New Centers for Disease Control and Prevention’s Guidelines on HIV Counseling and Testing for the General Population and Pregnant Women

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Summary: We review two new HIV counseling and testing guidelines by the U.S. Centers for Disease Control and Prevention. The guidelines, which address the general population and pregnant women, reflect an important shift in the goals and methods of counseling and testing that has widespread implications. The guidelines’ defining characteristic is the greater emphasis on increasing the numbers of people knowing their HIV status while maintaining the historical focus on extensive pretest counseling and consent procedures. We discuss the policy and practice implications by evaluating five factors: 1) Will the guidelines be adopted? 2) Will at-risk and infected individuals be identified for counseling and testing? 3) Will health care providers offer counseling and testing and patients accept counseling and testing, obtain their test results, seek treatment, and change risky behaviors? 4) Will the guidelines be relatively cost-effective? 5) Will the guidelines be compatible with ethical standards? Key Words: HIV counseling and testing—CDC counseling and testing guidelines—Perinatal counseling and testing guidelines.

We review two new guidelines for HIV counseling and testing (C&T) issued by the U.S. Centers for Disease Control and Prevention (CDC) (1). The guidelines, which address the general population and pregnant women, reflect an important shift in the goals and methods of HIV C&T that has widespread implications for health care providers who refer individuals for or conduct HIV testing. The guidelines are particularly important because their historical evolution reflects the continuing debates about HIV prevention that have characterized the response to the epidemic since its inception.

We describe the CDC guidelines and their historical context and discuss the implications of the guidelines for clinical practice and health policy. The Appendix summarizes the guidelines, which are described in greater detail below.

CDC GUIDELINES: CONTEXT, CONTEXT, AND IMPLICATIONS

Context

There has been a long and acrimonious debate over the purpose and methods of C&T—a debate that reflects the history of the entire AIDS epidemic. As treatments for HIV infection/AIDS have become more effective, there has been increased emphasis on more widespread testing so that infected individuals can obtain early treatment.
Several prominent studies have recommended that testing become more routine (2–5).

These voices reached a crescendo around the issue of HIV C&T of pregnant women. The finding that transmission from infected mothers to their children could be greatly reduced prompted calls for revision of the existing guidelines. The Institute of Medicine (IOM) issued widely cited recommendations in 1999 for C&T of pregnant women (6) that were dramatically different from the existing CDC guidelines as well as from many other guidelines and state regulations. The IOM recommendations broke new ground by promoting universal, routine testing with notification—i.e., making testing a standard procedure for all pregnant women while preserving a woman’s right to refuse. Under this approach, women would be simply notified that they could decline testing. Women would not be screened for risk, asked whether they explicitly accepted testing, or be routinely counseled before testing.

The radical shift represented by the IOM recommendations, along with other trends in the epidemic, provided an impetus for CDC to consider the revision of its C&T guidelines for both pregnant women and the general population (1). The earlier guidelines emerged from a paradigm that focused on behavior change as a primary goal of C&T and targeted C&T with risk screening as the primary means to achieve that goal—a paradigm that emerged in the era of therapeutic impotence (7). Therefore, the emphasis was on risk screening to determine which individuals should be offered C&T, detailed informed consent procedures, and extensive pretest and posttest counseling. By 1999, however, the context of C&T had dramatically changed. In addition to the IOM report and availability of new treatments for HIV infection, the availability of new testing technologies, such as rapid testing and home collection tests with results provided via telephone, forced a rethinking of the existing paradigm (8–10).

Both the IOM and CDC revisions emerged from evidence that the prevailing guidelines were failing to promote appropriate levels of C&T and that new approaches would have to be implemented to reach the year 2005 goal that 95% of HIV-infected individuals will know of their infection (11). It has been estimated that one third to one half of infected individuals are unaware of their infection (12,13), and the number of children born with HIV infection is “far above what is potentially achievable” (6). Infected individuals are still being tested and seeking care late in the course of their illness (14, 15), and C&T is often inadequate to promote behavior change (16,17).

