Center for Medical Ethics and Health Policy

Health & Science Policy Research Day – Poster Presentations

May 27, 2020

Baylor College of Medicine

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Ethical Challenges of State and Hospital DNR Policy in the Texas Response to COVID-19

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Background

- Historically, conversations on do-no-resuscitate (DNR) status have been guided by:
  - Patient wishes and values
  - Discussions with families
  - Physician medical expertise
- The U.S. response to COVID-19 has activated states and hospitals across the nation to develop and refine crisis standard of care policy
  - Of primary concern is the allocation of scarce resources, including ventilators, paralytics, ICU beds, and PPE.
- In developing triage frameworks, policymakers have considered universal do-not-resuscitate (DNR) policies and incorporation of prior DNR status into triage decisions
- Some hospitals across the nation have specified the use of unilateral DNR orders (orders placed by medical professionals without consent of proxy)
  - U.S. Association of Bioethics Program Directors member hospitals: Seven (26.7%) permit, and the rest (19, 73.1%) do not specify the use of unilateral do-not-resuscitate (DNR) orders

Overview of SB11/TADA 166.E

- Requirements for valid inpatient do-not-resuscitate orders in Texas passed in 2017
  - DNR: order instructing physician not to attempt CPR in the event of circulatory or respiratory function cessation
  - Not valid in the ED or out-of-hospital settings
- Rationale: patient protection during end-of-life care against unilateral and unnotified DNR orders
- Stakeholders: Texas citizens and families, hospitals (Texas Hospital Association), medical professionals and professional groups (Texas Medical Association), religious groups and associations
- Penalty – Class A Misdemeanor
- Limitation of liability for "good faith" decisions or if no knowledge

Ethical Question

- What ethical considerations are relevant to the unique requirements of SB11/TADA 166/E during the COVID-19 response and for future events requiring crisis standards of care?

Analysis

SB11/TADA 166.E Stipulations	Ethical Considerations
• Requirement for DNR issued by "attending physician", • is "not contrary to directions" of a patient competent at the time of conveyance with reasonable medical judgement of patient, • whose death is "imminent" regardless of CPR (166.203)	• In times of crisis, time and cognitive space constraints on patient's designated "attending" physician • Time, personnel, and resource constraints may hinder patient ability to give "directions" • Diagnosis of COVID-19 by itself may not meet criteria for imminent death
• Need for a witness that is not part of the medical team for oral DNR requests by competent patients (Issuance 166.203)	• Due to hospital visitor restrictions to limit spread of COVID-19, possibly may be infeasible for additional witness to be present in-person • Risk of additional exposure for witness to COVID-19 and use of PPE • Use of telemedicine to satisfy this requirement may infringe on patient's right to privacy
• Ability of surrogate/MPOA to rescind valid DNR previously in-place by patient, now without capacity (166.205(a)2)	• If decision not in line with previously expressed patient wishes, may infringe on patient autonomy and dignity • In case of scarcity of resources, may prevent other patients with COVID-19 from receiving necessary life-saving interventions
• In the case of a failure to execute DNR (166.206), attending must attempt to transfer	• If level of care required for patient during crisis times not available in other hospitals, physician unable to preserve professional integrity

Main Takeaways

- Constraints on scarce hospital resources, medical professional time and cognitive space, and institution of public safety measures due to COVID-19 reveal potential ethical challenges in implementing TADA 166.E during times of crisis
- Question: Do practical and ethical considerations during crisis standards of care justify exceptions to TADA 166.E?
- Importance of advance care planning as a part of routine care
  - Increased challenge for patients with COVID-19 to have quality goals-of-care conversations: lack of meaningful, in-person discussions with family and friends once hospitalized
  - Opportunity to institute policy to emphasize advance care planning

Acknowledgements

I would like to acknowledge and thank the BCM Center for Medical Ethics and Health Policy. Special thanks to Dr. Trevor Bibler for edits, feedback, and mentorship and Dr. Amy McGuire for guidance and support.

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Policy Options for Protecting Homeless Populations during the COVID-19 pandemic

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Background

- People experiencing homelessness are at **high risk** for disease spread and poor outcomes
  - Can't practice social distancing on streets or crowded shelters
  - Lack access to handwashing facilities
  - Advanced age and high comorbidity burden
- Current policies (e.g. stay-at-home orders) do too little to protect health of this population
- Large **outbreaks** found in shelters among largely asymptomatic persons
- **Federal funding** is available through CARES act ($4 billion for homeless assistance) and FEMA
- **What's at stake**: health of our most vulnerable members and general public as a whole

Methods

- Literature review and policy analysis

Stakeholders

- <u>People experiencing Homelessness</u>
  - Vulnerable to disease and loss of services
- <u>Government policymakers</u> (Dept of Housing and Urban Development, State, Local)
  - Approve, fund, enforce policy
- <u>Shelters and Homeless service providers</u>
  - Strained by loss of volunteers/staff; reduced capacity from social distancing
- <u>Hospitals and medical providers</u>
  - Cannot discharge symptomatic patients who are unable to self-isolate
- <u>Housing industry</u>
  - Hotels/motels largely empty; may have liability concerns
- <u>General public</u>
  - Pay for policy through taxes; benefit from slowing spread of disease

Goals and Measures of Success

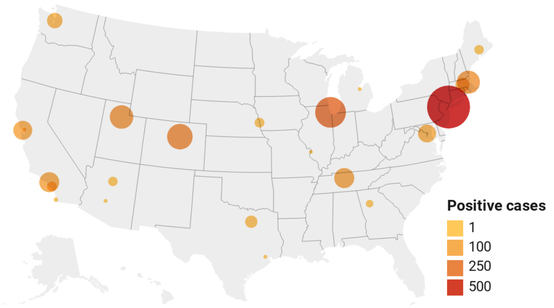
<u>Short-term</u>
- Reduce modifiable risk factors for COVID-19 spread
- Preserve access to critical needs (food, shelter)
- Sustainable with adequate funding

<u>Medium term</u>
- Reduce preventable hospitalizations and death
- Fair distribution of resources

<u>Long term</u>
- Process for resolution once pandemic subsides
- Readiness for future crises

Figure 1

Publicly Reported Positive COVID-19 Tests among Homeless Persons and Shelter Staff



Updated May 14, 2020

Source: Author's review of published reports and news articles • Created with Datawrapper

Possible Policy Solutions

Goals	Impact Category	Policies			
		No change	Congregate housing (convention centers)	Non-congregate housing (motels/hotels)	Handwash stations and street outreach
Effectiveness: Reduce risk of disease spread	*Social distancing and isolation of infected*	Minimal	Low; hard to achieve with high numbers	High	Low-Moderate
	Hygiene access	Minimal	Moderate; shared bathrooms	High	Moderate; public facilities
	Fraction of homeless population reached	Minimal	High; 100s-1000s capacity per center	Moderate- including those most at risk	Moderate- focused on areas with high density unsheltered
Economic Efficiency: maximize output/cost	*Direct cost to government*	None – but indirect costs through healthcare/ policing	Moderate- $62/bed/day[1]	High-$200/room/day (including food, staff, security)[2] -75% cost-share through FEMA	Low -$100/month per handwash station[3]
	Reliance on healthcare system (e.g. hospital stays for isolation)	High, >21,000 homeless hospitalizations[4]	Moderate	Low	Moderate
Equity	*Benefit to at-risk population*	Minimal	Somewhat high	High (older and with comorbidities)	Somewhat high (unsheltered)
Practicality	*Challenges to Implement*	N/A	Moderate- centralized location	High- secure rooms, staffing, supplies for multiple locations	Low- but need to clean/resupply
Political Feasibility	*Likelihood of Successful Adoption*	N/A- in place	Moderate	Moderate	High

Table 1: Policy Outcomes Matrix

(1): $2.8 million/month per 1,500 capacity: Avitabile R. Convention Center Shelter Project Now Targeting Homeless Still On Streets. NBC 7 San Diego. https://www.nbcsandiego.com/news/local/convention-center-shelter-project-now-targeting-homeless-still-on-streets/2305904/

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Recommendations

1. **Provide non-congregate housing for homeless individuals at hotels/motels**
   a. **Prioritize those most at risk**: homeless over 65 years old and those with medical comorbidities
   b. **Isolate** symptomatic or COVID-positive persons in separate complexes
2. **Expand testing for homeless people and shelter staff**
   a. Detect and prevent large outbreaks, isolate asymptomatic carriers, assess rate of spread
3. **Existing shelters must adhere to CDC guidelines for social distancing, cleaning, and providing masks and hygiene**
4. **Reach unsheltered populations with handwash stations and outreach teams**
5. **Develop plans for long-term housing solutions for after pandemic subsides**

Approval, Implementation, and Evaluation

- Approval through **State executive order** and **City Ordinances**, authorized under Texas Disaster Act
- **Secure federal funding** through FEMA and HUD grants
- **Educate** homeless population, shelters and homeless service providers, medical providers, law enforcement, and general public about policy
  - **Referrals** through shelters and homeless service providers, law enforcement, telephone hotline
- City government coordinates **staffing** for food, security, social work, nursing and provides hygiene supplies and masks
- Case workers help with **transition to long-term housing**
- **Collect and monitor data** on testing, disease cases, resource use–pressing need for research on policy outcomes

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Reducing Transmissible Infections in IV Opioid Users: A Policy Recommendation for Harris County

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Center for Medical Ethics and Health Policy

Background

- 1990s: completed opioid prescriptions increased
  - Rates of infectious diseases associated with IV opioid abuse increase
- 1990s-present: Bills creating SSPs in Texas are introduced to legislature
- 2007: Texas Legislature approves a needle exchange program in Bexar County, which is terminated shortly after due to district attorney's adherence to drug paraphernalia laws
- 2012: the CDC put forth the Program Collaboration and Service Integration model, which integrates the medical and social services needed by IV opioid users.
- 2018: Congress passed SUPPORT, a law that expands healthcare programs' ability to combat opioid use-related infections
- 2019: Bexar County's new DA permits existence of SSP allowing for funding and planning to begin

Key Facts

- Nearly 80 percent of heroin users reported using prescription opioids prior to heroin
- Injection opioid use was linked to 13% of new HIV diagnoses in the US in 2016
- Over 2,500 new HIV infections occur each year among people who inject drugs
- The CDC states that syringe services can increase voluntary admission into rehabilitation programs, lead to a 70% decrease in Hep C transmission, and prevent needlestick incidents in police officers
- Lifetime cost of treating HIV is $450,000 per person and US spends $15 billion annually in chronic Hep C care. $700 million dollars is spent annually on hospitalizations substance-use-related infections

Policy Considerations and Recommendations

	SSP with Education & Treatment Services
Effective	Reduce transmission and increase enrollment into treatment. SSPs decrease HIV and HCV infections and serve as an access point to addiction treatment. New members of SSPs are 5x more likely to enter treatment and 3x more likely to stop drug use.
Equity	Target urban areas with high rates of injected drug use 60% of Hep C infections in Texas are due to IDU Over 500,000 Texans are infected with HCV. New HCV infections rising most rapidly in young adults.
Efficiency	Depends on Harris County DA position and next legislative session. Will likely have to see results in Bexar County.
Practicality	299 US programs operating as of 2017. Methods well-established for operating safe program.
Financial Feasibility	ACLU estimates SSP cost $20 per user. Bexar County approved $80k for 2019-2020 Seek funding from Harris County or possibly Medicaid Waiver
Legality	Illegal in Texas. Must gain approval of Harris County District Attorney and/or exemption through Texas legislature.
Political Acceptability	Low-moderate. Supported by AMA and TMA. Has received bipartisan support when proposed in Texas State Legislature.

