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## Policy Perspective

# Improving Academic Biobank Value and Sustainability Through an Outputs Focus



Amanda Rush, MPH,\* Daniel R. Catchpoole, PhD, Rod Ling, PhD, Andrew Searles, PhD, Peter H. Watson, PhD, Jennifer A. Byrne, PhD\*

## ABSTRACT

Although it is generally accepted that human tissue biobanks are important to facilitate progress in health and medical research, many academic biobanks face sustainability challenges. We propose that biobank sustainability is challenged by a lack of available data describing the outputs and benefits that are produced by biobanks, as reflected by a dearth of publications that enumerate biobank outputs. We further propose that boosting the available information on biobank outputs and using a broader range of output metrics will permit economic analyses such as cost-consequence analyses of biobank activity. Output metrics and cost-consequence analyses can allow biobanks to achieve efficiencies, and improve the quality and/or quantity of their outputs. In turn, biobank output measures provide all stakeholders with explicit and accountable data on biobank value, which could contribute to the evolution of biobank operations to best match research needs, and mitigate some threats to biobank sustainability.

**Keywords:** biobank, research, value, outputs, sustainability.

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## Introduction

Biobanking, or the collection, processing, storage, and distribution of human tissue and data, is a process that has been recognized for its capability to support a wide range of biomedical and health research fields.<sup>1–5</sup> Recognition of the potential benefits of biobanking has extended beyond the scientific community, with consumers<sup>6</sup> and disease advocacy groups<sup>7</sup> becoming increasingly supportive of the role that biobanks play in facilitating health and medical research. Acknowledgement of the importance of biobanking from both scientific and societal perspectives parallels an increasing overall demand for biospecimens in research,<sup>8</sup> increasing biospecimen cohort sizes described in cancer research publications,<sup>9</sup> as well as rising numbers of publications on biobanking.<sup>10</sup>

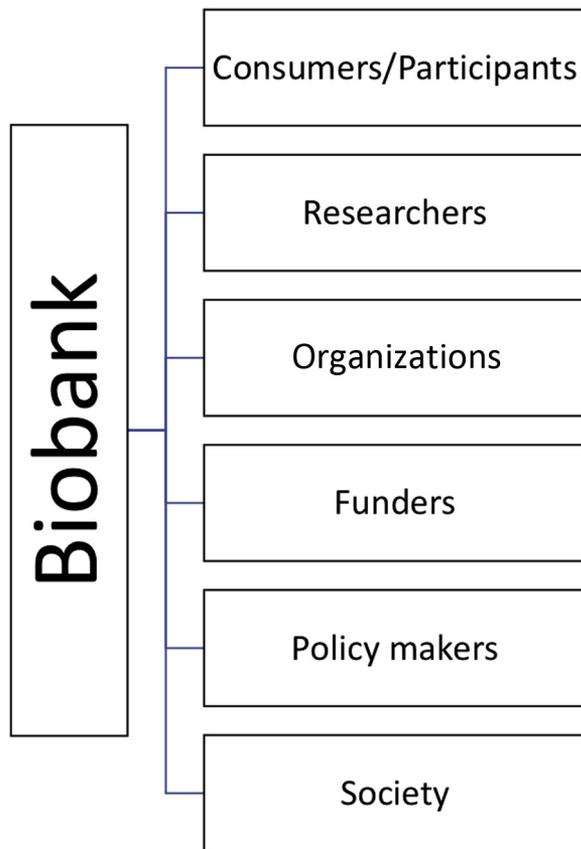
Academic biobanking of human biospecimens is influenced by external stakeholders who comprise what we describe as the Biobank Research System (Fig. 1). This system encompasses the resourcing capacities of funders and infrastructure providers; the needs and opinions of researchers, consumers, organizations, and society; and existing and planned policies relevant to biobanking. Each stakeholder within the system holds sometimes competing viewpoints and manages resource demands, and considers biobanking within different spheres of interest. For example, funders may consider biobanking as one of many competitors within the health and medical research funding envelope, and

consumers/participants may need to take into account competing requests to participate in research with consent to use their tissue and data from clinical trials and other research projects. This commentary focuses on 2 aspects of academic biobanking with varied stakeholder viewpoints, namely demonstration of biobank value and biobank sustainability.

