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The Stewardship Model

Current Viability for Genetic Biobank Practice Development

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The "stewardship model" of ethics relationships is a conceptual framework initially proposed by Jeffers in *Advances in Nursing Science*, 24(2), 2001. It conceptualized ethical responsibilities in the practice of systematic collection and storage of biospecimens in biobanks for future healthcare genetic research. Since the article's publication 8 years ago, genetic biobanks have grown in number around the world and discernible biobank relational conceptualizations were published. Nursing leadership adopted competency standards for all genetic nursing practices. The involvement of nurses has increased and is projected for further significant increase as biobank practices emerge from research into clinical care settings. This assessment of current viability of this previously established stewardship model offers fresh insights to existing and future nursing research and practice. The purpose of this article was to analyze the original stewardship model's components, the relational parties, and characteristics; by contrasting those with proposed conceptualizations and existing biobank practices developed subsequent to its publication. The model's current viability and theoretical development status are assessed for its ability to support a future nursing evidence base for best practices. Proposals for the model's expansion are suggested. **Key words:** *biobank*, *conceptual*, *contributor*, *genetic*, *gift*, *nursing*, *partnership*, *relationships*, *stewardship*, *subject*

NURSING PRACTICE INTERFACES WITH BIOBANKS

Collecting and storing of biospecimens for future use in genetic research is referred to as *biobanking*. Clinical settings and nursing practices within them are increasingly incorporating biobanking practices.[1,2] The Veterans Administration, the largest healthcare provider system in the United States, announced plans for its biospecimen collection initiatives for genetic healthcare research to take place in its primary clinical care settings. Research and clinical care are therefore being merged together into the primary healthcare setting.[3] Howard University has initiatives to collect biospecimens from African American clinical patients for its biobank to facilitate genetic healthcare research.[4] Another example of a biobank initiative in the pediatric clinical setting is ongoing at the Children's Hospital of Philadelphia, where the goal is to randomly select 1 million pediatric patients from the clinical care setting, to contribute their DNA, with consenting parents agreeing to not have access to study results.[1] A recent issue of *TIME* magazine featured biobank practices in clinical settings as one of 10 significant "ideas" that are changing the world "right now."[5]

Nurses are involved in several stages of biobanking practices. Most frequently, it is the clinical nurse who recruits participants for specimen contribution, educates, consents, collects, or is involved in specimen transfer to storage for future use, performing frontline

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functions in an extension of the genetic research biobank system. Nurse scientists may interface with previously collected, stored samples in their own genetic research studies. Other nurse researchers may access the existing genetic database for different studies. Under many existing biobank models, the steps of interaction between the original sample recruitment and its ultimate experimental use might not even be performed by the same nurse or under one organizational entity. For example, some biobanks may have nurses involved to recruit, consent, collect, and store the biospecimens for later distribution to nurse investigators and other scientists who are independent from the original collection site or accountable only by use agreement terms.

Early into the emerging personalized medicine era, a nurse bioethicist identified the need to examine understanding and expectations in relationships between biospecimen contributors, their contributed specimen, and those who handle it after collection, in order to develop best ethics practices, reduce risks, and promote patient protections in nursing practice.[6] Although the philosophical perspective in Jeffers's[6] description of the ethical issues in biobanking and stewardship role for nursing is not explicitly identified, the work in this author's estimation reflects a convergence of the 3 philosophical perspectives that are applied today in bioethics of Western cultures: consequentialist, deontological, and aspirational. This author's analysis and proposed conceptual expansion likewise is framed from a philosophical perspective valuing the convergence of these 3 philosophical paradigms traditionally applied in bioethical reasoning for Western scientific research and recently proposed for ethics applications in nursing practices.[7]

Since Jeffers's publication of the original stewardship model, professional nursing leaders from all perspectives of practice rallied to issue a consensus statement advocating that genetic competency be promoted as genomic technology emerges into all facets of the nursing profession.[8,9]

THE STEWARDSHIP MODEL AND OTHER BIOBANKING CONCEPTUALIZATIONS

The original stewardship model

Jeffers's stewardship model applies to interactions occurring during genetic healthcare research biobanking transactions. These interactions establish relationships arising from the parties' intent and mutual expectations.[6] The original publication described the framework by both written text and conceptual drawing. This analysis reviews the stewardship model's key features, followed by analysis of alternative parties and relational conceptualizations within other models.

