

# Public Value Mapping of Equity in Emerging Nanomedicine

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**Abstract** Public values failure occurs when the market and the public sector fail to provide goods and services required to achieve the core values of society such as equity (Bozeman 2007). That public policy for emerging health technologies should address intrinsic societal values such as equity is not a novel concept. However, the ways that the public values discourse of stakeholders is structured is less clear and rarely studied through the lens of public interests. This is especially true in the health sciences discourse. Using the public value mapping (PVM) model I present a case study of the intrinsic value of equity in nanomedicine for cancer and the imperatives for translational research, an instrumental value to achieve equity. After reviewing and coding nearly 700 value statements from several hundred public documents, I find that that the discourse on values varies between documents that address basic research and documents that address the application of the knowledge produced in basic research, with some especially notable disconnections. This paper demonstrates the importance of further refinement of methods for testing the PVM framework if the societal goal is to improve consistency of the public value discussion by those involved in developing and applying new technologies. The paper also demonstrates the value of a PVM approach for complex science policy analysis, especially for emerging technologies like nanomedicine.

**Keywords** Public values · Science and society · Nanotechnology · Health care disparities

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## Introduction

Among other imperatives The National Institutes of Health (NIH) Roadmap calls for translational research to reduce health disparities, with an emphasis on diverse multidisciplinary collaborative teams and expanded research funding for interventions to eliminate disparities (Zerhouni 2005). New NIH policy initiatives suggest that research impacts should not just improve individual health and well-being; public policy should result in public health benefits and address societal health problems like equity in treatment and access to novel technologies to reduce health disparities (Helmuth 2000, Smedley, Stith, et al. 2003). Within NIH, the National Cancer Institute (NCI) policies and initiatives, including nanotechnology for detection and treatment of cancer, are encouraging multidisciplinary collaborations between social scientists, policy-makers, biomedical scientists and health scientists, including clinicians. However, NCI policy is not always clear about how these interactions and the collaborative translation of research from bench to bedside should be implemented for social betterment (Kahn 2008). The basic strategy for the NIH translational research roadmap is to create an enabling culture to remove barriers that inhibit communication across the discovery-development-delivery continuum (Bland 2007). At the same time, NCI has embraced the idea that social science brings a broader perspective to the discussion of translational research, as well as highlight issues not often considered in natural or basic research and biomedical engineering (De Melo-Martin 2009). This paper uses social science approaches and an evolving theory of “public value mapping” or PVM (Bozeman 2007) to examine the discourse concerning the intrinsic value of equity in access to novel treatments like nanomedicine in cancer and the instrumental value of translational research that is designed to address societal imperatives, among other things. The intrinsic-instrumental value framework is inherent in the PVM model (Bozeman and Sarewitz 2005, and this issue).

In this study, I tested the proposition that value statements found in public documents related to translational research are consistent across the discovery-development-delivery continuum. If public documents reflect the values of the stakeholder group that produce them and the values statements found in the documents are inconsistent across documents or stakeholder groups, then values may not be shared across the translational research continuum. As such, translational research may be challenged to address societal issues like equity. I chose the intrinsic value of equity and the instrumental value of translational research for emerging nanomedicine in cancer because of their currency in the science policy arena (Resnik and Tinkle 2007).

Using the public value mapping model and results from review of over one hundred public documents addressing equity in discovery, development and delivery of nanomedicine for cancer, I find more emphasis on equity in the documents concerning delivery of the technology or policy-making than in documents related to basic research. The literature concerning “Mode 2” or “entrepreneurial science” puts a strong emphasis on societal implications of basic research (Gulbrandsen and Langfeldt 2004). Thus, this is not a new topic of discussion. But what may be new information from this study is the evidence that

even a core value of such importance as equity is not commonly asserted in public documents concerning basic research (Weingart 1998). More basic research declaration of public values for equity in access to novel medical technologies, such as nanotechnology, likely requires a continued emphasis on translational research and other science policies that address social betterment. Similarly, if equity efforts are to succeed and lead ultimately to more positive health outcomes for the population, then it would seem that we should be seeing frequent public statements related to equity and minority health in basic research documentation. The topic of the connection of science and societal priorities like equity has been debated for decades (Pielke and Byerly 1998). My study provides some evidence that more work on the “social contract of science” (Guston and Keniston 1994) and “Pasteur’s Quadrant” where basic research is guided by societal implications of potential application (Gulbrandsen and Langfeldt 2004, Stokes 1997) is needed.

