

A. Cover Page

1. Title: Leveraging Existing Health Systems and Community Infrastructure to Complete Pediatric Immunization Series in Urban Neighborhoods.

2. Grant ID#: 23151541

3. Collaborators:

Detroit Department of Health and Wellness Promotion; Detroit, MI

Henry Ford Health System, Detroit, MI

Interfaith Health and Hope Coalition, Detroit, MI

Michigan Care Improvement Registry, Lansing, MI

Wayne State University, Detroit, MI

2. Abstract:

Vaccines are widely viewed as one of the most successful public health tools in history. Despite great success globally, many children in medically underserved areas of the United States such as Detroit remain unvaccinated. At present, Detroit has one of the highest proportions of residents living below the poverty line in the United States. Although vaccines for disadvantaged children are made available free-of-charge through the federally-funded Vaccines for Children Program (VFC), recent data (June 2015) from Detroit shows that only 40% of children have completed primary vaccination series where Healthy People 2020 aims to reach 90% for several pediatric vaccines. The aim of this project is to evaluate a network of Faith-Based Organizations (FBOs) and vaccine champions who will be engaged to conduct outreach/education for vaccines and health literacy, and facilitate access points to help disadvantaged residents identify VFC clinics nearest to their current residence. The Henry Ford Health System Mobile Medical Clinic will also be engaged to provide supplemental immunization opportunities in coordination with FBOs. Parents and legal guardians will be surveyed to identify potential barriers they have encountered in the course of seeking immunizations for their children. Individual vaccines and primary vaccination series delivered to children will be recorded and tracked using the Michigan Care Improvement Registry. We expect this innovative program to significantly increase childhood immunization rates among disadvantaged Detroit families living in poverty. The lessons learned and best practices implemented during this project will be analyzed to identify optimal strategies for generalized use among other low income populations suffering from disparities in childhood immunizations across the United States.

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C. Reviewer Comments on LOI

Multiple panel members are concerned about the IRB timeline. While they appreciate the study design and desire to implement this intervention in a way that can be documented and disseminated, they feel the IRB timeline seems tight given the number of partners involved. Please address this concern in the Full Proposal. We sincerely appreciate this important insight and it is an excellent point. We have carefully revisited the IRB review timeline. Based on extensive local experience with multiple, sequential/parallel institutional reviews (e.g., Wayne State University, Henry Ford Health System (HFHS), and others), we will prepare IRB applications with requisite paperwork in advance of the anticipated project start date. Taking advantage of this additional lead time has been a highly effective strategy in expediting IRB Reviews across multiple institutions. In addition, WSU and HFHS IRB recognize reviews of one another's IRB review committees and this has the effect of streamlining reviews. The Interfaith Health and Hope Coalition (IHHC) is a key partner and a community-based organization that does not utilize an IRB but the Board of IHHC has already provided initial project review and when the full protocol is ready for IRB submission, copies of this document will be provided to the IHHC Board for their review and approval. The IHHC Board is composed of highly respected faith and health leaders across the City of Detroit and their insights will be extremely valuable in protocol development and implementation. In parallel with IRB reviews at WSU and HFHS, we will process through City of Detroit administration and the City of Detroit Department of Health and Wellness Promotion. A total of five months are allocated for the IRB application and review and is noted in the Project Timeline table. Our experience has proven that this will be sufficient time for approval.

Please provide a clearer description of what the project will entail in the program design and methods section of the Full Proposal. Specifically, include more detail on how faith based organizations will be engaged. In the project description, we provide description of the approach for FBO engagement. In brief, we have established a very close partnership with the IHHC over the past four years. In this partnership, we have been funded through two grants from the Detroit Community-Academic Urban Research Center (Detroit-URC; <http://www.detroiturc.org/>). Through our partnership with IHHC, we directly engage a broad coalition of faith-based organization (FBOs) whose congregations are located in the City of Detroit. For residents in zip codes targeted for immunization strengthening, IHHC will facilitate outreach and engagement with institutional leaders, congregants and in turn, residents and families in neighborhoods around the FBOs. Additional details are provided in relevant sections of the accompanying proposal.

Please provide clarity around the evaluation. Will need to clarify information around the process of administering and collecting data on the surveys. How will you ensure the return of surveys and health providers? How will the surveys be administered? Surveys will be conducted among parents/legal guardians and older adults who accompany children to immunization clinics. Surveys will be conducted in face-to-face interviews by Project Staff, Pharmacy and Public Health Students (as part of academic credit internships and directed study experiences). Surveys of providers will be conducted in a similar fashion. Survey form data will be abstracted and entered into electronic databases for data analysis. Additional details on survey data collection and analysis are provided in relevant sections of the accompanying proposal.

D. Main Section of the proposal

1. Overall Goal & Objectives

The goal of this program is to evaluate the impact of health system level innovations that improve delivery of pediatric immunizations among underserved children in Detroit, Michigan.

1. To identify barriers to delivery of infant and childhood immunizations in medically underserved neighborhoods with traditionally low vaccine coverage in Detroit.
2. To provide training for community-based Vaccine Champions that facilitates outreach and education efforts by members of faith-based organizations located in disadvantaged neighborhoods of Detroit.
3. To deploy the Henry Ford Health System (HFHS) Mobile Medical Clinic and coordinate mobile immunizations with VFC providers to facilitate visits by parents and children to vaccine access points to receive routine childhood immunizations.
4. To measure the effect of community-based interventions on individual childhood vaccine coverage rates and rates for standard pediatric vaccine series.

2. Current Assessment of need in target area

a. Describe the need for this project in your target area.

