Published in final edited form as:

Ann Intern Med. 2014 December 16; 161(12): 855–862. doi:10.7326/M14-1118.

The Importance of Purpose: Moving beyond Consent in the Societal Use of Personal Health Information

David Grande, MD, MPA^{1,2}, Nandita Mitra, PhD^{2,3}, Anand Shah, MD, MSHP⁴, Fei Wan, MS³, and David A. Asch, MD, MBA^{1,2,6,7}

¹Division of General Internal Medicine, Perelman School of Medicine, University of Pennsylvania

²Leonard Davis Institute of Health Economics, University of Pennsylvania

³Department of Biostatistics and Epidemiology, Perelman School of Medicine, University of Pennsylvania

⁴Department of Emergency Medicine, UT Southwestern Medical Center

⁵PCCI, Parkland Health and Hospital System, Dallas, TX

⁶Center for Health Care Innovation, Perelman School of Medicine, University of Pennsylvania

⁷Center for Health Equity Research and Promotion, Philadelphia VA Medical Center

Abstract

Background—Adoption of electronic health record systems has increased the availability of patient-level electronic health information.

Objective—Examine public support for secondary uses of electronic health information under different consent arrangements.

Design—National experimental survey to examine perceptions of uses of electronic health information when varying along three dimensions: *patient consent* (obtained vs. not obtained), *use*

Corresponding Author: David Grande, MD, MPA, 3641 Locust Walk – Colonial Penn Center 407, Philadelphia, PA 19014, dgrande@wharton.upenn.edu, 215-573-3804 (o); 215-898-0229 (f).

Author Mailing Addresses

David Grande, MD, MPA, 3641 Locust Walk – CPC 407, Philadelphia, PA 19104

Nandita Mitra, PhD, 423 Guardian Drive - 212 Blockley Hall, Philadelphia, PA 19104

Anand Shah, MD, MS, 8435 Stennon Freeway, Suite 1150, Dallas, TX 75235

Fei Wan, MS, 423 Guardian Drive, Philadelphia, PA 19104

David A. Asch, MD, MBA, 423 Guardian Drive – 1123 Blockley Hall, Philadelphia, PA 19104

Note: This is the prepublication, author-produced version of a manuscript accepted for publication in *Annals of Internal Medicine*. This version does not include post-acceptance editing and formatting. The American College of Physicians, the publisher of *Annals of Internal Medicine*, is not responsible for the content or presentation of the author-produced accepted version of the manuscript or any version that a third party derives from it. Readers who wish to access the definitive published version of this manuscript and any ancillary material related to this manuscript (e.g., correspondence, corrections, editorials, linked articles) should go to Annals.org or to the print issue in which the article appears. Those who cite this manuscript should cite the published version, as it is the official version of record.

Sponsor: NIH - National Human Genome Research Institute (5R21HG006047-02)

Conflicts of Interest

None of the authors has any conflicts of interest to report.

Reproducible Research Statement

Study protocol: Available from Dr. Grande (dgrande@wharton.upenn.edu).

Statistical code and data set: Not available.

(research vs. marketing), and *framing* of the findings (abstract description without results vs. specific results).

Setting—Nationally representative survey.

Participants—3,064 African American, Hispanic, and non-Hispanic White individuals representing a response rate of 65%.

Measurements—Appropriateness of health information use described in vignettes on a 1-10 scale (1=not at all appropriate; 10=very appropriate).

Results—Mean ratings ranged from a low of 3.81 for a marketing use when consent was not obtained and specific results were presented to a high of 7.06 for a research use when consent was obtained and specific results were presented. Participants rated scenarios where consent was obtained as more appropriate compared to when consent was not obtained (+1.01; 95% CI 0.69, 1.34, $P<0.001$). Participants rated scenarios where the use was marketing as less appropriate compared to when the use was research (−2.03; 95% CI −2.27, −1.78, $P<0.001$). Unconsented research uses were seen as more appropriate than consented marketing uses (5.65 vs. 4.52; difference = 1.13; 95% CI 0.87, 1.39)..

Limitations—Participants rated hypothetical scenarios and results could be vulnerable to non-response bias despite the high response rate.

Conclusions—Although approaches to health information sharing emphasize consent, public opinion also emphasizes purpose suggesting a need to focus more attention on the social value of information use.

