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Parallels Between the Development of Therapeutic Drugs and Cancer Health Disparity Programs:

Implications for Disparities Reduction

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Abstract

BACKGROUND—There are analogies between the development of therapeutic drugs for cancer and the development of interventions for reducing cancer health disparities. In both cases, it can take between 12 and 15 years for the benefits to become apparent.

METHODS—The initial preclinical phase of drug development is analogous to the development of community partnerships and helping the community learn about cancer. The preclinical phase of in vitro and in vivo testing is analogous to identifying the disparities in the community. Then clinical testing begins with phase 1, toxicity, and dose-establishing studies. Analogously, community-based participatory research is used to develop disparities–reducing interventions (DRIs) within the community.

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RESULTS—The phase 2 clinical studies to determine whether the drug has activity are analogous to the DRI being implemented in the community to determine whether it can cause behavioral changes that will reduce cancer health disparities. If a drug passes phase 1 and 2 studies, phase 3 clinical trials are initiated. These are controlled studies to examine the efficacy of the drug. The similar activity for disparities research is to determine whether the DRI is better than the current standard/usual practice in controlled trials. If the drug is beneficial, the final phase is the dissemination and adoption of the drug. Analogously in disparities, if the DRI is beneficial, it is disseminated and is culturally adapted to other racial/ethnic groups and finally adopted as standard practice.

CONCLUSIONS—The process of creating an effective DRI can be envisioned to have 4 stages, which can be used to aid in measuring the progress being made in reducing cancer health disparities.

Keywords

therapeutic drugs; cancer health disparity; disparities-reducing intervention; information dissemination; community-based participatory research

In 2000, the national goal of eliminating health disparities by 2010 was proclaimed[1]; however,as we draw closer to that target year, it is becoming apparent that, similar to curing cancer, eliminating cancer health disparities is likely to be much more complicated and involved than initially envisioned.[2] Our premise in this article is that the goal of eliminating cancer health disparities or the differences that exist among specific population groups in the US[3] is laudatory and inspiring, but the complexity of disparities makes reduction a much longer process than first expected. In examining the progress made to date, we observed that, similar to the development of drugs for cancer, the elimination of cancer health disparities represents a series of progressive steps that leads to the ultimate goal. Each step in the drug development process builds on prior foundations, all of which require various amounts of time, resources, and persistence. In this article, we developed a model for the reduction of cancer health disparities based on analogies with therapeutic drug development.

MATERIALS AND METHODS

Beginning in 2000, the National Cancer Institute (NCI) furthered its commitment to address the unequal cancer burden[4] experienced by racial/ethnic minorities by funding the Special Populations Networks (SPNs) for 5 years.[5] Eighteen such networks were funded and included national networks that focused on Appalachian residents and on each of the major racial/ethnic groups (African Americans, Hispanics, American Indians/Alaska Natives, and Asians and Pacific Islanders), as well as local and regional networks.[6–8] Being funded as cooperative agreements (U01 grants) rather than R01 grants fostered collaboration with these communities; they became partners in cancer awareness, research, and training, rather than being the objects of research. Over a 5-year period, these SPNs catalyzed or conducted greater than 1000 cancer awareness activities; trained greater than 2000 community lay health workers; formulated greater than 300 formal community partnerships through signed Memoranda of Understanding; trained greater than 150 minority researchers; produced greater than 290 peer-reviewed scientific publications; and leveraged the NCI's Center to

Reduce Cancer Health Disparities funding by obtaining in excess of $20.5 million from additional sources for training, cancer awareness, and research activities.[6] In recognition of the need to focus even further on the community-based reduction of cancer health disparities, the SPNs were succeeded by the Community Networks Program (CNP) in 2006. A total of 25 such CNPs have been funded to date, with 13 of them being former SPNs.