Relational parties to stewardship model

The original stewardship model frames a dyad relationship between the "investigator" who eventually uses the sample and the biospecimen "contributor." The DNA contributed is defined as a "human biological material." The conceptual drawing does not identify the nurse or the biobank storing the material as parties to the transaction. The genetic sample contributor is described alternately as a *research subject* and *donor*, and the contribution transaction is referred to as *research* and *donation* interchangeably. These inconsistent descriptions create ambiguity in conceptual constructs and are therefore addressed in this article's conclusions and proposed revisions.

Jeffers[6] cautions about "the possibility of stigmatization of individuals, families, and communities that share the same genetic makeup" arising from genetic research with biobank samples and the specimen contribution processes. Although contributor families and communities are reflected as having potential risks in the conceptual drawing, future generations are not specified.

Relational characteristics in stewardship model

Proposed relationships between the interacting parties are characterized with attributes of respect for human dignity, responsibility, accountability, service, cultivation, conservation, and protection. An integral characterization of the stewardship function is its facilitation of "change" processes.[6] It is inferred that this change is progress in healthcare therapeutic discovery. The stewardship model proposes that ethical expectations between the parties are established through the Belmont Report and the "international principles underlying the Human Genome Project," both sources that endeavor to protect DNA contributors in the context of being a research subject.[6] However, there are other contrasting models of contribution that conceptualize a DNA contributor not as a research subject but instead as a donor or a partner. Those models are reviewed next. The original stewardship model is shown in Figure 1. The stewardship model in Figure 2 reflects revisions and expansion proposed given the critique that follows.

CONTRASTING CONCEPTUALIZATIONS

Gift theory conceptualization

The relationship between the DNA contributor, biobank, and/or the investigator using the sample can also be conceptualized as a donor-recipient relationship, with the contributed DNA defined as the *donation* or *gift* to science. Donors give gifts and research subjects provide samples, and although altruism may motivate behaviors in both types of transactions, the terminology must be kept consistent in defining conceptualizations to deter ambiguity regarding the parties' mutual expectations. The ambiguity and interchangeable use of the terms donor and research subject, as occurred in the original stewardship model publication, results in ethicists advocating and prioritizing more specific characterization of contributed human biological material for clarity in ethics expectations, theory, and concept development.[10,11]

Relational parties to gift theory

Science has a long-standing history of accepting intentional, altruistically motivated gifts that contain human tissue in the forms of cadavers, organs, and blood for healthcare reuse, transplantation, education, and research. An analogy emerged with the advent of intentional DNA contribution to biobanks and use of "medical waste" for genetic research. The analogy is that these DNA contributions are likewise gifts from altruistic motivation, just as are blood, cadavers, and organs. Therefore, the contributor is a donor of a gift, not a research subject.[12] This analogy, recently applied to DNA biobanking, has a theoretical base developed in 1970s public health research of motivations and benefits of blood donation in England.[13-15] In this view, the gift's beneficiary is the general public's welfare.

Relational characteristics in gift theory

According to gift theory, donors who contribute biological gifts benefit by gaining a vested interest in future change for the public good. DNA donors thus expect biomedical and healthcare developments based on the genetic research use of their samples. Whether these are realistic expectations and whether biomedicine and healthcare can accurately suggest revolutionary outcomes are achievable is another question. The recipient biobanks and scientific community can only offer promises of future progress in healthcare while they rely on the donor to trust the biobank's future use of the samples within those goals.[16] The relationship between the donor and the recipient, therefore, is characterized by exchanges and responsibilities that differ in duration and expected benefits from those typically formed between research subjects and scientists. For example, in the research subject role, the individual is not expected to perceive a vested interest in