Primary Funding Source—National Human Genome Research Institute

Introduction

The widespread adoption of electronic health record (EHR) information systems has markedly increased the availability of patient-level electronic health information. This information has substantial value across a range of uses including research (e.g., observational comparative effectiveness research), public health (e.g., disease surveillance), and health care quality (e.g., measuring and monitoring the quality of health services).(1) This information also has substantial commercial value. For example, a pharmaceutical company might be interested in understanding the clinical circumstances when physicians choose one medication over another.(2) Given this value across a range of social and commercial purposes, there has been considerable debate around the role that patient consent should play in the use of electronic health information.

Although digital technology is increasing the availability and usability of patient information, the debate and ethical considerations around the release and reuse of this information are not new. One view is that health information should not be reused without patient consent. Since this information was derived from patients, it should be seen as their own and as such, patients should retain a right to privacy.(3) This right to privacy is foundational to trust in physicians and medical institutions.(4) Many studies support this view by revealing that patients' harbor substantial concerns about harm from loss of privacy,

including potential discrimination that could arise from disclosure of their personal health information.(5, 6) And even with assurances about information security, patients value autonomy so that, even if they intend to share their health information, they still want to be asked.(7-10)

An alternative view is substantially more goal-directed, reflecting the irreplaceable social value individual health information can provide when aggregated across individuals,(11, 12) that obtaining individual consent for such purposes would be infeasible,(13) and that individual refusals would create bias and undermine the social value.(14) Whereas the view that patient information should never be reused without consent focuses on the rights of individuals, this alternative view places importance on societal benefits that might trump the rights of individuals. More pointed arguments in favor of reuse suggest that patients may have some obligation to share information for socially beneficial purposes, based on conventions of societal participation or more transactional interpretations of who has paid for the health services that often generate these data.(15) Some experts have proposed blanket “opt-in” and “opt-out” consent policies to overcome these concerns. However, even modest rates of non-participation can lead to selection bias.(14, 16-18)

In the wake of this debate, the U.S. Department of Health and Human Services (DHHS) has proposed new regulations that would relax requirements for consent for information-based research that poses minimal risk to human subjects.(19) Specifically, the “exempt” category for research would be expanded to include studies where the risk is largely informational and not physical.(19) The “exempt” category would be renamed “excused” because these studies would not be subjected to IRB review but would have to comply with data security standards. This proposal mirrored recommendations from the Institute of Medicine (IOM). (20, 21) Both the DHHS proposal and IOM report argue that we ought to focus less on consent and more on data security to protect against harm. The proposal from DHHS has yet to move forward.

Because consent for information use has been central to current policies on data use, but both new proposals subordinate the role of consent, we examined public perceptions of the importance of consent for health information use. We performed a national experimental survey, structured as a randomized controlled experiment, to examine public perceptions of different uses of information (research versus marketing) and also different ways of framing the reporting of that information (an abstract future use versus a past specific use with reported results) with and without consent.

Methods

Participants and Survey Administration

We recruited participants from an online panel assembled by GfK Knowledge Networks(22) as previously described.(23) GfK Knowledge Networks recruited individuals to the research panel through a combination of probability-based random digit dialing and address-based sampling to create a nationally representative panel. This sampling provides coverage of households with and without telephone lines and with and without computer access. GfK Knowledge Networks provides a computer and internet access to individuals without

internet access in exchange for participation. Participants with computer and internet access receive modest compensation for participation. This method of sampling and panel creation has been shown to yield estimates similar to those derived from random digit dial telephone surveys.(24)

We limited our sample to three racial/ethnic populations: 1) Non-Hispanic African-Americans, 2) Non-Hispanic Whites, and 3) Hispanic African Americans and Hispanic Whites (English and Spanish-speaking households). We over-sampled African-Americans and Latino individuals from the panel to allow for sufficiently powered comparisons between the three racial/ethnic populations, given concerns of mistrust among minority populations of biomedical research.(25-27)

We excluded participants who completed the survey in less than half the median completion time. We made this decision prior to survey administration because we felt these individuals were unlikely to have fully read individual survey items before responding. Pre-test piloting revealed that these individuals demonstrated little item-to-item variation in their survey responses suggesting a low level of attention to item content.