Why focus on nanotechnology and equity? First, the emerging field of nanotechnology holds great promise for transforming both cancer research and clinical approaches to cancer care (Eng 2005, Heath and Davis 2008). Nanodevices are currently being used to: 1) detect cancer at its earliest stages, 2) pinpoint the location of cancerous cells within the body, 3) deliver cancer-fighting drugs to specific cells, and 4) assess the effectiveness of treatment. Nanomedicine approaches to drug delivery especially are touted as the breakthrough technology for curing cancer in all its forms. The significant and often fatal problems with current cancer diagnosis and treatment technology, for example chemotherapy toxicity and lack of specificity to tumor cells, may be resolved by nanotechnology (Best and Khushf 2006, Hede and Huilgol 2006). Second, typical of other emerging technologies, nanomedicine tends to be less accessible to minorities and those with low socioeconomic status, also disproportionately minority (Ford et al. 2008, Resnik and Tinkle 2007). Recognition of this problem is growing and there is evidence of increased efforts to address social issues such as equity and health disparities through translational research (Agrawal et al. 2005). I hypothesize that despite the emphasis on translational nanotechnology research to address intrinsic values such as equity, it will be difficult to see evidence in public documentation of shared values across the discovery-development-delivery continuum discourse.

## Method

The method used for this study is to identify stakeholders in emerging nanomedicine for cancer, develop a values statement analysis of a selection of public documents, and then provide additional evidence of potential public values failures. My unit of analysis is the public value statement, gleaned from over 100 public documents produced by the stakeholder group and identified as pertaining to the intrinsic value of equity in access to nanomedicine and the instrumental value of translational research. I manually created a coded data base of stakeholders, public document identification, and asserted value statements.

### *Stakeholder Identification*

The first step was to develop a process to identify the stakeholders whose public documents would be scanned. For some science policy issues, the asserted public value statements identify the groups and persons to consider for the PVM analysis, i.e. the stakeholders. Take for example the Feeney and Bozeman (2007) case study of the 2004 influenza vaccine shortage. In this situation, crisis occurred and public statements were generated. Feeney and Bozeman used the value statements in the flurry of public assertions in response to the crisis to identify the affected communities, including the “knowledge value collective” or the producers, users and resource contributors of the technology (Bozeman and Rogers 2002). My case is different in there is a longstanding discourse on a variety of interrelated issues of medical technology development and equity. Thus, the potential universe of stakeholder groups working with this topic is broad and their public discourse (the source of public value statements to be analyzed) is much larger. My approach began with identifying some of the most prominent stakeholder groups likely to be engaged in the discourse, and then analyzing their production and treatment of public value statements specific to equity and emerging nanomedicine in cancer.

The stakeholder communities for this issue are complex and composed of some members with long term collaborations and others with only intermittent engagements. Stakeholders in nanotechnology development were relatively easy to identify through the National Nanotechnology Initiative (NNI), managed within the framework of the National Science and Technology Council (NSTC), the Cabinet-level council by which the President of the United States coordinates science, space, and technology policies across the Federal Government. NNI is still in the formative stages of planning and organizing the nanotechnology discourse for communication to the public and policy-makers, yet they appear to represent most, if not all, of the organizations and agencies engaged in of assertion of public values for nanomedicine (Sandler and Kay 2006).

