

Chapter 1 : Vulnerable Populations: Who Are They?

Despite efforts and goals in the United States to reduce or eliminate disparities in healthcare by , significant disparities, including risk factors, access to healthcare, morbidity, and.

This article has been cited by other articles in PMC. Civil rights violations from the infamous Nazi and Tuskegee to radiation human experimentations have promoted sustained maturation and augmentation of clinical bioethical research environments. The lack of informed consent IC , or coercive, guileful, forceful influences and methods that were used to obtain consent from potential participants; this associated with impaired risk-benefit scales, unjustified research population selections have prompted international regulations to stand firm on principles advocating conscientious clinical and ethical research systems. Following marketing approvals, medicinal products are conventionally utilized by pharmaceutical organizations, medical practitioners and allied bodies across a wide range of age groups, genders, special populations, nationalities and races, who unfortunately had not been satisfactorily represented in pertinent clinical studies resulting in deficient evidence-based health care. Vulnerable communities need assiduous attention during designing studies with unique recruitment considerations and quality scrutiny measurements of overall safety and efficacy strategies ensuing research. Ethical dilemmas are widely prevalent in research involving these populations with regard to communications, data privacy and therapeutic deliberations. Non-therapeutic research participation is granted if the envisaged risks are minimal[2] and well-being of this community is not compromised. Research with this sub-segment of population is validated if reasonable direct benefits are foreseen, in compliance with local legal regulations. The interim analyses of research may be made available in public domain to apprise the scientific community of the integrity of the study and initiate public trust. Their role may be optimized by involving them in both, early and late trial phases[7] soliciting vulnerable subjects, to contribute recommendations to the scientific caliber, integrity, safety, lucidity, timeliness, and quality of data and documentation. Compliance to advocated norms and sustained monitoring by ethical review boards ERBs ,[8] governmental agencies and independent DSMC is obligatory. Any form of willful violations to Good Clinical Practices GCP with connotations to autonomy, voluntariness, distributive justice, other parameters of safeguards are to be imperatively scrutinized and those involved to be appropriately penalized by applicable authorities. Protection of rights, well-being, safety with measurements of risk-benefit scales, privacy and confidentiality of vulnerable subjects and ascertaining appended safeguards[4] are prerogatives of ERBs. Infringement of methodologies in data collection and dissemination could bring individuals into disrepute, especially in research involving socially sensitive issues associated with stigma, as with HIV, mental illnesses, genetic[4] or of epidemiological natures. Confidentiality transgressions with unethical usage of personal data may occur endangering the social fabric of this already disadvantaged community. Therefore, establishment of updated security mechanisms of human research data protections is of paramount priority to industry, ERBs and supervising committees. The concerned ERBs prior to decision making may establish site research conditions, example a prison site[10] with relevance to participant rights, safety and well-being. Presently due to disparate factors, there is neither uniformity nor equitable standards in the understanding and grading of risks globally for these populations with relevance to extent of acceptability and evaluation of quantum of risks to establish consistent safeguards in biomedical research aiding stakeholders. Role of regulatory in biomedical and behavioral research is maximal in providing scientific direction to industry and unambiguous thought-through instructions. International collaborations of regulatory organizations can establish scientific and regulatory policies to positively impact global safeguards for vulnerable populations. Stringent reporting guidelines should be followed by industry in maintaining validated databases for safety data dissemination highlighted for this community, with risks being regularly interpreted by expert clinical evaluators, steering committees and timely recommendations shared between stakeholders. There is a continual need to federate and be vigilant to develop strategies for establishing appropriate advancements in monitoring plans according to trends scrutinized from research. The quality of IC Process has an impressive influence on the tenets of research with direct implications to comprehension of proposed study