In Detroit, like other urban areas of the U.S., infants and children living in medically-underserved and economically disadvantaged neighborhoods are less frequently vaccinated with routine, recommended vaccines. Since the financial crisis, a number of demographic and socioeconomic changes have negatively affected the City of Detroit population and accentuated health disparities.^{1,2} During the financial crisis that preceded Detroit's bankruptcy, the City of Detroit health department transferred several public health programs to an independent, nonprofit agency (Institute for Population Health). In the past two years, a new City Administration as well as emergence from Bankruptcy has led to re-constitution of the City of Detroit Department of Health and Wellness Promotion. Within the City health department, immunization services are now managed and delivered through Vaccines for Children (VFC) clinics.

In 2004, Rosenthal *et al.*, measured the completion of 43133 series immunization coverage in children aged 19–35 months in medically underserved regions in Detroit, New York City, San Diego, and rural Colorado. In this study, Detroit had the lowest rates of primary immunization series completion (66%) when compared with San Diego (86%), New York (84%), and rural Colorado (75%).³ Approximately a decade later, in 2013, data from the Michigan Care Improvement Registry (MCIR) showed that rates of primary vaccine series completion in Detroit remain low at 66%. The flat rate of vaccine coverage for children underscore the urgent need to identify novel strategies that significantly increase immunization rates particularly in medically-underserved areas of the city in which rates of household poverty and numbers of children living in poverty is high.

b. Quantitative baseline data summary.

In Michigan, 312 babies are born daily who will need to be immunized before age two against 14 vaccine-preventable diseases (VPD). (Michigan Department of Health and Human Services, 2013) Despite efforts to make childhood vaccines available in socially-economically diverse populations, pockets of underimmunization persist across the US (including the City of

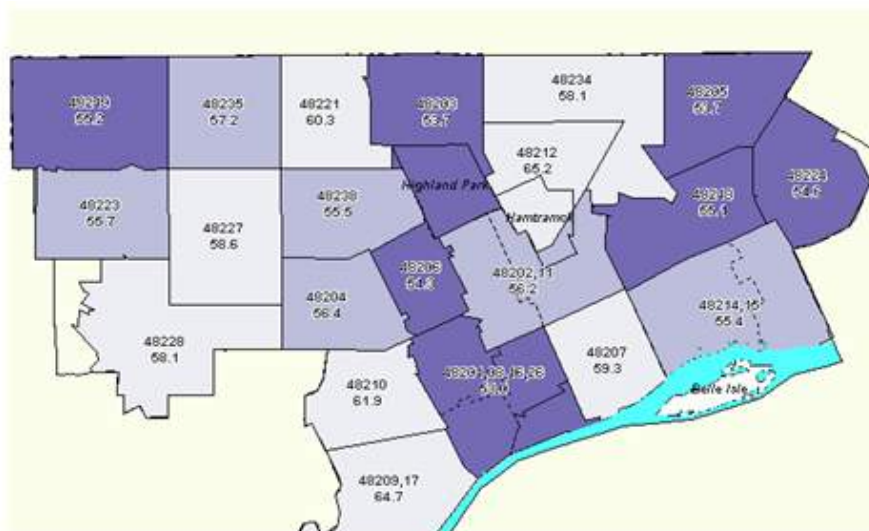


Figure 1. Percentage (coverage) of children 19–35 months immunized for 431331 series by zip codes in Detroit, 2009.

Detroit). **Figure 1** illustrates pediatric immunization series (431331) coverage among children 19-35 months of age across zip code areas in Detroit during 2009 (darker shaded areas show zip codes with lowest coverage). These data, from MCIR, shows that children of Detroit have had low vaccination rates compared with state-wide rates and national rates (<https://www.mcir.org/>).

In 2013, **66%** of Detroit children (19--35 months of age) completed the primary vaccine series (4313314) while state-wide coverage rate for these series of vaccines was 74%. In 2015, completion of 4313314 primary series has been maintained at 74%, the coverage rate in Detroit has dropped by 2.2% (**63.8%**). For the vaccine series including 2 doses of Hepatitis A vaccine (43133142), 2015 coverage in Michigan and Detroit stands at 51% and **40%**, respectively.

3. Target Audience

- a. Describe the level of commitment from the potential participants including your plan for recruitment as necessary.

A key audience for this project are lay persons

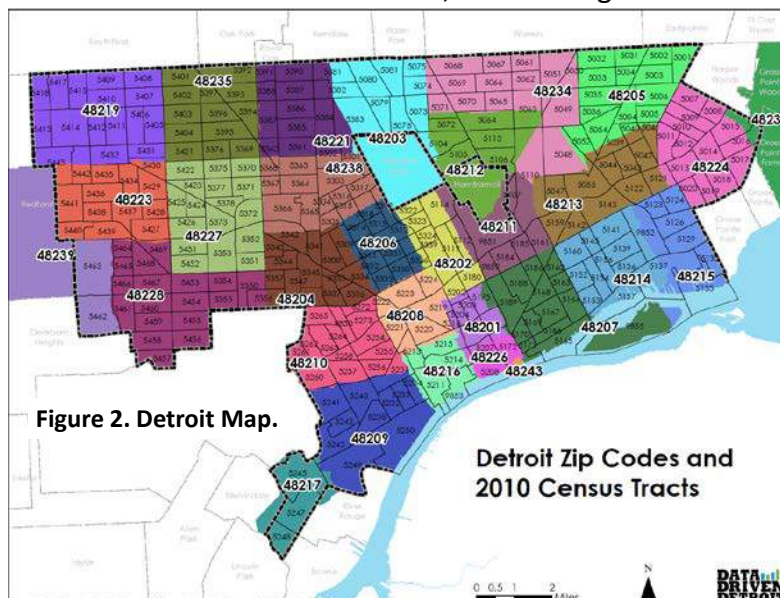


Figure 2. Detroit Map.