In contrast, the stakeholders engaged in policy to encourage equity and eliminate minority health disparities are many in number at the federal, state or local level. They are certainly less centrally coordinated than NNI and seemingly constantly changing, organizing and reorganizing. Some health-related agencies focused on equity may be more science than policy oriented or vice versa, and their efforts represent a wide variety of nominal to extensive activities to promote equity in access to novel treatment and improved minority health (Betancourt et al. 2005). Most agencies and entities engaged in discussions of equity and reducing health disparities have been in formal and informal dialogue and research since at least 1985 when the Task Force Report on Black and Minority Health was issued by the Department of Health and Human Services (DHHS 1985). Despite the history of discourse on minority health issues and concerted efforts of the Office of Minority Health of DHHS, disparities in specific emerging technologies like nanotechnology are not extensively analyzed or evaluated (Bruner et al. 2006).<sup>1</sup>

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<sup>1</sup> This pernicious problem of values aggregation is aptly described in the recent HHS Office of Minority Health (OMH) *Strategic Framework for Improving Racial/Ethnic Minority Health and Eliminating Racial/Ethnic Health Disparities*. See <http://www.omhrc.gov/npa/images/78/PrintFramework.html>.

Recognizing the complexity of efforts to relate all of the various agencies with public documents potentially rich with value statements, I chose to start at the websites for the two seemingly most distant potential sources of value statements, the National Nanotechnology Initiative (NNI) and the United States Department of Health and Human Services Office of Minority Health (OMH). On the websites of these two entities I used a variety of combinations of the terms nano\*,<sup>2</sup> clinical research, cancer, equity and health disparities to identify potential stakeholders in the discourse. The stakeholder scan provided numerous nanomedicine and equity stakeholder groups for study.

For example, within the group of stakeholders focused on eliminating cancer health disparities, the organizing cancer-related agency is the Center to Reduce Cancer Health Disparities in the NCI of NIH. Their focus is on both understanding disparities and disseminating interventions (Sung et al. 2003, National Cancer Institute 2006). Given NCI's priorities for eliminating health disparities, the logical connection between nanotechnology and equity should be the National Cancer Institute Alliance for Nanotechnology in Cancer. I expected this group to be a rich source of public value statements related to equity and some other more instrumental values related to emerging technologies and translational research. My intent was less to have all of the potential sources of statements than to have representation of as many government and non-governmental entities as possible. Table 1 below summarizes the sources for public values statements with a brief description of the source.

### *Public Documents and Compilation of Value Statements*

For each stakeholder group I identified public documents expected to be rich for examples of relevant value statements. This included stakeholder mission statements, a web page describing their "about us" information, their strategic plan, their annual reports, and descriptions of their products and major program initiatives. This resulted in over 100 documents and webpages for review. All of the documents were obtained through the Internet searches to ensure that they were publically available to any person performing similar research. Documents were categorized as pertaining primarily to basic research, clinical application, policy-making, translational research, technology development or some combination. An example of a "basic research" document would be the American Association for Cancer Research's document *AACR's Cancer Concepts: Nanotechnology* that includes discussion of "highly targeted treatments" and "minimizing side effects of treatments" but no discussion of equity or disparities.<sup>3</sup> Similarly, the Environmental Protection Agency National Center for Environmental Research's *NCER Program Brochure* discusses the need for "competition for science research funding" and

<sup>2</sup> Romig et al. (2007) have suggested that one of the core problems that policy-makers face is the ambiguity and loose usage of the term "nano." I did not attempt to ascertain if the use of nano in any of the public values statements was used with technical accuracy, but rather I assumed that any use of the term (i.e. nanomedicine, nanopolicy, nanoformulation) were all related to the same basic science.

<sup>3</sup> <http://www.aacr.org/home/public-media/patients-family/fact-sheets/cancer-concepts/nanotechnology.aspx>.