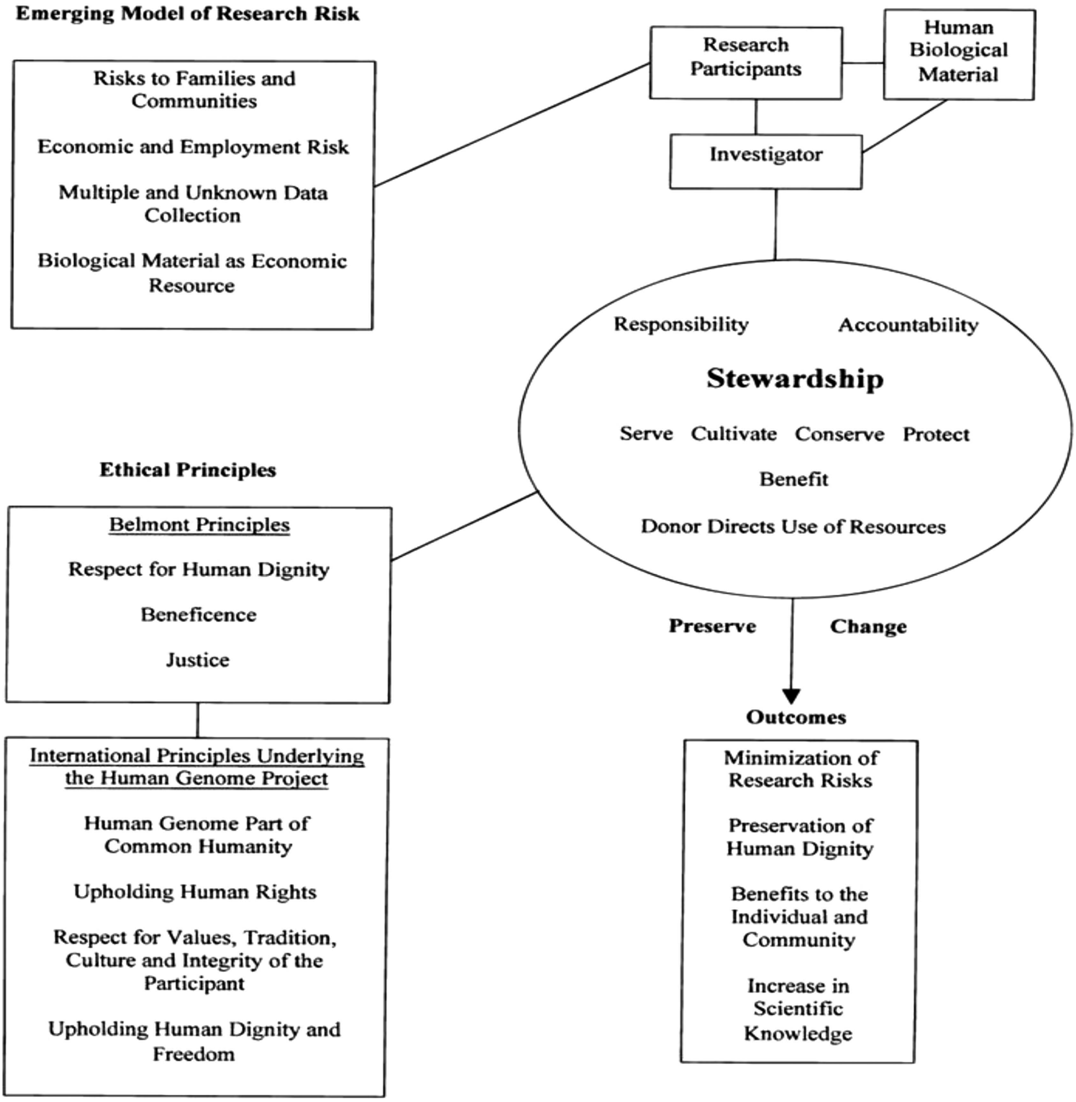

Figure 1. Jeffers's original stewardship model.

outcomes of the experiment using a contributed sample.

Partnership conceptualization

Relational parties to partnership conceptualization

A second model addressing DNA contributions is the *partnership model*. Where the stewardship model contemplates only family and community as having shared risks, the partnership model explicitly articulates the community as a party to directly shared benefits of potential future research discovery and the current process of intentionally uniting for a common cause, sense of community, and as an empowerment strategy.

