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*The voice of public health physicians, guardians of the public's health*

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***Preventive Services Toolkit***

**Module 6 –Data Management – Instructor’s Manual**

**Table of Contents**

Slide 1: Title Slide.....	1
Slide 2: Teaching Objectives.....	2
Slide 3: Preventive-Program Special Data Issues.....	4
Slide 4: Survey-Related Issues .....	5
Slide 5: HRA and HAS.....	5
Slide 6: Medical and Billing Records.....	5
Slide 7: Group Interview Sessions – Slide 1 of 4 .....	6
Slide 8: Groups Interview Sessions – Slide 2 of 4.....	6
Slide 9: Group Interview Sessions – Slide 3 of 4 .....	6
Slide 10: Group Interview Sessions – Slide 4 of 4 .....	6
<b>8. Group Interview Sessions – Slide 1 of 4.....</b>	<b>9</b>
<b>8. Group Interview Sessions – Slide 1 of 4.....</b>	<b>9</b>
<b>9. Group Interview Sessions – Slide 2 of 4.....</b>	<b>9</b>
<b>10. Group Interview Sessions – Slide 3 of 4.....</b>	<b>10</b>
<b>11. Group Interview Sessions – Slide 4 of 4.....</b>	<b>10</b>
<b>5. Definitions .....</b>	<b>13</b>
<b>6. Key Privacy/Confidentiality Issues .....</b>	<b>14</b>
<b>14. Notes Regarding Literature Review .....</b>	<b>16</b>
<b>15. Notes Regarding Publications of Results.....</b>	<b>16</b>
<b>16. Notes Regarding Public Health Reports.....</b>	<b>16</b>
<b>17. Q and A, Open Discussion .....</b>	<b>16</b>

***Slide 1: Title Slide***

**AAPHP  
Preventive Services Toolkit  
Module 4  
Data**

- **Preventive services have data needs different from therapeutic services.**
  - These needs are relatively easy to address and do not require costly data systems.
  - They do, however, require tools not otherwise used in healthcare settings, and raise issues relative to HIPAA compliance due to ambiguities in HIPAA regulations as currently drafted.

**▪Group interviews and simple surveys can be of substantial value**

- Generally speaking, many potential champions of preventive services in healthcare settings are not familiar with the most effective and most cost-efficient ways of using these tools.
- While most health professionals are familiar with the quantitative tools appropriate to confirm or deny a proposed hypothesis – most health professionals are not familiar with the much simpler qualitative tools needed to optimally frame hypotheses, and set the stage for the more definitive quantitative studies.
- The key to success in both preventive medicine and public health is not knowing the answer – but knowing what question to ask and how to frame it so that the answer emerges in a clear and convincing manner.
  - The qualitative skills needed to optimally frame such questions are not well taught in most MPH and other PM training programs –
  - Nor are they well demonstrated in public health and medical literature – where a passion for randomization and statistical significance often makes it difficult to get the best of qualitative studies published.
- We will attempt to introduce workshop participants to at least some of these qualitative skills in this brief data module

**▪Overly conservative interpretation of HIPAA regulations inhibit planning and evaluation of preventive programming.**

- In many healthcare settings, overly conservative interpretation of HIPAA regulations inhibit the development of new data systems for needs assessment and planning of preventive services.
- It’s impossible to do an optimal job with implementing, managing and demonstrating the value of a preventive program without program-specific data including cost, process and outcomes. Unfortunately, overly conservative interpretations of HIPAA regulations are very common, and can severely inhibit development and expansion of preventive programming.
- The root of this problem is the ambiguity of HIPAA regulations as they apply to data that does not neatly fit into the patient benefit, public health or research paradigms.

***Slide 2: Teaching Objectives***

- So far today, we have described a mix of approaches for implementing preventive services. Many of these approaches require both new data, and tabulation of currently available data in new ways.
- We will briefly address the problem with the HIPAA regulations to help you gather and manage the data needed without undo restriction.
- This module will focus on the new data and new small-scale data systems often required for optimal design and management of new or expanded preventive services in both clinical and community settings. There will be three major elements:
  - Group interview sessions to gather qualitative data on opinions, perceptions, and satisfaction;
  - Various types of surveys to gather baseline data, then evaluate program impact; and
  - Program-specific data systems considering cost, process, direct outcomes and indirect outcomes.