particularly in vulnerable subjects. The principles and spirit of GCP of respect for persons devoid of prejudice and therapeutic misconception is assured through an effective consent process. The informed consent document ICD should also comply with all applicable elements deliberated in the local regulatory norms. The font of the written documentation should be easy on the eye, accepting pediatric and geriatric patients[14] notably. The ICDs should not be lengthy[15] and at the tail end a frequently asked questionnaire with a simple summary of goals for the study maybe enumerated empowering the comprehension, in achieving a superior caliber of consent. Should the exclusion of this sub-segment be planned, a viable justification needs to be elucidated in the relevant research documents. If the data following exposure to medicinal or pharmaceutical products suggests significant maternal, fetal or neonatal harm, justifies desuetude of this population. Assimilation of safety and efficacy profiles of the intervention from available preclinical, clinical and post marketing experiences is the natural evolution ensuring detailed evaluation of foreknown risks versus benefits preceding inclusion of this population. Studies involving physically invasive examinations or interventions or in high risk maternal and fetal complications mandates special review by ERBs,[4] and DSMCs assuring unbiased analyses of retrospective data. Programs and registries for follow up evaluations subsequent to pregnancy research for fetus and child are prerequisites. Psychiatric patients, who are behaviorally or emotionally challenged and assessed to be incompetent to provide independent IC warrant surrogate consents. Patients with certain medical conditions may in the future regain reasoning capability to independently re-consent or resist further participation during the study, to be respected by the investigator and similar anticipatory conditions reflected in ERB reviewed documents. Medicinal preparations in the market are regularly prescribed to children as off-label use as pediatric labeling information is unavailable, thereby associated with perils of unproven efficacy and unknown safety. Parents are required to make the decision on their behalf[3] as children are believed to have limited cognitive and emotional capabilities from ethical and legal perspectives. Dedicated pediatric trials maybe essential where the disease predominantly affects this age group, uniquely in the scenario of being predisposed to certain medical conditions. Age-appropriate assent forms across pediatric to adolescent age groups may be developed which need to be simple, user-friendly, with pictures and illustrations[14] wherever possible. Pediatric studies are prone to sensitive issues and risks, needing periodic reassessments by the concerned ethics, scientific review boards with public concurrence. In non-therapeutic research, declination to participate by the child requires to be abided by the investigator. An impartial witness provides consent for an illiterate, legally blind or a physically challenged subject who may be unable to write, by participating in the entire consent process, in the absence of a literate LAR. Research in the terminally ill and in conditions of emergency medicine,[3] in these circumstances subjects are potentially very vulnerable as waiver from consent may be inevitable despite several social, legal and ethical debates. Considering the acuteness of the underlying clinical pathology, participants may reach the study endpoints early in the course of study based on protocol evaluation criteria, necessitating data reviewing committees to proffer early and frequent analyses with an obligation to provide cyclical efficacy, safety and risks versus benefits recommendations to stakeholders. Further in this form of research, befitting statistical designs and inferences are to be cogitated. Research in hierarchical organizations as in the armed forces, institutions or hospital groups, here employees or students by nature of adjacency of work or association with investigators, may acquiesce to participate in anticipation of favoritism, consternation, retribution or compelling socioeconomic backgrounds. Declination to participate should not affect their careers and credits. When the protocol sample study population incorporates the vulnerable subset of patients, rationale for their representation, scientific significance and contributions are to be discussed. The pillars of vulnerable participant safeguards are to be specifically expounded in the protocol and ICD. Gold standards of randomized controlled blinded trials are considered scientifically robust and well accepted ethically for unbiased evaluation of therapeutic credits to this population. Well-formulated monitoring plans with data validity maybe appended to the protocol. The higher the severity of risks encountered in this sample population, the more aggressive the monitoring. The need of the day is responsible, experienced, sensitive researchers[21] guiding conscientious teams to treat vulnerable communities with concern, patience, respect, equitably, allowing free will, ruling out any form of inducement, enticements, insensitivity or prejudice. The

goals of clinical research whether privately or publicly funded are to represent the best interests of this community within the framework of the protocol and by adherence to the principles of GCP. Awareness through continued education of stakeholders including media and public would result in better attitudes and approach to this form of sensitive research. Watchdog panels overseeing vulnerable participant protection should remain in an open ongoing dialogue with stakeholders, monitoring compliancy to advocated precautions and norms. Enhancing the interaction between the ERBs and investigators may expand their ability to comprehend the trends involved and engage in greater understanding of ongoing safeguards of these populations. Compassionate use of therapeutic interventions may be made available to vulnerable subjects following completion of research. Comprehensive mandatory pharmacovigilance and targeted risk management plans during post marketing are cardinal. Good science with responsible research provides an authentic groundwork to heighten best practices in medical management of vulnerable populations. Nevertheless, clinical research is metamorphosing and escalating in complexity, blurring the line between potential risks and benefits encumbering the development of comprehensive robust monitoring systems. We all walk down this inconstant dynamic path of research. But walk it we must. Footnotes Conflict of Interest: Politics and Clinical Trials: The Inclusion of Women. A Guide for the Ethics Committee. Guidance for Industry on Submission of Clinical Trial Application for evaluating safety and efficacy. Conducting qualitative research with people with learning, communication and other disabilities: University of Southampton; Monitoring Informed Consent Procedures: Making written information easier to understand for people with learning disabilities Guidance for people who commission or produce Easy Read information, revised ed. Department of Health U. BMC Medical Ethics; Dec 13, [Last accessed on Aug]. Consenting of the vulnerable: The informed consent procedure in advanced cancer patients in Mexico. Guideline on the Exposure to Medicinal Products during pregnancy: Title 21 Code of Federal Regulations Sec.

Chapter 2 : Chapter Eight: Focusing on Vulnerable Populations

Vulnerable population. There are several definitions available for the term "vulnerable population", the words simply imply the disadvantaged sub-segment of the community[] requiring utmost care, specific ancillary considerations and augmented protections in research.