Since Jeffers's original publication of the stewardship model, partnerships have evolved between DNA contributor communities and members of the scientific community in biobank initiatives for future

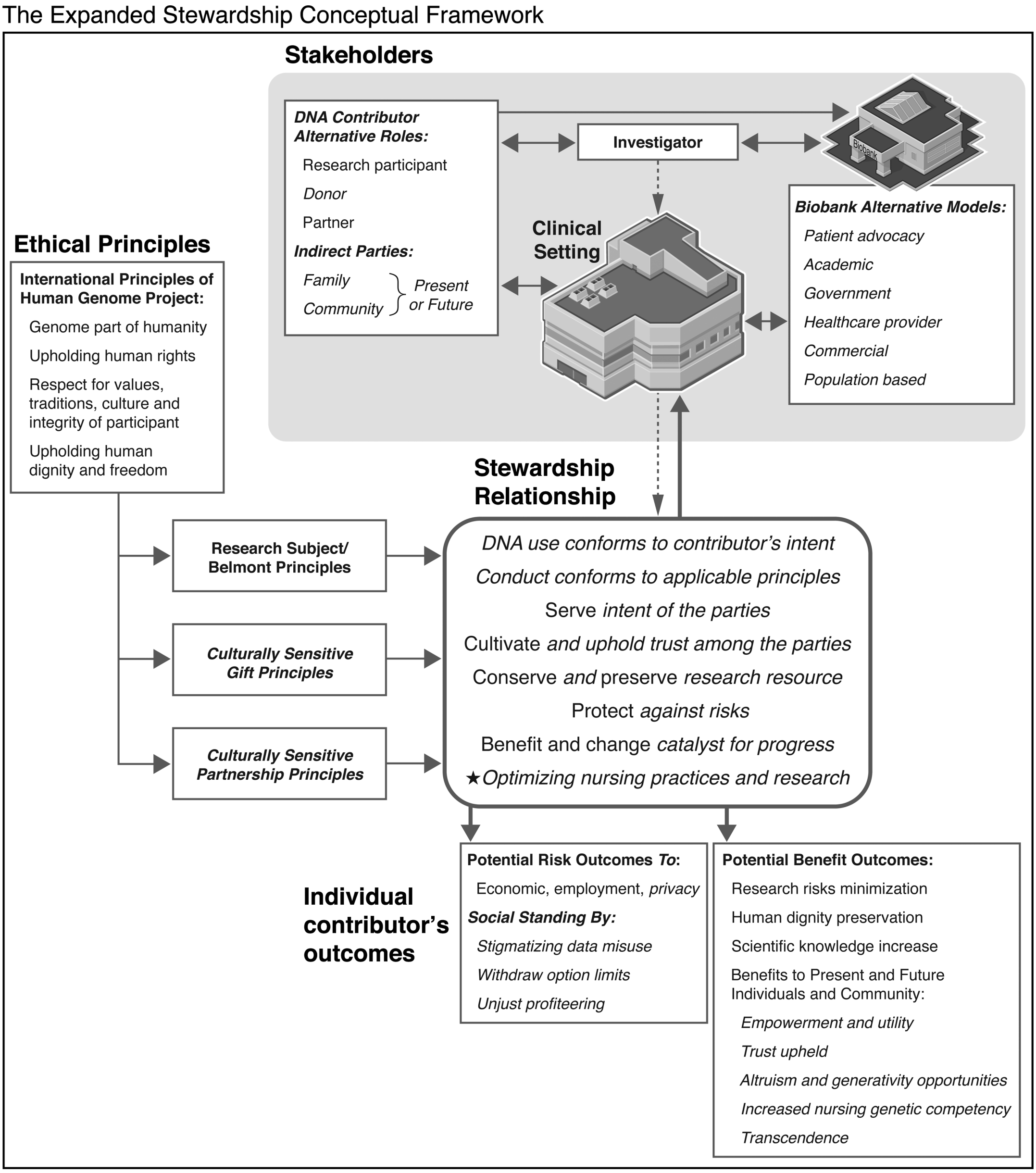

Figure 2. Revised and expanded Stewardship conceptual framework.