## Biobank Sustainability Challenges

Biobanks continue to demonstrate sustainability challenges,<sup>11–13</sup> where we define sustainability as the maintenance of biobank operations and value over the intended lifespan of the biobank. Impediments to biobank sustainability may render biobanks vulnerable to collecting fewer biospecimens of possibly reduced quality and offering fewer biobanking services. Eventually, sustainability may be threatened to a point where a biobank is no longer operational,<sup>11</sup> resulting in loss of further research output. In this circumstance, the expected time for the biobank operation to absorb initial capital costs<sup>12</sup> is reduced, and reestablishment costs are likely to be higher than the costs of continued operations.<sup>14</sup> Additionally, if biospecimens and associated data are not transferred to another facility at the time of biobank closure, their intrinsic value at collection time and any accrued longitudinal value<sup>12</sup> has no further opportunity to be used.

\* Address correspondence to: Amanda Rush, MPH and Jennifer A. Byrne, PhD, NSW Health Statewide Biobank, NSW Health Pathology, Professor Marie Bashir Centre, Missenden Rd, Camperdown, NSW, 2050, Australia. Email: [amanda.rush@health.nsw.gov.au](mailto:amanda.rush@health.nsw.gov.au) and [jennifer.byrne@health.nsw.gov.au](mailto:jennifer.byrne@health.nsw.gov.au)  
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**Figure 1.** The Biobank Research System.

### Defining Biobank Value

In broad terms, the value of a biobank as a form of research infrastructure can be defined in terms of its worth, utility, or importance. As the ultimate purpose of a human tissue biobank is to support advances in medicine and health,<sup>15</sup> any measure of value should reflect the biobank's contribution toward this goal. There are many possible measures of biobank value, including the cohort size, the extent of data annotation, the rarity of housed biospecimens, whether biospecimens are fit for purpose, the use of quality frameworks,<sup>16,17</sup> the presence or absence of biobank accreditation<sup>18</sup> or certification,<sup>19</sup> the extent of biospecimen/data utilization,<sup>20</sup> and the importance of biospecimen-supported scientific discoveries.<sup>21</sup>

The value of a biobank can also be viewed differently depending on the stakeholder and their primary goal. For example, funders and policy makers may value the extent of support of translational research,<sup>22</sup> whereas researchers are likely to value large, open-access, well-annotated biospecimen collections.<sup>23</sup> To date, it has been challenging to determine a comprehensive and accurate value that includes the full scope of individual biobank types, and that can be interpreted and used within and across biobanks and the broader research infrastructure landscape. This current lack of information on biobank value confers a threat to biobank sustainability. We propose that a greater focus on biobank outputs will provide stakeholders with data to inform measures of biobank value from their individual perspectives.

### Definition of Biobank Metrics

To allow the full measurement of biobank value, relevant metrics should first be defined. We<sup>20</sup> and others<sup>24</sup> have previously considered schemas for identifying and grouping metrics based on a methodology for assessment of research outcomes developed by a research funder,<sup>20</sup> and a methodology for comparison of biobank performance developed by a biobank network.<sup>24</sup> Here, to facilitate a financial assessment of value, we consider metrics broadly classified according to the phase of biobank operation, which we will categorize as (1) biobank inputs, (2) internal measures, and (3) biobank outputs (Table 1). *Biobank inputs* refer to human and physical capital, operating costs, and other resources that are used to meet planned objectives. *Internal measures* refer to measures of the activity and operations within the biobank itself. Lastly, *biobank outputs* refer to measures and impacts external to the biobank, including both direct monetary outputs such as cost recovery, as well as nonmonetary outputs.