We administered the survey electronically November 9, 2012 through December 2, 2012. The University of Pennsylvania Institutional Review Board approved the study protocol.

Survey Instrument

The survey instrument included measures of health and health care access, a separate conjoint experiment testing the importance of several factors on willingness to share health information in the context of cancer prevention,(23) and vignettes describing secondary uses of electronic health information described below. Participants were told that the survey was about “their views about health information technology and health care in the United States.”

Vignettes – Scenarios Describing Uses of Electronic Health Information—We created 8 vignettes describing the use of electronic health information reflecting the rate and predictors of use of a hypothetical pharmacologic treatment for diabetes. The 8 vignettes were identical except, in a 2×2×2 design, they systematically varied along three dimensions (Figure 1): *patient consent (obtained vs. not obtained)*, *use (research vs. commercial marketing)*, and the *framing* of how the findings would be or were used (an *abstract* future use without results versus a past *specific* use with reported results). For example, the vignette that described a scenario where consent was not obtained, health information was used for research, and the specific results were reported read as follows:

An analysis of thousands of electronic patient records identified people with diabetes. Because it would be very hard to contact all patients, the patients were not asked permission for their records to be reviewed. An ethics review board determined that this study provided acceptable safeguards to patient privacy. University researchers used this information to find out that on average 1 out of 10 patients with diabetes are receiving the drug Diamed for their diabetes. They

published their results in a medical journal so that doctors can learn how to improve diabetes care.

Other vignettes reported the goals to be for marketing. In this case which also describes an abstract future use without results (in contrast to the above example), the vignette read, “a drug company will use this information to learn more about which types of patients are receiving the company’s drug Diamed for their diabetes.” In cases where consent was obtained, the vignette read, “all of the patients will give permission for their records to be reviewed.” Because we were interested in how the three attributes (consent, use, and framing) influenced attitudes, we included a statement in all vignettes that “an ethics review board determined that this study provided acceptable safeguards to patient privacy” to standardize the level of privacy oversight across the scenarios. The full experimental design of the vignettes is shown in Figure 1.

We randomized each participant to receive two of the possible eight vignettes. To avoid influencing the response to the second vignette by highly contrasted elements of the first vignette, consent and future or past framing were varied between but not within subjects so that each participant received vignettes describing the same consent arrangement (with consent or without consent) and the same framing of information use (abstract future or specific past) but different uses (research and marketing) resulting in four experimental groups. Though we felt different uses would be the least susceptible to order effects, we accounted for potential within subject order effects in our analytic models as described in the analysis section below. After presenting the participant with the vignette, we asked participants, “how appropriate is this use of patient health information?” on a 1-10 scale (1=not at all appropriate; 10=very appropriate). Using this design, we measured the independent effects of consent, use, and framing on support for secondary use of electronic health information.

Health and Access to Care Measures—In prior studies, health status has been inconsistently linked to willingness to share health information for research purposes.(5, 28) We measured self-rated health with a single item from the Behavioral Risk Factor Surveillance System.(29) We measured whether a participant had a usual source of care, insurance coverage, and whether they had experienced cost-related barriers to care in the past year using items from the National Health Interview Survey.(30)

Demographics—We obtained previously collected demographic information on our study participants from GfK Knowledge Networks including: race, income, educational attainment, sex, age, and whether they live in a rural or metropolitan area.

Statistical Analysis

We compared demographic characteristics between responders and non-responders using chi-squared tests, t-tests and analysis of variance (ANOVA). We then compared responder ratings for each combination of the three information use attributes (consent, use, framing) between racial/ethnic groups (non-Hispanic White, non-Hispanic African American, and Hispanic) using ANOVA. We used linear regression models to assess the association between the outcome (appropriateness) on a continuous scale, the information use attributes

and participant characteristics. We used generalized estimating equations (GEE) with a working independence correlation structure and robust (Huber-White) variance estimation(31) to account for the correlation of vignettes nested within respondent induced by the study design. We also adjusted for vignette order in these models since each subject rated two vignettes describing two different uses of health information (research and marketing). To account for survey non-response and the planned over-sampling scheme, we utilized post-stratification weights provided by GfK Knowledge Networks. There was little to no missing data (<0.5% on all covariates); hence analyses were conducted on observed data only. We used Wald tests to compare parameters. All tests were two-sided with a type I error rate of 0.05. We conducted all analyses in SAS 9.3 (SAS Institute Inc., Cary, NC, USA).