genetic research.[17] These partnership conceptualizations are driven by new initiatives among patient advocacy groups who serve as stakeholder communities and collective negotiating parties in the biobanking system. Partnerships on the genetic research agenda define DNA contributor roles differently from those of a tradition research subject or donor of needed biospecimen material.[18]

The Genetic Alliance BioBank system provides an example of an existing set of biobank relationships that follow a partnership conceptualization for the DNA contributor, the biobank and the scientist who uses the sample. In these partnerships, the patient-driven biobank is an extension of a patient community that partners as peers with independent scientists in the research. There may be negotiated terms such as financial gain distribution and ownership of discovery. Indirect third-party beneficiaries of the partnership are the contributors' families and communities, current and future.[17,19-23]

Relational characteristics of partnership conceptualization

A partnership is formed between the individual DNA contributor, the scientific community, and representatives of the contributing community members, and it determines what the present or future scientific study will have access to the genetic material. The biobank is an extension of the DNA contributor's own community. The DNA contributors, therefore, have direct representation of their interests during execution of responsibilities of distribution, conservation, and stewardship by the biobank. A beneficial outcome of the partnership model, not included in the stewardship model, is the benefit of self-empowerment within rare genetic disease communities—populations that have been historically marginalized in the healthcare research agenda.[24] These groups are empowering themselves in partnership conceptualizations of biobanks to meaningfully participate in research agenda priorities beyond their own lifetime or existing health, rather than observing research unfold from the sidelines.[18,19,21]

MASS MEDIA CONCEPTUALIZATION

Since the introduction of the stewardship model, mass media has also published conceptualizations of biobanks as analogous to a monetary bank, with contributors entitled to an expectation of "interest" on an investment. For example, biobanks recently were conceptualized to the general public this way:

> Think of it [the biobank] as an organic bank account, where biomaterial is "put in" and earns medical interest in the form of knowledge and therapies that grow out of that "deposit"... No monetary reward, just the potential that you might benefit from the accumulated data at some later date.[5]

This conceptualization does not try to classify the biobank recruitment in the clinical setting as anything other than a significant change. The article describes the healthcare consumer, the clinical setting, genetic research, and future healthcare recipients as the parties to this change. This conceptualization focuses on the impending change to the healthcare consumer who is expected to trust that there is some beneficial knowledge or therapies to result in the future from the DNA contribution.

Implications of the conceptualizations

There are similarities and significant differences in the composition of the previously described conceptualizations. The following analysis of their implications reflects how these common and differing elements relate to the stewardship model.

Conceptual characteristics with implications for nursing: Diverse, potentially conflicting interests in biobank practices

Nurses and other professionals involved in the clinical or research biobank practices serve diverse, potentially conflicting interests regardless of the relevant biobank conceptualization. Serving diverse interests raises professional practice ethics issues, and in the clinical setting, they raise risks of "therapeutic misconception" by the DNA contributor.[25-27] These expertise and practice issues combined with patient values and preferences in biobanking practices require further nursing inquiry to support an evidence base for best biobanking practices.[28] A conceptual model that proposes transparent characterization of alternative, complex relationships between stakeholders in biobanking is needed to frame the study of important biobanking issues. Reasonable expectations among the parties to biobank transactions are best elucidated by concise, equitable conceptualization of the relationships in the biobank system. The parties may include clinical professionals, the investigator using the sample, the biobank itself, biobank funders,[2] DNA contributors, contributors' community, contributors' family,[6] and contributors' future generations.[5]

Common conceptual characteristic with implications for nursing: Reliance on trust

Trust is a defining attribute to all identified biobank conceptualizations. All include the scientific community and biobank's reliance on the public's trust to develop the sample collections. Biobanks assume that contributors will trust that there will be no future harm and misuse of the derived genetic information.[29] The trust assumption needs articulation as a relational characteristic in the stewardship relationship. The process of articulation raises awareness and reinforces nursing inquiry and intervention development of biobank practices that uphold and protect this trust. Therefore, trust is added to the stewardship model drawing as a beneficial outcome when upheld and as a characteristic of the stewardship relationship (see Fig 2).

