SUPPORTING STATEMENT

Part B

"Reduction of *Clostridium difficile* Infections in a Regional Collaborative of Inpatient Healthcare Settings through Implementation of Antimicrobial Stewardship"

Agency of Healthcare Research and Quality (AHRQ)

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B. Collections of Information Employing Statistical Methods

1. Respondent universe and sampling methods

The data will be collected from the antimicrobial stewardship (ASP) project team and from a sample of prescribers at each of the eleven participating hospitals. In the table below we have estimated the respondent universe and expected response rate for these units and in sum. Each ASP team, from whom we will collect focus group data, will have a core of 3-6 individuals, all of whom we expect to participate. Although it is possible that some of the larger sites could include more than 6, we expect that the maximum total number of focus group participants would be 66.

For the surveys, the respondent universe is based on an estimate of the hospital's bed size. The number of beds should be a good determinant of the number of prescribers working on the inpatient service. Prescribers are limited to those working on the inpatient units and include physicians, pharmacists, nurse practitioners and physician assistants. Therefore, we have decided to target a number of prescribers to survey that is equivalent to 15% of the inpatient beds at each hospital, rounded to obtain a maximum estimated number of surveys. There is no feasible way to obtain exact numbers but as this is a pilot study rather than a randomized controlled trial, we believe this estimate will give us sufficient numbers of respondents who would be affected by the ASP.

The numbers in the table below represent the maximum number of survey or focus group participants, as well as our expected response rate for each data collection activity. If some hospitals implement the intervention on only one unit rather than within the entire hospital, our number could be much smaller. However, for purposes of burden, we have assumed the maximum number possible.

FACILITY	FG participants	Expected Response rate	Approx # beds	Planned # prescriber surveys	Expected Response rate
Beth Israel - Petrie	6	100%	800	120	70%
Beth Israel - King's Highway	6	100%	250	40	70%
Bronx Lebanon	6	100%	481	75	70%
Montefiore Medical Center- Moses Campus	6	100%	700	105	70%
Montefiore Medical Center- Weiler Campus	6	100%	400	60	70%
Montefiore Medical Center - North Division	6	100%	312	50	70%
North Shore University Hospital at Southshore	6	100%	263	40	70%
North Shore University Hospital at Glencove	6	100%	200	30	70%
St. Luke's Roosevelt Hospital Center, St. Luke's site	6	100%	500	75	70%
St. Luke's Roosevelt Hospital Center, Roosevelt site	6	100%	500	75	70%
Richmond University Medical Center	6	100%	450	70	70%
Total	**66**	**100%**	**4856**	**740**	**70%**

2. Information Collection Procedures

For the focus groups a purposive sample will be selected, consisting of all the key members of the facility's ASP team. There are no estimation procedures or other sampling procedures since the sample is small and the individuals who will participate are targeted based on their role in leadership/core membership of the ASP team.

The focus groups will be conducted one time only, approximately 12 months after OMB approval (which will be approximately 12 months post-intervention implementation). The focus group procedures will involve using structured guides that will vary slightly for the two groups (control and intervention- see Attachments B and C from Supporting Statement Part A). They will be conducted via telephone by the BUSPH PI and Project Director; the GNYHA team will also participate. Because the focus groups will be done via conference calls, we expect that the participants will be in their offices or other locations in the hospital when they participate. The BUSPH research team is extremely experienced in the conduct and analysis of qualitative data. Prior to beginning each focus group, verbal consent will be obtained via telephone using procedures approved by the BUMC IRB. These instructions are included in the focus group protocols. The purpose of the focus group will be explained and all individuals will be informed that they have the option of not participating. Detailed notes will be taken during each focus group; the groups will also be audio-recorded as a back-up to the notes. Following the focus group, the data will be transcribed for analysis and then transformed into text files for use in HyperResearch 2.0 on a secure, password-protected database only accessible to the BUSPH researchers. The written transcripts and audiotapes will also be maintained securely in a locked filing cabinet in the office of the PI at BUSPH. Once the project is complete, these will be destroyed.

The surveys will be administered twice: upon OMB approval and 12 months after. The surveys are the same for the control and intervention sites. The procedures for the surveys will involve distribution to prescribers by the GNYHA primary contact at each site at provider meetings. The type of meeting during which the survey is distributed may vary, depending on the hospital, the units engaged in the intervention, and the method that will be most acceptable at each facility; for example, the GNYHA contact will stand outside of the auditorium at grand rounds and hand out the survey as participants enter the room and will stand outside of the room at the close of the meeting and collect the completed surveys. Importantly, GNYHA has an ongoing relationship with these hospitals and knows the types of methods to use that will work well with them and not feel burdensome. They will work with the ASP team to identify the opportune meetings and time to distribute the surveys. Additionally, both the GNYHA team and the BUSPH team have administered these types of surveys in the past and are experienced in these methods. Immediately after completion, the surveys will be copied and a duplicate sent to BUSPH via FedEx. Although the surveys will be anonymous, the copy remaining at GNYHA will be stored in a locked filing cabinet.