### Biobank Inputs

The full cost of biobanking includes both resources that are paid for with money and resources that are provided in kind.<sup>25</sup> Notwithstanding individual biobank variations, resources that are generally paid for include core staff, institutional overheads, consumables, contractors, and software (Table 1). Resources that are likely to be provided in kind by the host institution include specialist clinical services and shared infrastructure (Table 1). Clinical specialists such as surgeons and pathologists are typically not biobank employees, and biobanking is not the primary endpoint of patient surgery or disease diagnoses. Furthermore, the specialist equipment and consumables for collecting, processing, and characterizing tissue may be provided by surgical units or pathology departments and therefore not included in biobank budgets. Finally, laboratory facilities, fittings, and large equipment for biobank use may be provided by the parent institution, rather than being purchased by the biobank. Because in-kind resources can be difficult to quantify, actual biobanking costs are likely to be underestimated by not-for-profit biobanks.

Several publications refer to biobank inputs in cost modeling terms.<sup>26–30</sup> In their “biobankonomics” papers,<sup>26,27</sup> researchers at the National Cancer Institute modeled total lifecycle costs of ownership in the context of planning a biobank network, and also estimated the downstream economic benefits of a national biobanking framework in the United States. Odeh et al<sup>28</sup> developed the Biobank Economic Modeling Tool, which provides a comprehensive template to ascertain the financial costs of operating a biobank, and Matzke et al<sup>29</sup> developed a practical tool for modeling user fees. Nevertheless, there is a scarcity of publications that detail actual biobank costs. Gee et al<sup>31</sup> cite limited costing data from a UK biobank survey, and Clement et al<sup>25</sup> described methods and results from a cohort of European biobanks for the calculation of costs based on staff time and complexity of tasks. Gonzalez-Sanchez et al also developed<sup>30</sup> and implemented<sup>32</sup> a costing model, which did not include in-kind costs. Thus although there are limited publications on actual biobank costs, there are few to no available data on the combined monetary and in-kind costs of individual biobanks.

**Table 1.** Types of biobank inputs, internal metrics, and outputs with suggested associated units of measurement.

	Variable or measure	Possible measurement/s (How measured)
Biobank inputs	Human resources	Number full-time-equivalent staff (n= ); salary costs (\$)
	Overheads	Annual financial cost (\$)
	Assets	Capital cost (\$); maintenance cost (\$), depreciation (\$)
	Consumables	Annual financial cost (\$)
	Contractors	Annual financial cost (\$)
	Information Technology/software	Initial cost (\$); maintenance cost (\$), licensing cost (\$), depreciation (\$)
	In-kind services	Hours spent (n= ); equivalent hourly rates (\$)
	In-kind infrastructure	Percentage used for biobanking purposes (%); capital costs (\$); depreciation (\$)
	Internal metrics	Participants
Number of samples/aliquots		Total number (n= ); number per storage format (n= ); number with >1 storage format (n= ); number of longitudinal samples (n= )
Extent of data held		Number of essential data fields complete per specimen (n= ); availability of data linkage (yes/no); results of data audits (% data verified)
Biobank certification/accreditation		Type of certification/accreditation
Researcher satisfaction		Survey (Likert scale, free text)
Biobanking research grants		Funding attracted to support biobank operations (\$)
Staff career progression		Hours of training (n= ); salary increase (\$); career progression (description)
Biobanking conference presentations		Oral or poster presentations or non-peer-reviewed articles (n= , description)
Publications on internal biobank activities		Number of peer reviewed publications/year; number of citations per publication/overall (n= ); journal impact factor (JIF), other paper metrics (number downloads [n= ]; Altmetrics score per publication [n= ])
Biobank outputs		Inquiries managed
	Utilization rate of biospecimens	Number of biospecimens distributed/number of biospecimens held (%)
	Research publications supported	Number per year/in total (n= ); impact factor of the journal (x= ); number of citations per publication/overall (n= ); other paper metrics (number downloads [n= ]; Altmetrics score per publication [n= ])
	Research grants supported	Number per year/in total (n= ); funding attracted to support researchers using the biobank cases or services (\$)
	Research projects supported	Number per year/in total (n= ); number of biospecimens/data provided per study/overall (n= ); additional services provided (description, n= )
	Cost recovery	Funds received from research users per year/in total (\$), proportion of operating costs met through cost recovery (%)
	Research collaborations	Number per year/in total (n= ); collaborations developed by research users attributable to the biobank; multidisciplinary nature (n= , description)
	Clinical practice changes	Number of clinical trials supported (n= ); number of patients enrolled per clinical trial/overall (n= ); number of patients supported via personalized medicine (n=); number of molecular diagnoses supported per year/in total (n= )
	Training of external students and staff	Number of individuals trained (total number and hours spent [n= ]); processes/techniques learnt (n= , description); lectures/courses/ educational materials developed (n=, description); degrees awarded per year/in total (n= , description)
	Research conference presentations	Oral or poster presentations by research users of the biobank per year/ in total (n= , description)
	Publications on biobanking and biobank outputs	Number of publications/year by research users of the biobank; number of citations per publication/overall (n= ); journal impact factor (JIF); other paper metrics (number downloads (n= ); Altmetrics score per publication (n= )
	Conference presentations on biobank outputs	Oral or poster presentations by research users of the biobank (n= , description)
	Patents	Number and type of patents per year/in total support (n= , description)