This study was supported by the National Human Genome Research Institute (5R21HG006047-02). The funder had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; and preparation, review, or approval of the manuscript.

Results

Of 5,119 individuals from the GfK Knowledge Network panel invited to participate, 3,336 participated for a response rate of 65%. After excluding 272 who completed at less than half the median time, we had a final sample of 3,064 participants including 2,093 non-Hispanic whites, 455 non-Hispanic African-Americans, and 516 Hispanics. The characteristics of respondents are presented in Table 1. Non-responders were more likely to be younger, lower education, lower income, and slightly more likely to be female. We used post-stratification weights in our analyses to account for nonresponse bias. The demographic characteristics across the four experimental groups were similar except for small differences in the percent in fair or poor health (range: 13.3% - 18.2%, $p=0.032$).

Mean participant ratings ranged from a low of 3.81 (1=not at all appropriate; 10=very appropriate) for the scenario describing a marketing use when consent was not obtained and the framing was specific to a high of 7.06 for the scenario describing a research use when consent was obtained and the framing was specific. The unadjusted means for the eight scenarios are presented in Table 2. For marketing uses, there were differences by race and ethnicity (lower support among non-Hispanic whites) but no differences in the research uses regardless of whether consent was obtained or not. When we pooled across all vignettes where each attribute was included and account for the multiple vignettes per respondent, participants rated scenarios where health information was used for research higher than when used for marketing (6.27 vs. 4.25; 95%CI = 1.89, 2.13; $P<0.001$). They also rated scenarios where consent was obtained higher than when it was not obtained (5.77 vs. 4.75; 95%CI = 1.20, 0.79; $P<0.001$). Participants rated scenarios equally regardless of whether it was described with specific results from a past use or an abstract future use without results (5.30 vs. 5.21; 95%CI=-0.29, 0.13; $P=0.46$).

We tested for independent and joint effects of the three health information use attributes using adjusted interacted generalized estimating equations (Appendix 1). Participants rated

scenarios where consent was obtained as more appropriate compared to scenarios where consent was not obtained (+1.01; 95% CI 0.69, 1.34; $P<0.001$). Participants rated scenarios where the use was marketing as less appropriate compared to when the use was research (−2.03; 95% CI −2.27, −1.78; $P<0.001$). Participants rated the scenarios with different framing equally (−0.03; 95% CI −0.37, 0.30; $P=0.85$ for future abstract benefits vs. past specific benefits).

We tested for interactions among the information use attributes (consent, use, and framing) as well between these attributes and race-ethnicity while adjusting for other demographic and health characteristics. Overall, the interactions of use with consent as well as use with race/ethnicity were significant (Appendix 1). When we described marketing uses to participants, the increase in support from obtaining consent was on average 0.58 points (95% CI: −0.80, −0.36) smaller than the increase in support with research uses. However, participants rated research uses without consent substantially higher than marketing uses with consent (5.65 vs. 4.52; difference: 1.13, 95% CI: 0.87, 1.39). Non-Hispanic African American and Hispanic respondents rated the marketing scenarios 1.18 (95% CI: 0.91, 1.45) and 1.16 (95% CI: 0.85, 1.47) points higher, respectively, than whites. However, respondents from the three racial-ethnic groups rated the consent arrangements similarly. The interactions between consent, use and race/ethnicity are shown in Figure 2. Since each participant evaluated two scenarios describing two different uses (research and marketing), we controlled for order effects. Participants rated marketing uses slightly more favorably when preceded by a scenario describing research use (+0.28; $P=0.015$); however, they rated research uses similarly regardless of whether it preceded or followed a scenario describing marketing use ($P=0.194$). In a separate analysis to further test for order effects, we excluded each participant's response to the second health information use scenario they rated and found similar results.

Discussion

As more health information is available in easily searchable electronic formats, the potential uses of health information will continue to grow. The debate about appropriate stewardship of electronic health information has emphasized developing consent policies that balance patient autonomy with the social benefits of data use. However, researchers and policymakers have not been able to develop a single policy around consent that a majority of the public supports.⁽⁷⁾ As a result, there has not been a clear path for managing the use of electronic health information for secondary purposes. Both the IOM and the federal government have proposed loosening requirements for consent for information-based research but regulatory changes have not moved forward.