There is widespread agreement that the goals of C&T are both to identify HIV-positive individuals and facilitate their entry into care and to change risky behaviors to prevent new infections. However, the debate is over the extent to which it is possible to simultaneously increase the population of individuals who know their HIV status, while maintaining the extensive pretest counseling and consent procedures that may inhibit testing.

Although the IOM recommendations only address C&T of pregnant women rather than the general population, they are critical in understanding the context within which CDC revised its guidelines for the general population as well as pregnant women. Not only did the IOM recommendations challenge the existing paradigm and serve as a catalyst for CDC revisions, but also they provided evidence and rationales that can be applied more broadly. We thus refer extensively to the IOM prenatal guidelines. Although guidelines for pregnant women are inherently different in some ways from guidelines for the general population, the “lessons learned” are similar. Therefore, we discuss both guidelines simultaneously, but we point out critical differences.

The IOM report served as an impetus to revising the historical C&T paradigm by marshaling the evidence that targeted C&T with extensive consent and counseling requirements may impede the ability to identify infected individuals—evidence that is also supported by numerous studies of other populations. A review of the relevant literature can be summarized as follows (18–32):

- Many individuals do not receive their test results when in-person visits to obtain counseling are required.
- Individuals often do not seek or accept C&T under targeted approaches because of the need to disclose personal risks and the stigma associated with being “singled out.” Individuals may be more likely to accept C&T when presented as a routine part of care and when informed consent procedures are less extensive (e.g., “right of refusal” approach).
- Primary care providers often do not provide counseling because of the time and expense required as well as discomfort and inadequate training. The result is that many health care providers do not offer C&T unless patients request it or they use ad hoc risk screening and provide limited counseling.
- Targeted C&T may provide fewer societal benefits than universal, routine C&T by hindering efforts to reduce HIV stigmatization and by being more costly relative to the benefits.
- Many HIV-positive individuals are missed under targeted C&T approaches because individuals do not disclose risk behaviors, health care providers do not use
valid and reliable screening approaches, and targeting based on HIV prevalence is difficult due to the epidemic’s shifting epidemiology.

The IOM recommendations thus offered not only an impetus but also a rationale for CDC to move toward recommendations that focused more heavily on the goal of identification using routine testing. An expert panel was convened in 1999 to review the first of several draft revisions of the general guidelines, with proposed guidelines issued in the Federal Register in 2000 (33,34) followed by final versions issued on the World Wide Web and in Morbidity and Mortality Weekly Report in 2001 (1). The guidelines’ revision process, particularly for the general guidelines, took several years, the input of large numbers of individuals and groups, and multiple iterations to develop the final versions.

It initially appeared that CDC would propose radical changes in C&T policies, more akin to those recommended by IOM, by recommending more routine testing with less emphasis on extensive consent procedures and counseling. The final guidelines, however, revert at least partially to the prevailing model of C&T that includes targeted testing, risk screening, and maintenance of extensive counseling and consent procedures. The guidelines are therefore of interest not only for what they do include, but also for what they do not include.

The guidelines are also of interest because they reflect the politics of HIV prevention and therefore serve as a “case study” of the challenges of incorporating differing perspectives when multiple interest groups are involved. Two of the authors of this article were directly involved in the general guideline development (R.B. was a member of the 1999 expert panel and provided input into multiple drafts, while K.P. was a reviewer for the December 1999 draft of the general guidelines and was a member of the 1999 IOM Panel on Implementation of the Perinatal Guidelines; B. Aliza and M. Stoto, unpublished data).

With their emphasis on routine C&T in high-risk and high-prevalence settings but targeted C&T in low-prevalence settings, along with a continued emphasis on extensive pretest counseling and consent procedures, the guidelines represent a carefully constructed compromise between approaches that have historically been in conflict. The marriage of these approaches may signal both the enduring impact of the “HIV exceptionalism” that has set HIV policy apart from the approach to other infectious diseases and the erosion of that approach (35,36). Such erosion would be a “paradigm shift” that would have important implications for other HIV policies.