## Internal Metrics

Internal metrics provide important information to stakeholders on a biobank's capacity to support research. For example, internal metrics of biobanking include variables such as the number of participants and the number of biospecimen aliquots that are captured in a biobank's inventory system, thus providing accessible data for publications describing biobanking activities (Table 1).<sup>33–35</sup> Nevertheless, information on internal metrics of individual biobanks may not reflect the expectations and needs of external stakeholders such as funders, participants, researchers, and society. It has thus been argued that data on internal biobank activities cannot be used in isolation to measure biobank value or sustainability.<sup>36–38</sup> Favorable biospecimen utilization rates may be used to demonstrate value to external stakeholders; however, biospecimen underutilization has been reported as a concern for some biobanks.<sup>39–41</sup> We have included biospecimen utilization rates as a biobank output, because although the denominator is derived from internal metrics, the rate is dictated by the number of biospecimens distributed to researchers in a given period.<sup>20</sup>

## Biobank Outputs

Biobanks support well-recognized, quantitative research outputs including the awarding of research grants and generation of publications, as well as qualitative aspects such as new research collaborations, the provision of advice and assistance to researchers on biospecimen use, and research student and staff training (Table 1). Biobanks also underpin basic research discoveries that contribute to the global body of scientific knowledge, and the evolution of clinical medicine toward a more personalized, biomarker-driven process.<sup>42</sup> The support of personalized medicine includes the return of stored biospecimens for additional clinical tests,<sup>43</sup> the development of clinical testing procedures or techniques, the support of clinical trials, and implementation of personalized medicine.<sup>42,44</sup> Both quantitative and qualitative biobank outputs can be of value to external stakeholders.

The Biobank Research Impact Factor, a standardized measurement of biobank-supported research publications, was first proposed in 2003,<sup>45</sup> and then updated in 2011<sup>46</sup> and 2013.<sup>47</sup> The Biobank Research Impact Factor aims to link individual biobanks to publications using a unique digital resource identifier, and thus does not incorporate biobank outputs that do not result in publications, such as clinical practice support.