Individuals may be vulnerable to health care quality problems for one or a combination of underlying reasons, including those pertaining to their financial circumstances or place of residence; health, age, or functional or developmental status; or ability to communicate effectively. Other personal characteristics, such as race, ethnicity, and sex also have been shown to be associated with differential experiences in obtaining quality health care. Furthermore, characteristics of the evolving health system -- such as an eroding safety net -- can interact with personal characteristics to contribute to vulnerability. There is a clear need to increase the level of attention paid to vulnerable groups, including both those who, because of their chronic illness or disability, have many interactions with the health system, and those who have difficulty accessing the system and may be most likely to fall through the cracks during this period of rapid health system change. In the Consumer Bill of Rights and Responsibilities, the Commission articulated that consumers have the right to considerate, respectful care, free of discrimination. In this chapter, the Commission extends this work by specifically addressing ways in which the particular needs of vulnerable populations should be accounted for in the design of systems for health care delivery, quality measurement, and payment. The lack of evidence of effective approaches to enhance the health and functional status of persons with chronic illness or disabilities suggests the need for significant additional investment in research and innovation for health care and rehabilitation programs serving these patients. In addition, telemedicine and similar innovations, incentives for health care professionals to practice in underserved areas, and enhanced availability of prehospital emergency services should be assessed as approaches for improving the access to care of those facing geographic barriers to appropriate care. Development and evaluation of health care quality measures and measurement methods for vulnerable populations should be supported. A focus on vulnerable populations in the design of quality measurement initiatives is valuable, in part, because their experiences may provide new insight on systemwide problems. Attention to vulnerable populations should be integrated within general quality measurement strategies, recognizing that quality measures and measurement methods tailored to vulnerable groups will, in some cases, be required. Payments to health plans and providers should promote quality health care and improved health and functional status for all patients, including vulnerable populations. Adjusting payments for differences in health or functional status is especially important for Medicare, Medicaid, and other payers that have significant enrollment of individuals with chronic illness or disability so that health plans and providers have an incentive for developing innovative models of care that best serve these individuals. Risk-adjusted payments are also critical to sustaining the safety-net mission of certain providers that provide a disproportionate amount of care to vulnerable populations, such as community health centers, rural health clinics, and academic health centers. The Federal government should convene high-level stakeholders to determine how best to implement risk-adjusted payments for Medicare. Payment systems also can be better aligned with quality care for vulnerable populations by being broadly based across groups of providers and related health care services to encourage multidisciplinary, coordinated care; providing coverage for health care delivery approaches that have been demonstrated to improve outcomes, functional status, and satisfaction; and rewarding quality performance through financial incentives. Among others, these groups include the uninsured, the poor, the elderly, children, those living with mental or physical disabilities, racial and ethnic minorities, and the terminally ill. The vulnerability that these groups experience usually can be attributed to one or some combination of three factors: Not all sources of vulnerability can be fully explained by these factors, however, raising important questions for further research. Economic Status and Geographic Location Individuals may be vulnerable by virtue of their financial circumstances or geographic location. These factors can present obstacles to obtaining needed health care and can result in increased exposure to health risks. These barriers to access can lead to a lack of continuity, delays in obtaining care, and limited choices about

where and from whom care may be received Newacheck et al. These patterns of utilization can contribute to adverse health care outcomes, including higher rates of preventable hospitalizations Billings et al. Poverty and lack of insurance can result not only in decreased access to health care, but also increased risk of poor health. Any of these factors can magnify exposure to environmental risks such as secondary tobacco smoke, poor sanitation, or lead exposure , safety risks such as traffic hazards and family violence , social and psychological stressors such as fear of crime , and lack of infrastructure supports such as counseling or educational services that contribute to an increased burden of poor health. For example, a recent study of Medicare enrollees in managed care plans found that nonelderly individuals with disabilities, the frail elderly, the functionally impaired, and persons in fair or poor health were much more likely than the general beneficiary population to report problems with access to care Nelson et al. Many of these same groups also have been shown to be vulnerable to access problems in fee-for-service Medicare PPRC, These vulnerable groups may be especially prone to difficulties in using the health care system, including discontinuity and lack of coordination among multiple providers, inability to obtain care from providers who have expertise in treating their conditions, and difficulty in receiving approvals for treatments that are expensive or not widely used. In addition, individuals with some conditions, such as mental illness or HIV disease, may face or fear undue stigma that makes it difficult to receive appropriate care. Developmental status and age can also be associated with vulnerability. Children have health and developmental needs that are markedly different from adults, and require age-appropriate care. Developmental changes, dependency on others, and different patterns of illness and injury require that attention be paid to the unique needs of children in the health system IOM, The elderly also have unique health care needs due not only to the increased incidence of illness and disability, but also to the multiple and complex interactions of other types of physical and social consequences of aging. Communication Barriers Vulnerability can in some cases be attributed to limitations in the ability to communicate with providers and other actors in the health care system. Persons who have difficulty communicating may experience problems in expressing treatment preferences, providing informed consent, obtaining services that are consistent with their cultural norms, finding providers who are sensitive to their particular concerns, getting problems resolved, and understanding or complying with treatment options. Unexplained Vulnerability Associated with Race, Ethnicity, Sex While categorizing sources of vulnerability in this manner is helpful in a number of respects, the above conceptual framework does not fully encompass the full range of vulnerable population groups. Other characteristics also have been shown to be associated with differential health care and inferior health status. Significant differences in treatment have been documented by race, ethnicity, and sex that are not explained by other demographic differences, insurance status, clinical factors, or provider characteristics. For instance, African Americans with colorectal cancer have been found to be treated less aggressively than their white counterparts Ball and Elixhauser, A number of studies have consistently demonstrated that African Americans are about half as likely as whites to receive interventional therapy for coronary artery disease Ford and Cooper, Differences between Latinos and nonhispanic whites in the use of invasive cardiac procedures also have been documented Carlisle et al. These studies are just a sample of the large and growing health services research literature documenting the vulnerability of these groups. Differences across racial and ethnic groups exist not only in treatment patterns, but also in indicators of health status. The underlying reasons for these demonstrated differences are not well understood. Whether these findings can be attributed to discrimination, cultural factors, or other causes is an important area for further study because of the implications for eliminating unwarranted variation in the provision of health services and for improving the health status of all Americans. In particular, populations vulnerable to health care quality problems need to be accounted for in the design of effective systems for health care delivery, the choice of appropriate health care quality measures, and the adaptation of payment mechanisms. Innovative models of health care delivery have emerged that attempt to better incorporate these elements of care, but continued research and development of more effective and efficient approaches for meeting the health care needs of patients with chronic conditions, disabilities and other sources of vulnerability remain important. While continued innovation in this area is important, it also must be accompanied by evaluation to determine effectiveness. To date, there is a lack of evidence supporting improved functional status or other clinical