Detroit Zip Codes and 2010 Census Tracts

including parents, families with newborns, infants and children <5 years of age living in the City of Detroit

(Figure 2). In 2013, the total population of Detroit was 688,701 with ~7% (n=~48,209) <5 years. (United States Census Bureau, 2013) Within Detroit, 83% are Non-Hispanic Black/African-American, 11% Non-Hispanic White and 6.8% Hispanic/Latino, 1.1% Asian and 0.4% American Indian.⁴ Such groups (and their care providers) are known to have disparate health beliefs including those around immunizations.^{5, 6} This project will engage community leaders, immunization program staff, nurses, clinicians who deliver immunizations in Detroit as well as established medical societies. In Detroit, several faith-based organizations (FBOs) exist across a wide range of religious affiliations and denominations **(Figure 3).**

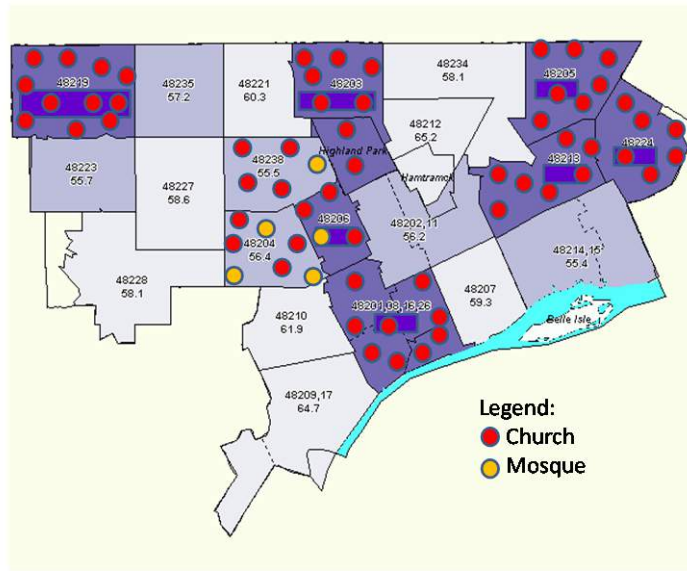


Figure 3. Distribution of faith-based organizations in intervention zip codes.

In coordination with leading regional health systems such as the HFHS, our Project Team will work in close partnership with HFHS Community Outreach Team, clinicians and social service staff. This partnership is further strengthened by the presence of the Interfaith Health and Hope Coalition (IHHC) that is a Project Partner organization. In cooperation with IHHC, we have mapped out FBOs in zip codes where children are at higher risk of underimmunization **(Table 1).**

Table 1. Faith-Based Organizations in Zip Code areas where children are underimmunized.		
Zip Code	FBO Name	Street Address
48201	Cathedral Church of St. Paul	4800 Woodward Ave.
	Cass Community United Methodist Church	3901 Cass Ave.
	Plymouth United Church of Christ	600 E Warren Ave.
	WSU, Islamic Center of Detroit	4646 Cass Ave.
48203	Glad Tidings Church-God-Christ	625 E 7 Mile Rd
	New Mt Moriah Baptist Church	13100 Woodward Ave.
	Prayer Temple of Love	17 Highland St.
	St Benedict Catholic Church	60 Church St.
	Soul Harvest Ministries	16300 Woodward Ave.

Table 1. Faith-Based Organizations in Zip Code areas where children are underimmunized.		
Zip Code	FBO Name	Street Address
	Metropolitan A.M.E. Zion Church	17816 Woodward Ave.
	New Life Christian Assembly Church	19975 John R St.
48204	God's Word Baptist Church	4100 Oakman Boulevard
	Northwest Church of Christ	5151 Oakman Blvd
	Unity Baptist Church	7500 Tireman Ave.
	Nazareth Evangelical Lutheran	4321 Vicksburg St.
	Islamic Center Of Detroit	14350 Tireman Ave.
	Bait ul Muzaffar Mosque	8218 Wyoming Ave.
	Al-Huda Islamic Association	5838 Lawndale St.
48238	New Destiny Baptist Church	8100 Davison W.
	Linwood Church of Christ	14001 Linwood St.
	Church of the New Covenant Baptist Church	3426 Puritan St.
	Greater Emmanuel Church of Christ	15701 James Couzens Fwy
	Muhammad's Mosque	14880 Wyoming Ave
48226	Fort St. Presbyterian Church	631 W Fort St.
	St. Aloysius Parish	1234 Washington Blvd.
	Second Baptist Church of Detroit	441 Monroe Ave.
	Central United Methodist Church	23 E Adams Ave.
48208	Spirit of Hope Church	519 Martin Luther King Jr.
	Tabernacle Missionary Baptist Church	2080 W Grand Blvd.
	Mayflower Missionary Baptist Church	2270 W Grand Blvd.
	Moorish Science Temple-America	5601 Grand River Ave.
48206	Shrine of the Black Madonna	7625 Linwood St.
	Masjid Wali Muhammad	11529 Linwood St.
	Clinton Street Bethlehem Church	2900 Chicago Blvd.
	Grace Temple COGIC	12521 Dexter Ave.
48216	St Anne's Detroit	1000 St Anne St.
	Grace to Grace Christian	2300 17th St.
	New Westside Central Baptist Church	1426 18th St.
	Messiah Church	3816 Toledo St.
48219	First Baptist World Changers	22575 E 8 Mile Rd.
	Harvest Christian Church	24400 W Seven Mile Rd.
	New Hope Tabernacle	20221 Lahser Rd.
	Corpus Christi Church	19800 Pembroke Ave.
	Detroit Free Methodist Church	17377 Westbrook St.
	St Scholastica Parish Catholic Church	17320 Rosemont Ave.
	Redford Lutheran Church	22159 Grand River Ave.
	Christ the King Church	20800 Grand River Ave.
	Community of Christ - Detroit Hope	16621 Lahser Rd.