Conclusion

Addressing transmission of infectious diseases due to IV opioid abuse requires a multifactorial approach, which may include needle exchange programs that also offer education, counseling, risk-reducing resources, and referral to prevention and treatment services. By providing these services in Harris County, the transmission of infectious diseases can be curbed and healthcare-associated costs can be lowered in the long-term. Outcomes such as number of participants in the program, cost-per-participant analysis, cost-saving analysis at the county level, and incidence of communicable disease in Harris County should be monitored longitudinally.

Future Steps

- Facilitate conversations among stakeholders
- Draft formal policy proposal
- Facilitate coordination of players within Harris Health to implement solution
- Measure outcomes at predetermined time points

Social Resources at Emergency Department Discharges: Evaluation of Patients Request and Utilization

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Objective

1. To categorize the medical and social resources requested by ED patients at Ben Taub Hospital.
2. To evaluate patient utilization of resources following ED visit.

Background

- Emergency Department (ED) visits in the United States have outpaced the rate expected from population growth.[1]
- Few studies examine ED discharge interventions to improve health outcomes and decrease unnecessary subsequent ED visits, particularly in underserved, immigrant, and non-English speaking populations.[2-3]

Methods

Intervention

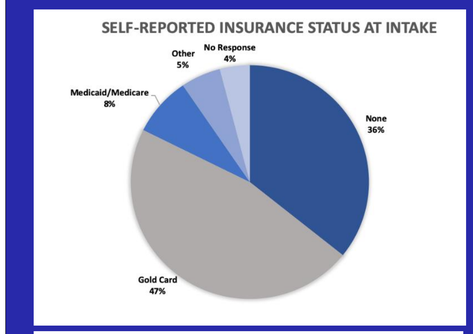
The Patient Discharge Initiative (PDI) is a volunteer organization that provides educational interventions to discharged ED patients through counseling, follow-up telephone calls, and connection to social resources including: applications for Gold Card, SNAP, and CHIP; transportation resources; financial assistance resources; housing resources; low-cost dental resources, and more. All patients who were part of the PDI project received a follow up phone call from a student volunteer one week after their initial encounter and then again after one month.

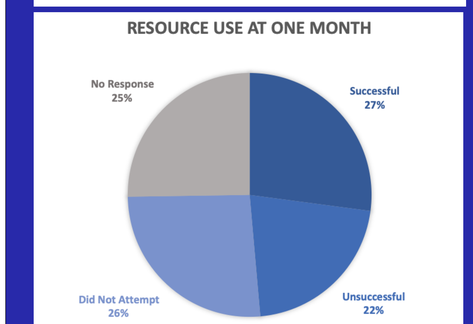
Setting

The PDI is based at Ben Taub Hospital, Houston, TX with approximately 89,000 patient visits annually. PDI volunteers approached patients prior to discharge.

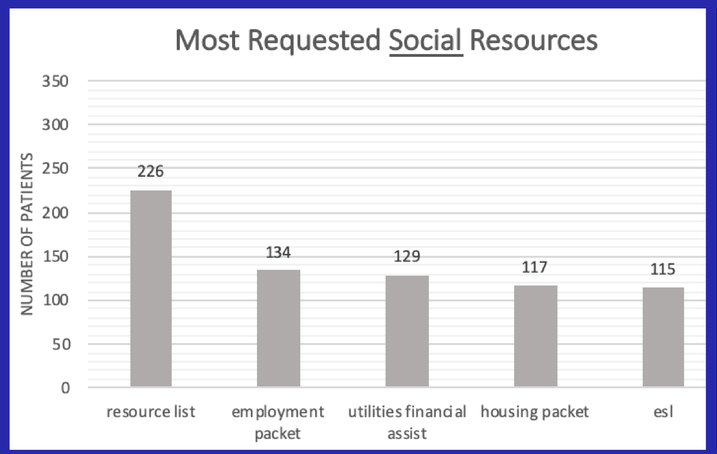
Data Analysis

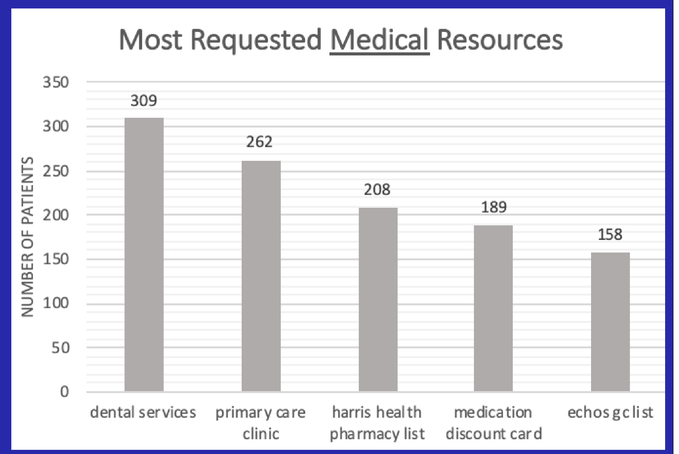
Quantitative data was analyzed using descriptive statistics. A total of 442 patients received resources and phone call follow ups from January 2018 to April 2019. This data is part of a preliminary analysis of a nonblinded randomized control trial.





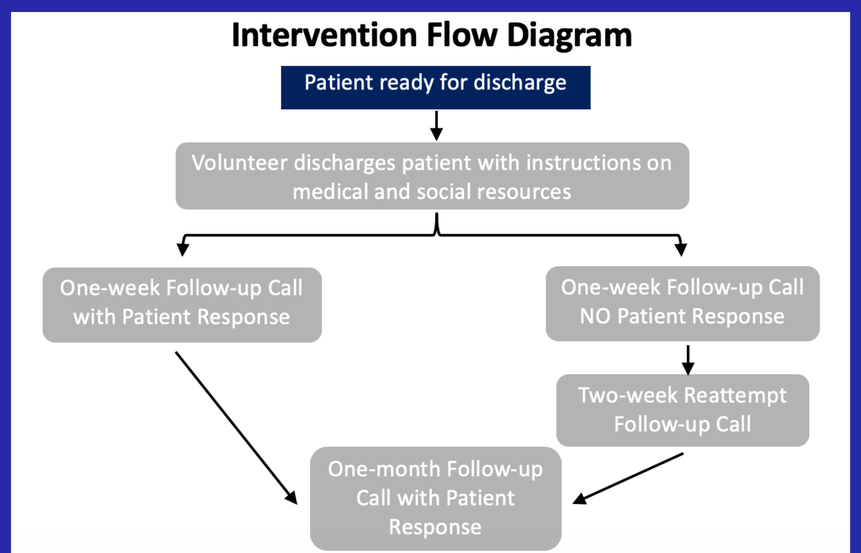
Results





Patient feedback

- Patient cited lack of service availability as a major barrier to utilization, highlighting the need for clinicians to be cognizant of this prior to offering resources.
- Patients noted difficulty finding time and transportation that would allow them access to additional resources.



Conclusions

- When offered, patients are receptive to medical and social resources and often successfully utilize them.
- The next phase of this study will involve the use of electronic health records to gather data regarding the project's effect on resource utility and outcomes and compare to a control group.

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Creative Solutions for Vulnerable Mothers: Increasing One-Year Coverage Rates for Postpartum Women in Texas

Co-Authors: Andrea Grimbergen, Mary Robichaux, Felixnando Rubio, Mary Taylor Winsten, Sowmya Yennam

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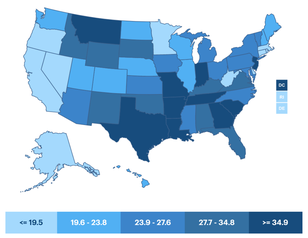
The Problem

The US has the worst maternal mortality rate (MMR) of similarly wealthy countries

- 2018 MMR was **17.4 deaths per 100,000 live births** per the Centers for Disease Control and Prevention (CDC)
- However, this rate only includes deaths up to 42 days postpartum
- Pregnancy-related deaths still occur up to 365 days postpartum

Texas has the 9th highest MMR nationally when using 365-day postpartum data from the CDC

- National MMR = 29.6 deaths per 100,000 live births
- Texas MMR = 39.2 deaths per 100,000 live births



Lapses in insurance coverage are a major issue in the perinatal period

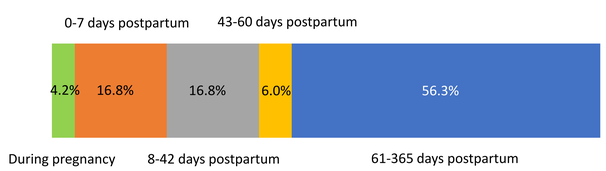
- One in 3 women experiences a disruption in coverage before, during, or after pregnancy and 60% of affected women experience a period of no insurance

Too few Texas women are covered in the first year postpartum

- 53% of births are covered by Texas Medicaid
- Medicaid for Pregnant Women **ends 60 days after delivery**
- Texas mothers are auto-enrolled into the Healthy Texas Women (HTW) program at 61 days postpartum
- However, HTW only covers limited women's health and family planning services and is part of a temporary 1115 waiver demonstration project

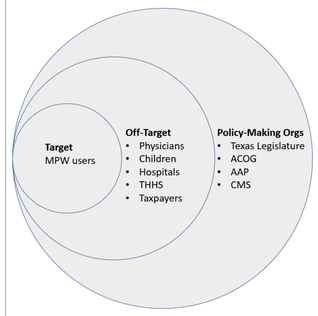
Most maternal deaths occur after coverage has lapsed in Texas

- 56.3% of deaths occur **61+ days postpartum**
- 38% were pregnancy-related; 56% were pregnancy-associated
- 60% of pregnancy-related deaths had a **"strong" or "good" chance of being prevented** through better care or management in the perinatal period per the 2018 Texas Maternal Mortality and Morbidity Task Force Report



There is a fundamental mismatch between the window of greatest maternal mortality risk and insurance coverage in Texas.