## Bibliometric Analysis of Biobank Outputs

Despite biobank outputs representing the overarching purpose of biobanking, there is an imbalance between the numbers of publications that describe biobank outputs versus other core biobank activities. This was demonstrated by a Scopus<sup>48</sup> search conducted for the period January 1, 2015 to December 31, 2018 that compared the number of journal abstracts that included keywords corresponding to biobank outputs with the number of journal abstracts that included either biobank *processing*, *consent*, or *storage* (Fig. 2). The 12 biobank output terms were derived from the list of biobank outputs in Table 1, and were intended to encompass a broad range of biobank support of health and medical research. *Processing*, *consent*, and *storage* were selected as biobank input keywords, because these terms correspond to 3 core aspects of biobanking.

Despite the fact that biobank output publications were measured collectively across 12 output synonyms, approximately half as many publications were associated with the biobank input terms *consent*, *processing*, and *storage* (Fig. 2). Although recognizing that these analyses may not have captured all synonyms for biobank outputs, these results indicate an underrepresentation of biobanking research literature on biobank outputs. This comparative lack of publications that describe biobank outputs will correspond to a lack of information about the types and amounts of biobank outputs generated, the strength of possible relationships between input resources and outputs, and any possible relationships between outputs and the model of biobanking used.

## Underreporting of Biobank Outputs

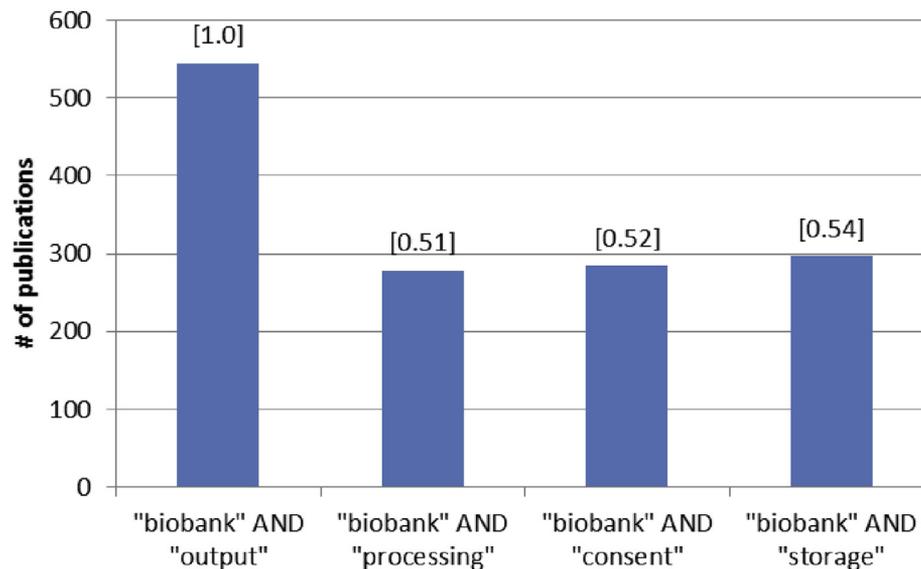
Discovering the full scope of the use of biobank biospecimens and associated data is required to identify accurate measures of biobank value, yet this has proved to be a challenging task.<sup>44</sup> A major biobank output is the comprehensive list of research publications arising from supported projects.<sup>33</sup> Although biobanks usually communicate directly with biospecimen researchers, and conditions of use such as acknowledgment in publications are agreed in advance, there are few real incentives for researchers to acknowledge biobanks that have assisted them during the course of their research. Years can also pass between the time of biospecimen provision and study publication,<sup>33</sup> which can reduce the likelihood that researchers will inform the biobank that publications have been accepted and/or that the biobank has been acknowledged. This can require the biobank to proactively search the literature for publications and acknowledgements. Such approaches are unlikely to identify all supported publications, because there are no mandatory criteria for reporting biospecimen use. Furthermore, Meredith et al<sup>49</sup> reported that the Biospecimen Reporting for Improved Study Quality (BRISQ) biospecimen reporting strategy,<sup>17</sup> recommended by some journals, was not widely or uniformly used. In our experience, biobank outputs such as clinical support, staff and student training, and grants supported are not always captured by biobanks, and are more challenging to identify by searching publicly available data. Thus, the combination of the lack of researcher incentives to acknowledge biobanks with a lack of biobank focus on recording outputs leads to the incomplete capture and therefore reporting of biobank outputs.