This study reveals two key findings that can advance this debate. First, although obtaining consent was an important factor, the purpose of the use of health information was also important. For example, even when consent was obtained, respondents viewed research uses as more appropriate than marketing uses. Second, views about consent policies were consistent across the three racial-ethnic groups included in our study though minority participants rated marketing uses higher than white participants.

When policymakers discuss and debate the privacy of electronic health information and policies concerning secondary uses, they often focus on consent policies. This focus implicitly privileges notions of privacy and autonomy, and assumes that consent is the only factor to consider in managing health information. This study suggests that singular focus may be misplaced. Our study shows that patients place as much importance on the purpose toward which their information is used as whether consent is obtained. Thus, we may need to focus more attention on the social value of the information use. Such an approach contrasts with current policies where research uses of this information are often subjected to the strictest standards of consent(12), in part because of an established set of rules and processes that surround human subjects participation in academic settings. At a minimum, research is needed to identify better ways to meaningfully obtain consent, particularly for non-research uses where there is currently less oversight.

Our study has important limitations. First, we asked participants to rate hypothetical scenarios about the use of electronic health information of other patients as opposed to actual uses of their own information. Thus, we do not know how differences in attitudes toward these scenarios would predict differences in personal behavior such as a willingness to share vs. not share health information for a particular use. In addition, we only tested three attributes and there are likely other important factors that would influence participant attitudes. However, we utilized an experimental survey design that can more rigorously identify underlying preferences rather than relying on individual subjects to express their views across abstract and competing dimensions. Second, within the vignettes we included a statement that “an ethics review board determined that this study provided acceptable safeguards to patient privacy,” to standardize the level of privacy oversight. While this statement could make participants feel the use of data was more appropriate than they otherwise might have reported, it also reflects the likely reality that an IRB would have approved research studies performed in real settings. Third, like all survey research, our findings are vulnerable to non-response bias. However, we achieved a relatively high response rate and also used post-stratification weights to adjust for non-response. Furthermore, we randomized participants to alternative scenarios and would have to postulate an unlikely interaction term between non-response and the dimensions we studied for non-response bias to affect our findings.

As more and more health related information is captured electronically in health, insurance, and purchasing records and in an enlarging variety of digital devices and other media, individuals are increasingly leaving electronic footprints. That information is of enormous value when aggregated across individuals. The absence of socially balanced stewardship of this resource potentially squanders its value. The results of this study suggest a need to emphasize not just consent but the purpose of use and the extent to which the public supports that use.

Acknowledgments

This research was supported by the National Human Genome Research Institute (5R21HG006047-02). The funder had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; and preparation, review, or approval of the manuscript. Dr. Grande had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