Stakeholders



HB744 (TX) - Proposed to extend Medicaid coverage to twelve months postpartum

- It ***passed in the TX House*** but did not progress within the TX Senate

HR4996 (US) - Helping Medicaid Offer Maternity Services (MOMS) Act of 2019

- Introduced in the US House with ***bipartisan support***

Goals

Short-Term

- Increase the **number of women** covered in the first year postpartum
- Expand **services offered** to this population
- Increase coverage across **all demographics**

Long-Term

- Reduce morbidity and mortality for **all causes** in first year postpartum
- Increase **overall health** of women of childbearing age
- Improve **pediatric and family health** outcomes

Proposed Solutions

Expand Healthy Texas Women (HTW)

- ***Expand services covered*** to include screening and treatment for the common causes of maternal mortality after 60 days postpartum
- ***Ensure funding*** through renewal of 1115 waiver or allocation of dedicated state funds

Expand Medicaid for Pregnant Women (MPW)

- ***Lengthen the eligibility period*** for MPW to a year following delivery
- ***Expand services covered*** to include screening for and treatment of common maternal mortality causes after 60 days postpartum
- ***Ensure funding*** through new 1115 waiver or allocation of dedicated state funds

Expand County Indigent Care ("Safety Net")

- ***Entrust coverage expansion efforts*** to county-level governments or providers
- ***Examples include*** expanding existing county care to smaller adjacent counties or building new safety net infrastructure

Short-Term Demonstration Project

- ***Evaluate financial impact*** thorough a grant-funded demonstration project
- ***Provide essential healthcare*** services and targeted maternal mortality screenings to MPW patients after coverage lapse
- ***Partner*** with private foundations or insurance companies

Measures of Success

Effectiveness	Increase in number of women covered 365 days after birth with expanded service offerings Reduction in mortality and morbidity 365 days after birth
Equity	Equalization of morbidity and mortality across ethnic backgrounds and socioeconomic classes
Efficiency	By June 1st, 2021
Practicality/ Sustainability	Ensure appropriate eligibility requirements and ease of access for qualifying women Track number of late or unfulfilled reimbursements
Financial Feasibility	Funding allocated by appropriate payor Measure financial impact on taxes, potential savings, and budgeted allocation of spending
Political Feasibility	Achieve bipartisan buy-in
Legality	Legal within current Texas requirements

Optimal Solution

Expand MPW + Demonstration Project

Effectiveness	Captures larger number of uninsured and underinsured women in need of care
Equity	Supports all counties equally regardless of size and existing resources
Practicality/Sustainability	Application process already in place No disruption in coverage for women already enrolled in MPW Provider network and reimbursement protocols already established
Financial Feasibility	Less investment required to build infrastructure No burden on overleveraged local counties to fund program Potential for cost savings by decreasing ER visits and serious complications or medical events

Vaccine Exemption Rates in Texas: A Health Policy Analysis

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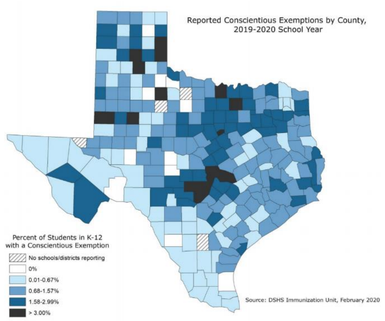
: Indicates Equal Contribution

Background

- Too few Texas school children are vaccinated against MMR
- Current state vaccine policies allow for medical, religious and philosophical exemptions
- Vaccine exemptions vary per state and within states; Currently, California, Mississippi, and West Virginia, New York, Maine, and Washington (MMR) only allow medical exemptions.
- Measles (eliminated in 2000 from the US) has seen an increase in cases since[1]
- The number of children getting conscientious vaccine exemptions has increased every year since 2007[2]

Figure 1. Percent of Students in Kindergarten through 12th Grade with a Conscientious Exemption on File for at Least One Vaccine, 2019-2020 School Year



Stakeholders

- Healthcare providers
  - Support the end of all non-medical exemptions
- Policy makers (i.e. state government)
  - Texas government allows for both religious and personal belief exemptions
- Public schools
  - Alarmingly high rates of exemptions exist among TX public schools; therefore, support idea of eliminating non-medical exemptions due to public health risk in schools
- Texas general public
  - Poll from University of Texas found a vast majority (78%) of the general public in Texas supports mandatory vaccination
- Texans for Vaccine Choice
  - Major opposition to policy; organize to end legislation over what they view as taking away a right of choice
  - Major tools include emotions, fear, and patriotism
- Religious and faith-based organizations
  - Exemptions have stemmed from vaccines violating the tenets of these organizations
  - Also can reach rural populations to vaccinate[3]

Goals and Measures of Success

	Current	Goal
NME Rate	2.15% in 2018-19[4]	<0.6%[5]
Counties with MMR Vaccination Rate <95%	16.5%[6]	<5%

Table 1. Current non-medical exemption rates in Texas and proposed goals

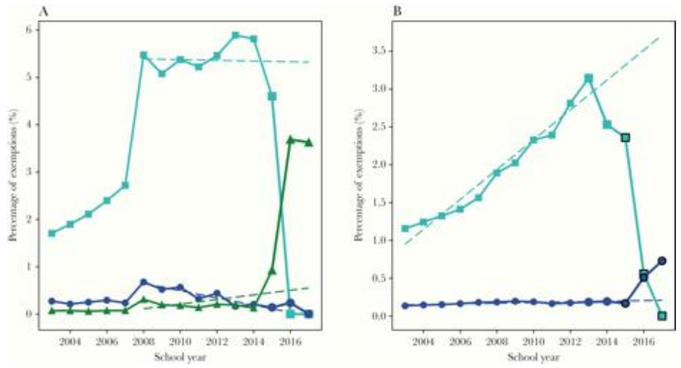


Figure 2. (A) Philosophical belief (teal), religious (green), and medical (blue) exemption rates in Vermont. (B) Combined philosophical and religious (teal) and medical (blue) exemption rates in California.

Graph adapted from Garnier et al. 2020

Possible Policy Solutions

	Goal	No Change	Removing the option of non-religious conscientious exemption to vaccines from Texas law	Removing the option of all conscientious exemption to vaccines from Texas law	Statewide vaccine campaign with education & targeted ads	Requiring counseling & education prior to granting exemption
Financial Feasibility	As inexpensive as possible - funding for lobbying from independent advocacy organization	No change in cost	Lobbying can be expensive, political campaigning, fundraising requires upfront costs	Lobbying can be expensive, likely the most expensive of the options upfront-requires most political action	Requires money for commercials, online ads, education materials, flyers, and cost is ongoing	Likely requires new positions in local governments, new infrastructure put in place, education materials
Legality	Accepted as Texas law, accepted by medical governing bodies, enforceable	Already a set law	Has to be drafted into an accepted law - precedent exists in other states	Has to be drafted into an accepted law - precedent exists in other states	Not many legal implications - need a overseeing body who runs the campaign	Who is authorized for giving counseling? Who regulates the process?
Politically Acceptable	Moderate or opinions can be influenced /changed	Moderate	Moderate - less opposition because religious groups are unaffected	Low - will require opinions to change, particularly those of religious groups	High	Moderate
Practicality/ Sustainability	Maximize the short and long term practicalities - long term taking precedence over short term	No issues	Requires lobbying and policy change at the state level, may take years to implement, once it is done it is "permanent"	Requires lobbying and policy change at the state level, many stakeholders involved, also "permanent"	Easy to implement, can model existing education campaigns, must be continually kept up & updated	Easy to implement if existing infrastructure is used, likely accepted by most stakeholders
Predicted Efficacy	NME Rate <0.6% <5% of counties with MMR rate <95%	Rates are currently ~2%	Likely to have a moderate reduction in exemptions (but compensatory increase in other exemptions - like Vermont)	Likely to have the largest overall reduction in non-medical exemptions (California dropped from 2.37% to 0.56%)	Likely to have the lowest impact on reducing exemptions	Likely to have a moderate reduction in exemptions (Washington rates decreased by 40%)
Can we meet our goal with this method?	Yes	No	Maybe	Yes	Probably not	Maybe

Recommendations and Possible Objections

- **We recommend eliminating conscientious exemptions, including religious exemption, from immunizations required for school entry.**
  - Alignment with the majority of stakeholder goals
  - Evidenced based for meeting stated goals based on outcomes from other states
  - The infrastructure for implementation and measuring outcomes is already in place
- **Possible Objections**
  - Texas average vaccination rates are over 95%, satisfying accepted requirements for "herd immunity"
  - This proposal is unconstitutional, and the government has no right to mandate vaccines
  - The claim/belief that vaccines are unsafe

Approval, Implementation, and Evaluation

- **Major advocacy efforts** from stakeholders needed for passage through legislature
- Enforced by **Texas Department of State Health Services** and **school districts**
- Educate **all parents** with school-age children
  - Information from schools, pediatricians, TV/online ads
- Continue **access to low-cost/free vaccines** through TX Vaccines for Children, community outreach programs
- **6-month grace period** and written warning from schools
  - Conditional enrollment for children who have started series with Doctor's note
  - Ensure compliance while minimizing disruption to school
- Measures of success
  - **Effectiveness**: Are vaccination gains offset by lower school enrollment or rise in medical exemptions?
  - **Equity**: Which communities see most/least change?
  - **Sustainability**: Need adequate buy-in and enforcement for sustaining over time
  - **Legal**: Challenges expected from vocal groups, but legal precedent has been established

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A Shot Against Cancer

The State of HPV Infection and Vaccination in Texas

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Background

- US Centers for Disease Control & Prevention (CDC) states that "HPV is so common that nearly all sexually active men and women get the virus at some point in their lives" if unvaccinated.
- **79 million Americans are infected currently,** most of whom are adolescents and young adults, and **14 million are infected annually.**
- Of 200 strains of HPV, over 40 are transmitted through different forms of intimate mucosal contact, and at least 12 cause cancer.
- HPV costs Texans **$170 million a year** in healthcare expenses to treat cancers and other medical conditions associated with the virus.
- In the next few years, oropharyngeal cancer rates are predicted to continue increasing, and even more Texas families will be affected by the cancer-causing, preventable Human Papillomavirus (HPV).
- Concrete, feasible changes to policy that would increase awareness and access to vaccination could increase the amount of Texans who are protected from HPV-related cancers.

