Ethics in the human right to health  
| -Access to health care and the human right to health | 1. Written essay on the challenges related to health and human rights reform in Mexico.  
| 2. Elaborate a glossary of key concepts.  
| 3. Summary of the papers including a critical personal opinion  
| 4. Create a glossary of key concepts in healthcare regulation  
| 3. Create a hypothetical case study taking into consideration the issues raised in class discussion.  
| 5. Presentation by students of their created case study.  
| 6. Short presentation by students of an ethical dilemma in a healthcare setting involving ethics, regulation and human right to health.  
| 7. Written essay related to the presentation, the student needs to identify different ethical positions and ways of regulating according to the each ethical standing. | UC Berkeley |
| Mexican Health System and Health Laws Overview | Basics of the Mexican health system and its interaction with the government | 1. Three questions will be formulated in the online forum:  
   a. students will be able to post their responses and comments to each of the responses in order to develop a discussion.  
   b. Tutor will be able to read and respond to contributions formulated by the students  
   2. Problem sets by tutor and generates discussions and creates new questions for deeper analysis of the issues raised by the class.  
   3. Moral debate: A debate is a discussion between two individuals or groups of people who take on opposing views about the same subject. It provides a non-threatening way to start a discussion about sensitive subjects, regardless of whether agree or disagree with the motion that they will debate. (This methodology of learning is based on the resources books provided by UNESCO regarding the teaching of ethics. Ref. Moral games for teaching bioethics) | Summary of the papers including a critical personal opinion.  
2. Create a glossary of key concepts in healthcare regulation.  
3. Create a hypothetical case study taking into consideration the issues raised in class discussion.  
4. Presentation by students of their created case study.  
5. Written essay on regulatory improvement and oversight of the Mexican relevant health agency.  
6. Elaborate a glossary of key concepts.  
7. Elaborate a mind map with all the relevant health laws and official norms in the Mexican legal arena.  
8. Short presentation by students of an ethical dilemma in a healthcare setting involving ethics, regulation and human right to health.  
9. Written essay related to the presentation, the student needs to identify different ethical positions and ways of regulating according to the each ethical standing. | TBD |

<table>
<thead>
<tr>
<th>Public Health Regulation</th>
<th>International Health Law</th>
<th>International Health Law</th>
<th>International Health Law</th>
<th>International Health Law</th>
<th>International Health Law</th>
<th>International Health Law</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subunit</td>
<td>Themes</td>
<td>Lesson</td>
<td>Assessment</td>
<td>Faulty</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| International Health Law | - Soft Law  
- Binding public health instruments  
- Best regulatory practices  
- Global health justice | Students must provide a solution to a global public health problem using soft law and binding instruments. The solution should include aspects to achieve global health justice. | Students should write a short assignment in which they discuss how international public health instruments can influence country specific regulations. In the assignment they must identify how differences among countries impose an additional burden to them in trying to adapt its norms to the international standards. | Dr. Alejandro Madrazo Lajous (CIDE) |
### Environmental regulations
Generals of environmental laws and regulations

Students should discuss in small groups an environmental problem that needs a regulatory solution. Students should make their proposals.

Students will answer a short quiz about the studied items.

Dra. Marisol Anglés Hernández (IIJ)

### Food regulations
Generals of food laws and regulations

Students should be able to answer a specific questionnaire about the themes reviewed in the lessons.

Students will develop a short proposal to solve a specific food problem using the regulations explained during class.

Dr. Simón Barquera (INSP)

### Work safety regulations
Generals of work safety laws and regulations

Students will discuss a specific case related to work safety regulations (for example, pregnant women and work safety).

Students will write a show assignment in which they develop a solution.

Dra. Shalila Curioca (ITAM)

### Legal and illegal drugs and substances regulations
Generals of legal and illegal laws and regulations

Students will engage in a general discussion about the implications of Mexican illegal drugs regulations on health.

Students will answer a short quizz about the studied items.