REFERENCES

1. Digital Data Improvement Priorities for Continuous Learning in Health and Health Care. The National Academies Press; Washington, D.C.: 2013. Institute of Medicine Roundtable on Value and Science-Driven Health Care.
2. Grande D, Asch DA. Commercial versus Social Goals of Tracking What Doctors Do. *N Engl J Med*. 2009; 360(8):747–9. [PubMed: 19228616]
3. Hall MA, Schulman KA. Ownership of medical information. *JAMA*. 2009; 301(12):1282–4. [PubMed: 19318657]
4. Hall M, Dugan E, Zheng B, Mishra A. Trust in physicians and medical institutions: What is it, can it be measured, and does it matter? *Milbank Q*. 2001; 79:613–40. [PubMed: 11789119]
5. Survey finds Americans want electronic personal health information to improve own health care. Markle Foundation. 2006
6. National consumer health privacy survey 2005. California Health Care Foundation; Oakland, CA: 2005.
7. Damschroder LJ, Pritts JL, Neblo MA, Kalarickal RJ, Creswell JW, Hayward RA. Patients, privacy and trust: Patients' willingness to allow researchers to access their medical records. *Soc Sci Med*. 2007; 64(1):223–35. [PubMed: 17045717]
8. Whiddett R, Hunter I, Engelbrecht J, Handy J. Patients' attitudes towards sharing their health information. *Int J Med Inform*. 2006; 75(7):530–41. [PubMed: 16198142]
9. Robling MR, Hood K, Houston H, Pill R, Fay J, Evans HM. Public attitudes towards the use of primary care patient record data in medical research without consent: a qualitative study. *J Med Ethics*. 2004; 30(1):104–9. [PubMed: 14872086]
10. Nair K, Willison D, Holbrook A, Keshavjee K. Patients' consent preferences regarding the use of their health information for research purposes: a qualitative study. *J Health Serv Res Policy*. 2004; 9(1):22–7. [PubMed: 15006236]
11. Bloomrosen M, Detmer D. Advancing the Framework: Use of Health Data: A Report of a Working Conference of the American Medical Informatics Association. *J Am Med Inform Assoc*. 2008; 15(6):715–22. [PubMed: 18755988]
12. Rhodes R, Azzouni J, Baumrin SB, Benkov K, Blaser MJ, Brenner B, et al. De minimis risk: A proposal for a new category of research risk. *Am J Bioeth*. 2011; 11(11):1–7. [PubMed: 22047112]
13. Berry JG, Ryan P, Duszynski KM, Braunack-Mayer AJ, Carlson J, Xafis V, et al. Parent perspectives on consent for the linkage of data to evaluate vaccine safety: A randomised trial of opt-in and opt-out consent. *Clin Trials*. 2013; 10(3):483–94. [PubMed: 23568940]
14. Woolf SH, Rothenich SF, Johnson RE, Marsland DW. Selection Bias From Requiring Patients to Give Consent to Examine Data for Health Services Research. *Arch Fam Med*. 2000; 9(10):1111–8. [PubMed: 11115216]
15. Schaefer GO, Emanuel EJ, Wertheimer A. The obligation to participate in biomedical research. *JAMA*. 2009; 302:67–72. [PubMed: 19567441]
16. Buckley B, Murphy AW, Byrne M, Glynn L. Selection bias resulting from the requirement for prior consent in observational research: a community cohort of people with ischaemic heart disease. *Heart*. 2007; 93(9):1116–20. [PubMed: 17502325]
17. Tu JV, Willison DJ, Silver FL, Fang J, Richards JA, Laupacis A, et al. Impracticability of Informed Consent in the Registry of the Canadian Stroke Network. *N Engl J Med*. 2004; 350(14):1414–21. [PubMed: 15070791]
18. Ingelfinger JR, Drazen JM. Registry Research and Medical Privacy. *N Engl J Med*. 2004; 350(14):1452–3. [PubMed: 15070797]
19. Emanuel EJ, Menikoff J. Reforming the regulations governing research with human subjects. *N Engl J Med*. 2011; 365(12):1145–50. [PubMed: 21787202]
20. Nass, S.; Levit, L.; Gostin, L. Beyond the HIPAA privacy rule: Enhancing privacy, improving health through research. National Academies Press; Washington, DC: 2009.

21. Gostin LO, Nass S. Reforming the HIPAA privacy rule: Safeguarding privacy and promoting research. *JAMA*. 2009; 301(13):1373–5. [PubMed: 19336713]
22. GfK Knowledge Networks. KnowledgePanel Demographic Profile. Feb.2012 :2012.
23. Grande D, Mitra N, Shah A, Wan F, Asch DA. Public preferences about secondary uses of electronic health information. *JAMA Intern Med*. 2013; 173(19):1798–806. [PubMed: 23958803]
24. Yeager DS, Krosnick JA, Chang L, Javitz HS, Levendusky MS, Simpser A, et al. Comparing the accuracy of RDD telephone surveys and internet surveys conducted with probability and non-probability samples. *Public Opin Q*. 2011; 75(4):709–47.
25. Corbie-Smith G, Thomas SB, St George DM. Distrust, race, and research. *Arch Intern Med*. 2002; 162(21):2458–63. [PubMed: 12437405]
26. Corbie-Smith G, Thomas SB, Williams MV, Moody-Ayers S. Attitudes and beliefs of African Americans toward participation in medical research. *J Gen Intern Med*. 1999; 14(9):537–46. [PubMed: 10491242]
27. Freimuth VS, Quinn SC, Thomas SB, Cole G, Zook E, Duncan T. African Americans' views on research and the Tuskegee Syphilis Study. *Soc Sci Med*. 2001; 52(5):797–808. [PubMed: 11218181]
28. Willison DJ, Schwartz L, Abelson J, Charles C, Swinton M, Northrup D, et al. Alternatives to project-specific consent for access to personal information for health research: what is the opinion of the Canadian public? *J Am Med Inform Assoc*. 2007; 14(6):706–12. [PubMed: 17712084]
29. 2010 Behavioral Risk Factor Surveillance System Questionnaire. Centers for Disease Control and Prevention (CDC); Atlanta, GA: 2009.
30. Centers for Disease Control and Prevention (CDC). National Health Interview Survey: questionnaires, datasets, and related. documentation: 1997 to the present.
31. Liang KY, Zeger S. Longitudinal data analysis using generalized linear models. *Biometrika*. 1986; 73(1):13–22.