Content

The importance of the CDC guidelines can only be understood in a historical context. Therefore, we reviewed and categorized the key C&T guidelines issued since 1987 (Table 1).

Primary Goals of C&T and Scope of Recommendations

The new CDC guidelines focus on strategies to increase the number of people knowing their HIV status, noting that “providers in all settings (traditional and non-traditional) should ideally recommend C&T to all clients on a routine basis” (1). The increased emphasis on knowledge of HIV status as a primary goal is a significant shift from previous guidelines. However, the guidelines also continue to place a strong emphasis on the need for prevention counseling.

The scope of the general guidelines has also changed, increasing their potential influence. Although earlier guidelines were directed primarily to publicly funded sites (Table 1), the new guidelines are directed to all health care providers, such as primary care doctors. Publicly funded C&T programs represent only 15% of non-blood donation HIV testing in the United States (37), and primary care settings are the most common site for C&T (38).

Routine or Targeted Testing

The defining characteristic of the guidelines is the increased emphasis on routine, universal testing in high-risk and high-prevalence (e.g., >1%) settings and for circumstances where HIV preventive treatment exists (e.g., pregnant women), while maintaining targeted testing in low-prevalence settings. High-risk settings are defined as those where the population is at increased behavioral or clinical risk regardless of HIV prevalence (e.g., sexually transmitted disease clinics and drug treatment centers). A prevalence of ≥1% is considered to provide very general guidance for determining a high-prevalence setting (39), and most general health care settings are assumed to have low prevalence.

Informed Consent

A critical distinction between the CDC guidelines and the IOM recommendations is the nature of the consent process. Both the CDC and IOM recommendations require that patients consent to be tested—that is, testing is voluntary and patients are informed that they will be
<table>
<thead>
<tr>
<th>Goals and scopes</th>
<th>General population guidelines</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Primary goals of testing</td>
<td>1) Behavior change a primary focus</td>
<td>1) Behavior change a primary focus</td>
<td>1) Continued emphasis on behavior change</td>
<td></td>
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<tr>
<td></td>
<td>2) Identify HIV status</td>
<td>2) Identify HIV status</td>
<td>2) More emphasis on identifying HIV status</td>
<td></td>
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<tr>
<td>Scope of recommendations</td>
<td>Publicly funded sites</td>
<td>Publicly funded sites</td>
<td>All providers</td>
<td></td>
</tr>
<tr>
<td>Whether testing should be routine or targeted</td>
<td>Primarily targeted</td>
<td>Primarily targeted</td>
<td>More emphasis on routine testing in high risk and high prevalence settings. Continued targeted testing in low prevalence settings.</td>
<td></td>
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<tr>
<td>Informed consent</td>
<td>Opt-in</td>
<td>Opt-in</td>
<td>Opt-in</td>
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<td>Whether testing is routine with informed right of refusal (“opt-out” w/verbal consent only); or patients must explicitly accept or refuse testing (“opt-in” w/written consent required or recommended)</td>
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<tr>
<td>Information &amp; counseling</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes for high risk settings, but risk screening recommended in other settings to determine whether counseling is recommended.</td>
<td></td>
</tr>
<tr>
<td>Whether prevention counseling is routinely recommended</td>
<td>Information an important emphasis of pretest counseling</td>
<td>Information important but not a substitute for prevention counseling</td>
<td>Information important but not a substitute for prevention counseling</td>
<td></td>
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<tr>
<td>Relative emphasis on provision of information about HIV test, HIV transmission, and meaning of results</td>
<td>In-person implied</td>
<td>In-person</td>
<td>Phone counseling an option</td>
<td></td>
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| Goals and scope | Prenatal guidelines | | | |
|------------------|------------------|------------------|------------------|
| Primary goals of testing | 1) Avoid becoming infected | 1) Prevent perinatal transmission | 1) Primary emphasis on preventing perinatal transmission | 1) Primary emphasis on preventing perinatal transmission |
| | 2) Delay pregnancy if HIV+ and pregnant | 2) Behavior change | 2) Continued emphasis on behavior change | |
| Scope of recommendations | All providers | All providers | All providers | All providers |
| Whether testing should be routine or targeted | Targeted | Routine | Routine | Routine |
| Routinely offered to all members of a population or targeted to specific members based on risk screening | Opt-in | Opt-in | Opt-out | Opt-in |
| Informed consent | | | | |
| Whether testing is routine with informed right of refusal (“opt-out” w/verbal consent only); or patients must explicitly accept or refuse testing (“opt-in” w/written consent required or recommended) | | | | |
| Information & counseling | Yes | Yes | No | No, but risk screening recommended as routine part of prenatal care to determine whether counseling is recommended. |
| Whether prevention counseling is routinely recommended | | | | |
tested. However, IOM recommends “routine testing with notification” (known as “opt-out” consent)—i.e., women are notified that they will be tested unless they decline, and written consent is “not necessary.” In contrast, the CDC guidelines continue to recommend “opt-in” consent—i.e., consent for HIV testing is specifically discussed, clients make an explicit decision to accept or decline testing, and written consent is recommended.