**Table 1** Sources of Public Value Statements in Emerging Nanomedicine

| Key     | Source   | Key      | Source   |
|---------|--|----------|--|
| AHRQ    | Agency for Healthcare Research and Quality   | KFF      | Kaiser Family Foundation   |
| AACR    | American Association for Cancer Research   | WKK      | WK Kellogg Foundation  |
| ACS     | American Cancer Society  | KKI      | Kennedy Krieger Institute  |
| AMA     | American Medical Association   | MCPHI    | Morehouse College Public Health Institute - Research Center on Health Disparities                  |
| AMHPS   | Association of Minority Health Professions Schools   | NCICRCHD | National Cancer Institute Center to Reduce Cancer Health Disparities                               |
| CDCOMH  | CDC Offices of Minority Health and Health Disparities and Office of Public Health Research | NCIANC   | NCI Alliance for Nanotechnology in Cancer  |
| CEHDMSM | Center of Excellence on Health Disparities – Morehouse School of Medicine                  | NCMHHD   | National Center on Minority Health and Health Disparities  |
| CF      | The Commonwealth Fund  | NIEHS    | National Institute of Environmental Health Science   |
| CHDPRG  | Cancer Health Disparities Progress Review Group  | NMA      | National Medical Association   |
| EPANCER | Environmental Protection Agency National Center for Environmental Research                 | REACH    | REACH US: Racial and Ethnic Approaches to Community Health Across the US                           |
| DHHSOMH | DHHS Office of Minority Health   | DSMD     | David Satcher, M.D., Ph.D.   |
| HDC     | Health Disparities Collaborative   | DCHMHAC  | State of Georgia Department of Community Health's Office of Health Improvement and Minority Health |
| RWJ     | Robert Wood Johnson Foundation Finding Answers   |          |  |

“innovation in research design,” without mention of equity or disparities.<sup>4</sup> An example of a translational research document that was generated through the stakeholder-document search is the CDC Offices of Minority Health and Health Disparities and Office of Public Health Research’s *Funding Opportunity Announcement Elimination of Health Disparities through Translational Research*.<sup>5</sup>

For this research I manually prepared a data set of public values statements. The research procedures were to:

1. *Develop a preliminary inventory of public values, derived primarily from Jorgensen and Bozeman’s (2007) approach where they analyzed the role and relationships of politicians, public administration and their constituents. I*

<sup>4</sup> [http://www.epa.gov/ncer/publications/handouts/ncer\\_flyer\\_2008.pdf](http://www.epa.gov/ncer/publications/handouts/ncer_flyer_2008.pdf).

<sup>5</sup> <http://www.cdc.gov/od/pgo/funding/CD08-001.htm>.

- found that Jorgenson and Bozeman's value set was comprehensive, though the categorization they used would obviously need to be modified for my case.
2. *Identify at least one document on the stakeholder website that describes the entity's mission and/or purpose.* This document was used to ensure that the entity was indeed concerned with nanomedicine and/or cancer disparities. The introductory document was often found to be one of the richest sources of value statements.
  3. *Prepare an inventory of other public documents from the stakeholder source and prioritize the documents according to their relevance to the case.* A quick scan of the high priority documents revealed additional stakeholder sources and these were added to the source list and included in the data collection process.
  4. *Create a spreadsheet with stakeholder source, entity description, description of the document and documented public values statements.* Two scans, one of the electronic copy and one of the hard copy, were completed, with at worst only one or two omissions of public value statements per document. Multiple references to the same value statement were not noted, though with additional analytical resources like content analysis software, counting value statement references within a document might be an interesting quantitative analytic contribution to this type of research in the future (Slade 2009).
  5. *Organize the value statements by category.* The public values statements in the spreadsheet were sorted and organized by categories, developed for this case according to the type of document in eight major categories including basic research, clinical trials, health care delivery, public health, individual health, government, community/society and education.

Table 2 presents the key instrumental public values statements for the stakeholder groups identified in Table 1, using the search methodology previously described.<sup>6</sup> Better evidenced in the full data set but also recognizable in Table 2 is that there is no shortage of instrumental value statements related to equitable benefits and risks of nanomedicine in cancer resulting from this type of public document search.

## Findings

One of my initial findings from the public values statement scan concerns the breadth of stakeholder interests in societal values and the sheer number of public values statements identified. To make the list, the stakeholder source document had to articulate public values related to equity, translational research for nanotechnology or nanomedicine in cancer. I had no difficulty finding agencies and entities with documents explicitly attributing policies and programs to public interest, especially equitable access to emerging technologies. Nearly 700 statements in 100 documents represents a remarkable amount of attention to public interests. In addition, I found certain documents of particular interest for the study. For example, the NCI Alliance

<sup>6</sup> The full data set can be found at <http://www.cspo.org/pvm-nanomedicine/>.