HPV Vaccine Dose Schedules by Age

Age Range	# of Doses	Schedule (months)
9-14	2 (immunocompromised need 3)	0, 6-12
15-26	3	0, 1-2, 6
27-45	3 (not routinely recommended by CDC, case-by-case basis)	0, 1-2, 6

Epidemiology of HPV

Cancer	Annual US Cases	Annual US Deaths	Annual TX Cases	Annual TX Deaths	% Cases Related to HPV	Vaccine Prevents
Anal	Total: 8,590 Male: 2,690 Female: 5,900	Total: 1,350	Total: 344	NA	>90%	YES
Cervical	Female: 13,800	Female: 4,290	Female: 1,247	Female: 407	>90%	YES
Oropharyngeal	Total: 19,000 Male: 15,500 Female: 3,500	Total: 7,890	Total: NA	Total: NA	>70%	YES
Penile	Male: 2,200	Male: 410	Male: 128	NA	>60%	YES
Vaginal	Female: 6,230	Female: 1,450	Female: 58	NA	75%	YES
Vulvar	Female: 6,120	Female: 1,200	Female: 217	NA	70%	YES

Current State of Texas

How Texas Compares

- Texas' adolescent HPV vaccination rate was similar to the average US rate in 2013, but Texas has since failed to keep up with increased rates nationwide.
- In 2016, <50% of Texans aged 13-17 had received a dose of the HPV vaccine and only ⅓ had received the full series.
- Only 4 states (MS, SC, UT, WY) have HPV vaccination rates lower than Texas.
- Other non-HPV adolescent vaccination rates are much higher in Texas, suggesting that our low HPV rate is not entirely explained by general vaccine hesitancy.
- The FDA approved the HPV vaccine in 2006, but legislation to increase its use in Texas has mostly stagnated since 2007, when Gov Rick Perry failed to mandate it.

Texas State Legislative Review

Year, Bill, Status	Description
2007: HB 1098, SB 438 Signed into Law Overrode EO 4	Prohibited any public elementary or secondary school mandate for the HPV vaccine, but required schools to provide medically accurate info to parents. Overrode EO 4, which tried to mandate for all females entering 6th grade in public schools, with public coverage until age 21 and parental right to refuse.
2007: HB 1379, SB 110 Signed into Law	Required DSHS to develop and distribute medically accurate info in Eng & Esp. Must include that sexual contact not required for transmission, vertical transmission possible, and screenings required after vaccine.
2017: SB 2042 Referred to Senate Health & Human Services Committee	Allowed pharmacists to be first-line providers of all clinically indicated vaccines, including HPV vaccine, to any patients age 7+ (lowered from previous age of 14+). No established patient-physician relationship required. No requirement to determine that a physician is unavailable or inaccessible.

Other State & National Policies

Initiatives successfully implemented in other states and countries can serve as a model for Texas.

- **North Carolina**: In 2009-2010, schools and the health department in Guilford County, NC teamed up to administer the HPV vaccine to girls aged 10-17. This initiative was successful: the completion of the HPV vaccine series was 80%.
- **Idaho**: Idaho allows pharmacists to administer the HPV vaccine to females 9-years old and older without a prescription. Idaho also has a lower incidence rate of cervical cancer than the entire US (5.9 per 100,000 compared to 7.4 per 100,000). The vaccination rates for males and females have increased after the implementation of this bill.
- **Australia**: Australia expects to eliminate cervical cancer within the next two decades. They introduced a national vaccination program in 2007 that provided the vaccination series to teenage girls at no cost. Teenage boys were included in the program starting in 2013. As of 2016, about 80% of the population aged 15 had received all three doses which led to a 77% reduction in the incidence of HPV strains that cause cancer. Due to increased vaccination, Australia is able to reduce screening and save money on both screening procedures and cancer and genital wart treatment. They are expected to eliminate cervical cancer as a public health problem by 2028.

In contrast, we can also learn from the consequences of decreased vaccination rates in countries like Japan.

- **Japan**: In 2013, Japan had a vaccination rate of 70%; today, less than 1% of young adults are vaccinated. This sharp decline is attributed to the government's suspension of recommendations for the vaccine after an unsubstantiated study was published regarding vaccine side effects. Public health analyses estimate significant fallout from this change in policy, predicting 24,600–27,300 preventable cervical cancer cases attributable to resulting missed vaccination and 700-800 cervical cancer-related deaths for each year that these trends continue.

Policy Recommendations

"Recommending" (Not "Requiring") the HPV Vaccine:

Currently, DSHS is required by state law to provide info on HPV vaccine. DSHS informs all public school parents on required booster Tdap and MCV vaccines for all children aged 11 (same age for HPV vaccine). Info sheets on Tdap/MCV and HPV are separate.

- DSHS should combine sheets so that HPV vaccine is listed as "recommended" alongside "required" Tdap and MCV.
- Parents should be encouraged to take their children for all 3 vaccines.

Partnering with Physicians & Pharmacists:

Currently, SB 2042 language allows HPV vaccine provision outside CDC guidelines, and expands pharmacist scope at expense of physicians.

- SB 2042 should be modified to align with CDC guidelines; require established patient-physician relationship (with required follow-up after first dose of vaccine).

Collaborating with Campuses and Communities:

Currently, Cancer Prevention & Research Institute of Texas (CPRIT) is a $6 billion state fund for cancer programs.

- Grant programs should be created for middle-school-based health centers to host pop-up HPV vaccine clinics.
- County or city health departments should collaborate to create plans with school districts to target high-risk hot spots.
- Local healthcare institutions should help implement these programs.

Improving ImmTrac2 Data Collection (Texas Immunization Registry):

Currently, opt-in system that requires parental consent as minor and re-consent when patient turns 18. Patients may have moved, switched providers, or be receiving HPV vaccine for the first time after turning 18.

- All patients aged 18 should be offered re-consent form during any visit.
- Providers should be reimbursed for offering re-consent form.

Acknowledgments

We would like to thank our faculty advisors, Claire Bocchini, MD (of Baylor College of Medicine, Texas Children's Hospital Center for Child Health Policy & Advocacy, and Doctors for Change), Lois Ramondetta, MD (of the University of Texas MD Anderson Cancer Center), and Rekha Lakshmanan, MHA (of the Immunization Partnership) for their content expertise and support of our project. We also credit Dr. Bocchini for her Clinic to Capitol elective course at Baylor, during which we wrote a policy brief that served as the foundation for this report.

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Clarifying the Roles of Consent and Assent in Surgical Intervention on Atypical Genitalia in Intersex Minors

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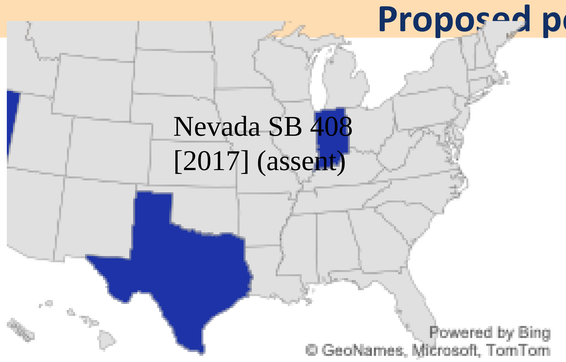
Background

In recent years, Nevada, Texas, Indiana, and California have each attempted but failed to pass legislation that would delay non-urgent surgical interventions on atypical genitalia of minors. California's efforts are the most mature and include the state legislature's passage of a concurrent resolution and two proposed bills.

Notably, these states have diverged with respect to the role of minors in the decision-making process. Using California's proposed policy as a case study, we describe the significant confusion that has surrounded policy efforts intended to ensure the involvement of intersex minors in these surgical decisions and identify additional considerations for policy makers.

Proposed policies



Indiana HB 1461
[2017] (consent)

Texas SB 1432 [2017],
HB 2462/SB 1383 [2019]
(consent)

Conclusion

Given state activity on this issue (in the past and likely in the future – see NY[4]), it is critical that policy decisions be based on understanding of the legal, ethical, and practical distinctions between consent and assent. If consent is endorsed, an age likely must be selected. But it is unclear what it should be. Traditionally, exceptions look at a cut-off age in adolescence, but is that too late for intersex individuals?

We think the better approach is to endorse assent because it provides flexibility. If assent is chosen as the default rule, there are still important questions that need to be addressed.

- *How should assent be defined in this context?*
- *What should the conversation between provider, parent, and child look like (ensuring that there is no coercion)?*
- *How should disputes be resolved between two parents? Between parent and child?*

These are questions that always attend assent circumstances in health policy but are particularly heightened in this context because the surgical intervention is permanent and there are social, cultural, psychosocial and identity issues involved that can have long-lasting impacts on the child's and family's overall well-being. Therefore, it is vital that key stakeholders heavily deliberate and answer these questions going forward.

The Role of Minors in Decision-making

Informed consent:

- Permission to proceed with the proposed care
- Must be obtained as a matter of law
- Requires decision-making capacity, which is legally presumed at the age of 18
- In pediatric care, parents provide informed consent. There are few legal exceptions where minors can consent (e.g. STI treatment)

Assent:

- Expression of willingness to accept the proposed care
- Sought as an ethical matter
- No consensus on required elements of assent
- Depending on the formulation, can be obtained from a school age child (developmentally appropriate understanding) or only from an adolescent (fulfilling elements of adult informed consent)[1]

California's proposed policy: a case study

TABLE 2. Decision-making Standards Endorsed in the Californian Legislative History of Pediatric Intersex Surgical Decisions

Californian legislation	Standard endorsed	Language	Reference	Status
Resolution	Assent	"That the Legislature calls upon stakeholders in the health professions to foster the well-being of children born with variations of sex characteristics, and the adults they will become, through the enactment of policies and procedures that…defers medical or surgical intervention, as warranted, until the child is able to participate…"[2]	Senate Concurrent Resolution No. 110 [2018]	Passed
Bill 1	Consent	"Absent a medical necessity, a physician and surgeon shall not perform any treatment or intervention on the sex characteristics of an intersex minor without the informed consent of the intersex minor…"[3]	Senate Bill No. 201 [2019]	No vote; Deferred to 2020 legislative session
Bill 2	Assent	"A treatment or intervention on the sex characteristics of a person born with variations in their physical characteristics who is under six years of age shall not be performed unless the treatment or intervention is medically necessary…until the individual can participate in the decision"[3]	Senate Bill No. 201 [2020]	Failed passage on Jan 2020. Reconsideration granted.