- This module will suggest cost-efficient approaches to development and management of the needed data without running afoul of HIPAA regulations.
- HIPAA regulations provide much more flexibility than is commonly in place in many healthcare settings. In our experience, most institutions appear to be using overly conservative legal interpretations of the regulations and penalties. This module will facilitate management and appropriate communication of the data needed for preventive and quality assurance services.

### **Slide 3: Preventive-Program Special Data Issues**

▪It’s important to be clear about why the data is to be gathered from any group interview, survey or medical records review. If the purpose is primarily “qualitative”—that is to develop a clearer understanding of the problem or to develop hypotheses for future exploration, then the approach can and should be relatively unstructured, and there are no specific requirements for the number of persons to be sampled, or how they are to be selected. If, however, the purpose is to confirm or deny an impression, then the data-gathering will be considered “quantitative,” should be highly structured, and will have specific guidelines as to sample size.

▪The question of **Identity of individual participants** is either not gathered or managed as protected information

▪Survey reports must be managed in a way that assures that identity of individual participants cannot be gleaned from the report data (give examples of this possibility when there are only single responses in a given location or characteristic).

▪Staff conducting surveys must be HIPAA- trained and HIPAA-compliant

#### **Sample frame and sample size**

▪A wide range of sampling techniques can be used, from a grab sample, random sample, stratified random sample, or other. The technique will depend on the information to be gathered and the nature of the report to be generated.

▪A sample as small as 6 to 10 can often suffice to pilot a questionnaire, or to develop a preliminary impression as to opinion or perception, or to decide whether a larger survey would be of value. Grab samples often work well for these purposes.

▪For planning and evaluation purposes partially or fully randomized surveys with a sample sizes in the range of 50 to 100 should be sufficient to generate baselines or differences significant at the level of  $p < 0.2$ .

▪Sample sizes in excess of 300 are often required if there is a perceived need to detect differences significant at  $p < 0.05$  or less.

▪The StatCalc tool in Epi Info software includes a utility designed to help epidemiologists with limited biostatistical training determine sample sizes on the basis of expected percentage differences, and desired level of power, and desired level of statistical significance. If you are not familiar with any of the software packages used to ascertain sample size, and the process for doing so—you will then need to contact an epidemiologist or biostatistician for assistance.

**Identity of individual participants** is either not gathered or managed as protected information

▪Survey reports must be managed in a way that assures that identity of individual participants cannot be gleaned from the report data (give examples of this possibility when there are only single responses in a given location or characteristic).

▪Staff conducting surveys must be HIPAA- trained and HIPAA-compliant. The time required for **HIPAA training** depends partly on the prior experience and HIPAA training of the involved staff.

### **Slide 4: Survey-Related Issues**

### **Slide 5: HRA and HAS**

### **Slide 6: Medical and Billing Records**

- In addition to the usual hospital and clinic data sources – medical and billing records, pharmacy, lab, x-ray, etc – Individual clinical units and programs may maintain some of their own data for their own purposes – and some of these data systems, especially case registries may be extremely useful and much more up to date than hospital billing records.
- Sample sizes and sampling frames are the same as for other survey work.
- Electronic v. paper (guidelines same, time required to gather and process data markedly different)
- The general guideline for what can and cannot be included in reports, tabulations and summaries
  - is the same as group interviews and other forms of survey work – that the person doing the sampling will often need access to individually identifiable data, but the report should not directly or indirectly reveal the identity of the patient.
  - There is, however, a question about the purpose of the record review. If it is for the individualized care of the patient, or for regulatory compliance – individualized patient permission is not required. If it is for quality improvement, patient permission is generally not required. If it is for research or any commercial purpose – patient permission is required. Record reviews for the purpose of planning or evaluating preventive programming seem to fall into a gray area, in between patient care and research. It is our perception that the HIPAA regulations allow such record review without patient permission, as they are for the patient’s benefit. This issue, however, is best discussed with institutional review committees before such reviews are conducted
  