Dr. Rodolfo Vazquez (ITAM)

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### Medical facilities and practice of medicine regulations

<table>
<thead>
<tr>
<th>Subunit</th>
<th>Themes</th>
<th>Lesson</th>
<th>Assessment</th>
<th>Faulty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health facilities</td>
<td>-The market of medical facilities&lt;br&gt;-Best practices in health facilities regulation</td>
<td>Students will engage in a group discussion about how health facilities work and how can they be improved.</td>
<td>Students will answer a short quiz about the reviewed items.</td>
<td>UC Berkeley</td>
</tr>
<tr>
<td>Practice of Medicine</td>
<td>-The market of medical practice&lt;br&gt;-The medical professional rights and obligations&lt;br&gt;-Patients' rights&lt;br&gt;-Malpractice and negligence&lt;br&gt;-Challenges of conflicting or uncertain regulations, laws&lt;br&gt;-Best practices in the regulation of the practice of medicine</td>
<td>Students will discuss in small groups different problem sets about malpractice, negligence, etc. They will identify the regulatory problem and provide solutions.</td>
<td>Students will write a short essay about the reviewed items.</td>
<td>UC Berkeley</td>
</tr>
<tr>
<td>Mexican health facilities regulations</td>
<td>-Generals of government entities regulating health facilities&lt;br&gt;-Mexican market of health facilities (public and private) and its relationship with insurers&lt;br&gt;-Laws and regulations of facilities certifications, authorizations, surveillance&lt;br&gt;-Electronic health record regulations&lt;br&gt;-Challenges of Mexican laws and regulations of health facilities</td>
<td>Students will make short presentations about the different elements of Mexican health facilities regulations.</td>
<td>Students will answer a short quiz about the reviewed items.</td>
<td>TBD</td>
</tr>
</tbody>
</table>
The population perspective: the reality of access to health facilities

Mexican regulation of the practice of medicine
- Generals of government entities regulating the practice of medicine
- Laws and regulations regarding the practice of medicine
- Medical practice associations
- The medical professional rights and obligations
- Patients' rights
- Malpractice and negligence
- The challenges of the practice of medicine regulation
- The population perspective: the reality of access to a medical professional

Students will solve a case study on the general items reviewed into his module.

Students will answer a short quiz about the reviewed items.

Dr. Francisco Ibarra (IIJ - UNAM)