The surveys will be self-administered using written instruments that have been pre-tested for readability, accessibility and ease of completion with prescribers from other hospitals. The survey itself will be one page only, front and back. The introductory paragraph will explain that all information in the surveys will be kept confidential. No informed consent will be obtained, as the surveys will include no respondent names, or other sensitive or identifying data. The research team will be unable to link specific survey responses with any specific employees. If a respondent answers both times, no codes or other information will be put on the surveys that will allow the BUSPH research team to track individual respondents' responses over time from the first to second survey. Once surveys are received, the data will be coded and entered into

a secure, password-protected database in PASW (formerly SPSS) 18.0 in preparation for data analysis. The written surveys copies sent to BUSPH will be maintained securely in a locked filing cabinet in the office of the PI at BUSPH. Once the project is complete, these will be destroyed.

All staff who will be involved in this research have been trained in research with human subjects and have NIH certification.

3. Methods to Maximize Response Rates

The investigators will use proven methods to maximize participation in the study. For the focus groups, we expect 100% participation from the ASP team members who are invested in and lead the project. The focus groups will be scheduled at times convenient for the participants. The GNYHA project liaisons will work with each facility to schedule the focus group at a time that is convenient for them. Additionally, as part of GNYHA's standard initial application for any project, team members agree to participate in regular calls and meetings, and this focus group meeting will be similar to those they have participated in for past projects. Moreover, BUSPH has achieved almost 100% participation in qualitative interviews and focus groups in past studies, including a recent hepatitis project conducted in New York. We will allow individuals to call-in from their own or office telephones and will provide a call-in number.

For the surveys, we will target a 70% response rate. We believe this rate is achievable for several reasons. First, the instrument itself is designed to maximize response rates. The survey is extremely brief and takes no more than 10 minutes to complete; our pilot of 5 prescribers completed it in a mean of 7 minutes. The style is clear and the instructions are straightforward, with no skip patterns or other items that might be confusing. Second, we will have the support and active involvement of GNYHA and each site will have a GNYHA liaison that is known to the facility. Third, the ASP team at each facility will encourage participation from their peers. The ASP team may include a hospital administrator who will strongly support participation and ask prescribers to participate; if an administrator is not part of the core team, he/she will have signed off on the project application for participation and will be a strong supporter. Employee communications will be utilized in the facilities to make staff aware of the research study and to encourage them to participate if/when asked. No person-specific reminders will be used, but reminder emails and/or calls will be used in the units to encourage participation if there is a non-response problem. Fourth, the hospitals are all part of the GNYHA CDI collaborative and their prescribers are extremely interested in finding ways to reduce c-difficile, as this infection is virulent and deadly. The cover letter will convey the importance of the survey to AHRQ and CDC, and will indicate that the respondent will not be identified to any government agency, BUSPH or GNYHA. As with the focus groups, both GNYHA and BUSPH have conducted surveys with hospital staff in the past and have found that using these methods leads to high response rates.

4. Tests of Procedures

Both the focus group and survey procedures used in this study are very similar to those used successfully by this research team in other studies of the implementation of new clinical practices. As described, we have pre-tested the survey with 5 prescribers who work at two Boston-area hospitals; all completed the survey without difficulty, liked the format and completed it in a mean of 7 minutes. The format is based on AHRQ's patient safety survey. The focus groups will not be pilot-tested, as they will be specific to having participated in the project, either as an intervention or control site. However, the general form and administration of the focus group guide is very similar to those used in the past. It has been our experience that staff members are generally willing and able to participate in focus groups and surveys regarding the

implementation of new clinical practices in their workplaces, particularly if they are a member of the team, and the information derived from these methods yields valid data about these experiences. In addition, facilities are almost always willing to share their experiences about successes and challenges, and to discuss promising practices in a new and important area to them.

5. Statistical Consultants

The survey data will be collected by Maria Woods of GNYHA. These data will be initially analyzed by Mari-Lynn Drainoni and Elisa Koppelman of BUSPH; both are trained in basic statistical analysis. Simple univariate and bivariate statistics will be used to explore and characterize the survey data; therefore, the services of a biostatistician are not required. However, BUSPH has extensive statistical resources available via trained PhD-level Statisticians through both its Department of Health Policy and Management (where the ACTION initiative is housed), as well as a separate Department of Biostatistics. Therefore, if any statistical consultation is required, these resources are readily available. GNYHA will also actively participate in survey data analysis via Rafael Ruiz and Ismail Sirtalan, both of whom are extensively trained in data analysis and statistical methods.

The focus group data will be collected by Mari-Lynn Drainoni and Elisa Koppelman of BUSPH, who will also conduct the qualitative data analysis. Both have expertise in qualitative data collection and analysis. No consultations are necessary.