Nursing is identified consistently as the most trusted professional practice among the general public.[30] Nursing, therefore, has a responsibility to develop best nursing practices to maintain this trust in the biobanking context.

Difference in conceptualizations with implications for nursing: Representation and control

The diverse conceptualizations of the DNA contributors' role—research subject, gift donor, and partner—differ in the degree DNA contributors have representation and control in biobank practices after the sample leaves their possession. The language of biobank recruitment and consent documents may or may not clarify the contributors' role. DNA contributors may not be aware that they have choices among biobank models regarding their role and its relationship to the biobank.

The diverse contributor roles in the stewardship model highlight and frame the need for future nursing education and counseling interventions. Nursing can actively develop and promote a set of stewardship practices that are flexible and relevant to all biobanking conceptualizations: donor/recipient, research subject/investigator, and partner/partner. The trust of nursing and biobanking can be sustained by future nursing interventions that include educating and supporting decision making for patients and potential DNA contributors regarding choices and consequences in where, how, and for whom they contribute their DNA. The divergent conceptualizations—research, gift, and partnership relationships—demonstrate diverse sources of applicable ethical principles beyond those limited to research subject roles.

Nursing is the leading discipline proposing integration of the stewardship model into biobank practices. Figure 2 shows a proposed expansion of the stewardship model that explicitly incorporates nursing practice to beneficial outcomes and as a definitional component of the stewardship relationship. The inclusion of *nursing* in the model revision in Figure 2 explicitly communicates that nursing must be represented in all interdisciplinary endeavors to develop biobank stewardship relationship's best practices.

CONCLUSIONS AND SUMMARY

This analysis provides evidence that the stewardship model is still viable if supplemented and refined. Biobank practices are a change in research study processes to bring about promised beneficial changes in healthcare outcomes. The process of change is an explicit integral part of stewardship relationships.[6] When compared with the research subject, gift, or partnership conceptual characteristics, the stewardship model's change component is its key attribute that justifies its significance to future biobank best practices. The stewardship model's integral promotion of change gives it the viability and plasticity to remain conceptually relevant to present and future biobanking phenomena changing the healthcare paradigm. Five primary refinements are proposed to the original stewardship conceptual figure that updates the model to its new edition—Figure 2. These revisions are proposed to sustain the stewardship model's viability.

1. Three potential relationships are included that reflect the biobank and potential DNA contributor's original motivation to contribute DNA in the capacity of a *research subject*, *donor*, or *partner*. The principles of stewardship relationship are invoked, and its conceptual attributes apply regardless of the mutual bioethical expectations applicable in those divergent relationships. The attributes of the revised stewardship relationship's principles are amended beyond those originally expressed, explicitly articulating nursing involvement and upholding trust as key attributes.
2. Parties to the biobank transactions are supplemented by adding future families and communities and the biobank entity itself, conforming the model to present existing operational models.
3. The clinical setting is added to the model, as this is an additional venue for stewardship practices.
4. The model refinement incorporates the diverse conceptualizations (research subject sample, gift donation, or partnership contribution) of the contributor and the tangible biospecimen material. This refinement acknowledges the distinguishable applicable ethical expectations between the parties.
5. Nursing is included as an integral element to stewardship relationships, reflecting its unique positioning to foster earned trust in stewardship relationships, frame nursing research, and practice development and inclusion in interdisciplinary biobank policy and practice development. Improved nursing practice is added as a beneficial outcome of application of the stewardship relationship to acknowledge that best practices consider the conceptual elements. A recent example of nursing research framed by implicit conceptualizing that the nursing discipline has an integral position from which to contribute to understanding and foster trust in biobank participation was the 2007 work of Sanner and Frazier.[31]

These described revisions and those reflected by the figure build on a strong original conceptual model. The revisions help to conform the model to current and emerging biobanking practices and ethics discussions that have evolved since its original publication. The revised model in Figure 2 now stands ready to frame interdisciplinary development of best biobank practices. The stewardship model as revised now also stands ready to stimulate developments in research and practice to provide an evidence base that supports stewardship as best nursing practice.

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