As stated in the requests for applications (RFA), the goal of the CNP (RFA-CA-05-012) is to reduce cancer health disparities using 5-year cooperative agreement grants.[9] Cancer health disparities occur when beneficial medical interventions (eg, smoking cessation, mammography, Papanicolaou smears, colorectal cancer screening, and beneficial cancer treatments) are not shared by all. The goal of the CNP is to increase access to and utilization of these beneficial medical interventions. This goal was conceived to occur in 3 phases:1) phase 1: capacity building and community education; 2) phase 2: community-based research and training programs; and 3) phase 3: credibility and sustainability of the CNP. An examination of the progress and achievements of these programs over the course of 8 years (5 years of SPN and 3 years of CNP) provides insight into the steps needed to reduce cancer healthcare disparities.

RESULTS

Parallels between Therapeutic Drug Development and Reducing Cancer Health Disparities

Developing a drug to market or distribute is a complex process that typically requires between 12 and 15 years.[10] Reducing cancer mortality rates in the general population has taken approximately the same number of years. The advent of large-scale cancer screening, such as the use of mammography, initially caused cancer incidence rates to rise beginning in 1982,[11] and it was not until 1993 that a consistent pattern of decline in breast cancer mortality occurred. Importantly, the decline in mortality was found to occur at different times in different racial/ethnic groups. Twelve years (1982–1993) were needed to demonstrate the declines for whites.[12,13] For blacks, it took until 2000-19 years-to observe these changes in mortality rates, a total of 7 years longer.[12,13] Thus, it takes many years to reduce cancer mortality rates because of beneficial cancer interventions and even more to reduce cancer health disparities. Furthermore, the issue of cancer health disparities and their reduction is extremely complex, involving the individual with the disparity, their primary care provider, their community, and the healthcare system that serves them. For progress to be measured during a relatively short period of 5 years requires evaluating the procedures or interventions that attempt to reduce the disparities, rather than changes in the incidence or mortality rates.

In drug discovery,[10] molecular target identification begins with an understanding of the basic pathways involved in the carcinogenic processes. In cancer health disparities research, the first stage is capacity building and understanding the community's disparities and their determinants. This involves multiple steps. The first is to identify the cancer health disparities in the racial/ethnic populations within a geographic area. These include differences in cancer incidence and/or mortality rates or differences in the use of recommended cancer procedures, such as screening guidelines. The next preclinical stage is the development of the drug affecting the molecular target. Once the target for the drug is

identified, the development or identification of a drug to impact the target is the next challenge. The development of community and clinical partnerships in the racial/ethnic populations within the geographic areas is the analogous step in disparities research. The partnerships are the link between the disparities and groups that can affect changes. The process of forming partnerships also helps in understanding the community power structure and functioning. The next step for drug development is in vitro studies, the use of cell lines to determine whether the drug can affect the target site. The scientific question is “does the drug affect the target site?” For community-based programs, educating the partners about cancer and the principles of community-based participatory research are essential. The key element of trust grows through the transparent sharing of data with the community, and open engagement in the community-based participatory research process.[14] The next step in drug design are animal in vivo studies: “Does the drug work in an in vivo system? Is it likely to work in humans? Is it too toxic for human use? What is the likely dose for humans?” The in vivo studies use a small number of animals to determine the answers to these questions. In health disparities, the analogous activity is needs assessments, key informant surveys, and focus groups to confirm the disparities and determinants that should be addressed, with priority assignments of these disparities. This process is likely to include the development of a community action plan (via a community-based participatory process) to address the targeted disparity.

In drug development, the completion of the preclinical phase initiates the study of the drug in humans, which is the clinical phase. It begins with phase 1 clinical trial studies. These studies are performed in a small number of patients. There is a determination of the safe dose, any toxicity is identified, and modifications are implemented if necessary. The analogous activity in cancer health disparities is the development of the intervention with community participation. This may involve an evaluation of the acceptability and ease of administration of the intervention within the community and the intervention may undergo modifications as necessary. This phase ends when the community approves the intervention to be implemented within the community. For drug development, phase 2 clinical trial studies are begun to determine whether the drug has any efficacy (eg, assessing partial and complete response rates, disease-free survival, and overall survival). In health disparities, the analogous activities are the implementation of the intervention in targeted racial/ethnic geographic populations with the measurement of behavioral change. The metrics may be pretests and post-tests, comparison with historical controls, changes in behavioral surveys, and other measures that can determine whether the intervention can affect behavior changes within the targeted disparities.