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Vaping and Electronic Cigarettes in Adolescents: A Policy Recommendation

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The Problem:
Adolescents and young adults disproportionately vape and **use e-cigarettes** despite having **more misconceptions** regarding the health risks and harms of said devices.

BACKGROUND

What is Vaping?

Electronic cigarettes are alternatives to tobacco smoking that function by creating an aerosol containing propylene glycol, flavorings, nicotine, and/or other substances, which is then inhaled.

Policy Issues:

- Components, such as flavors and disposables, are less regulated
- Easily accessible and readily available
- Cultural appeal of vaping, particularly in online media, is not addressed by current policies
- Variability in taxation and state regulations can lead to trafficking across state borders
- Enforcing bans on sales to minors is problematic, particularly online sales

Stakeholders and their Values:

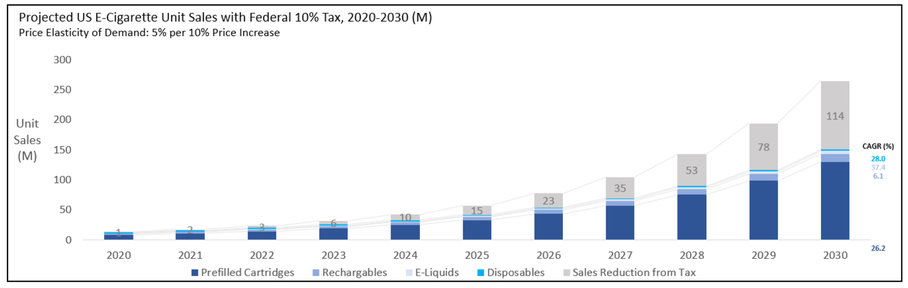
- **Vaping companies:** profits, reputation
- **Adolescent users:** social acceptance
- **Adult users:** smoking cessation
- **Parents:** child's health/safety
- **Insurance companies:** profits
- **Health officials and physicians:** health and wellness of their patients
- **Local and federal governments:** taxes, protecting public health

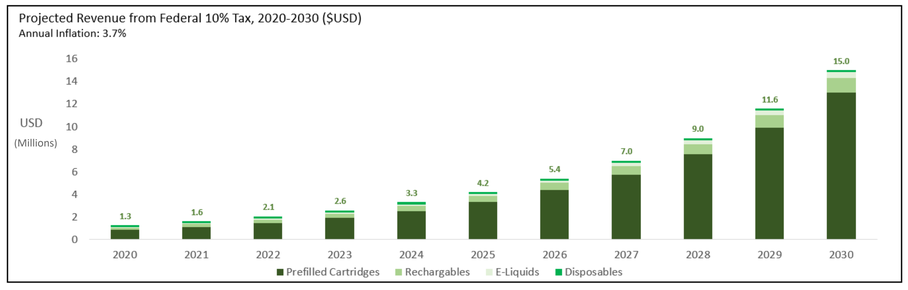
Charts 1-4 demonstrate that a Federal 10% tax on e-cigarettes between 2020-2030 would:

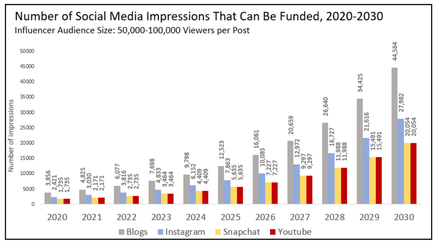
- Reduce e-cigarette sales by 340M+ units by price elasticity of demand
- Generate $63M+ in revenue to fund 10,000+ social media influencer impressions

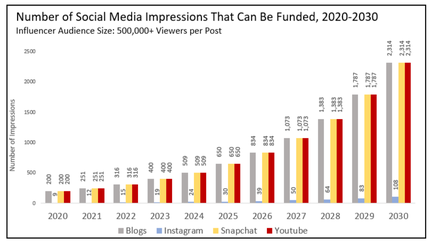
POSSIBLE SOLUTIONS	Anti-e-cigarette social media campaign	Regulate e-cigarette aesthetic design	Regulate e-cigarette advertising on TV and radio	Raise minimum legal age of sale of tobacco to 25	Increase taxes on e-cigarettes
Political Acceptability	FDA's "Real Cost" campaign serves as national precedent in public sector; other privately and charitably funded campaigns have utilized social media and video streaming sites to capture youth audience	Aspects that directly facilitate youth consumption (such as accessories to hide vapes in bookbags) can be regulated, but regulating design may result in retaliation from lawful users and manufacturers	TV and radio ads for combustible cigs banned since 1969; e-cigs not included, but consistent historical precedent for combustibles may build public and political support to extend ban to e-cigs	US Congress and FDA just increased MLAS to 21 this year; many states increased to 21 in the last few years; MLAS of 21 already controversial and requires graded implementation	E-cigs not currently subject to excise taxes on combustibles; e-cig taxes can be increased to discourage usage, but kept below combustible taxes to ensure that combustibles continue to be seen as less preferable than e-cigs
Financial Feasibility	Request voluntary sponsorship by celebrities, social media sites, and e-cigarette manufacturers	Requires public funds and personnel for investigation, meticulous rulemaking, enforcement, and notification	Active monitoring of products not required for enforcement, simple blanket ban on TV and radio ads	Requires increased public funds for monitoring and enforcement, especially during graded implementation	Increased taxes provide additional revenue to compensate for any costs and use for other initiatives
Effectiveness	Celebrity pressure discourages new uptake, but may not dissuade purchases by existing users	Aesthetic design may be a broad category with too many potential features to effectively regulate	Removes 2 entire sectors of advertising where e-cigs are advantaged compared to combustibles; both should be disadvantaged	Further reduces prevalence of tobacco use disorder, long-term use of e-cigs, use of devices for other substances, and transition from e-cigs to combustibles	Taxes on unhealthy products effectively reduce consumption; public funds can be used for tobacco cessation projects
Efficiency	Existing public health campaigns serve as template for messaging, social media posts easy to produce	Difficult to define features subject to regulation, requires debates with manufacturers and public comment on draft rules	Simple blanket ban would require relatively simple rulemaking without need for active monitoring	Current state laws raising MLAS to 21 implemented in stages over many years; raising to 25 would require even longer timeline	Blanket tax on all e-cig products is relatively easy to implement, no variations to consider in rulemaking
Equity	Widely promoted and adapted to various interest groups based on celebrities and platforms	Applies to all manufacturers' products, but aesthetic variation may result in inconsistent enforcement	TV and radio may target older populations; does not address internet and physical ads; internet ads likely strongly impact adolescent choices	Racial discrimination in enforcement and punishment for youth substance possession and consumption in minority populations	Impacts lawful adult users as well as recent youth users; may discourage current combustible smokers from switching to e-cigs

Combined Solution:
An anti-e-cigarette social media campaign that is funded by tax revenue from e-cigarette sales









IMPLEMENTATION

Advertising Corporations

- Create advertising content and messaging

Social Media Influencers

- Contract with influencers to create sponsored content

Government Systems (IRS, State Public Health Department, County Committees)

- Lobby for taxation increases and establishment of advertising fund

Education system

- State Public Health Dept notifies State Dept of Education about campaign

How we know the solution is implemented

- Advertisements appear on social media
- Monitor statistics on social media campaign views
- Monitor number of calls into quit lines
- Track tax revenue from IRS reports

EVALUATION

USAGE RATES	**Decrease in absolute use** **Decrease in relative use** **Shift in demographics**
SALES RATES	**Decrease in revenue generated from companies** **Increase in revenue generated for advertising campaign**
VOLUME OF PRODUCTS	**Overall decrease in product supply**

CONCLUSION

- Increasing taxation on e-cigarettes could **decrease usage** by **340M+ units**
- **$63M+** generated in tax revenue could be used in an **anti-e-cigarette campaign** targeted at adolescent audiences via **Social Media Influencers**

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Ethical Oversight of Quality Improvement: A Side-by-Side Comparison of Recommendations in the Literature

Anoosha Moturu; Mary Majumder, PhD
Baylor College of Medicine Center for Medical Ethics and Health Policy

Baylor College of Medicine

A side-by-side comparison of leading quality improvement (QI) oversight recommendations shows variation in optimal oversight structure. This work provides a foundation for analysis of the implications for policy development and practice in QI oversight.

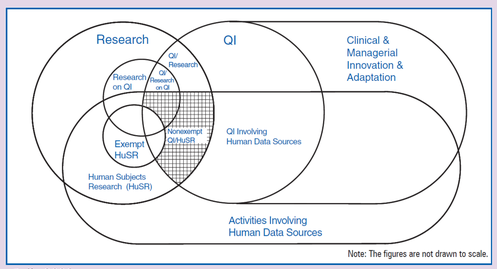
INTRODUCTION

Human Subjects Research

- **Definition**: a systematic question to be applied to broader contexts and for which individually identifiable human data are being collected
- **Regulated by**: the Department of Health and Human Services' Federal Policy for the Protection of Human Subjects or "Common Rule"
- **Regulation**: 45 CFR 46.101-46.401
- **Oversight requirement**: Institutional Review Board (IRB) oversight
  - Exceptions: expedited review, waive informed consent (IC)
- **Criteria**: risks minimized and reasonable to anticipated benefits, subjects selected equitably, informed consent, safety monitoring, privacy and confidentiality of data

Quality Improvement

- **Definition**: systematic data-guided activities designed to bring about immediate improvements in health care delivery in particular settings
- **Regulated by**: variable
- **Regulation**: must comply with Health Insurance Portability and Accountability Act (HIPAA)
- **Oversight requirement**: variable
- **Criteria**: variable



Baily 2006,

METHODS

- Pubmed search for terms:
  - Quality Improvement
  - Oversight
  - Ethical Oversight
- Cited > 5 times
- Was the abstract relevant?
- Development of key questions
- Review of identified articles
- Construction of table

73 ↓ 9

DISCUSSION TABLE

Comparison Factors	Articles (below)	Points of Conversation
Ethical & Policy Considerations: Ethical and policy imperatives related to QI		- *Feasibility of standardization between hospitals* - *Scarce resource allocation* - *Expectations of professionals and patients* - Avoiding hefty and unnecessary oversight - Inappropriate randomization - Measurement of benefits - Cost containment versus necessary QI
QI Projects - Key Ethical Concerns: Concerns all should be mindful of, regardless of whether their QI project meets oversight criteria		- In what scenarios to obtain informed consent - Social/scientific value and validity of scientific data - Exposure to no more than minimal risk - Appropriate allocation of risk - Privacy and confidentiality - Supervision without bias - Ethical imperative of patients and physicians to participate in QI
QI Projects - Oversight – Criteria: Features that make third-party oversight necessary		- Interventions with comparison groups - Prospective QI evaluations - More than minimal risk or less care than current standard of care - Conflict of interest of researchers or funding source - Untested interventions
QI Projects - Oversight - Form(s): What should the oversight structure be?		- Where should oversight be housed? *IRB expedited process, QI-IRB, privacy boards, standing QI committees, or multidisciplinary committees?* - Who should multidisciplinary team include? *ethics consultants, patient advocates, QI experts, IRB members* - Should there be oversight and regulation from regulatory bodies? *OHRP, JCAHO, etc.*

Left to Right: Kass 2011, Bellin 2001, Grady 2007, Finkelstein 2015, Fiscella 2015, Lo 2003, Baily 2006, Lynn 2007, Layer 2003

Patient-Physician Communication at the time of Malignant Bowel Obstruction:

a qualitative analysis of discrepancies and strategies

Claire Hoppenot, MD[1]. Faye Hlubocky, PhD, MA[2]. Julie Chor, MD, MPH[3]. S Diane Yamada, MD[2]. Nita K Lee, MD, MPH[2].