**Table 2** Instrumental Public Values Statements in the Discourse on Nanomedicine and Cancer Treatment Equity

| Value Statement                           | Sources   | Examples   |
|---|---|--|
| access                                    | AHRQ, CF, CHDPRG, DCHMHAC, DSMD, HDC, KFF, NCICRCHD, NCMHHD, NMA  | The Community Networks Program of the National Cancer Institute's Center to Reduce Cancer Health Disparities... aims to increase access to and use of beneficial cancer interventions, such as proven approaches for... early detection and treatment of breast, cervical, prostate and colorectal cancers ( <a href="http://www.erchd.cancer.gov/about/overview.html">www.erchd.cancer.gov/about/overview.html</a> ).       |
| collaboration                             | AACR, ACS, AHRQ, AMA, AMHPS, CDCOMH, CEHDMSM, CF, CHDPRG, DCHMHAC, EPANCER, HDC, KKI, NCIANC, NCICRCHD, | "The American Cancer Society's international mission concentrates on capacity building in developing cancer societies and on collaboration with other cancer-related organizations throughout the world in carrying out shared strategic objectives" ( <a href="http://www.cancer.org/ACSMissionStatement">www.cancer.org/ACSMissionStatement</a> ).   |
| consumer empowerment                      | AACR, AHRQ, CEHDMSM, CF, DHHSOMH, HDC, KKI, NMA   | The specific aims of the community partnership development resource of the Center of Excellence on Health Disparities of the Morehouse School of Medicine are to... create consumer participant groups... that will act as advisors to academic researchers on community based projects ( <a href="http://www.web.msm.edu/EXPORT/cpd.html">www.web.msm.edu/EXPORT/cpd.html</a> ).  |
| data and analytical methods               | CF, CHDPRG, DCHMHAC, KFF, NCMHHD, NMA   | The call to action for the Trans-HHS Cancer Health Disparities Progress Review Group includes establishing "new approaches for data collection and sharing to aid in the study of the effects of cancer and their relationship to variables such as race, ethnicity, and socioeconomic status" ( <a href="http://www.hhs.gov/chdprg/about/">www.hhs.gov/chdprg/about/</a> ).   |
| education                                 | ACS, AMA, AMHPS, CF, DCHMHAC, NCMHHD  | The AMHPS is intended to... build and strengthen institutional infrastructure supporting the development and implementation of effective programs to advance professional development, education, and research training for racial and ethnic minorities ( <a href="http://www.cdc.gov/omhd/CoopAgree/BAA.html">www.cdc.gov/omhd/CoopAgree/BAA.html</a> ).   |
| effective research and interventions      | AHRQ, CDCOMH, CEHDMSM, CF, DHHSOMH, HDC   | Center of Excellence on Health Disparities at the Morehouse School of Medicine's goal is to increase the critical mass of talented research faculty pursuing health disparities research training in biomedicine and provide the research infrastructure needed for investigators to pursue excellence in the 21st century ( <a href="http://www.web.msm.edu/EXPORT/history.html">www.web.msm.edu/EXPORT/history.html</a> ). |
| minority participation in clinical trials | AHRQ, CEHDMSM, DHHSOMH, NCMHHD, NMA   | The AHRQ concludes that "clinical investigators need effective strategies to improve participation of underrepresented populations in cancer clinical trials" ( <a href="http://www.ahrq.gov/clinic/tp/recruitip.htm">www.ahrq.gov/clinic/tp/recruitip.htm</a> ).  |



**Table 2** continued

| Value Statement        | Sources  | Examples  |
|------------------------|--|---|
| systematic change      | DHHSOMH, DSMD, HDC, NCIANC, WKK                        | The Strategic Framework for Improving Racial/Ethnic Minority Health and Eliminating Racial/Ethnic Health Disparities presents a vision – and provides the basis – for a “systems approach” to addressing racial/ethnic minority health problems within and outside of HHS. A systems approach implies that all parties engaged...are themselves part of system or nested systems ( <a href="http://www.omhrc.gov/npa/framework/">www.omhrc.gov/npa/framework/</a> ).  |
| translational research | AHRQ, CDCOMH, CEHDMSM, DHHSOMH, MCPHI, NCIANC, NCMHHID | The Translational research core [of the CEHD of Morehouse School of Medicine] will offer a centralized location where researchers can share and collect biological information that will aid in leading-edge basic science technologies to probe the biological basis of health disparities. This integration of knowledge from lab bench to bedside to community is another fulfillment of the “three dimensional” approach to health disparities research ( <a href="http://www.web.msm.edu/EXPORT/translational.html">www.web.msm.edu/EXPORT/translational.html</a> ). |