If phase 1 and 2 drug development studies are successful, phase 3 clinical trials are then initiated. These are controlled studies to determine whether the drug is better than the current standard of care. These can be large studies that involve cooperative groups, cancer centers, and community cancer oncology programs. They are characterized as requiring additional funding, apart from the funding for the phase 1 and 2 studies already performed. In cancer health disparities, the controlled testing of the intervention in communities also may require additional funding, such as from investigator-initiated sources (eg, R01 and P01 grant mechanisms).

The final stage is the dissemination, adaptation, and adoption of the intervention so that communities can use the intervention to reduce healthcare disparities. In drug development, if the intervention is successful, providers are educated about the drug to make the distribution of the drug more readily available. This can allow for the adoption of the drug as the standard care. In cancer health disparities, the successful intervention is made available to others so that they can disseminate the intervention to other communities, and adapt it to the cultural issues of other racial/ethnic groups, leading to its adoption as standard/usual practice. See Table 1 for the comparison of drug discovery and development and reducing cancer health disparities.

A simple metaphor for these stages is the example of diagnosing and treating a patient. The development of partnerships is similar to the patients telling the physician about their illness and the physician performing a clinical examination of the patient and taking the vital signs (blood pressure, temperature, and pulse) and assessing the anatomy of the patient. This dialogue, similar to the formation of community partnerships, is a critical first step. Conducting needs assessments and assets mapping of the community to determine their priorities, resources, and disparities are similar to clinical tests of blood and tissue samples collected from the patient to assess physiology. Developing the disparities-reducing interventions (DRIs) with the community is analogous to diagnosing the patient using all the information collected and proposing a treatment based on a determination of the pathology of the patient's symptoms. The evaluation of the DRI is similar to examining whether the treatment proposed works to help the patient by assessing the pharmacology to treat the problem. The dissemination of the results to the community is similar to the provider informing/educating the patient's family and friends about the illness and its successful treatment.

In the mid-1980s, a 5-phase cancer control process was created for the development of cancer interventions.[15] Those phases include 1) hypothesis development; 2) methods development; 3) controlled intervention trials; 4) defined population studies; and 5) demonstration and implementation.[15] The scheme we propose herein varies in several ways from the model developed in the 1980s. The first step is not hypothesis development; rather, it is capacity building (the development of community partnerships) and identifying and prioritizing the disparities within the community. Methods development can be viewed as similar to the development of the DRI. Our controlled studies include both efficacy studies (phase 3 controlled studies) and effectiveness studies (phase 4 defined populations studies). The need for the individual trial phases becomes less clear given the effects of the intervention on cancer statistics and the costs of individual trials. The final phases are similar, with the dissemination, adaptation, and adoption of the intervention for standard use. Thus, the 5 stages developed in the 1980s can become the 4 stages we propose in the current study.

DISCUSSION

The process of therapeutic drug development and the development and implementation of strategies to reduce cancer health disparities are complex, painstaking, and time-consuming. Both require careful development, evaluation, and substantial time for completion. The CNP

is a 5-year grant, which is certainly too brief to allow for the measurable reduction of cancer mortality rates. However, that timeframe may allow a CNP program to affect the determinants of cancer health disparities (ie, factors such as lack of knowledge, limited access, noncompliance with treatment, and lack of follow-up that potentially lead to disparities). The goal of the CNP is to increase access and use of the beneficial cancer interventions at the community level. It starts by identifying the determinants and then creating solutions to overcoming those factors so that beneficial medical interventions are accessible and used at the community level. The CNP develops community-based DRIs in progressive steps analogous to drug development.

The CNPs are directly involved in 2 of the 4 stages of DRI development. The first stage, capacity building with the CNP and the community, begins with developing partnerships with the community organizations and leaders. It is enhanced by partnerships with organizations that have resources that can help to reduce the disparities, such as the American Cancer Society. The CNP develops and administers cancer education programs to the community partnerships to impact their knowledge, attitudes, and behaviors about cancer. These activities help to establish trust between the CNP and the community. Trust begins with engaging the community through education, power sharing, and open dialogue. Needs assessments and key informant surveys are then performed to allow for the identification and priority assignment of community disparities and the assessment of existing programs that may be helpful in reducing the disparity.