- **Case population, numerators and denominators** is trickier than it appears. If you are a clinician comparing the efficacy of two drugs in a patient population – your set of patients with the diagnosis in question is the denominator. If, however, you are considering preventive services to prevent the disease in question, then the cases in the case series become the numerator, and one has to figure out how one or more denominator populations can be identified.
- As noted in an earlier module, the secret to success is not knowing who your cases are – but in identifying and characterizing the (denominator) population from whence they came so that preventive interventions can be designed to meet their specific needs.
- **ICD9 and procedural paradigms:**
  - Many of us are so used to describing health problems and their proposed solutions in terms of medical diagnosis or procedure, that we forget there are other ways to approach these issues. When dealing with the medical treatment of sick individuals, framing our thoughts in terms of medical diagnosis.

When dealing with preventive services, however, there are at least two other ways to frame our thinking and identify alternative approaches – as presented in the Epidemiology module.

- From a data management perspective, however, the point is that data in the public health or community/mental health paradigm is unlikely to be represented in any of the healthcare data systems.

### ***Slide 7: Group Interview Sessions – Slide 1 of 4***

These topics will be discussed in the ensuing slides. The privacy and reporting issues are the same for both group interview and survey purposes.

### ***Slide 8: Groups Interview Sessions – Slide 2 of 4***

- We recommend informal sessions in which two staff (one serving as moderator, and the other as observer and recorder) meet with a group of 6 to 15 community people, or patients, or staff to inquire about perceptions and opinions regarding a proposed program or current practice – to assist in the advocacy for, planning or evaluation of the program. The sessions should be planned to be about an hour in length, recorded only by written notes of the staff involved, and be based on a short list of questions to be posed to the group. Some of these can be one-time gatherings of patients recruited informally. Others can be ongoing dialogues. Yet others may benefit from the full COPC Cluster Committee process as described in the COPC module.
- The recruitment process will depend on the purpose of the group interview and who you wish to gather in the room. If you will be asking people to make an extra trip to the facility to participate – some remuneration may be in order.
- The better the session is thought through beforehand, the more likely it is to succeed in providing useful and reliable information. If your interest is in securing community perspectives, it might be wise to briefly pilot the intended questions on one or two friendly and easily accessible patients to make sure they will be interpreting the questions as intended.

### ***Slide 9: Group Interview Sessions – Slide 3 of 4***

- Groups established to get patients' input generally require protection of the identity of individual patients. This is especially important if the patient groups are selected on the basis of health-related criteria such as diagnosis, number of visits, or cost of care. The more restrictive the health-related criteria for selection of group members, the more information would be conveyed by disclosure of the participants' identities -- and the more concerned you should be to maintain both privacy and confidentiality of the information.
- Even though IRB approval is technically not needed for program planning and evaluation activities, it would be a good idea to meet with the committee, to assure they know what you are doing and why – and to seek their guidance as to when and if there may be any requirement for written permission.

### ***Slide 10: Group Interview Sessions – Slide 4 of 4***

▪If a lot is at stake -- for instance, if group membership would imply a socially significant diagnosis such as HIV, or a socially stigmatized status such as transgendered identity -- your invitations should be delivered in a sensitive manner, in a private setting, by a trusted person. Mailed invitations that discuss a diagnosis could be opened by someone other than the patient. Group members should understand what questions will be asked in the group. They should understand whether participants' real names and full names will or will not be used in the group. We recommend that participants be requested to sign a document of mutual understanding with the healthcare institution about the confidentiality "ground rules" for group discussion. The reports generated from a focus group session should specify the topic, the criteria for selection of participants, the number of participants and the most substantial findings. Verbatim minutes are not appropriate, and the identity of the participants should be held as confidential information.