outcomes resulting from many health care delivery approaches for individuals with chronic illness or disability. Some elements of health care delivery that are particularly relevant to patients with chronic conditions include the use of multidisciplinary teams, continuity of care, patient and family empowerment, case management, and outreach or home-based care. A review of more than 50 published studies assessing whether innovative health care programs emphasizing these elements improved outcomes for individuals with chronic illness or disability ¹ found that improved clinical and functional outcomes were not consistently demonstrated. The review did find evidence that in general these approaches improved patient satisfaction with their care, but other improved outcomes were limited to specific models of health care within particular populations of patients. Specific areas where evidence demonstrated that innovative health programs improved outcomes are summarized below: Hospice care created increased patient and caregiver satisfaction at costs lower than or similar to conventional care; Programs providing aggressive community-based care to certain patients with mental illness were preferred by patients and resulted in reduced severity of symptoms and a more rapid and larger improvement in functioning; ² Community-based care for the frail elderly resulted in improved satisfaction; Patient empowerment among the frail elderly and adults with disabilities increased patient satisfaction and knowledge about their care; Multidisciplinary teams resulted in lower rates of homelessness for the mentally ill and decreased morbidity for patients with diabetes or congestive heart failure in some studies, but the beneficial effects were generally limited to the duration of the intervention. The lack of consistent evidence for improved clinical outcomes highlights the need for significant investment in research and innovation of health care delivery models addressing the needs of individuals with chronic conditions and other vulnerable populations. Evidence of enhanced patient satisfaction from models of health care delivery that emphasize continuity of care, multidisciplinary approaches, patient empowerment, and outreach to community settings should guide the development of innovative approaches to care that also aim to improve functional status and clinical outcomes. As evidence is developed to demonstrate effective models of care, health care providers should commit to practicing evidence-based care. Appropriate approaches to caring for individuals with chronic conditions, however, should recognize the unique needs of individual patients. For example, while innovative approaches to caring for individuals with mental illness e. Several health plans have designed innovative programs intended to provide better care for individuals with chronic conditions, and further demonstration and evaluation of such programs should be encouraged. Examples of these unique programs include: Harvard Pilgrim Health Care implemented a case management program to provide HIV- infected enrollees with more specialized care focusing on early intervention, education, and use of home care services. Oxford Health Plans has designed care management programs for individuals with serious heart conditions and asthma sufferers that combine health care treatment with lifestyle education and training programs. Health Partners in Minnesota has developed a program for chronically ill children to improve coordination of services, develop flexible benefit packages appropriate for children, expand case management services, and link families with social support services AAHP, Other populations beyond individuals with chronic conditions also face vulnerabilities that should be addressed in designing health care delivery systems. The availability of culturally-sensitive health care professionals and systems is particularly important for patients with communication barriers as well as for racial and ethnic minorities as further discussed in Chapter Telemedicine technologies, public programs that provide incentives for health care professionals to practice in underserved rural areas, and the availability of prehospital emergency services are delivery system characteristics that have the potential to improve health care delivery for patients whose location poses a barrier to accessing quality care. In addition, certain types of providers, including academic health centers and community health centers, have played an especially important role in delivering comprehensive, high quality care to vulnerable populations who otherwise could be underserved. Finally, establishing national aims for improvement, while not targeted specifically to vulnerable populations, is intended to stimulate efforts to improve the quality of health care delivery see Chapter 3. The setting of aims, while national in focus, should be sufficiently robust to reflect the needs of specific vulnerable populations and localities. This can be achieved through establishing specific objectives within the broader aims that reflect the unique needs of vulnerable populations, and ensuring that the tracking of national aims can support

efforts to identify particular areas of concern to local areas and vulnerable populations. Quality Measurement Vulnerable populations require special attention in the design of health care quality measurement strategies for three distinct reasons. First, a focus on the quality of care experienced by vulnerable populations could provide new insight into health system problems or identification of problems that otherwise could go undetected. Second, some vulnerable groups are more likely to fall through the cracks. The same factors that contribute to their vulnerability can also affect their ability to safeguard their own needs and interests adequately. Third, for a variety of technical and other reasons, health care quality problems experienced by vulnerable populations are not well captured by measurement efforts designed for the general population. For the most part, these efforts do not utilize data collected over time or across multiple different settings for health care delivery. Finally, because individuals with chronic illness and disability consume a disproportionate share of health care resources relative to their share of the population, measuring the quality of their experiences with the health care system will lead to a focus on high-cost areas. Health care quality measurement for vulnerable populations either could be undertaken separately or be included in general strategies for evaluating quality. The combination of general and targeted strategies is most likely to identify efficiently and effectively the highest priority quality problems for vulnerable populations. In some cases, it may be less expensive to oversample one group in the population to explore whether the subgroup is experiencing more or different quality problems. In other cases, the use of specially tailored measures may be more effective. Including vulnerable populations in general strategies for quality measurement is likely to be more sustainable over the long run and sends the important signal that evaluating quality for vulnerable populations is equally, if not more, important. This strategy allows comparisons between vulnerable and general populations when the same measures are used. Such approaches may be more efficient if special sampling procedures can augment a generally applied measure so that evaluating problems for vulnerable populations can be done simultaneously. There are a few reasons, however, why targeted approaches might be necessary. For persons vulnerable due to economic circumstances, the key to including them in monitoring systems is the availability of variables to identify such persons and methods for bringing data on their patterns of utilization into integrated data systems e. For persons vulnerable due to health status, the key to inclusion in monitoring is the expansion of appropriate criteria for evaluating their care and the development of methods that can support analyses of quality problems using small samples. For persons who are vulnerable due to communication challenges, the key to inclusion will be the development of measurement tools that can be used with such populations. Different Quality Measures Needed. In some cases, different quality measures may need to be used to assess the care provided to vulnerable populations. Certain health care problems experienced by vulnerable populations differ from those encountered by others in the health care system either by their nature or in the frequency with which such problems are encountered , and will require a different set of measures to evaluate the quality of care they receive. For example, evaluating the quality of care delivered to persons with certain rare conditions may require developing clinical measures specific to the particular condition e. In other cases, existing measures might be adapted or refined to better accommodate vulnerable populations. Medicare and Medicaid, as public programs that insure a disproportionate share of many vulnerable populations e. In efforts to develop new health care quality measures, the deficits in quality that pose the greatest risk to vulnerable populations and the types of measures most likely to identify such deficits should be taken into account. Focusing new measure development on technical process quality has a number of advantages. First, scientifically sound measures of technical process quality are the most sensitive dimensions for providing an early warning of potential threats to health outcomes. A good measure of technical quality is one that is linked to health outcomes-- meaning that adhering to the indicator process more often will increase the likelihood of producing better health outcomes.