Table 1. Faith-Based Organizations in Zip Code areas where children are underimmunized.

Zip Code	FBO Name	Street Address
	Christian Fellowship of Love Baptist Church	22400 Grand River Ave.
	Miracle Tabernacle Church-God	20210 Schoenherr St.
48205	St Raymond's Parish	20103 Joann Ave.
	Light of the World Christian Church	14550 Gratiot Ave.
	St. Jude Roman Catholic Parish	15889 E 7 Mile Rd.
	Mt Calvary Lutheran Church	17100 Chalmers St.
	Assumption Grotto Catholic Church	13770 Gratiot Ave.
	New Beginnings Baptist Church	12434 Seven Mile E.
	St Ignatius Church	5555 Conner St.
48213	Miracle-Faith MBC Miracle	10510 Sterritt St.
	Faith Clinic	12260 Camden Ave.
	Immanuel Lutheran Church	13031 Chandler Park Dr.
	Impact Church	12844 Elmdale St.
	Community Christian Fellowship	8131 Outer Dr. E.
	Peace Lutheran Church	15700 E Warren Ave.
48224	Saved By Grace Christian	16225 E Warren Ave.
	Bethany Lutheran Church	11475 Outer Dr. E.
	Bethany Christian Church	5901 Cadieux Rd.
	St Matthew Church	6021 Whittier Ave.
	Peace & Goodwill Baptist Church	20500 Moross Rd.

b. Demonstrate the scope of your target audience has a potential to impact the goal established in this proposal.

Over the past 3 years, we have carefully consulted with community organization partners, pediatric and public health care experts, faith-based organization leadership, community members and parents to understand health priorities, system challenges and recent trends in immunization rates among Detroit’s children. These efforts have been essential to identifying barriers to childhood immunizations in Detroit.^{7,8,9} MCIR data provide a stark picture across more than 25 zip codes of Detroit. Comprehensive data from MCIR provide numbers of children less than age 2 years who are eligible for childhood vaccinations. The MCIR system also allows tracking of immunization coverage data by zip code. Our analysis shows that several thousand children <2 years are in need of routine immunizations. To impact immunization rates in this project, we will focus on zip codes with the lowest immunization rates in order to effect maximum impact of our partnerships. Our target audience for this project is also represented by vaccine professionals working in Southeast Michigan who have organized to form the Alliance for Immunizations in Michigan (AIM; <http://www.aimtoolkit.org/>). AIM tools have been developed for professionals in Michigan based on national standards.¹⁰ Our project also represents a superb opportunity for sharing of these best practices across a broad group of stakeholders in Detroit.

c. Describe who will directly benefit from the project outcomes. Include in this description whom, beyond the primary target, would potentially benefit from the project in terms of this being a model for others to replicate or expand.

Families (including infants, children, parents, legal guardians, grand parents and other family members) will directly benefit from the outreach, education and immunization intervention delivered in this project. Intervention areas are identified by zip code (**Table 2**) and list the estimated number of children based on eligibility figures determined in MCIR.

Through strong existing community organization partnerships maintained through existing research collaborations by the PI, the leadership of partner organizations will be brought together with attention in this project focused on representative Detroit neighborhoods in need. In addition to the direct beneficiaries (i.e., babies, children, parents and families in Detroit), this project will strengthen ties between academic leadership, multi-disciplinary scientists, faith-based organizations (including their leadership and congregants), community-based health providers (e.g., Federally-Qualified Health Centers [FQHCs], health systems (e.g., HFHS) and local government agencies.

With our focus on immunization of babies and children, this project is directly aligned with and complements the Detroit Mayor's initiative and partnerships established to reduce infant, child and maternal mortality. In addition, the presence of the US NIH Perinatal Research Branch (an intramural unit of the US NIH) on the Medical Campus of Wayne State University provides a unique resource as well as an additional group of beneficiaries with whom lessons learned and best practices will be shared (www.med.wayne.edu/prb/). We also anticipate that results of this project will be instructive in learning how interaction with parents/guardians and families around immunizations will serve as a gateway or conduit for family and children's enrollment into Medicaid or other health insurance programs. This project also will have potential for connecting families to sustained care in a designated medical home that will enable well child visits and continued access to immunizations in adolescence and adulthood.¹¹

Geographically, because the City of Detroit is contained within Wayne County, by direct extension, this project will provide additional benefit through sharing of experience, lessons learned and best practices with health and human service agencies of Wayne County. As a leading urban National Research University, Wayne State University also maintains strong ties to neighboring universities (e.g., University of Michigan, Michigan State University, Oakland University) and county governments (Oakland, Macomb and Washtenaw).

A important additional beneficiary and partner agency is the Detroit Community-Academic Urban Research Center (Detroit URC).^{12, 13} The Detroit URC has funded two previous community research focused grants that support the IHHC (Mr. Ronald Beford, Executive Director) and Dr. Kilgore. The Detroit URC and its Board have a well-established track record of community-participatory research and it is these research principles and methods that the IHHC, Dr. Kilgore and partner organizations apply in their ongoing studies in Detroit. As a model for community-based participatory immunization program strengthening, the collaboration demonstrated in this project provides an excellent model for urban populations in which FBOs and regional health systems join forces to leverage their existing networks and resources. We look forward to sharing all lessons learned, tools and evidence from this project with stakeholders across the U.S.