for Nanotechnology in Cancer produced a document entitled *Cancer Nanotechnology Plan: A Strategic Initiative to Transform Clinical Oncology and Basic Research through the Directed Application of Nanotechnology 2004*. Collaboration, cooperation and partnership in research are recognizable value statements presented as solutions to societal problems of suffering and death from cancer (NCI). Since this is in the vein of PVM, I consider this to be some evidence that PVM continues to emerge as a unifying framework that can help tie non-economically driven public values to solutions to societal problems like cancer.

Perhaps most remarkable in this catalogue of public values statements is the lack of statements concerning equity in documents that address public priorities for basic research (as in the AACR's Cancer Concepts: Nanotechnology and the NCER Program Brochure examples noted above). While the basic research-related documents I reviewed were often produced by entities also generating public documents concerned with equity, I found no mention of equity in any of the basic research-type documents. This is an important finding for this case given that much of the promise of nanomedicine in cancer is currently in the hands of the basic research enterprise. Further there are NIH imperatives for translational research where basic research is tied to health care delivery through communication and coordination between stakeholders. Perhaps PVM could be better integrated into policy for improving translational research to result in expanded discussion of societal values like equity in the basic research enterprise.

### **Additional Public Values Failure Assessment**

In the research previously described, I use a method of scanning for value statements in public documents of stakeholders in the policy discourse of equity in access to evolving nanomedicine in cancer to demonstrate potential differences or gaps in public value statements. Another aspect of the PVM model is to identify, through real or deduced examples, the potential public policy failures that relate to a wider variety of core or intrinsic values. The purpose of this second analysis is to further show the value of the framework, to identify some gaps in policy and to make the risk of public failure for equity in emerging nanomedicine more recognizable and actionable. Bozeman (2007) emphasizes the need for very specific cases to ensure meaningful and effective demonstration of application of the public value failure model. For the public failures analysis portion of this paper, I chose access to clinical trials to refine my case study. I focus on clinical trials because they represent the mechanism for novel technologies like nanotechnology to become standards of diagnosis and treatment. In addition, clinical trials represent one of the first opportunities for inequities; patients may have access to the technology or be discriminated against.

Table 3 below summarizes my diagnostic of public failure for a broad range of intrinsic values related to equity for nanomedicine in cancer clinical trials. I use Bozeman's (2002, 2007) model of public failure, including his seven core value criteria: 1) mechanisms for articulating and aggregating values, 2) imperfect monopolies, 3) benefit hoarding, 4) scarcity of providers, 5) short time horizon, 6)