1. Div of Gynecologic Oncology, Baylor Medicine, Houston, TX. 2. Div of Gynecologic Oncology, University of Chicago, Chicago, IL 3. Dept of Ob/Gyn, University of Chicago, Chicago IL

Background

- Malignant bowel obstructions (MBO) occur in up to 40% of women with recurrent gynecologic cancers such as ovarian, uterine and cervical cancer. They are cared for by gynecologic oncologists.
- A MBO diagnosis marks an increase in symptoms and transition in care, with a decrease in treatment options. It is associated with complex communication involving realistic prognostication and collaboration with patients, family and team for decision-making and support.
- Median survival after MBO from recurrent gynecologic cancer is 3-4 months

Objectives

1) Determine what were the discrepancies in the approaches to a new MBO diagnosis by patients and physicians
2) Highlight factors that strengthened the patient-doctor relationship at this time, and
3) Discuss communication strategies that helped physicians organize their discussion of MBO with patients.

Methods

- Qualitative study of patients with MBO and gynecologic oncologists in a single metropolitan area

- Patient interviews
  - Inclusion criteria: admitted for a MBO between 5/2016 and 10/2018 at one of two affiliated institutions, recurrent/progressive gynecologic cancer with previous treatment, 18-89 years of age, English-speaking, able to participate in an interview
  - Interviews were conducted a few days prior to discharge
  - Semi-structured interviews were conducted in person (CH) and recorded then transcribed verbatim. Interviews focused on decision-making, symptom control, and support during admission for MBO.

- Physician interviews
  - Gynecologic Oncologists on a department list were contacted via a standardized email. Response was considered to be consent.
  - Interviews were conducted in person or by phone (CH), recorded and transcribed verbatim for analysis. Interviews focused on the approach to MBO in terms of treatment and counseling.

- Transcribed interviews were stored in QDAMiner and analyzed using a Framework analysis with themes predetermined from the literature and expanded based on transcript analysis. The code dictionary/themes were reviewed by 2 additional investigators familiar with the interview data (FH, NL). The total number of interviews was determined by thematic saturation.

Table 2: Discrepancies between patients and physicians in discussing MBO

	Patient quotes	Physician quotes
Treatment after MBO	I'm worried about how soon can I get back on track with my treatments. (PT8)	For most of these patients the reality is that we have reached the end of the road in terms of active chemotherapy or tumor therapy. (MD10)
Information gaps	[My doctor] acts as though he doesn't want to talk to me about certain things that are painful. […] It's like he's close-mouthed, like, "I don't want to say anything that's going to make her feel bad." I'm a grown-up woman. I am 81 years old. I can take anything. (PT12)	You can't predict completely how things are going to go, so that's really hard because you want to counsel appropriately but sometimes things don't go that way. So I think the unknown for the patient is really hard, then it makes it, then it makes it hard for you too. (MD15)
Approach	Don't give up. They say oh, well, this isn't going to work, that isn't. Don't do that. Don't stop. Keep going. Because there is a way. God is good. And He will pull out all our needs for us. So don't give up. Don't say no. (PT7)	Their expectation of health outcomes were more black and white. This is my problem, it should be a solvable problem. And solving a problem should mean that I should get back to exactly where I was before, to how I was feeling a number of years ago. And that's where it's hard. (MD2)
EOL readiness	I don't care about my hair. I don't care about any of that. I just want to live. (PT9) I just have to pray to God and tell him, I don't want cancer, take it away, but if I die, I die (PT12).	The way I try to bring it up is that “we know this is not going to be a curative situation. We do know there's a limited amount of time that you have, ... but it is important to think about what you want to do with the time that you have.” (MD15)

Analysis

- 14 of 20 approached patients agreed to interviews, and 15 of 27 approached gynecologic oncologists participated. Characteristics are shown in Table 1.
- Discrepancies in approaches are shown in Table 2
- Protective aspects of the patient-doctor relationship that were discussed by both patients and physicians included:

1) Trust: “He was very calm and you didn't see any panic in his eyes, you didn't see like, oh, we're going to cure you in his eyes, so I trusted him to tell me the way it is now. (PT5)”
2) Understanding patient preferences: “I think it's important for everybody to sometimes trust the patient, and especially if they've been sick for a while, to trust where they're at in their sickness.” (PT2)
3) Corroboration of information: “It’s been always really good that [my doctor] reaches out to other colleagues to get their input.” (PT10) “I want to do some more research on [an ostomy] and what life is like with that routine.” (PT11)
4) Time, both since diagnosis and to be allowed to process the information: “Sometimes, I just need a few minutes of just taking it all and putting it on the side for a while. Not thinking about it. Then come back to it and think about it. Instead of just diving in.” (PT10)

Physicians discussed some of their communication strategies for decision-making

1) Shared decision-making
2) Providing options (patient autonomy approach)
3) Directive recommendations (paternalistic approach)
4) Use of data/ statistics
5) Emphasizing risks to convince patients towards their recommendation
6) Best case/worst case scenarios and benchmarking

Table 1: Physician characteristics (n=15)		Patient characteristics (n=14)	
Gender		Age (med, range)	61 (36-81)
Female	8 (53%)	Race	
Male	7 (47%)	White	8 (57%)
Practice type		Black	4(29%)
Academic	10 (67%)	Hispanic	2 (14%)
Academic/community	5 (33%)	Cancer type	
Years since fellowship:		Ovarian	10 (71%)
<15	10 (67%)	Cervical/uterine	4 (29%)
>15	5 (33%)		

Bottom Line

- MBO is a stressful experience impacting the patient-physician relationship. The relationship relies on communication to allow counseling and decision-making around treatment planning and end of life.
- Participating patients appreciated a direct recommendation but wanted more information. Physicians were divided between paternalistic and patient-autonomy approaches, and worried about recommendations given the amount of uncertainty in MBO diagnosis and prognosis.
- Decision aids have been used in other situations to help facilitate discussions and balance providing information and providing a recommendation. Piloting a decision aid in these situations could leave patients feeling better informed and trigger both patients and physicians to address issues, such as going home, end of life, and nutrition, in an unbiased and personalized fashion.

“A cohort of pirate ships”: biomedical citizen scientists’ attitudes towards ethical oversight

Isabel Canfield[1], Whitney Bash-Brooks[1], Meredith Trejo[1], Christi J. Guerrini[1]
[1]Baylor College of Medicine, Center for Medical Ethics and Health Policy

Introduction

- Policymakers paying increased attention to research conducted by biomedical citizen scientists outside of traditional institutions
- This research generally not subjected to ethical oversight (i.e., IRB review)
- Several new mechanisms of ethics review proposed, but little known about biomedical citizen scientists’ attitudes towards such oversight

Methods

- Qualitative interviews with 35 biomedical citizen science stakeholders
- Probed interviewees about ethical priorities, general attitudes towards ethics oversight, and features of proposed mechanisms

Results

- Interviewees represented four continents (Fig. 1) and were primarily male (60%, n=21)
- Identified 13 ethical priorities related to their work (Fig. 2)
- Interviewees endorsed ethics oversight mechanisms that are voluntary, community-driven, and offer advice
- Interviewees rejected mechanisms that are mandatory, hierarchical, and inflexible

Conclusions

- Peer-to-peer IRB and community ethics consultation models align with interviewees’ preferences (Table 1)
- Traditional IRBs and crowdsourced review models do not align with interviewees’ preferences (Table 1)

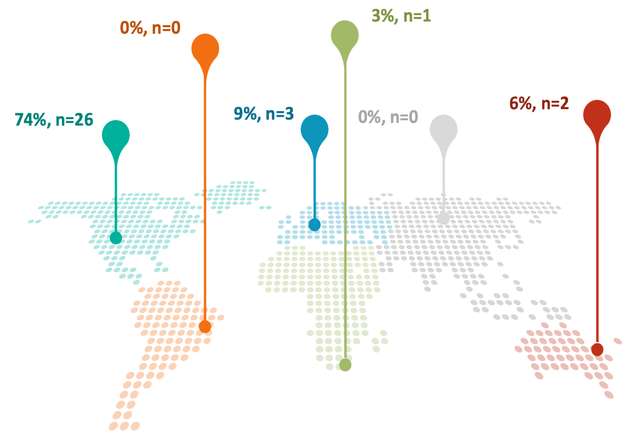
This study was funded by National Human Genome Research Institute grant K01-HG009355 (Guerrini, PI).The authors thank the interviewees for their participation.

Created by Weltenraser from Noun Project

Biomedical citizen scientists are interested in ethics review and prefer mechanisms that are voluntary, community-driven, and offer advice rather than enforce rules. Peer-to-peer IRBs and community ethics consultation committees are most aligned with their ethical priorities and preferences.