Chapter 3 : Vulnerable Populations Guidance

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Home Blog Safeguarding Vulnerable Populations Safeguarding Vulnerable Populations Articles Doctor of Nursing Practice Every day millions of Americans with complex medical problems struggle with the rising cost of healthcare, the complicated health insurance market and the shrinking pool of medical professionals. These at-risk populations across the country – the working poor, elderly, homeless, racial and ethnic minorities, and uninsured – are at an increased risk of developing severe medical problems due to substandard healthcare, poor health literacy, and a higher rate of communicable diseases. Despite nationwide efforts to provide services to offset health disparities, healthcare providers, medical researchers and government agencies are continuing to search for solutions. At the forefront of leading changes to assist the medically vulnerable are Doctors of Nursing Practice DNPs, nursing specialists who focus on improving outcomes for patient care and population health. DNPs are advanced practice registered nurses APRNs who utilize clinical expertise, data-driven decision making and inter-professional collaboration for leadership and policy changes. Vulnerable Populations Across the United States At-risk populations live in both urban and rural areas, often in impoverished communities with neighbors facing similar situations. They do not have access to stable healthcare because it is not available or too expensive. In some cases, they have untreated chronic medical conditions, such as diabetes or high blood pressure, or untreated infectious and communicable diseases, such as the human immunodeficiency virus HIV that causes AIDS. In other cases, they have unaddressed mental health conditions, such as bipolar disorder or major depression, that have a negative trickle-down effect on themselves and their families. They have trouble maintaining independence, a lack of reliable transportation and poor communication skills. Their health problems intersect with social problems, such as illiteracy, homelessness, and poverty. Department of Health and Human Services launched its Healthy People initiative, a year project aimed at improving health outcomes. Among the goals is to boost access to quality healthcare services across the nation. At the same time, an American Hospital Association AHA task force explored the ways hospitals, often used as healthcare access points, can further assist patients. The two organizations found strategies to accomplish policy-level changes for the goal of health equality, as follows: Improve social determinates to promote healthy living Healthy living depends on factors that happen throughout a lifetime. The most common health-related social challenges include lack of employment, food and housing insecurity, poor social support, and illiteracy. Healthcare providers must address these social determinates of health through a series of steps that include screening patients and providing proactive services, the AHA found. Utilize a global budgeting national healthcare system The AHA said replacing the current fee-for-service healthcare system with a global budget system would allow the federal government to determine the total sum that is available to reimburse all medical facilities over a fixed period. Proponents of a global budgeting system said it would control healthcare spending. Provide access to virtual healthcare Virtual healthcare provides immediate, around-the-clock access to medical advice and treatment. Providers can examine and diagnose patients and perform high-tech monitoring. Proponents said virtual healthcare could be used to improve management of chronic diseases, treat minor illnesses, support primary care access, and provide improved referrals to specialists for more effective treatment. Match hospitalization needs to surrounding communities As outpatient medical services become more common, medical facilities must look to ways to reduce inpatient bed capacity. Fewer hospital beds could drive down medical costs in local communities, the AHA said. Support community-appropriate healthcare access Rural hospital health clinics, frontier-area health services, and partnerships with Indian Health Services IHS offer targeted medical assistance. For rural communities, the targeted services means integrating care between rural hospitals and local health centers for medical, behavioral, and oral health. Frontier-area health services must address healthcare access challenges for those living in extreme geographic isolation. Barriers to Serving Vulnerable Populations The leading barrier to healthcare is the high cost of medical services and medical insurance. Despite regulations aimed at reducing healthcare costs, insurance coverage remains financially out of reach for

many people. In the first quarter of , the percentage of U. The federal Office of Disease Prevention and Health Promotion also found a lack of medical services nationwide and factors such as age, race, gender, and ethnicity negatively impact access to health services. The lack of health literacy, or the capability to understand and follow through on basic healthcare information, has also crippled vulnerable populations. Further exacerbating the problem is the forecasted nationwide shortage of more than one million nurses by and some 43, primary-care physicians by , mainly due to retirement. DNP coursework includes healthcare policy, changes in healthcare framework, social justice, and global health perspectives. The DNP program at Duquesne University focuses on creating leaders who will improve healthcare for the general population through policy changes and clinical practice. DNPs work with communities to focus on prevention and health promotion. Students working toward a DNP degree are trained to manage the evolving and emerging roles in nursing. The programs build on skills to prepare graduates for a comprehensive understanding of the field and strong leadership and clinical skills.