**Table 3** Public Values Failure Model Applied to Nanomedicine in Cancer

| Public Failure                           | Failure Definition   | Illustration for this case   |
|--|--|--|
| Interest articulation or aggregation     | Political processes and social cohesion insufficient to ensure effective communication and processing of public values.  | Even within NIH, there is no consistent or effective policy/strategy to increase minority participation in clinical trials. NIH requirements for minority participation in sponsored research dating back to 1993 have been ineffective in increasing proportion of minorities in trials.  |
| Imperfect monopolies                     | Private provision of goods and services permitted even though government monopoly deemed in the public interest.   | Minorities, especially low income persons in minority groups tend to receive their health care in private community settings that are least likely to have physicians with access to or an interest in participation in sponsored research including clinical trials.  |
| Benefit hoarding                         | Public commodities and services have been captured, limiting distribution to the population.   | Lack of diversity in potential study populations (those with access to participating physicians or centers) results in inequitable distribution of clinical trials (often life-saving) resources. Most trials limit co-morbid conditions that are more prevalent in minority populations.  |
| Scarcity of providers                    | Despite the recognition of a public value and agreement on the public provision of goods and services, they are not provided because of the unavailability of providers. | In addition to a lack of minority physicians in general, only 3 to 4% of board-certified minority physicians participate in clinical trials (compared to several times that for white physicians).   |
| Short time horizon                       | A short time horizon is employed when a longer-term view shows that a set of actions is counter to public value.   | Healthy People 2010 and 2020 short-term goals for cures for cancer and elimination of health disparities are inconsistent with timeframes for nanotechnology development. This could result in some technologies being favored for sponsored research and clinical trials in the short-term (to get a quick bang for the buck) to the exclusion of those with better long-term benefits and efficacy, especially for minorities. |
| Conservation of resources                | Policies focus on substitutability (or indemnification) even in cases when there is no satisfactory substitute.  | Health care and health science resources not equitably distributed and not easily redistributed.   |
| Threats to human dignity and subsistence | The core value of subsistence is violated.   | Results of clinical trials often have limited generalizability to the population as a whole and with even less generalizability to minority groups that may experience different biological responses to drugs and devices than most study participants. The result could be greater risk to minorities of the "unintended consequences" of nanotechnology.  |

substitutability versus conservation of resources, and 7) threats to subsistence and human dignity (Bozeman 2002, p. 151). In the paragraphs following the Table, I explain the failure definition and illustration in more detail.

### *Interest Aggregation or Articulation Criterion*

The PVM model suggests that public failure can result from an inability to aggregate interests. In my case, the NIH especially has detailed policies and requirements for including minorities in clinical trials, yet with little positive impact so far (Bruner et al. 2006). Conversely, NIH has limited specific policies for translational research; at this point it is only a roadmap. Garber and Arnold (2006) suggest that the admirable plans of NIH are often distorted through their policies, perhaps because the arguments minorities receive for clinical trials participation are not compelling or tailored to their needs or desire for novel treatment. This is an example of lack of aggregation of interests among key stakeholder groups.

### *Imperfect Monopolies Criterion*

Imperfect monopolies occur when the government's lack of protection of its appropriate monopoly leads to public value failure. Health care is a public-private venture, undeniably fraught with challenges. To be of societal benefit nanomedicine must fit into a myriad of government policies, programs and processes. Government appropriately "owns" a monopoly over the regulatory process for medicine and research. Yet, as Long et al. (2004) suggest, a scan of the recent health disparities literature shows few if any new interventions; policy research is almost entirely devoted to documenting continuing disparities. That the government has failed to create insurance programs to reduce disparities in access to cancer clinical trials (Colon-Otero et al. 2008) suggests that the polity is overconfident in the private provision of insurance coverage of clinical research. I contend that public failure already exists and, given the existence of entrenched inequities, it can only get worse as nanomedicine creates an explosion of clinical research activities, absent decisive interventions (e.g. Woodhouse and Sarewitz 2007).

### *Benefit Hoarding Criterion*

Health disparities, especially in minority access to clinical trials, are not entirely the result of financing. Murthy, Krumholz and Gross (2004) demonstrated that accession and participation disparities often result from preexisting condition and co-morbidity exclusion criteria that are more prevalent in minority populations. The NIH requires justification for explicitly excluding minorities from clinical trials, suggesting that approved trials have access that is fair and equitable. Yet, the research design of the trial itself may subtly limit access to minorities resulting in the benefits of novel treatments being captured by certain population groups. For example, the clinical trial may restrict access to persons with certain types of chronic conditions such as diabetes or hypertension. Because underrepresented

minorities are more likely to have comorbid conditions such as these, then this becomes one of several of the more subtle barriers to clinical trial access that results in greater benefits for advantaged whites in particular (Ford et al. 2008).

#### *Scarcity of Providers Criterion*

Cancer research is widely geographically distributed. However, limited progress has been made to ensure that community physicians can participate. Pinto et al. (2000) documented the myriad of reasons why community physicians are challenged to participate in clinical trials to the benefit of their patients. Regardless of the source of barriers to community physician participation (Swanson and Ward 1995), suffice it to say that limited access for community physicians, the primary source of health care for minorities, will result in a scarcity of providers to accession minority patients to trials of novel treatments like nanotechnology. Minority access to clinical trials through providers that engage in clinical research does not in itself ensure more equitable health outcomes, but it does ensure that minorities have the same opportunities as whites to benefit from novel treatments in the research and development process.