## Consequences of a Lack of Biobank Output Data

A gap in knowledge on biobank outputs affects individual biobanks, the broader field of biobanking, and stakeholders within the Biobank Research System (Fig. 1). Without full knowledge of their outputs, individual biobanks are currently and will continue to be unable to assess past and current activities, and thus track fluctuations in activity. They may also be unable to calculate realistic resource costs that align with their outputs. Finally, they may not have the necessary information to conduct adequate internal economic analyses or build robust business cases for funders. Furthermore, if the field of biobanking is not aware of, or underestimates, their collective outputs, it can negatively affect stakeholders' perceptions of the importance of biobanking. Ultimately, this could result in reduced funding and opportunities for the entire discipline.

A lack of data on biobank outputs also prevents funders and policy makers from making informed decisions on strategic biobank investments and policy positions. For example, there is

**Figure 2.** Scopus search of biobank-related terms.



presently no evidence to indicate whether open- or restricted-access biobanks provide better or equivalent value for biobanking investments, and whether or how biobank networks provide economies of scale compared to single biobank entities. Likewise, when consumers and advocates do not have a clear view of the breadth of outputs that biobanks support, they cannot make informed decisions about supporting biobanks through participation, advocacy, and/or financial donations. Researchers may also be unaware of the extent of support provided by biobanks, which could lead them to underestimate associated biospecimen and data costs in their own research grant applications. Such underestimates will reduce the capacity of biobanks to recover costs through research funding.

### Achieving a Biobank Output Focus

A shift in focus from internal measures to comprehensive biobank outputs is required for biobanks and their stakeholders to promote the collection, analysis, and open communication of biobank outputs. Firstly, individual biobanks should place greater emphasis and resources on identifying, recording, and communicating the full scope of their outputs. This may require an initial shift in existing resource allocation, or additional biobank resources. Monitoring biobank outputs over time will also require improved engagement with researchers who use biospecimens. This could have the additional benefit of understanding their current and emerging biospecimen and data requirements,<sup>23</sup> and in driving further business for the biobank.

A biobank output focus should also be reinforced by funders, policy makers, journal editors, and conference organizers. Funders and policy makers could consider the introduction of output-focused reporting and/or altering current funding models to reward individual researcher biobanks, networks, or centralized biobanks with more economically sustainable business plans. Currently, the literature on biobanking (and its outputs) is largely written by the biobanking community, and as documented above, tends to focus more on biobank inputs and internal activities. To encourage change at an academic level, relevant journals could

specifically encourage submissions and journal subsections devoted to biobank outputs. Biobanking conferences could consider dedicated biobank output sessions to encourage greater focus and priority on discussing biobank outputs and value.

### Benefits of a Biobank Output Focus

Quantifying outputs allows biobanks to achieve operational efficiencies through informed redirection of their resourcing. Specifically, biobanks can monitor biospecimen utilization rates to determine whether researchers' scientific needs are being met. Biobanks can then target improvements to the quality and/or quantity of outputs through the identification of benchmarks to maximize the types and numbers of distributed biospecimens.<sup>20</sup> This would establish a clearer relationship between biospecimen inputs and utilization. Output data can also inform a biobank's biospecimen culling strategy<sup>20</sup> via the identification of biospecimen types and formats that may no longer support biobank outputs. Finally, a focus on biobank outputs may encourage biobanks to consider or reconsider marketing plans, engaging (more) clinical clients/collaborators, and/or providing updated or additional staff/student training.