Take a picture to email me for more information

Fig. 1. Origin of interviewees (n=35)[1]



[1]3% of interviewees declined to answer (n=1), 6% reported multiple origins (n=2)

Fig. 2. Ethical priorities reported by interviewees

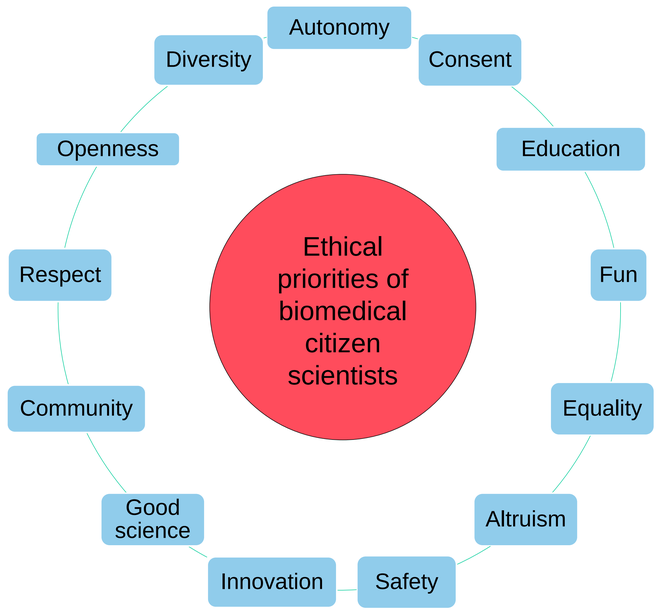


Table 1. interviewee attitudes towards proposed ethics oversight models

Proposed oversight model	Description	Pros	Cons
Traditional IRB	Formal group of experts evaluates human subjects research	• Expert, credible review	• Formal, hierarchical, mandatory, hard to coordinate
Community ethics consultation committee	Community members review projects and provide opinions on ethics	• Range of opinions, similar to existing lab safety boards	• Requires community resources, potential for hierarchy
Peer to peer IRB	Ethics experts make themselves available to provide opinions on projects	• Informal, voluntary, fosters mentorship	• Distrust of ethicists, credibility, no enforceability
Crowdsourced review	“Citizen ethicists” provide opinions, often online	• Decentralized, diverse opinions	• Online monitoring difficult, no enforceability
Individual ethical reflection	Project members identify risks and benefits together	• Input from those directly involved	• Different understandings of ethical principles
Code of ethics	Document of shared ethical principles	• Credibility, guides decision making	• Not specific, no enforceability

Shared Decision Making Policy and Practice: 15 Month Results of a Multi-Site Study of Decision Aid Implementation

Meredith Trejo[1], Kristin M. Kostick[1], J.S. Blumenthal-Barby[1]

[1]Baylor College of Medicine, Center for Medical Ethics and Health Policy

Introduction

- Implementation of **shared decision making (SDM)** into routine clinical care is a **goal of policymakers**.
- **Decision aids** (DAs) are tools that **facilitate SDM.**
- Policymakers have successfully used "**nudges**," drawing on principles of behavioral economics, to positively **change health behaviors at a population level**.
- **Little evidence exists regarding best practices** for using **behavioral economics** to achieve policy goals **at the clinical level**.
- This project **evaluated implementation of a DA** for left ventricular assist device (LVAD) surgery at eight U.S. hospitals with a **focus on using behavioral economics to facilitate increased SDM and DA use**.

Methods

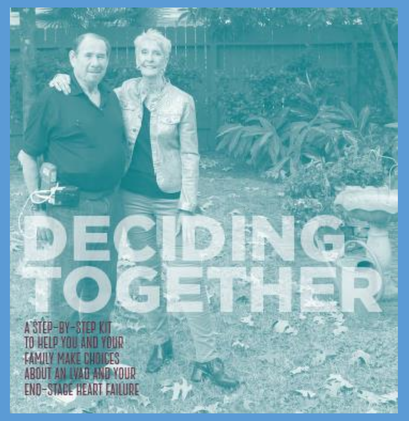
- Participating sites received tailored implementation plan and SDM training.
- LVAD coordinators completed a 10-item **Implementation Fidelity Checklist** for each patient.
- Primary outcome, **reach to patients**, calculated by dividing checklists received by the total number of patients receiving pre-LVAD education evaluation.
- **Implementation plans** continually **tailored** using innovative behavioral change model **(MINDSPACE)** during reinforcement and feedback sessions**.**

Results

- **607 patients** received a DA over 15 months.
- **Reach** ranged from **29.3%-87.9%** of patients across sites with **overall reach of 58.2%.**
- Over one-third (37.5%) of sites achieved overall reach > 80%.
- Applying certain elements of the MINDSPACE **behavior change framework**, we **improved reach** by increasing clinical champion stakeholder engagement (Table 1).

Conclusions

- DAs can be **implemented into busy clinical care settings** with sustained use by clinicians, patients, and caregivers.
- **Behavioral economics** can facilitate wider reach of **tools for SDM and increase physicians' motivation** to use these tools.



Strategies used by policymakers to motivate behavioral change, including behavioral economics, can be translated into use at the clinical level to promote increased use of tools for shared decision making

Take a picture to view the LVAD Decision Aid online

Take a picture to read more about our use of behavioral economics

This work was supported through a Patient-Centered Outcomes Research Institute (PCORI) Program Award (DI-2017C2-7726). All statements in this report, including its findings and conclusions, are solely those of the authors and do not necessarily represent the views of PCORI, its Board of Governors or Methodology Committee.

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Findings

DA Implemented with high fidelity (intended use) (mean=8.4/10)

37.5% of sites (n=3) achieved high reach (>80% eligible patients received DA)

607/1043 LVAD patients received a decision aid for a cumulative reach of 58.2%

Site specific reach to patients ranged from 29.3%-87.9%

Figure 1. Monthly Decision Aid Reach across Eight Sites: September 2018 - December 2019

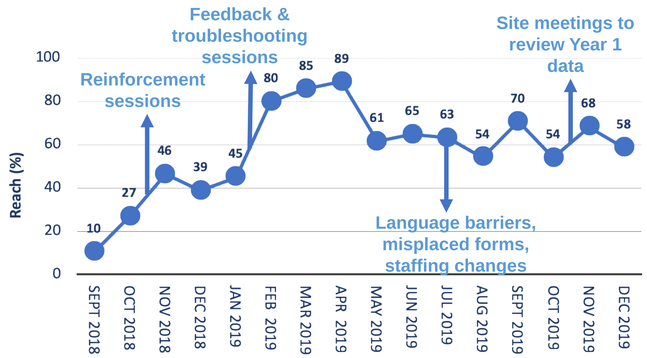


Table 1. Use of MINDSPACE Framework and Nudges to Foster Behavior Change

MINDSPACE Element	Behavior Change Strategy
Messenger	• Increase engagement of physician champions to motivate LVAD coordinators to use decision aid
Incentives	• Promote self-direction and ownership over how decision aid is used in practice.
Norms	• Share how colleagues at other sites successfully use decision aid
Defaults	• Integrate decision aid use with existing clinical processes
Salience	• Keep decision aid at forefront of LVAD coordinators' attention
Priming	• Employ patient-centered terminology in interactions with coordinators and clinicians
Affect	• Celebrate examples of patient benefits and improved shared decision-making
Commitments	• Remind physician champions of commitment to the project
Ego	• Share site specific RE-AIM data and focus on successes

Identifying and Ranking Key Barriers to Data Sharing:

Stakeholder perspectives on a cancer gene variant commons

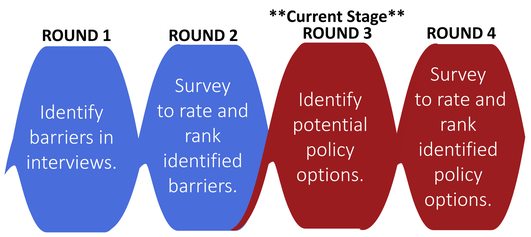
Matthew Blank, Isabel Canfield, Jill Robinson, Janis Geary, Juli Bollinger, Mary Majumder, Christi Guerrini, Robert Cook-Deegan, and Amy McGuire

Introduction

- Open science suggests that a commons consisting of the ever-increasing number of inherited cancer gene variants would advance biomedical research and the clinical significance of each variant.
- Propriety data practices and open science compete for control.
- Identifying barriers to creating a commons is critically needed in order to generate potential policy options.

Methods

- Conducted modified policy Delphi with Advisory Committee (AC) members (n=23).



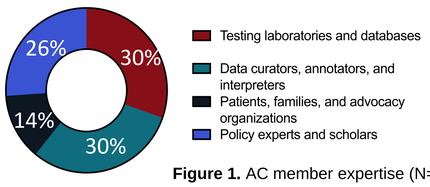


Figure 1. AC member expertise (N=23)

Results

- 16 barriers to developing a cancer gene variant commons were identified from round 1 of the Delphi.
- Broad consensus in defining a knowledge commons proved difficult across interviews.
- 4 top-ranking barriers were identified from the round 2 of the Delphi.

THE SULSTON PROJECT

The most important challenges in the development of a cancer gene variant commons underscore concerns of data ownership, financial sustainability, privacy, and trust.

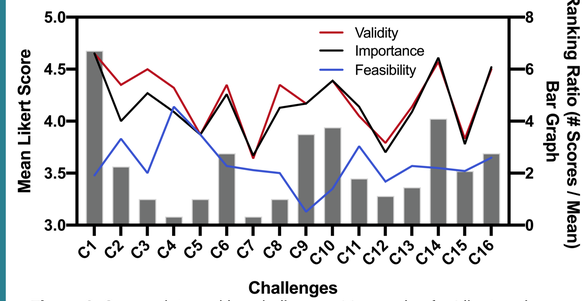


Figure 2. Survey data ranking challenges. Mean value for Likert scale responses plotted for each challenge (5=strongly agree to 1=strongly disagree). Ranking challenges ratio of the total number of votes divided by the mean value for each challenge are represented by the bar graph.

Top 4 Challenge Descriptions
C1. Some entities that generate data are not sharing it because of countervailing incentives and values.
C9. Trust in the security of a commons is difficult to build given that privacy laws/regulations and norms change over time.
C10. A wealth of linked data is necessary to solve complex problems, but then the data become more identifiable and privacy risks increase.
C14. The commons has characteristics of a global public good, which makes ensuring long-term financial sustainability difficult.

Table 1. Top-rated challenges identified following second Delphi round.

DATA OWNERSHIP

"Oh sure, data ownership is a problem, yeah. Because one problem is just even figuring out what that term, data ownership even means. What do I mean when I say I own your data? What data do I own? Do I own the raw reads?... what, do I own, the interpretation?"

TRUST

"If we're honest we go back and look at things like the Henrietta Lacks story and Tuskegee...we know that there is a general lack of trust in certain communities [and]…it's super important to be sensitive to those concerns…around, somehow the data being used to impact a person's ability to have healthcare coverage…"

PRIVACY

"I think the issues around small populations being represented in databases raises the issue of potential for re-identification or being able to narrow down to a small list of people…"

FINANCING

"The most important challenge to address is funding free from conflict of interest of infrastructure to support both a scientific and patient driven commons."

Figure 3. Illustrative quotes representing the broad categories of challenges.

Discussion

- Identified barriers highlight the inherent need for a commons that requires critical, thoughtful, and creative consideration of policy options and alternative structures.