Chapter 4 : Vulnerable Populations Programs | U.S. Agency for International Development

Vulnerability is the degree to which a population, individual or organization is unable to anticipate, cope with, resist and recover from the impacts of disasters. Environmental health in emergencies and disasters: a practical guide. (WHO,) Children, pregnant women, elderly people, malnourished.

Research involving sensitive subjects

Minors Children defined as anyone under 18 years of age can participate as research subjects only if the research meets certain standards. Specifically, the research may not be greater than minimal risk unless it provides a direct benefit to the child. Children who are able to read and write usually grades 4 and older should participate in the consent process by using an assent form written in language especially for the child. This definition includes individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, as well as individuals being held prior to arraignment, trial or sentencing. Research involving prisoners must have as its goal either a direct benefit to the individual subject or seek an understanding of issues and conditions specific to prisoners. Research with prisoners will be reviewed by the full IRB at a convened meeting.

Decisionally Impaired Individuals Decisionally impaired individuals are those who have a diminished capacity for decision-making and who may be unable to fully understand the risks of research. If the subjects are not capable of giving consent for themselves, it must be obtained from their legal guardians. In that case assent from the subject must be obtained.

Marlboro College Students or Employees as Research Subjects Students recruited as participants in faculty- or staff-initiated research, and employees recruited for research initiated by Marlboro faculty, staff or students, are considered vulnerable populations and special considerations apply for engaging them in research. Investigators recruiting students or employees in research should:

- Avoid using Marlboro College students, staff, or faculty strictly for convenience purposes
- the population should be appropriate for the study.

Research with students and employees may be expedited or exempted from continuing IRB review if it is minimal risk.

Institutionalized Individuals Institutionalized individuals, such as those at mental health institutions require special consideration. Written permission for the conduct of the research at the institution must be obtained from the appropriate officials at that institution. In addition, if the subjects are not capable of giving consent for themselves, it must be obtained from their legal guardians.

Economically or Educationally Disadvantaged Individuals Economically or educationally disadvantaged individuals may be particularly vulnerable to the risks of research. Educationally disadvantaged subjects may not be able to fully understand the concepts presented by the research and the investigator should take extra precautions to ensure that the subjects fully understand what is being asked of them. Similarly, economically disadvantaged subjects may be easily persuaded to participate in research if the economic compensation is so great that it would result in the subject ignoring or disregarding the research risks because of the income generated by the study. It is also important in such cases that the risks to the subjects be made clear to the subjects. Research with economically or educationally disadvantaged individuals may be expedited if it is minimal risk. The ability to understand information about the research and provide voluntary consent is key to the autonomy of and respect for research subjects. The IRB is tasked with ensuring that the proposed research includes a consent process in the language most appropriate for the subjects. If your potential participants speak English, but are unable to adequately read a consent document, a verbal consent process may be more appropriate. An oral consent script i.

For participants whose native language is not English, the researcher must carefully consider how these individuals would be consented into the study. If the study targets non-English speakers or if the majority of the participants are expected to be non-English speakers, then the consent process should be conducted in the language appropriate to those participants. An English version and a fully translated version of the consent form should be submitted for IRB review. The IRB would also expect that the study instruments e.

People living outside the US Investigators conducting international research must provide the IRB with sufficient information on the settings including any cultural or language considerations of the research, and demonstrate to the IRB that they have the necessary permissions to conduct the research in that setting. It is often helpful to have local collaborators involved in

the study as co-investigators, interpreters, community liaisons, etc. Research that requires oversight of multiple review boards should be appropriately planned for in your study timeline. HIV Positive Individuals HIV positive individuals will be considered a vulnerable population because of the risks of social stigma, employability and insurability facing them if their HIV status were revealed. The College will comply with federal and state guidelines, including those concerning notification of seropositivity, counseling, and safeguarding confidentiality where research activities directly or indirectly involve the study of human immunodeficiency virus HIV. At such a review the IRB may determine that a particular research study is sufficiently low in risk so as to allow continuing review to be conducted on an expedited basis. Recruitment and Advertisements The IRB must review and approve all advertisements and recruitment materials before they can be used. If they are not submitted at the time of initial IRB review and approval, they must be submitted as an amendment before recruitment is initiated. Payments to Subjects It is sometimes appropriate to offer payment to subjects as compensation for their time and involvement and to cover expenses incurred by their participation. However, it is not appropriate to offer payment that is so high that it would encourage an individual to ignore or disregard the research risks – this amount can vary depending on the research population. Excessive compensation, whether in the form of money or in-kind payments, is coercive and will not be allowed. Deception in Research The use of deception in research raises special problems that the IRB will review closely. One consideration is whether the deception is necessary. An investigator proposing to use deception should justify its use. Deception should not be used if it places subjects at greater than minimal risk. The IRB may modify the normal informed consent process for research involving deception when subjects are not placed at risk. However, potential participants should be advised in the consent form that the information they are given is not complete and they should also be debriefed after the research procedures are completed. The debriefing should include a detailed description of the ways in which deception was used. The investigator is responsible for ensuring that the subject leaves the research setting with an accurate understanding of the deception. The debriefing process, including any written materials, should be explained to the IRB as a part of submitted protocols. Some research designs require that the full intent of the study not be explained prior to participation. Although we have described the general nature of the tasks that you will be asked to perform, the full intent of the study will not be explained to you until after the completion of the study. At that time, we will provide you with a full debriefing which will include an explanation of the hypothesis that was tested and other relevant background information pertaining to the study. You will also be given an opportunity to ask any questions you have about the hypothesis and the procedures used in the study. Sexual orientation, incest, rape, sexual molestation, deviant sexual behavior or attitudes regarding sexual conduct pedophilia, bestiality, etc. Illegal or taboo behavior.