4. Project Design and Methods

a. Description of overall strategy, methodology and analysis linking them to project goal. Our program will leverage a) an existing public health Vaccines for Children (VFC) clinics, b) a faith-based organization network and c) the HFHS Mobile Medical Clinic and apply these resources to raise awareness and access to childhood immunizations. The planned program will

complement existing delivery points of pediatric vaccines for underserved populations that are delivered through approved Vaccines for Children (VFC) immunization providers in Detroit.¹⁴

In coordination with the Detroit Department of Health and Wellness Promotion (DHWP), existing VFC providers in the intervention zip code areas of Detroit.

Notably, our project will engage VFC providers across Detroit that take care of a range of residents including those without insurance,

undocumented children as well as those who are homeless.^{15, 16} Clinics will be equipped and staffed for an addition two days per month to administer pediatric immunizations in the 4313314 and 43133142 series. To increase health literacy, vaccine awareness, FBO leaders in minority communities located in eight intervention zip codes (**Table 2**) will be networked in close collaboration with the Interfaith Health and Hope Coalition (IHHC). The FBOs network, led by IHHC will bring together nominated FBO Vaccine Champions who are members of their

Table 2. Number of children in intervention and non-intervention zip codes.		
Zip Code Area	Intervention Arm Population Estimated # Eligible Children	Non-Intervention Arm Population Estimated # Eligible Children
48201, 48208, 48216, 48226	587	--
48204	395	--
48205	--	1,178
48206	490	--
48213	--	758
48219	837	--
48224	--	927
48238	378	--
Total	2,687	2,863

respective congregations with an active concern for the health of children and who will serve as FBO neighborhood-level resource persons for vaccine-related health information. Vaccine Champions will also serve to guide parents/guardians and other family members to existing VFC clinics and will actively announce and disseminate information so residents will also be able to plan their visit to the HFHS Mobile Medical Clinic (**Figure 4**) when the Mobile Clinic is due to be in their neighborhood.

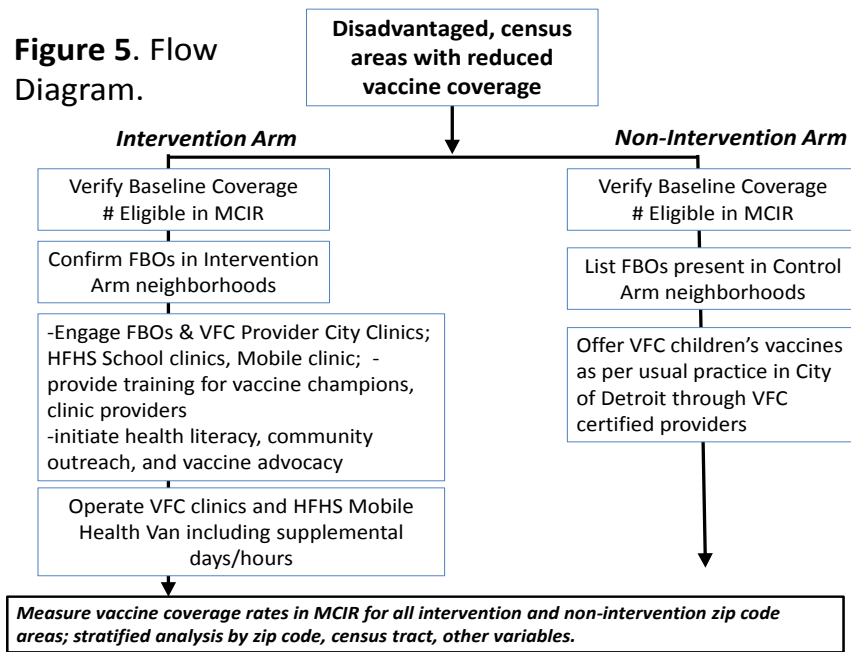


Figure 4. Mobile Medical Clinic, Henry Ford Health System.

Operationally, the HFHS Mobile Medical Clinic is operating routinely from 8:30am to 3:30pm (school hours), Monday through Friday. In this project, the Van will be mobilized to vaccinate

children in pre-announced, advertised designated areas of FBOs (e.g., parking lots). The Van will be mobilized on pre-determined days during which the van will be made available either during evening hours (e.g., 7pm to 9pm) and/or weekend days (Saturdays or Sundays, e.g., ~11am to 3pm). Hours to be offered will be coordinated with FBO leaders to maximize outreach and attendance (e.g., Sunday hours after church services to provide direct access to Van after church services; Mosque services on Friday mean that services Friday Prayer best offered ~2pm to 5pm). The HFHS Mobile Medical Clinic has wireless internet access onboard and all children vaccinated will have their state immunization record electronically updated in real-time using the internet-based MCIR.

Figure 5. Flow Diagram.



The project protocol and relevant appendices will be provided for Institutional Board Review (IRB) review and approval at Wayne State University, HFHS, and the City of Detroit.

To facilitate evaluation of intervention impact,

this project has identified zip code areas with low childhood immunization coverage rates (**Figure 5**). A control (non-intervention) study arm has been assembled for this study (**Figure 6**). The non-intervention arm zip codes represent areas within the City of Detroit that also suffer from low vaccine coverage. The majority of zip code areas allocated to either the intervention or non-intervention groups are contiguous to minimize opportunities for cross-contamination with respect to the study intervention (i.e., increased vaccine access through the HFHS Mobile Medical Clinic and outreach/education through FBOs). The remaining zip codes are non-contiguous and therefore, the likelihood of cross-contamination has been minimized. For both groups, baseline immunization rates for all vaccine antigens and for the standard series (4313314 and 43133142) will be measured using the most recent MCIR data (data now being processed by the MCIR staff will be shared in forthcoming communications with Pfizer staff and external reviewers as desired). Our project team members are performing regular updates to ensure that the list of faith-based organizations located in the City of Detroit is accurately listed by zip code. In addition, through our cooperation with the City of Detroit Department of Health and Wellness, our project team performs regular updates of all VFC-certified immunization clinics (including address, resource staff and hours of operation).