## **8. Group Interview Sessions – Slide 1 of 4**

- **How to do group interviews**
- **Privacy issues (same as surveys)**
- **Reports (same as surveys)**
- **De-identification**

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These topics will be discussed in the ensuing slides. The privacy and reporting issues are the same for both group interview and survey purposes.

## **9. Group Interview Sessions – Slide 2 of 4**

### **How to do group interviews**

- **Purpose and design**
- **Type of participant**
- **Recruitment**
- **Healthcare v. community perspectives**

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▪ We recommend informal sessions in which two staff (one serving as moderator, and the other as observer and recorder) meet with a group of 6 to 15 community people, or patients, or staff to inquire about perceptions and opinions regarding a proposed program or current practice – to assist in the advocacy for, planning or evaluation of the program. The sessions should be planned to be about an hour in length, recorded only by written notes of the staff involved, and be based on a short list of questions to be posed to the group. Some of these can be one-time gatherings of patients recruited informally. Others can be ongoing dialogues. Yet others may benefit from the full COPC Cluster Committee process as described in the COPC module.

▪ The recruitment process will depend on the purpose of the group interview and who you wish to gather in the room. If you will be asking people to make an extra trip to the facility to participate – some remuneration may be in order.

▪ The better the session is thought through beforehand, the more likely it is to succeed in providing useful and reliable information. If your interest is in securing community perspectives, it might be wise to briefly pilot the intended questions on one or two friendly and easily accessible patients to make sure they will be interpreting the questions as intended.

## **10. Group Interview Sessions – Slide 3 of 4**

### **Privacy issues (same as surveys)**

- **Written permission**
- **IRB approval/waiver**

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▪ Groups established to get patients' input generally require protection of the identity of individual patients. This is especially important if the patient groups are selected on the basis of health-related criteria such as diagnosis, number of visits, or cost of care. The more restrictive the health-related criteria for selection of group members, the more information would be conveyed by disclosure of the participants' identities -- and the more concerned you should be to maintain both privacy and confidentiality of the information.

▪ Even though IRB approval is technically not needed for program planning and evaluation activities, it would be a good idea to meet with the committee, to assure they know what you are doing and why -- and to seek their guidance as to when and if there may be any requirement for written permission.

## **11. Group Interview Sessions – Slide 4 of 4**

### **De-identification**

- **Recruitment**
- **Management of data by investigators**
- **Internal and confidential reports**
- **Public reports**

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▪ If a lot is at stake -- for instance, if group membership would imply a socially significant diagnosis such as HIV, or a socially stigmatized status such as transgendered identity -- your invitations should be delivered in a sensitive manner, in a private setting, by a trusted person. Mailed invitations that discuss a diagnosis could be opened by someone other than the patient. Group members should understand what questions will be asked in the group. They should understand whether participants' real names and full names will or will not be used in the group. We recommend that participants be requested to sign a document of mutual understanding with the healthcare institution about the confidentiality "ground rules" for group discussion. The reports generated from a focus group session should specify the topic, the criteria for selection of participants, the number of participants and the most substantial findings. Verbatim minutes are not appropriate, and the identity of the participants should be held as confidential information.



**The following issues deserve consideration:**

- **Need for written permission**
- **IRB approval required**
- **Levels of de-identification**

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▪ Several specific questions deserve special attention.

- **When is individual written permission required?**

- Written permission is required for participation in research projects and for selected other activities that may not be directly related to the current treatment of the patient.

- **IRB approval**

- Whether or not such permission will be required is an issue to be discussed with the Institutional Review Board. It’s important that they fully understand the value of the preventive services being proposed, and the importance of gathering and managing group interview, survey, medical record review and other data. The request to the IRB should be for a blanket waiver, as requiring separate written permission prior to the data gathering activities is likely to be extremely costly in time, and is likely to result in substantial selection bias.