Chapter 5 : WHO | Vulnerable groups

The National Program to Eliminate Diabetes-Related Disparities in Vulnerable Populations ("Vulnerable Populations," hereafter) was a five-year cooperative agreement (). The main goal of the agreement was to identify and carry out public health activities specific to the culture of.

Newsroom –” Published on: July 20, 5 Vulnerable Populations in Healthcare Laura Joszt For vulnerable populations, their health and healthcare issues may be exacerbated by social factors. Here are just 5 vulnerable populations who experience greater risk factors, worse access to care, and increased morbidity and mortality compared with the general population. In the United States, significant disparities exist in healthcare for vulnerable populations. There are a number of groups that are considered vulnerable populations, including racial and ethnic minorities, the economically disadvantaged, and those with chronic health conditions. For vulnerable populations, their health and healthcare issues may be exacerbated by social factors. Chronically ill and disabled People with chronic diseases are at risk of poor health outcomes and they, obviously, consume more healthcare dollars than healthy individuals. The chronically ill are twice as likely to report poor health days as the general population. Disabled individuals, like the chronically ill, usually have many interactions with the health system, but, due to their disability, they may have difficulty accessing care. The chronically ill and the disabled may face special challenges in obtaining services. People with low incomes are also disproportionately racial and ethnic minorities. Being low-income, they may be less likely to have coverage and, as a result, have less interaction with the healthcare system, explained Pamela Riley, MD, MPH, vice president of delivery system reform at The Commonwealth Fund. People with lower incomes are also more likely to have co-occurring conditions –”meaning they might have behavioral health issues, such as depression or substance use problems, as well as chronic medical conditions like obesity or diabetes. Since people experiencing homelessness may not have a safe place to stay, they are at an increased risk for adverse health-related outcomes. In , the US Department of Housing and Urban Development reported that almost , people in the country were homeless on a single night. These individuals are less likely to have a regular source of care and more likely to forgo care. Certain geographical communities Americans living in rural areas often have worse health than the general population. The reason for this disparity is that rural populations experience geographic isolation, have a lower socioeconomic status, have limited job opportunities, and tend to be older. Exacerbating these issues in rural communities is the fact that this population has trouble accessing care. The New York Times reported that people in rural America, especially pregnant women, are far from care. In addition to the fact that 85 rural hospitals have closed since , fewer than half of rural counties have a hospital offering obstetric care. Native Americans living on reservations are also vulnerable. Native Americans also have issues accessing care, partly because their health programs are underfunded , but also because one-fourth of Native Americans have reported experiencing discrimination when they do go to the doctor or a health clinic, NPR reported. For instance, black transgender women are disproportionately burdened with HIV. Healthy People reported that discrimination against LGBTQ people is associated with higher rates of psychiatric disorders, substance abuse, and suicide. Some of the social determinants that affect the health of the LGBTQ community include discrimination in access to safe housing and a shortage of healthcare providers who are knowledgeable and culturally competent in LGBTQ health. A recent study has found that people who presented as transgender or gender nonconforming before their 18th birthday have a higher prevalence of mental health conditions, including anxiety, depression, and attention-deficit disorders compared with cisgender counterparts. The very young and very old The American Public Health Association has focused on how climate change affects vulnerable populations like children, who have developing organs, low immunity, spend more time outdoors, and breathe more air and drink more water per body weight than adults. In addition, there has been a lack of adequate pediatric research and testing of medical interventions with pediatric populations. Similarly, older adults are more vulnerable to health issues since they also have low immunity and often numerous medical conditions.

Chapter 6 : Safeguarding Vulnerable Populations

Vulnerable Populations. The well-being of the United States depends upon the well-being of our children and youth. At present, populations of young people may be identified as vulnerable based on situational characteristics such as early parenthood, disconnection from school and work, homelessness, and involvement in the juvenile justice and foster care systems.