The second stage in the development of the DRI is when the CNP works with the community to develop a plan to reduce and eliminate the determinants of disparities. For example, after the determinants have been identified, the CNP, working with the community, can develop culturally appropriate educational curriculum and educational materials so individuals from the community will gain knowledge regarding the use of beneficial medical interventions. The final step in this stage is to have the community support and approve plans to evaluate the efficacy of the DRI by assessing its impact on behavioral changes that can reduce disparities. This initial evaluation, generally performed with small numbers of individuals from the community, can be measured in several ways. If the determinants affect knowledge and attitudes, pretests and post-tests of an educational curriculum can be used. If 1 determinant is affecting screening rates, historical controls may be useful. After the DRI has been tested, the CNP can inform decisionmakers and others of the results of the DRI via publications, presentations, media events, and feedback to the community involved, thereby creating the third phase of the CNP: creditability and sustainability.

Two further stages in evaluating a DRI are beyond the scope of the current CNP grants. The next stage is testing the efficacy (does the intervention work in the study population?) and effectiveness (does it work in multiple populations?) of the DRI in controlled studies (analogous to phase 3 drug development trials). The DRI is compared with a control group (usually individuals receiving usual/standard practice) to determine whether it can reduce disparities compared with usual practice. Cost-effectiveness studies also may be needed. Investigator-initiated grants (such as R01s and P01s) or special initiatives (such asRFAs) are the general funding mechanisms for this stage.

The final stage is the dissemination of the results and adaptation and adoption of the DRI to those populations that are affected by the disparities. The DRI may need to be culturally adapted to other racial/ethnic groups, leading to the general adoption of the DRI as usual practice. These stages and CNP phases are shown in Table 1.

We have identified 4 stages in creating effective DRIs, similar to the stages in drug development. These stages mark the progressive steps toward the development of the DRI, each building on the foundation laid by the previous step. Without these progressive steps, the adaptability, effectiveness, and relevance to the community may be weak. The development of partnerships with the community is time-consuming, but is a necessary and critical factor in the success of the intervention. The development of educational programs for the community without engaging the community in the development certainly jeopardizes a successful community-based intervention. The joint development of the educational programs creates a level of trust between the community and researcher that is needed to demonstrate to the community that the researchers are genuinely concerned about its members. Finally, the community-based research participatory research principles[14] should serve as a guide for all aspects of the development of the DRI. The community is engaged as a full partner in reducing their own healthcare disparities.

In Table 2, we report the activities of the CNP in the area of community partnerships, clinical partnerships, educational activities, needs assessments, and interventions to be developed as a result of the first 2 years of activites.[16]

These stages may be useful in assessing programs to reduce cancer health disparities. Because it takes more than 10 years to observe actual declines in mortality rates, intermediate endpoints, such as developing interventions to affect determinants of health disparity, are needed to assess programs such as the CNP, which is a 5-year grant. The more than 900 partnerships with communities noted with the CNP require time to develop. The nearly 5400 educational activities performed with these partnerships allow these partnerships to grow into trusted relationships. The subsequent needs assessments of the communities demonstrate that community-based participatory research is community driven. The development of DRIs within the community in primary prevention (201) and more in secondary prevention (1501) within 2 years are important metrics for assessing how CNPs are moving toward reducing cancer health disparities. The processes in the development of DRIs can be important ways with which to evaluate progress in reducing cancer health disparities for programs of ≤5 years.

The parallels between drug discovery and population-based strategies to reduce cancer health disparities resulted from our cumulative experiences in working with at-risk populations. We encourage others to elaborate on the emerging discipline of cancer health disparities to develop metrics for documenting and evaluating the determinants and, more importantly, developing solutions to these determinants, thereby leading to the elimination of these disparities.