Part 1	ALL VIGNETTES An analysis of thousands of electronic patient records identifies people with diabetes.			
Part 2	CONSENT: NOT OBTAINED Because it would be very hard to contact all patients, the patients will not be asked permission for their records to be reviewed.		CONSENT: OBTAINED All of the patients will give permission for their records to be reviewed.	
Part 3	ALL VIGNETTES An ethics review board determined that this study provided acceptable safeguards to patient privacy.			
Part 4	USE: RESEARCH FRAMING: ABSTRACT University researchers will use this information to learn more about which types of patients are receiving the drug Diamed for their diabetes.	USE: RESEARCH FRAMING: SPECIFIC University researchers used this information to find out that on average 1 out of 10 patients with diabetes are receiving the drug Diamed for their diabetes.	USE: MARKETING FRAMING: ABSTRACT A drug company will use this information to learn more about which types of patients are receiving the company's drug Diamed for their diabetes.	USE: MARKETING FRAMING: SPECIFIC A drug company used this information to find out that on average 1 out of 10 patients with diabetes are receiving the company's drug Diamed for their diabetes.
Part 5	USE: RESEARCH They will publish their results in a medical journal so that doctors can learn how to improve diabetes care.		USE: MARKETING They will use this information to sell more of their drug.	

Figure 1. Experimental Design of Survey Vignettes

Eight vignettes were developed by systematically varying the three attributes shown in Figure 1: consent (not obtained, obtained), use (research, marketing), and framing of use (an abstract future use, a past specific use with results). In the vignettes that reported "specific" results, the vignettes were written in the past tense.

Figure 2. Appropriateness of Use of Information

The figure shows the interaction of race and ethnicity with different health information uses (research, marketing) and different consent policies (consent obtained, consent not obtained) but holds the framing (a future use) constant. The coefficients represent differences in appropriateness ratings on a 1-10 scale (1=low, 10=high). The reference group in the figure is white participants rating a scenario when consent was not obtained and the use of health information would be for research. The error bars indicate 95% confidence intervals for the point estimates.

Table 1

Participant Characteristics (unweighted percentages)

	Overall (n=3,064)	Non- Hispanic African American (n=455)	Hispanic (n=516)	Non- Hispanic White (n=2,093)	P- Value
Age					<0.001
18-29	13.2	13.9	22.5	10.7	
30-44	21.5	20.7	32.0	19.1	
45-59	32.4	32.5	28.9	33.3	
60+	32.9	33.0	16.7	36.9	
Female	49.8	53.6	49.0	49.2	<0.001
Lives in a metropolitan area (MSA)	85.7	91.7	94.0	82.4	<0.001
Education					<0.001
Less than high school	8.9	9.5	24.0	5.1	
High school	29.1	29.7	29.7	28.9	
Some college	30.4	36.7	27.7	29.6	
Bachelor's degree or higher	31.6	24.2	18.6	36.5	
Income					<0.001
<\$25,000	18.8	29.9	25.8	14.7	
\$25,000-49,999	23.6	25.3	31.2	21.3	
\$50,000-74,999	19.0	17.6	18.6	19.5	
\$75,000 and above	38.6	27.3	24.4	44.5	
Insured	82.9	80.6	59.1	89.3	<0.001
Has a personal doctor or other provider	75.8	77.8	56.2	80.2	<0.001
Did not receive care in past year due to cost	16.8	21.7	26.1	13.4	<0.001
Health Status: Fair/Poor	16.4	21.0	20.4	14.4	<0.001

Table 2

Respondent Rating of Appropriateness of Use of Health Information (unadjusted means)