The differences in recommendations appear subtle, but they are important because informed consent procedures have served as symbolic “lightening rods” for debates over C&T. These procedures were contentious issues in the guideline development process, as different CDC drafts veered dramatically from recommending opt-out consent in high-risk settings and for pregnant women to recommending opt-in consent but with the flexibility of obtaining verbal consent to the final guidelines that revert to opt-in, written consent.

**Prevention Counseling**

The guidelines continue to recommend relatively extensive provision of information about HIV testing and prevention counseling, although some flexibility is encouraged in determining who obtains counseling. Prevention counseling—defined as a direct, personalized, and client-centered intervention designed to help initiate behavior change to avoid infection or, if already infected, to prevent transmission to others, and to obtain appropriate referral(s): Opt-in: voluntary informed consent to testing where the individual has the explicit option to accept or decline HIV testing; explicit written consent required or recommended; Opt-out: voluntary informed consent to testing where the individual has the informed right of refusal; testing routinely performed as standard of care unless refused by the individual; no explicit written consent.

### TABLE 1. Continued.

<table>
<thead>
<tr>
<th>1985 CDC</th>
<th>1995 CDC</th>
<th>1999 IOM</th>
<th>2001 CDC</th>
</tr>
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<tbody>
<tr>
<td>Relative emphasis on provision of information about HIV test, HIV transmission, and meaning of results</td>
<td>Not explicit</td>
<td>Information important but not a substitute for prevention counseling</td>
<td>Minimal information needs to be provided</td>
</tr>
<tr>
<td>Whether disclosure of results &amp; counseling for HIV negatives should be in-person</td>
<td>In-person</td>
<td>In-person</td>
<td>No</td>
</tr>
</tbody>
</table>

This review was designed to capture the key differences among guidelines and trends over time. However, given the differences among guidelines in working, format, and level of explicitness, out categorizations should not be construed as definitive. In addition, the review does not cover all of the topics in the guidelines (e.g., referral) and therefore should not be considered comprehensive.

Note that, although the initial overall CDC guidelines were issued in 1996, the 1997 guidelines expanded those initial guidelines.

Definitions of key terms: High risk setting: setting where most individuals are at increased behavioral risk, e.g., STD clinics; Risk screening: a brief screening process to identify who should receive testing; Prevention counseling: a direct, personalized, and client-centered intervention designed to help initiate behavior change to avoid infection or, if already infected, to prevent transmission to others, and to obtain appropriate referral(s); Opt-in: voluntary informed consent to testing where the individual has the explicit option to accept or decline HIV testing; explicit written consent required or recommended; Opt-out: voluntary informed consent to testing where the individual has the informed right of refusal; testing routinely performed as standard of care unless refused by the individual; no explicit written consent.


Policy and Practice Implications

We adapted the approach used by IOM (6) to evaluate what factors along a “chain of events” would promote or impede achieving the guidelines’ goals and thus the recommendations’ potential clinical and policy implications.