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TABLE 1

Comparison of Drug Discovery and Development with Community-based Cancer Health Disparities Research

Drug Development Phases	Drug Discovery and Development	Stages in Community-based Cancer Health Disparities Research	Community-based Activities to Develop Disparities-reducing Interventions	CNP Phases
Preclinical	Molecular target identification Development of drug/ molecule affecting molecular target	Stage I Capacity building and identifying disparities	Identification of cancer health disparities to be targeted, racial/ethnic population, geographic area (3–6 mo)	Phase 1: Capacity building and identifying disparities
	In vitro studies • Does the drug/ molecule affect the target? In vivo studies • Does it work in an animal model? • Is it likely to work in humans? • Is it too toxic for human use? • What is the likely dose for humans?		Development of community and clinical partnerships in targeted racial/ethnic and geographic population (12 mo)	Create partnerships
			Partnership education about cancer and principles of community-based participatory research (6–12mo)	Educating partners to build trust
			Needs/assets evaluation, key informant interviews, focus groups (6 mo)	Assessing the needs of community partners
			May develop Community Action Plan (via community-based participatory process)	
Clinical studies	Phase 1 clinical trial Safe dose Toxicity Modification as necessary	Stage II Developing interventions	Development of intervention, work with community to develop intervention with feedback and changes and then approval (is the “dose” appropriate and/or is it too “toxic”?) (6–2 mo) Field testing of intervention with initial evaluation of acceptability and ease of administration and modifications of plan as necessary (3– mo) Approval of intervention by community	Phase 2: Research and training Developing disparities reducing interventions
			Field testing of intervention with initial evaluation of acceptability and ease of administration and modifications of plan as necessary (3– mo)	
			Approval of intervention by community	
	Phase 2 clinical trial Efficacy (partial and complete response rate, disease-free survival, overall survival)		Full implementation of plan in targeted racial/ ethnic geographic population with measurement of behavior change (24–6 mo)	Implement intervention in community Phase 3: Sustainability and credibility – informing about disparities reducing interventions

Drug Development Phases	Drug Discovery and Development	Stages in Community-based Cancer Health Disparities Research	Community-based Activities to Develop Disparities-reducing Interventions	CNP Phases
	Phase 3 Randomized controlled trials	Stage III Evaluate intervention -Test in controlled studies	Controlled randomized trials comparing different interventions or intervention vs standard practice. Establish efficacy of the intervention then its effectiveness. May need to assess cost-effectiveness.	
	Delivery/ dissemination of new drug/product, adoption in practice	Stage IV Disseminate results to community and their adoption	Dissemination, adaptation, and adoption of intervention in practice by organizations/policy makers/providers	

CNP indicates Community Networks Program.

TABLE 2

Types of Community Network Program Activities

Types	No.
Community partnerships	
Total	949
Faith-based	188
Specific racial/ethnic group	246
Underserved populations	371
Clinical partnerships (services offered)	
Primary prevention	
Smoking cessation	84
Hepatitis B vaccination	70
Diet management	82
Exercise management	71
Secondary prevention	
Breast cancer screening	191
Colorectal cancer screening	148
Cervical cancer screening	165
Prostate cancer screening	139
Treatment	106
Educational activities (topics)	5377
General cancer education/awareness	1489
Breast cancer	1264
Cervical cancer	782
Colorectal cancer	664
Prostate cancer	369
Tobacco cessation/education	434
Cancer screening	1048
Nutrition/obesity education	369
Cancer research/clinical trials	138
Survivorship	226
Patient navigation	227
Needs assessment	
Need for information/education	27
Need language-specific information/services	14
Need culturally specific information/services	17
Need financial support	15
Overcoming physical barriers	16
System access assistance	14
Geographic access assistance	14
Logistical assistance (appointments)	15
Interventions under development*	

Types	No.
Primary prevention	
Smoking cessation	3
Diet/nutrition	2
Physical activity	1
Hepatitis B vaccination	1
Secondary prevention	
Mammography	3
Clinical breast examination	4
Papanicolaou smear	4
Human papillomavirus DNA	2
Prostate-specific antigen testing	5
Digital rectal examination	4
Fecal occult blood test	6
Sigmoidoscopy	2
Colonoscopy	5

* Number of community networks program grantees.