Health Information Use Scenario			Appropriateness of Information Use (1=low, 10=high)				
Consent	Use	Framing	Overall Mean ¹ (SD)	Non-Hispanic White Mean ¹ (SD)	Non-Hispanic African-American Mean ¹ (SD)	Hispanic Mean ¹ (SD)	P-Value ²
No Consent	Research	Future	5.68 (2.92)	5.56 (2.94)	5.66 (3.04)	6.00 (2.74)	0.27
Consent	Research	Future	6.80 (2.56)	6.73 (2.56)	7.19 (2.39)	6.72 (2.70)	0.60
No Consent	Marketing	Future	3.96 (2.77)	3.49 (2.60)	4.73 (2.99)	4.98 (2.75)	<0.001
Consent	Marketing	Future	4.43 (2.78)	4.05 (2.70)	5.51 (2.77)	4.98 (2.80)	<0.001
No Consent	Research	Past	5.55 (2.83)	5.55 (2.83)	5.34 (2.97)	5.73 (2.75)	0.85
Consent	Research	Past	7.06 (2.41)	7.17 (2.33)	6.83 (2.60)	6.81 (2.53)	0.53
No Consent	Marketing	Past	3.81 (2.69)	3.50 (2.52)	4.25 (2.97)	4.93 (2.90)	<0.001
Consent	Marketing	Past	4.80 (2.81)	4.48 (2.74)	5.33 (2.90)	5.55 (2.80)	<0.001

¹ The means that are presented are unadjusted and unweighted.² P-values calculated using ANOVA to test for differences across the three racial/ethnic groups.

Appendix 1

Adjusted Respondent Ratings of Appropriateness of Use of Health Information for Difference Use Scenarios

	β	P-Value	95% CI
Data Use Attributes			
<i>Consent</i> : Not obtained	ref		
<i>Consent</i> : Obtained	1.01	<0.001	0.69, 1.34
<i>Use</i> : Research	ref		
<i>Use</i> : Marketing	-2.03	<0.001	-2.27, -1.78
<i>Framing</i> : Future use	ref		
<i>Framing</i> : Past use	-0.03	0.85	-0.37, 0.30
Interactions of Data Use Attributes			
Marketing * Consent	-0.58	<0.001	-0.80, -0.36
Marketing * Past Use	-0.04	0.73	-0.26, 0.18
Consent * Past Use	0.41	0.04	0.02, 0.80
Race-Ethnicity			
White	ref		
African-American	0.01	0.97	-0.52, 0.55
Hispanic	0.02	0.95	-0.52, 0.55
Interactions (Race/Ethn*Attributes)			
Consent * African American	-0.17	0.58	-0.77, 0.43
Consent * Hispanic	0.08	0.78	-0.47, 0.63
Marketing * African American	1.18	<0.001	0.91, 1.45
Marketing * Hispanic	1.16	<0.001	0.85, 1.47
Past Use * African American	-0.44	0.15	-1.04, 0.16
Past Use * Hispanic	-0.13	0.64	-0.68, 0.42
Covariates			
Age			
18-29	ref		
30-44	-0.01	0.96	-0.33, 0.31
45-59	-0.20	0.23	-0.52, 0.12
60+	-0.18	0.30	-0.52, 0.16
Female	0.03	0.77	-0.16, 0.22
Lives in a metropolitan area (MSA)	0.13	0.33	-0.13, 0.40
Education			
Less than high school	ref		
High school	-0.19	0.35	-0.57, 0.20
Some college	-0.20	0.34	-0.60, 0.21
Bachelor's degree or higher	-0.08	0.71	-0.49, 0.33
Income			
<\$25,000	ref		
\$25,000-49,999	0.08	0.62	-0.23, 0.40
\$50,000-74,999	-0.25	0.16	-0.59, 0.10

	β	P-Value	95% CI
\$75,000 and above	-0.2	0.34	-0.52, 0.13
Uninsured	0.01	0.97	-0.30, 0.32
Does not have a personal doctor or provider	-0.13	0.31	-0.37, 0.12
Did not received care in past year due to cost	-0.22	0.14	-0.51, 0.07
Health Status: excellent, very good, or good	0.13	0.37	-0.16, 0.42
Question order: Research first	0.15	0.19	-0.07, 0.37
Question order: Research first * Marketing	0.28	0.02	0.05, 0.50