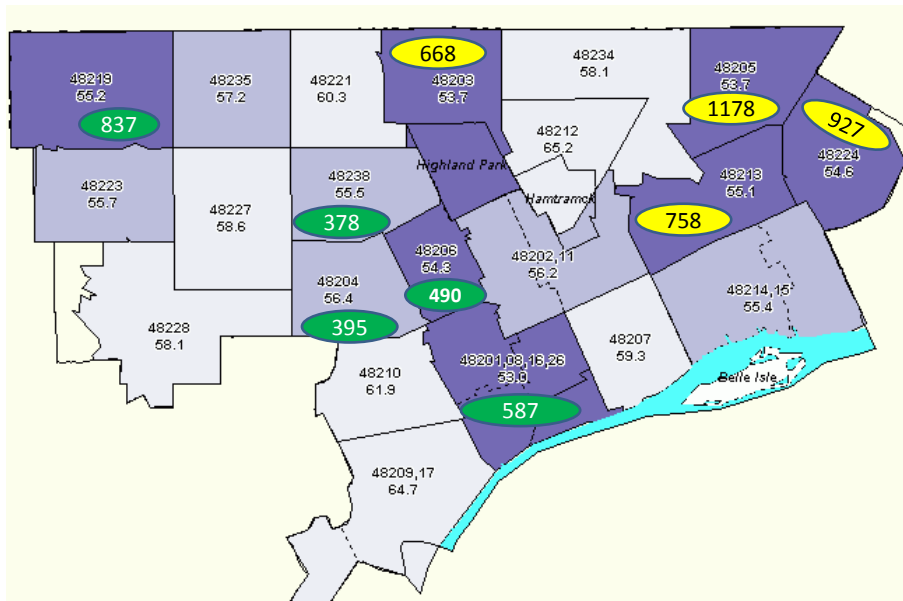


Figure 6. Percentage (coverage) of children 19—35 months immunized for 431331 series by zip codes in Detroit, 2009. ● Intervention arm. ● non-intervention arm

b. Describe way project planned addresses established need and produces desired results.

This program is directly focused on leveraging existing community assets to effect significantly increased rates in childhood immunizations. The children in need have been objectively identified in an evidence-based

fashion using MCIR data. Residents living in disadvantaged neighborhoods in zip code areas with eligible children with the focus of community-FBO family outreach, education and advocacy. Our project team will also liaise directly with existing social service organizations, homeless shelters, FQHCs, and women’s/infants/children (WIC) program providers to ensure broad communication of project mission, objectives, avenues for immunization, and resources for families needing immunizations. During roll-out of the outreach and education, our implementation plan incorporates a series of monthly community meetings held in rotating locations within the intervention zip code areas. These monthly meetings will enable recognition of community resident contributions to immunizing children, reporting back to community on numbers of children immunized, types of vaccines provided, review of potential missed opportunities, review of lessons learned and communication of best practices for outreach, education and advocacy.

In this project, Project partner organizations (including IHHC, Wayne State University, and HFHS) will work in directly with faith based organizations. Drs. Kilgore and Salim have engaged FBO leaders over the preceding four years across Detroit and this foundational work together with small grant funding to Dr. Kilgore and the IHHC (Mr. Ron Beford) provides a superb platform for FBOs engagement. In Detroit, with the prominent role of faith-based leaders and their congregation members (congregants), community residents will be provided with immunization educational information, information on where to access vaccines and deepened understanding of vaccine safety and effectiveness.

To facilitate engagement of FBOs, a series of four focus groups will be conducted to identify perceived barriers and facilitators to health literacy, vaccine education and community outreach in intervention arm neighborhoods. Results of these focus groups will be reported back in face-face meetings with FBO leaders and roundtable discussions organized by Mr.

Ronald Beford of the IHHC. In addition, three focus groups will be conducted with nurses and other VFC clinic staff to identify potential barriers to improving vaccine coverage rates in children of Detroit. Focus group findings will be reported back to participants as well as organizational leadership in the FBOs, the City of Detroit, the HFHS, and all VFC providers in Detroit and surrounding counties. The focus group discussions and FBOs outreach to community leaders will be used to finalize the deployment strategy that maximizes impact of the HFHS Mobile Medical Clinic in the zip codes targeted for intervention.

The participation of FBO leaders from the outset of this project represents a unique component. In particular, FBO leaders and their designated Vaccine Champions will:

1. Help to educate parents, grandparents, families, neighbors and teachers regarding the benefits and availability of important life saving vaccines (educate for vaccination).
2. Help community residents understand when, where and how they can bring children to be immunized (advertise and market sites for vaccination).
3. Help to set up and coordinate evening or weekend vaccination clinics on selected dates so parents and families can bring babies and children to receive free vaccines (vaccination clinics).
4. Identify ways in which vaccination clinics can add value to existing spiritual health programs in different communities across Detroit.
5. Communicate with parents, grandparents, friends, family, neighbors, teachers and others to identify ways in which future vaccination activities can be planned to best fit the needs of residents in the community.

c. Sample size estimation.