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Research and Bioinformatics

<table>
<thead>
<tr>
<th>Subunit</th>
<th>Themes</th>
<th>Lesson</th>
<th>Assessment</th>
<th>Faulty</th>
</tr>
</thead>
</table>
| Research and development| - Product lifecycle
- Basic, experimental, clinical and post marketing research.
- Ethical considerations in clinical trials
- Innovations in clinical trials
- Post trial obligations and benefits | 1. Three questions will be formulated in the online forum: a. students will be able to post their responses and comments to each of the responses in order to develop a discussion b. Tutor will be able to read and respond to contributions formulated by the students 2. Games that may help to plan, act, monitor, evaluate and reflect on ethical choices regarding the ways of regulation in accordance with the needs and tools available in the Mexican context. 1. Relevant ethical dilemma will be posed by the tutor, in each of the case two different ethical standings will be exposed by the tutor. This case will be linked to a court resolution which offers a description of the type of ethical and legal issues involved. The tutor will monitor group discussion and the students could edifficate different possible solutions and reject the one that the | 1. Summary of the papers including a critical personal opinion. 2. Create a glossary of key concepts in healthcare regulation. 3. Create a hypothetical case study taking into consideration the issues raised in class discussion. 4. Presentation by students of their created case study. 5. Writer assignment on: a. Information about different clinical trial or alternative treatments for rare diseases b. Ethical ways to experimenting on animals avoiding harm and balancing benefits for the discovery of new drugs and treatments. c. Assumed consent of an unconscious human research subject. d. Assumed consent of an unconscious human research subject. e. Use of new medicines or procedures- different questions to be addressed: i. Unwitting patient | UC Berkeley |
| Intellectual property | International standards | 1. Three questions will be formulated in the online forum:  
   a. Students will be able to post their responses and comments to each of the responses in order to develop a discussion  
   b. Tutor will be able to read and respond to contributions formulated by the students  
2. Games that may help to plan, act, monitor, evaluate and reflect on ethical choices regarding the ways of regulation in accordance with the needs and tools available in the Mexican context.  
3. Relevant ethical dilemma will be posted by the tutor, in each of the case two different ethical standings will be exposed by the tutor.  
4. This case will be linked to a court resolution which offers a description of the type of ethical and legal issues involved.  
5. The tutor will encourage group discussion and the students could edification different possible solutions and reject the one that the tutor has provided. In addition the students will be able to produce their own resolution participation  
   ii. Well advised of new drugs  
   iii. Experimental vs. evidence-based medicine  
6. Short presentation by students of an ethical dilemma in a healthcare setting involving ethics, regulation and human right to health.  
7. Written essay related to the presentation, the student needs to identify different ethical positions and ways of regulating according to the each ethical standing. | 1. Summary of the papers including a critical personal opinion.  
2. Create a glossary of key concepts in healthcare regulation.  
3. Create a hypothetical case study taking into consideration the issues raised in class discussion.  
4. Presentation by students of their created case study.  
5. Short presentation by students of an ethical dilemma in a healthcare setting involving ethics, regulation and human right to health.  
6. Written essay related to the presentation, the student needs to identify different ethical positions and ways of regulating according to the each ethical standing.  
7. Elaborate a mind map with all the relevant international treaties which shows whether these are part of soft law and which ones are binding for Mexico. | Dr. David Koepsell (UAN-Xochimilco) |
| Mexican regulation of research and development | -Product lifecycle  
-Basic, experimental, clinical  
and post marketing research  
-Ethical considerations in clinical trials  
-Innovations in clinical trials  
-Post trial obligations and benefits | 1. Relevant ethical dilemma will be posted by the tutor, in each of the case two different ethical standings will be exposed by the tutor. This case will be linked to a court resolution which offers a description of the type of ethical and legal issues involved. The tutor will incentive group discussion and the students could edificate different possible solutions and reject the one that the tutor has provided. In addition the students will be able to produce their own resolution according to their ethical standing and relevant regulation in the Mexican context.  
2. Three questions will be formulated in the online forum:  
   a. students will be able to post their responses and comments to each of the responses in order to develop a discussion  
   b. Tutor will be able to read and respond to contributions formulated by the students  
3. Games that may help to plan, act, monitor, evaluate and reflect on ethical choices regarding the ways of regulation in accordance with the needs and tools available in the Mexican context. | 1. Summary of the papers including a critical personal opinion  
2. Create a glossary of key concepts in healthcare regulation  
3. Create a hypothetical case study taking into consideration the issues raised in class discussion.  
4. Presentation by students of their created case study.  
Written assignment by students of their created case study.  
Written assignment on: assumed consent of an unconscious human research subject  
Written assignment on: Do animals have rights? Should we experiment on animals?  
b) Developing of new treatments that are experimental and risky, how do we obtain consent?  
c) Protection of biomaterials and their content. Media and big data. Medical publicity and advertising.  
d) Procedural informed consent, do we have to grant 'general' or 'specific' consent to develop new treatments?  
e) Which will be the consequences of each one of the choices?  
f) Post-trial access could guarantee after the creation of a patent derived from biomaterial provided by the human research subject? | TBD |

| Mexican regulation of intellectual property | -Mexican patent laws and regulations  
-Property over genetic material  
-Access to medicines and patent law  
-The Transpacific Partnership Trade Agreement | 1. Three questions will be formulated in the online forum:  
   a. students will be able to post their responses and comments to each of the responses in order to develop a discussion  
   b. Tutor will be able to read and respond to contributions formulated by the students | 1. Summary of the papers including a critical personal opinion  
2. Create a glossary of key concepts in healthcare regulation  
3. Create a hypothetical case study taking into consideration the issues raised in class. | Dr. David Koepsell (UAN-Xochimilco) |
and respond to contributions formulated by the students.
2. Games that may help to plan, act, monitor, evaluate and reflect on ethical choices regarding the ways of regulation in accordance with the needs and tools available in the Mexican context.

Discussion.
4. Presentation by students of their created case study.