- **De-identification**

- De-identification is the process by which information is removed from the records being used by the investigating team and the reports being generated.
- **The first level is removing the name and patient number** prior to research team manipulation of the data. This is often done by replacing the original patient number with a new one specific to the project – for purposes of minimizing the risk of duplication of patient data. This still leaves the risk that individual patients can still be identified by age, sex, diagnosis, and place of residence. Deleting these data, however, prior to handing it to the research team and deny the team information of importance in needs assessment, program planning and program evaluation. This first level denies the research team access to the data in question, and, for this reason, is extremely problematic..
- **The second level** is removal of information and restriction of tabulation by the research team in the process of preparing reports for publication or other public use. This universal practice is relatively easy to deal with, and poses no restrictions on the analyses that can be done.

## 5. Definitions

- **Privacy**
- **Confidentiality**
- **HIPAA**
- **Protected health information**
- **De-identification of data**

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- **Privacy** is the right to keep secret information secret

- **Confidentiality** is the right to control who has access to personal information that may or may not be secret. (45 CFR 164.304, April 17, 2003)

- **HIPAA** is the Health Insurance Portability and Accountability Act of 1996. This piece of legislation was passed to make it easier for people to retain their health insurance and continuity of care when changing employers. For better and for worse, extensive privacy and confidentiality provisions were written into this legislation – ostensibly to reduce, if not eliminate, inappropriate commercialization of health and medical record data.

- **Health Information** means any information, whether oral or recorded in any form or medium, that (1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual. (45 CFR 160.103, April 17, 2003.)

- **Protected Health Information** means individually identifiable health information [except certain educational or employment records]" that is "transmitted" or "maintained" in any medium. (45 CFR 160.103, April 17, 2003.)

- "Confidentiality" means the property that data or information is not made available or disclosed to unauthorized persons or processes."

- References summarized at <http://www.hhs.gov/ocr/hipaa> .

- **De-identification of data** is as discussed in the previous slide.

## 6. Key Privacy/Confidentiality Issues

- **Ethics**
- **State and federal laws and regulations**
- **Protections from disclosure**
- **Direct and indirect/inferential disclosures**
- **Electronic vs. paper records**
- **Whose privacy must be protected**
  - **Patients**
  - **Facilities and clinicians**

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▪ **Ethical constraints** have always precluded violations of privacy and confidentiality. Some of these ethical constraints have been codified in HIPAA and other **federal and/or state regulations**. The laws are generally framed as **protections against disclosure** of personally identifiable health information.

▪ Healthcare institutions are not allowed to release most health-related information in ways that identify an individual directly. They also may not release this information in ways that could be used to identify an individual indirectly or by inference. For instance, one might safely speak of "an African-American male in his 30's" in a particular Zip code in the Bronx. This could be any one of thousands of people. However, in many Zip codes, especially in rural areas outside the Southeast, there may be very few who fit this description and that may be enough information to determine the individual's identity.

▪ Protections against disclosure apply to all health-related information in an institution's records. **The information is protected regardless of whether it is in electronic or paper format.** HIPAA rules require that **privacy protections must remain** with the information even when it is transferred to contractors and other third parties.

▪ **The right to privacy belongs to the patient, not to clinicians or to the facility.** Even though clinicians and facilities don't have a right of privacy, though, it is wise to treat them with respect.

▪ Privacy regulations are sometimes misinterpreted in healthcare settings in ways that severely inhibit the gathering and management of the data needed to determine need for, manage, and evaluate preventive and quality assurance services.

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**14. Notes Regarding Literature Review**

- Literature review should be done prior to group interviews, surveys or medical record reviews
- Primary review should be for evidence, baselines and benchmarks (per Evidence and Planning modules)
- Conventional review of articles in journals may prove difficult and impractical

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**15. Notes Regarding Publications of Results**

- Local studies unlikely to generate case/control or pre/post differences significant at  $p < 0.05$
- Publication in peer-reviewed journals difficult
- Publication in newsletters and presentation at state and national meetings encouraged
- Data may be of value in attracting funds for more definitive study

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**16. Notes Regarding Public Health Reports**

- HIPAA waiver for reports to public health agencies
- Data to be reported to Public Health agencies
  - Reportable diseases
  - Other
- Internal use of Public Health data
  - Patient benefit
  - Group benefit/prevention/quality improvement
  - Community benefit
  - Research

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**17. Q and A, Open Discussion**