To estimate the minimum number of parents and children to engage in this project to evaluate the effect of the community-based intervention, we formulated our sample size based on a binary outcome superiority trial design.¹⁷ In this way, our primary outcome of interest is vaccinated (yes/no) compared in the intervention versus non-intervention population. With goal of demonstrating that the community-based education and outreach through FBOs and the Mobile Medical Clinic delivering vaccines for children, we assumed a significance level (alpha) equal to 5% (0.05), Power (1-Beta) equal to 90%, percentage ‘success’ (i.e. vaccinated in the non-intervention arm) of 65%, percentage ‘success’ in the intervention (experimental) group equal to 80%. With these assumptions, a total of 364 children (182 per arm) are required to have a 90% chance of detecting an increase in vaccination rates from 65% in the non-intervention arm to 80% in the intervention arm.

Alpha	Beta	% Success, Non-Intervention	% Success, Intervention	Total SS	Adjustment for Crossover	Adjusted SS
5%	90%	65%	80%	364	10%	450
5%	80%	65%	80%	272	10%	336
5%	90%	70%	80%	778	10%	962
5%	80%	70%	80%	582	10%	720
5%	90%	70%	80%	778	20%	1,216

Table 3. Sample Size Estimations including total and adjusted minimum sample sizes (SS).						
Alpha	Beta	% Success, Non-Intervention	% Success, Intervention	Total SS	Adjustment for Crossover	Adjusted SS
5%	80%	70%	80%	582	20%	910

Assuming the possibility of cross-over from non-intervention to intervention groups once community education, outreach and advocacy programs are in full-swing, and assuming a cross-over of 10% in the non-intervention group, the adjusted total sample size required would be 450 (225 per arm). Additional sample size estimates are provided assuming 20% adjustment for non-compliance or cross-over from the non-intervention to intervention group (**Table 3**). This sample size is based on the formula: $n = f(\alpha/2, \beta) \times [p_1 \times (100 - p_1) + p_2 \times (100 - p_2)] / (p_2 - p_1)^2$ where p_1 and p_2 are the percent 'success' in the control and experimental group respectively, and $f(\alpha, \beta) = [\Phi^{-1}(\alpha) + \Phi^{-1}(\beta)]^2$ Φ^{-1} is the cumulative distribution function of a standardized normal deviate.¹⁸ Adjustment for cross-over based on formula: $n_{adj} = n \times 10,000 / (100 - c_1 - c_2)^2$ where c_1 and c_2 are the percent cross-over in the control and experimental group respectively.

d. Indicate how you will determine if target audience was fully engaged.

Social marketing, advertising and outreach will be conducted and closely coordinated with the Detroit DHWP. The research team will conduct survey FQHC patients, FBO congregants, residents of homeless shelters. Surveys will query a sample of 300 parents and guardians in waiting rooms of Detroit area FQHCs regarding their awareness of immunization access and awareness of immunization education information delivered through print, radio, TV, internet, person-to-person means of communication and through leadership of FBOs. This survey, conducted at two time points (See Timeline, will also assess barriers to immunization.

e. Description of measures taken to assure project idea is original.

The project team has undertaken a comprehensive review of published and unpublished work through PubMed and other databases. The project team conducts ongoing networking with US CDC, Michigan Immunization Program of the Michigan Department of Community (MDCH) Health and the National Association of County and City Health Officials (NACCHO). We have confirmed that this project has not been duplicated elsewhere.

f. Show how project builds on existing work, pilot projects, or ongoing projects developed either by your institution or other institutions related to this project.

This proposed project builds on work that our project team and community partners have conducted in the City of Detroit over the previous five years to understand system-level factors affecting immunizations. We have conducted quantitative and qualitative research focused on community and healthcare organizations using community-based participatory models. We have identified system level barriers to adult immunization for residents of Detroit from socio-economically disadvantaged areas. Mr. Ron Beford of the IHHC and Dr. Kilgore are also currently funded through a small grant program from the Detroit URC—a University of Michigan-sponsored organization originally funded by the US CDC to develop community-based participatory research in and around the Detroit area. Through this

existing community-based partnership grant funding, Dr. Kilgore and Mr. Beford have established a very strong network with local FQHCs, the Detroit Parish Nurse Network of Southeast Michigan and FBOs.

g. If project includes development of tools note if they be available publically at no cost.

This project will make all parent/guardian survey tools, test evaluations, questionnaires and other tools available publicly at no cost. Dissemination of these tools will be through the Wayne State University Website, HFHS information network, Community organization websites and Faith-Based Organizations. Because the PI, Co-PIs and collaborating organizations are nationally networked, tools developed in this project will be disseminated and made available in a national network that includes immunization experts, National Association of County and City Health Officials (NACCHO), state immunization program directors in state health departments and staff of the US CDC, Atlanta, GA.

5. Evaluation Design

a. In terms of metrics used to assess need for project, describe how you will determine if the practice gap was addressed for the target group.

- *Identify the sources of data that you anticipate using to make the determination.* For this project, we have directly engaged staff of the State of Michigan Immunization Division and MCIR (Please see the organizational page for more information on MCIR). To evaluate changes in resident knowledge, we will conduct pre-post surveys of knowledge, attitudes and beliefs around pediatric immunization. These survey responses will be analyzed in conjunction with qualitative data obtained from parent, provider and FBO leader focus groups conducted to assess barriers and opportunities for immunization in Detroit.
- *Describe how you expect to collect and analyze the data.* MCIR electronic data will be collected from zip codes within Detroit to compare rates of immunization for children living in intervention and non-intervention zip code areas. MCIR databases will be accessed to abstract demographics including age, gender, and zip code information. Address information will be recoded to estimate vaccine coverage by census tract area based on existing US Census Bureau tracts. Univariate data analysis and multivariate modeling will be performed to evaluate the impact of the project intervention. These analysis will utilize variables on age, gender, geographic area (zip code, census tract), and other socio-demographic variables to example differences across variable categories in both the intervention and non-intervention arms of the study. Geographic analysis of immunization coverage rates as well as timeliness of immunizations will be evaluated using MCIR databases.¹⁹⁻²¹
- *Describe how you will determine if the results evaluated are directly related to the intervention.* The neighborhoods allocated to the intervention and control groups will be identified through analysis of baseline and pre-intervention MCIR pediatric immunization rates stratified by zip codes in Detroit. Intervention neighborhoods will be selected from zip codes with lower immunization rates across at least 3 ranges