### Health care products regulation

<table>
<thead>
<tr>
<th>Subunit</th>
<th>Themes</th>
<th>Lesson</th>
<th>Assessment</th>
<th>Faulty</th>
</tr>
</thead>
</table>
| Drugs and biomedicine        | - Pharmaceuticals and small molecule pharmaceuticals<br>- Vaccines<br>- Biologics<br>- Diagnostic<br>- Generic and biosimilar products<br>- Nutraceuticals and other supplements | 1. Three questions will be formulated in the online forum:  
   a. students will be able to post their responses and comments to each of the responses in order to develop a discussion  
   b. Tutor will be able to read and respond to contributions formulated by the students  
2. Games that may help to plan, act, monitor, evaluate and reflect on ethical choices regarding the ways of regulation in accordance with the needs and tools available in the Mexican context. | 1. Summary of the papers including a critical personal opinion.  
2. Create a glossary of key concepts in healthcare regulation.  
3. Create a hypothetical case study taking into consideration the issues raised in class discussion.  
4. Presentation by students of their created case study.  
5. Written assignment on: cost-benefit analysis of biosimilar products? and Obligatory or compulsory vaccination?  
6. Short presentation by students of an ethical dilemma in a healthcare setting involving ethics, regulation and human right to health.  
7. Written essay related to the presentation, the student needs to identify different ethical positions and ways of regulating according to the each ethical standing. | UC Berkeley |
| Treatments and innovations    | - Cellular tissue and genetically engineered products<br>- Medical devices<br>- Nutraceuticals and other supplements | 1. Three questions will be formulated in the online forum:  
   a. students will be able to post their responses and comments to each of the responses in order to develop a discussion  
   b. Tutor will be able to read and respond to contributions formulated by the students  
2. Games that may help to plan, act, monitor, evaluate and reflect on ethical choices | 1. Summary of the papers including a critical personal opinion  
2. Create a glossary of key concepts in healthcare regulation  
3. Create a hypothetical case study taking into consideration the issues raised in class discussion.  
4. Presentation by students of their created case study.  
5. Written assignment on: who has access to genetically | UC Berkeley |
regarding the ways of regulation in accordance with the needs and tools available in the Mexican context.

6. Short presentation by students of an ethical dilemma in a healthcare setting involving nutraceutical and other supplements.
7. Written essay related to the presentation, the student needs to identify different ethical positions and ways of regulating according to the each ethical standing.

Mexican regulation of drugs and biomedicine

- Generals of Mexican laws and regulations of authorizations and production of facilities that process pharmaceuticals, vaccines, biologics, diagnostics and generic or biosimilar products.
- Mexican laws and regulations of the licensing of pharmaceuticals, vaccines, biologics, diagnostics and generic or biosimilar products.
- Mexican laws and regulations of the licensing of adverse events in México

1. Students will discuss a specific problem set about licensing of HIV products in México.
1. Students will write a short essay about a solution to reduce the price of drugs in México using the reviewed regulatory framework.

Mexican regulation of treatments and innovations

- Generals of Mexican laws and regulations governing treatments of cellular tissue and genetically engineered products.
- Generals of Mexican laws and regulations of medical devices.
- Generals of Mexican laws and regulations governing nutraceuticals and other supplements.

1. Three questions will be formulated in the online forum:
   a. students will be able to post their responses and comments to each of the responses in order to develop a discussion
   b. Tutor will be able to read and respond to contributions formulated by the students
2. Games that may help to plan, act, monitor, evaluate and reflect on ethical choices regarding the ways of regulation in accordance with the needs and tools available in the Mexican context.
1. Summary of the papers including a critical personal opinion
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4. Presentation by students of their created case study.

Mtra. Fernanda Cobo (ITAM)

Dra. María de Jesús Medina (IIJ-UNAM)
BINATIONAL NETWORK ORGANIZATION

Network Leadership

Co-Chair: Dr. Sofia Charvel, ITAM
Co-Chair: Dr. Ken Taymor, UCB

Faculty

Dr. Alejandro Madrazo Lajous, CIDE
Dr. Marisol Anglés Hernández, IIJ
Dr. Simón Barquera, INSP
Dr. Shalila Curioca, ITAM
Dr. Rodolfo Vazquez, ITAM

PROJECTED BUDGET

<table>
<thead>
<tr>
<th>UCOP Budget Categories</th>
<th>Project Period 1</th>
<th>Project Period 2</th>
<th>Total Expenditures</th>
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<tr>
<td></td>
<td>UCB</td>
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<td>UCB</td>
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<tr>
<td>Administrative Support</td>
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<td>Faculty Support (to oversee various modules)</td>
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<tr>
<td>Maintenance Expenses</td>
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<tr>
<td>Travel Expenses (Project Related)</td>
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<td>Total Direct Costs</td>
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