Acknowledgments

NIH

R01-CA237118 to RC-D and ALM

Baylor College of Medicine

CENTER FOR MEDICAL ETHICS & HEALTH POLICY

ASU SCHOOL FOR THE FUTURE of Innovation in Society ARIZONA STATE UNIVERSITY

A Reason for Engaging: Ethics and the Environment
The Gulf Coast Center for Precision Environmental Health

Sharon A. Croisant, MS, PhD;[1,2] Chantele Singleton, MS, MBA; [1,2] John Prochaska, DrPH, MPH; [1,2] Stephen H. Linder, PhD;[1,3]
Lea Steele, PhD;[1,4] Lance Hallberg, PhD; [1,2] Cornelis Elferink, PhD;[1,2] Elaine Symanski, PhD, MSPH;[1,4] Cheryl L. Walker, PhD[1,4]
[1]Gulf Coast Center for Precision Environmental Health, [2]The University of Texas Medical Branch,
[3]UTHealth School of Public Health, [4]Baylor College of Medicine

GC-CPEH

The Gulf Coast Center for Precision Environmental Health (GC-CPEH) was selected as one of the NIEHS Environmental Health Sciences Core Centers (EHS-CC). A partnership among Baylor College of Medicine (BCM), UTHealth School of Public Health (UTH-SPH), and The University of Texas Medical Branch (UTMB), the Center serves the Texas Medical Center and Gulf Coast communities as the focal point and catalyst for impactful EHS research, bi-directional communication with local communities and stakeholders, and the engine driving translation of precision environmental health research advances to improve human health. The Goals for the GC-CPEH are to:

- integrate and foster impactful EHS research
- provide inter-institutional access to resources and state-of-the-art technologies
- support and encourage community engagement
- enable rapid coordination of research and response activities during and after environmental disasters

Center research foci include:

- Early Life Genetic and Epigenetic Environment (GE2) Interactions
- Disaster Research Response (DR2)
- Mechanisms and Interventions in Human Environmental Disease

Community Engagement Core (CEC)

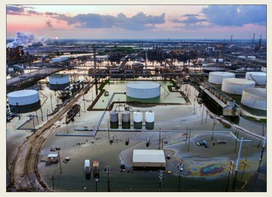
- The CEC facilitates translation of science, increases health literacy, and builds relationships that lead to research responsive to our community needs
- We improve community awareness and understanding of environmental health issues, while assisting researchers to understand concerns of importance to the community and thus inform their scientific studies
- We utilize approaches based upon the tenets of Community-Based Participatory Research, including recognizing all stakeholders as equitable partners
- Stakeholders include: investigators, community members, patients, clinicians, advocacy groups, municipalities, institutional leaders, industry partners, policy makers, veterans, and other NIEHS EHS Centers

Partnerships for Environmental Public Health (PEPH) Key Principles
Engage diverse communities
Promote the worthiest science
Respond to current issues
Focus on prevention
Foster unified, integrated, and synergistic activities
Support research to improve theories, methods, and practice
Share the value of scientific advances and translational efforts
Promote research into action

From Research to Action. . .

Research to action—including policy as a means of addressing inequities and reducing exposures—is the very basis of many past and current initiatives of the GC-CPEH Community Engagement Core.

Hurricane Harvey & Disaster Response



GC-CPEH DR2 research endeavors led to BCM receiving 5 NIEHS Time-Sensitive R21 grants for Hurricane-related research

PI	Title
Aagaard	Impact of Hurricane Harvey on the Maternal and Infant Microbiome and Birth Outcomes
Anderson	Hurricane Harvey DR2: Individual Chemical Exposure Assessments (Oregon/BCM)
Bondy	Environmental Health Outcomes Research Among Hurricane Harvey Survivors
Hamilton	Environmental Exposures, Health and Resilience before and after Hurricane Harvey in a Houston-Area Cohort of African-American Adults with Poorly Controlled Asthma
Petrosino	Incorporating the Microbiome into DR2 Activities to Inform Health Outcomes

NIH National Institute of Environmental Health Sciences
Your Environment. Your Health.

Assessment of Indoor Air Quality and Health after Hurricane Harvey

Determine the short and longer-term health effects of living in a home flooded and subsequently remediated of mold and contamination from flood waters.

- Currently, standards for remediation and clean-up are typically suspended following disasters--need to inform policy

UTMB-Rapid Acquisition or Pre- and Post-Incident Disaster Data

Umbrella disaster IRB protocol to expedite research while maximizing human subjects' protection. UT-RAPIDD protocol modeled on NIEHS protocol, which relies on a modular construction using customizable materials that can be readily reviewed and approved (1-2 days) since methods are already preapproved.

From Research to Policy. . .

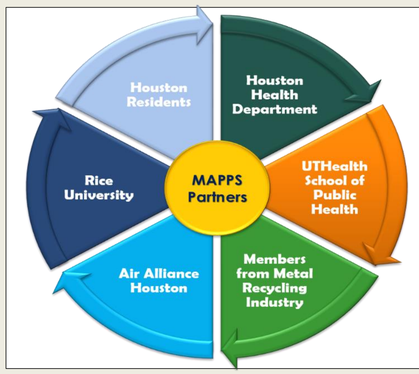
Health of Houston Survey

Supports efforts of health agencies, service providers, and community organizations to have more accurate and up-to-date health information about Houston at community level.

Regional Air Quality Assessment

BCM, UTHealth, and UTMB all contributed to regional air quality assessment planning in Houston in 2019-20. GC-CPEH also working on sharing of monitoring instrumentation and data with public health during emergent air quality events at the onset and during a disaster.

Metal Air Pollution Partnership Solutions (MAPPS)



Collaborative research-to-action project to study and address health risks associated with air emissions from metal recycling facilities in Houston.

Children's Health and Research on Metals (CHaRM)

Assessed metal exposure among children in Houston neighborhoods residing near heavy industrial activity and evaluated the impact of flooding on exposure.

Ethical Issues in Clinical and Environmental Research

- Trust
- Equity, inclusion, power
- Tolerance and conflict
- Cultural humility

- Ensuring genuine informed consent
- Sharing of data
- Acknowledging partner contributions
- Sustaining relationships w/ no funding

Gulf Coast Center for Precision Environmental Health, Baylor College of Medicine with support from the National Institute of Environmental Health Sciences under Award Number P30ES030285.

Pursuit to Post: Ethical Issues of Social Media Use by International Medical Volunteers

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Case

- During a global health elective in a low-income country, a short-term medical volunteer (MV) uses a smartphone without her consent to record a patient delivering her child.
- The MV later posts the content to their social media profile.
- Discovering this, the host clinical director freezes all current and future visiting medical volunteer participation.
- The MV defends the action by pointing out the intentional effort to avoid recording the woman's face.
- Concerned about the erosion of patient care, host leadership requests to meet with the sending program leadership to discuss the future of the partnership.

Background

- Short-term experiences in global health (STEGH), increasingly sought out by MV, last 1-4 weeks and represent a multi-billion-dollar annual enterprise.[1,2]
- Services include medical and surgical patient care, teaching, service-learning, and research.
- Many critiques exist including burdening hosts, working beyond one's skillset, dismissing local clinical practice, and power imbalances.[3,4,5]
- Far less critically examined is the escalating use of social media by MVs participating in STEGH.
- In 2019, 4 billion people had internet access, with 3.5 billion on social media.[6]
- Issues with medical professional's use of social media include professionalism, patient privacy, data management, and misinformation.[7,8]
- We present a framework to analyze ethical use of social media use by medical volunteers during STEGH.

International Partnership

Sending Program

- Does the sending program have social media use guidelines?
- Are medical volunteers required to follow these guidelines? What are the consequences if these guidelines are breached?
- Does the memorandum of understanding with the host organization cover social media use?
- Has the host organization contributed to social media guideline development?
- How is the sending program's own online activity consistent with their social media use guidelines?
- What pre-departure preparation is provided that covers ethical use of social media?

Medical Volunteer

- What is the intended use of the content? Who is it meant to benefit?
- What unintended negative consequences might result from the content capturing and dissemination process?
- Would the content perpetuate negative stereotypes or cause harm?
- Has the volunteer consulted the hosts regarding the appropriateness of content collection?
- Has consent been obtained for the collection as well as the dissemination of social media content?

Host Community

- What consequences might social media content collection and dissemination have for local hosts? For medical care?
- Has consent been obtained? Is there a process for re-consenting?
- Is there a way to retract permission at a later time?
- Have community leaders been consulted for permission?
- In which ways does local culture provide privileges to guests that might facilitate inappropriate social media use?

Host Institution

- What are the host organization's social media use policies?
- Has there been a memorandum of understanding established with the sending program covering ethical social media use?
- Has the host organization sufficiently contributed to the partnership's guidelines?
- Does the host organization have the authority to enforce consequences for guideline breaches if they occur?
- How do inherent power imbalances in the partnership challenge ethical social media policy? What pressures might host programs feel to be complicit?

Fig 1. Key considerations for stakeholders involved in STEGH

Recommendations

Medical Volunteers	• Ask, why am I capturing and disseminating this content? For the benefit of whom? • Ask, would you practice social media use the same way in your home country? • Avoid content that perpetuates negative stereotypes. • Maximize anonymity, including avoiding identifying tags within posts. • Request informed consent. Offer an opportunity for re-consent. • Consider how you would feel if the roles were reversed.
International Partnerships	• Partnerships should be built on a philosophy of mutuality and host input should be prioritized when developing guidelines. • Create an memorandum of understanding with the host institution covering social media use as well as consequences for when those policies are breached. • Create a formal consenting process that covers intended use, posting location, access, data permanence and ownership, and how to remove it. • Incorporate ethical use of social media into pre-departure training.

Conclusion

- Working overseas is not an opportunity to take a vacation from practicing professional ethics.
- Insufficient attention has been paid to social media use by MVs in STEGH and guidelines for the ethical use of social media are lacking.
- Input from host countries is essential to establish policies with the best interest of those communities most vulnerable to harm from image content extracted and disseminated by MVs.
- Sending organizations must equally value these guidelines and enforce them.
- MVs should view the visual media collection process through a lens of solidarity in order to maximize benefit and minimize harm in their use of social media.

Case Resolution

- Host leadership met with leadership for the sending program of the MV to outline appropriate hospital behavioral and social media use guidelines for visiting MVs.
- During policy deliberations, other international partners had to suspend their STEGH programs that involved clinical care.
- The host site ended the prohibition after developing guidelines and once each international partner agreed to enforce them with MVs as a requirement of continued partnership.

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