Vulnerable Populations Guidance Version Date: June 16, The purpose of this document is to provide guidance on the inclusion of vulnerable populations in human subjects research, specifically the information that needs to be provided to the IRB when vulnerable populations will be subjects. Vulnerable Populations A population may be considered vulnerable because their enrollment involves issues of coercion and undue influence and may require additional safeguards to protect their rights and welfare or because their enrollment requires special consent processes e. The federal regulations specify certain groups as being vulnerable, outlined in 45 CFR Other groups may be considered vulnerable populations based on regulatory criteria, state law or other factors. These include, but are not limited to: The Vulnerable Justifications page is where study teams are required to justify the inclusion of vulnerable populations and detail the procedures being implemented to safeguard the rights and welfare of each vulnerable group that may be enrolled. Application types that display the Vulnerable Group Checklist The Vulnerable Group Checklist page will display for the following application types if study activities involve interaction or intervention with human subjects: Full review, Exemption, and Non-exempt medical records applications. The Vulnerable Justifications page will display any time a vulnerable population is selected on the Vulnerable Group Checklist page. Selecting a vulnerable population from the checklist Study teams should select the appropriate boxes when they intend to knowingly enroll a subject that falls into a vulnerable population. This would include situations where: Examples include research directed at children, pregnant women, or the elderly. Because federal regulations require additional considerations to safeguard the rights and welfare of subjects who are potentially vulnerable, study teams should not knowingly enroll a subject from a vulnerable group if enrollment of subjects in that vulnerable group has not been approved by the IRB. Justifying enrollment of a vulnerable population The requirements to enroll a vulnerable population vary by the particular population. In all cases, the study team must provide detailed justification as to why the enrollment of a vulnerable population is necessary to answer the research question, ensure the generalizability of results, and the appropriate population to ensure the equitable selection of subjects. This information should be provided in Q3. In providing justification, it is important to keep in mind that, in accordance with the Belmont Report, the IRB typically requires that research be conducted on the least vulnerable subject population possible. The study team must describe the additional safeguards in place to protect the rights and welfare of subjects in each vulnerable population that may be enrolled. The specific procedures will vary by the nature of the study and the vulnerable population involved. In many cases, special procedures related to recruitment, consent, payments, and ongoing participation may be needed. Specific regulatory requirements must be met if a study involves children, pregnant women, fetuses, or prisoners. In addition, there are special regulations if veterans enrolled at the VA and state laws that apply to individuals with impaired decision-making capacity. As described above, enrolling a vulnerable population requires justifying the inclusion of the vulnerable population and outlining the procedures in place to adequately safeguard the rights of those subjects. It may also require the use of special consent processes and consent forms. Including these populations unnecessarily may create unneeded delays during the IRB review process for the study team. If a study is not approved for the enrollment of a vulnerable population but an eligible subject from that population is identified and interested in participating, a change of protocol would need to be submitted to allow for their enrollment. Please note that in some cases, such as individuals who are considered prisoners under the federal regulations, the IRB must have a special composition i. Please contact the HS IRBs office if this issue arises in a study and we can assist in walking you through the process for approval. Additional Resources for Working with Vulnerable Populations.

Chapter 7 : Vulnerable Populations | National Institute of Food and Agriculture

The Center of Excellence on Democracy, Human Rights and Governance Human Rights Team houses the Programs for Vulnerable Populations, which works to reduce risks to vulnerable populations and to help communities, non-governmental organizations, and governments provide services and protection for at-risk groups.

November 01, Vulnerable Populations: Despite efforts and goals in the United States to reduce or eliminate disparities in healthcare by , significant disparities, including risk factors, access to healthcare, morbidity, and mortality, continue in vulnerable populations. For example, studies find that Americans living in poverty are much more likely to be in fair or poor health and have disabling conditions, and are less likely to have used many types of healthcare. Those with multiple problems also face more significant comorbidities and cumulative risks of their illness than those experiencing a single illness. For instance, the number of individuals with chronic medical conditions has risen from million in to million in This number continues to increase as the baby boom generation ages. Additionally, the impact of these illnesses is more severe among the unemployed, uninsured, and less educated. For example, patients with a chronic illness who have less than a high school education are 3 times more likely to report being in poor health than those with the same illness who hold a college degree. They found that those without insurance were 7 times odds ratio [OR], 7. Meanwhile, adults with low incomes were more likely to delay or not receive necessary medical, dental, and mental healthcare and to not fill prescriptions. Although certain chronic conditions, such as dyslipidemia, may not presently be disabling to the patient, they have potentially disabling effects in the future. In addition, although some individuals with chronic conditions live full, productive, and rewarding lives, others live with isolation, depression, and physical pain resulting from their illness. The most common chronic conditions among those 65 years and older are hypertension, arthritis, heart disease, and eye disorders. Among those 18 to 64 years, the most common chronic conditions are hypertension, respiratory disease, arthritis, and mental health diseases. When comparing the insured versus those without healthcare coverage, the cost of healthcare delivery is disproportionately greater for the uninsured. Patients with multiple chronic illnesses are at an increased risk for hospitalization and require more prescriptions. As seen in Figure 2, those with 3 chronic conditions fill an average of The majority of out-of-pocket expenses for patients with chronic conditions is for prescription drugs, whereas patients without chronic conditions spend the most on dental care. Employers and Chronic Healthcare Coverage Employees with chronic health conditions, or those with a close family member with 1 or more chronic conditions, put tremendous strain on employers, with the impact extending beyond direct medical costs. In comparison to the general population, decreased productivity resulting from required absenteeism to care for those with chronic conditions is a direct cost to employers. As seen in the Table, the chronically ill are twice as likely as those in the general population to report poor health days. It also affects employer costs related to presenteeism, which is defined as the impact of a health condition on work performance. There is some evidence that presenteeism may be underreported and may represent a larger percentage of overall indirect workplace costs for medical conditions than previously thought.

Chapter 8 : What does vulnerable populations mean?

For vulnerable populations, their health and healthcare issues may be exacerbated by social factors. Here are just 5 vulnerable populations who experience greater risk factors, worse access to.

Chapter 9 : Vulnerable population and methods for their safeguard

Archive. CHAPTER EIGHT _____ Focusing on Vulnerable Populations. Throughout its work, the Commission has been particularly cognizant of the special concerns associated with assuring quality health care for vulnerable populations.