(e.g., <50%, 51-60% and \geq 61%). The comparison, non-intervention areas will be identified from neighborhoods within zip codes with immunization rates. We will balance other factors (e.g., demographic, clinic access) that could potentially influence immunization rates using our detailed data on the distribution of population and clinics in Detroit. Neighborhoods across these 3 strata will be randomized to intervention and control groups in order to balance these factors outside of the intervention. In our pre-initiation and baseline periods for this project, we are now conducting and will continue to conduct active outreach to government and community organizations around the City of Detroit to ascertain the presence of other programs or initiatives focused on maternal and child health. Due to our extensive professional network that extends into clinical pediatrics, family medicine, public health, academia, FQHCs, community organizations, and the faith-based organizations throughout the City of Detroit, we are extremely well positioned to become aware of any programs that may positively or negatively influence childhood immunization coverage rates.

b. Quantify amount of change expected from this project in terms of your target audience (e.g., a 10% increase over baseline or a decrease in utilization from baseline between 20-40%).

We expect at least a 15% improvement in the series childhood immunization rates among children who have been targeted by the intervention.²² Analysis of specific vaccine antigen coverage will also be performed using the MCIR datasets that also capture individual immunization coverage data. This estimate is based on a review of potential interventions. For this project, we have constructed a dedicated *Statistical Analysis Plan* document. This document contains a detailed roadmap for data analysis and takes into account neighborhood, community and individual level variables that we have accessed in data from sources including the US Census Bureau, Data Driven Detroit, and MCIR. Statistical analysis will be performed to evaluate series immunization completion & up-to-date status as recommended by ACIP.

c. Describe how you plan for the project outcomes to be broadly disseminated.

Results will be widely disseminated to a) local government health agencies and offices in Detroit, b) State of Michigan Immunization Division and the MICR offices; c) US CDC childhood immunization program staff; d) and medical society Boards, Officers and membership. Results will be shared with VFC providers, FBOs and community organizations, local Michigan and Wayne County medical society members, professional organizations and societies via webinar format, PowerPoint slides, newsletters, pamphlets, radio and through public relations offices of Detroit and Wayne State University. Interim and final results will be presented at the professional meetings including the National Immunization Conference, the American Public Health Association Conference, the Pediatric Research Conference and IDSA/ICAAC Annual Meetings. Results will be submitted for publication to US and international peer-reviewed scientific journals within 4 months of project conclusion.

6. Detailed Work plan and Deliverables Schedule

Program activities, milestones, deliverables and anticipated completion dates.

The following activities span a 2-years project period starting January 2016—December 2017 (Table 4). A comprehensive project implementation strategy will be enacted in November 2015 to anticipate a series of activities due to take place starting with final editing of project SOPs and preparation of educational and outreach materials.

Activities	Month	Milestones	Deliverables	Completion
Organizational meetings, Standard Operating Procedures (SOP), educational materials preparation	-2, +1	- Completed SOPs -Educational materials prepared & incorporated into the final protocol	Completed SOP, educational materials & protocol manual	Jan. 30, 2016
Preparation of educational materials for organizational leaders, FBO champs, clinic staff)	-1, to +2	-Michigan and National sources of vaccine information are identified, reviewed & synthesized	Assembled collection of vaccine educational brochures, slides, and handouts	Feb 20, 2016
Advertising, educational and other vaccine info for stakeholders	-1, +2	-Input received following stakeholder review of materials	Final version of advertisements, printed materials	February 28, 2016
Finalize project protocol for IRB	-1, +2	-Partner organizations input received on final protocol	Printed protocol readied for IRB app.	February 28, 2016
IRB submission for review and approval	+2 to +4	-Completed Institutional Review Board application	-IRB approval letters	April 30, 2016
Updated final 2015/early 2016 baseline coverage data	-2 to +4	-Completed baseline data collection	-Electronic report of baseline data	April 30, 2016
Preparatory activities for enhanced vaccine clinics	+5 to 7	-Completed all clinic visits & staff meetings -Verify vaccine supplies -Targets for advertising identified -Outreach plan reviewed	-Full plan for vaccination clinic activities, clinic schedules, advertising roll-out and FBO champ	July 31, 2016

Table 4: Timeline and Milestones and Deliverables.

Activities	Month	Milestones	Deliverables	Completion
		by all stakeholders	outreach	
Community outreach training	+8 to +8	-Completed training of vaccine champions, other FBO members and vaccine clinic staff in education of residents	-Report of training workshops; pre/post test results & list of vaccine champions, clinic staff and their areas of outreach	Aug 30, 2016
Delivery of vaccines for children and monitoring of vaccination program	+8 to +20	-Monthly review of MCIR coverage data with vaccination sites -Community mtgs to gather input on progress	-MCIR vaccine coverage data reports -Narrative report on community engagement	Aug 30, 2017
Parent/guardian survey of barriers	+9, +16	-qualitative & quantitative assessment completed	-Written report of parent/guardian surveys	Oct 2016; May 2017
Outcomes, final analysis	+22	-acquisition of final MCIR data on vaccine uptake and distribution	-electronic dataset on immunization with covariates	Oct 30, 2017
Results reporting and dissemination to stakeholders	+23 to +24	-aggregation of final vaccine coverage dataset from MCIR	-final project report, peer-reviewed publications	December 15, 2017

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