1. Will the guidelines be adopted?

The first challenge to implementation is knowledge, since previous studies have found that knowledge of CDC guidelines and state testing laws varies widely (6). In addition, a barrier to implementation is the need for additional funding and technical support (45).

Even if health care providers become aware of the guidelines, the fundamental issue is how the guidelines will be interpreted. There has been concern that the guidelines are too complex (e.g., the guidelines comprise 85 pages in the Morbidity and Mortality Weekly Report). In particular, health care providers may become confused about the subtle complexities of distinguishing whether routine or targeted testing and prevention counseling should be offered and how informed consent should be obtained. Specifically, the distinctions between the offering of routine or targeted testing and routine or targeted prevention counseling are subtle and are thus likely to be a source of confusion. The guidelines recommend that risk screening be used to determine which clients in high-prevalence settings should be counseled, even though it is recommended that all individuals in such settings should be offered routine testing and these individuals may be more likely to benefit from counseling than individuals in other settings.

The result may be the infamous “slide down the slippery slope” toward testing without consent that has been hotly debated for many years (27). Thus, guideline dissemination in user-friendly formats will have to be a high priority.

2. Will at-risk and infected individuals be identified for C&T?

One challenge is to appropriately define high-risk and high-prevalence settings where testing should be universally offered, since the definition of such settings must be inclusive enough to include most individuals at risk. The guidelines state that the cutoff of 1% prevalence among individuals 15—54 years of age can be considered as “very general guidance,” but they note that limited data exist. One partial solution is for CDC to provide ongoing information on how these settings should be defined at the local level, based on the latest epidemiologic data.

Since individuals in low-prevalence settings will receive targeted rather than routine C&T, another challenge will be to ensure that these individuals are screened for HIV risk and offered testing if appropriate. The guidelines note that there is limited evidence on the efficacy of different screening approaches, and therefore they offer only general guidance to health care providers—e.g., they suggest that one open-ended question can be used (“What are you doing now or what have you done in the past that you think may put you at risk for HIV infection?”). Clearly, more work is needed to develop reliable, valid, and feasible risk screening approaches (25).

A fundamental issue is that the concerns about risk screening raised by the IOM report continue to be relevant to the CDC guidelines. The guidelines recommend risk screening to determine whether individuals in low-prevalence settings should be tested and whether individuals in settings other than those where the population is at increased risk and pregnant women should be counseled. Therefore, the guidelines still recommend some form of risk screening for most persons being tested or being considered for testing, despite the lack of convincing evidence demonstrating its practicality and validity.

3. Will health care providers offer C&T and patients accept C&T, obtain their test results, seek treatment, and change risky behaviors?

Even if health care providers become aware of the guidelines and are able to determine whether they should be offering routine C&T, the guidelines cannot achieve their goals if health care providers do not offer C&T and patients do not accept it. Herein lies the crux of the difficulty in the guidelines’ attempt to simultaneously increase the numbers of persons knowing their HIV status while maintaining extensive pretest counseling and informed consent procedures. The C&T approaches that are most likely to increase the numbers of persons knowing their HIV status are those that offer routine, universal testing, less exacting pretest counseling and consent procedures, and rapid or phone results (19). Conversely, the C&T approaches that are most likely to change behavior—those that use risk screening and more extensive counseling—may be impediments to clinicians’ offering of testing.

The guidelines attempt to deal with this dilemma by recommending routine C&T in high-risk and high-prevalence settings and targeted C&T in low-prevalence settings. It is therefore likely that the success of the
guidelines will differ in these settings. High-risk settings such as publicly funded clinics are more likely to find it feasible to emphasize both identification (through routine testing) and prevention (by providing more extensive counseling). Conversely, previous studies suggest that low-risk settings such as primary care practices—where many HIV-infected persons are identified—are less able or willing to emphasize counseling (32). Although the strongest evidence to date on the effectiveness of counseling considered “brief” counseling to consist of two 20-minute sessions (40), this model is unlikely to be feasible in most primary care practices (32), and as noted previously, there are substantial other barriers to counseling in primary care settings. The guidelines acknowledge the need for flexibility in how health care providers implement C&T, yet they still recommend relatively extensive provision of information, counseling, and risk screening—which are major barriers to increased testing in such settings. Therefore, since the CDC guidelines for low-prevalence settings are similar to previous guidelines, it is possible that the status quo approach to C&T in primary care settings—ad hoc offering of testing and minimal pretest counseling—will predominate, and the opportunity to increase the numbers of persons knowing their HIV status will be compromised.