#### *Short Time Horizon Criterion*

Public value failure can occur when a short-term solution is applied to a situation clearly requiring longer term action. In my case, the charge to curing cancer (or more realistically, substantial advances in cancer prevention and treatment in lieu of a perfect solution and cure) by 2015 (see Healthy People 2010, 2000), could supersede equitable distribution of the benefits of novel treatments. Lacking minority participation in cancer trials, the research community could come to the conclusion that the War on Cancer is won, even when there is no evidence that effective treatment for non-minorities works for minorities as well (Yancy 2008). Perhaps, substantially different results from clinical trials and, more important, different allocation of resources for drug development and other treatments and diagnostics would result if there were greater minority participation in trials.

#### *Conservation of Resources Criterion*

Conservation of resources deals with the issue of substitutability. In the current case, this would mean that access to novel treatments would not deplete key resources, such as funding for health care delivery or the use of health care facilities and services. The funding for clinical trials of novel treatments is often misconstrued; clinical trials in many respects are financed with private insurance coverage just the same as standard treatment. It has been well-documented that the insured are more likely to participate in research than the uninsured and that minority populations are less likely to be insured (Garber and Arnold 2006). The NIH Revitalization Act of 1993 mandates that NIH create programs and policies to not allow cost to be an acceptable exclusion from clinical research. So long as the treatment aspect of

clinical research is essentially financed through health insurance programs, then disparities in access will continue to occur. Since health care resources and access to services due to insurance constraints are not equitable, then resources from clinical trials are likely being depleted by some well-insured persons to the detriment of others who have more limited access. There is no reason to believe this situation would not continue as there are new advances in nanomedicine for cancer treatments.

### *Threats to Human Dignity and Subsistence Criterion*

The failure to make cancer clinical trials, even those related to nanotechnology, accessible to all has resulted in less generalizability to all groups within the population. In the case of nanomedicine, the results of this incomplete information could have unintended consequences for minorities who are less involved in trials that produce the knowledge used to further research enterprise.

## **Conclusions and Recommendations**

This public values statements analysis shows no shortage of value statements for consideration among stakeholders focused on equity in nanomedicine for cancer. Working groups and more long-term stakeholder entities are producing numerous public documents that are value-laden. Yet, the discourse is complex. I suggest that engaging PVM approaches early in the development of science and technology, specifically at the basic research level, could promote translational research for societal betterment. For example, and as a start and certainly using more sophisticated content analysis methodology and technology, why not scan federal grant applications for basic research for value statements consistent with public priorities and policy for clinical application of the science?

At this point the results of this analysis are more descriptive than prescriptive, but the findings suggest potential enhancements to science policy analysis. My investigation thus far suggests that translational research efforts of NCI, especially as they relate to the implications of emerging technologies such as nanotechnology on health disparities, could benefit from use of additional unifying frameworks for discourse on public priorities among the many stakeholders. Public value mapping holds promise in this respect, yet it needs further testing and methodological development, especially with respect to identifying and analyzing public values statements in frequency and context and in the way public values change over time.

Potential public value failure of nanotechnology in cancer is not entirely a government policy/program problem, which is why I believe it lends itself especially well to the PVM analytic framework. For example, in addition to the short-term inequitable access of minorities to nanotechnology trials, the long-term effects could be additive and cumulative as a result of the current system for technology development and commercialization in medicine (Hede and Huilgol 2006). The means of access to emerging and promising cancer technologies should

be no different for minorities than for the rest of the population and barriers for all include lack of: insurance coverage; adequate financial resources; proximity to providers; and the like. In addition to be less likely to be insured, minorities are less likely to pursue or agree to experimental treatment or access to novel technologies and too little is known about the reasons (Garber and Arnold 2006). A public value mapping treatment would bring an additional tool for consideration of social implication and values, irrespective of whether the sources of potential problems are public or private entity responsibility or considered in conjunction with discussion of market efficiency technologies.

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