Collating and assessing a full range of biobank inputs, internal measures, and outputs also allows for subsequent economic analyses such as cost-consequence analyses. Cost-consequence analyses allow all components of biobank inputs and outputs to be presented in their most appropriate units, enabling stakeholders to interpret and focus upon outcomes that they perceive as most important<sup>50</sup> and providing a more comprehensive and transparent decision-making tool.<sup>51</sup> Monetary costs for capital and operational biobank activities can be recorded, along with estimated in-kind costs derived from equivalent staffing, equipment, and infrastructure costs. Biobank outputs can be assigned monetary values where possible, with nonmonetary outputs provided as line listings and/or case studies. For example, biobank-supported publications can be described in terms of journal impact factors or citations. This becomes important when comparing, for example, the value of a biobank's

provision of a small number of biospecimens to a large study published in a high-impact journal versus the provision of a larger number of biospecimens to a lower-profile research project with high societal value.

### Possible Risks of a Biobank Output Approach

Valuing biobanks based on their outputs has barriers and associated risks. Firstly, placing an economic value on a range of biobank's output is resource-intensive, and requires specialist skillsets that may not be available to all biobanks. Although there are no published data on the costs of recording, interpreting, and communicating biobank outputs, biobanks would need to balance additional costs with the perceived benefits of describing and communicating outputs. Furthermore, because many models and types of biobanks exist,<sup>52</sup> the identifiable costs and benefits that are used for economic analyses vary between biobanks, leading to possible misinterpretations of individual biobank value. For example, restricted-access biobanks may have lower operating costs through reliance on dedicated institutional support, which could be justified by their support of internal research. Nevertheless, open-access biobanks may have wider and varied biospecimen distribution patterns,<sup>12</sup> which could support more diverse research projects.<sup>23</sup> Similarly, owing to reduced tissue availability, rare disease biobanks may support fewer publications and/or clinical activities than biobanks focused on common diseases. It is therefore important for biobanks to reflect on their unique contributions to research and to communicate these effectively to their stakeholders.

Specific funder-imposed benchmarks or targets may also encourage biobanks to focus on short-term outputs, by supporting research projects that are likely to generate rapid publications, at the expense of higher-risk or longer-term projects. A focus on value that is based on output data may nevertheless encourage the evolution of alternate models of biobanking (for example, through networked or centralized approaches), and could also lead to the cessation of operations for some biobanks. Stakeholders could consider a staged adoption of output-focused reporting, to allow biobanks time to acquire the necessary data and to change their operations if required.

### Summary and Conclusions

Historically, biobanks have tended to research and publish on internal metrics, because these data are most readily available from inventory databases and do not rely on end users or other stakeholder input. An output focus provides biobanks with the opportunity to assess their resourcing, create output benchmarks, and better engage with their clients, and could also stimulate the evolution of alternative operating models, ensuring greater utilization of biospecimens. For other stakeholders within the Biobank Research System, quantifying biobank outputs provides accountability to their decision-making processes, and allows the evaluation of different biobank business models. Bringing attention to biobanking outputs could also resolve important unanswered questions such as which biobank business models best support research.

In summary, the current lack of understanding of biobank outputs by biobanks themselves and their stakeholders represents a threat to the overall sustainability of biobanking. Focusing on biobank outputs would confer operational benefits to biobanks and strategic benefits to all stakeholders, by providing evidence of the explicit and accountable value of biobanks or groups of

biobanks. This is necessary for biobanks' continued survival, and for their better support of health and medical research.

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**Authors' Affiliations:** Discipline of Child and Adolescent Health, Sydney Medical School, Faculty of Medicine and Health, The University of Sydney, Sydney, NSW, Australia (Rush); Children's Cancer Research Unit, Kids Research, The Children's Hospital at Westmead, Westmead, NSW, Australia (Catchpoole); Health Research Economics, Hunter Medical Research Institute, New Lambton Heights, NSW, Australia (Ling, Searles); Office of Biobank Education and Research, Department of Pathology and Laboratory Medicine, University of British Columbia, Vancouver, Canada (Watson); NSW Health Statewide Biobank, NSW Health Pathology, Professor Marie Bashir Centre, Camperdown, NSW, Australia (Byrne)

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