One approach to increasing the number of health care providers who offer prevention counseling is for CDC to provide “tools” such as prepackaged approaches to risk screening and counseling. Approaches will also be necessary to increase receptivity to screening and counseling among patients. We found in previous focus groups and surveys that some individuals object to required prevention counseling and that 59% of individuals would prefer being offered routine testing rather than risk screening by their doctor (46).

4. Will the guidelines be relatively cost-effective?

The IOM report cites the cost-effectiveness of routine C&T as one rationale for their recommendations. The report notes that prior economic evaluations of prenatal C&T have generally established its cost-effectiveness and states that their own calculations indicate that universal, routine C&T can be “very cost-effective, even in low prevalence areas” at approximately $15,600 per case found (page 307) (6).

In contrast, the CDC guidelines argue that routine C&T in low-prevalence settings might be less feasible. Since the CDC report does not include cost-effectiveness analyses, we conducted a preliminary cost-effectiveness analysis of the new guidelines (47). We found that the new guidelines are likely to be more cost-effective than previous guidelines that relied more heavily on targeting. However, the results are highly sensitive to the definition of high-risk populations and whether the primary outcome is identification or prevention. These results are similar to those of previous studies that found that assumptions about HIV prevalence, behavior change, and outcome measures are key predictors of cost-effectiveness (48–51).

5. Will the guidelines be compatible with ethical standards?

The guidelines reflect the long and complex debate over the ethics of C&T. We focus here on three issues of particular relevance. First, one rationale for the IOM endorsement of routine testing without the use of risk screening is that it may reduce the stigma and discrimination associated with being singled out for C&T (18). The CDC guidelines continue to emphasize risk screening; thus, ethical concerns about asking individuals to disclose personal risk factors remain. Furthermore, since the CDC guidelines do not recommend routine testing for all populations, there is concern that individuals who use high-risk settings or live in high-prevalence areas—populations consisting largely of the poor, minorities, and other marginalized populations—will be stigmatized.

Second, in a fundamental sense, the guidelines raise the issue of ethical trade-offs. Are extensive counseling and consent requirements ethically justifiable to protect individuals’ rights to voluntary, informed testing? Or are these requirements, since they may be barriers to the offering or acceptance of testing, denying individuals the right to know their HIV status and avoid transmission to others? Which ethical imperative should be paramount?

A related issue is the differential C&T procedures for pregnant women, which are supported by the ability to prevent HIV transmission to children. Although this rationale is certainly powerful, the benefits of C&T do not begin when women become pregnant, nor do they end when they give birth. The guidelines raise the issue of when it is ethically justifiable to treat individuals differently based on their group status when the criteria for doing so may be changeable—in this case, because pregnancy is a temporary condition—and when doing so may inhibit the ability of individuals to learn their HIV status. Knowledge of HIV status is most important before pregnancy—a fact noted explicitly in the prenatal guidelines. Many women would choose not to get pregnant if they knew that they were infected with HIV; for example, 61% of infected women in a nationally representative
sample of HIV-positive persons receiving treatment said that they definitely or probably would have an abortion if they got pregnant (52).

Yet, most women do not learn of their HIV status until they become pregnant (6). Furthermore, an important benefit of C&T of pregnant women is the prevention of HIV in adult sexual and drug-using contacts, which is relevant whether women are pregnant (53). Last, even universal C&T of pregnant women will have little impact on the epidemic because HIV prevalence among pregnant women is very low (6) and few HIV-positive children are being born (54). This does not negate the benefits of prenatal C&T, but it does underscore the importance of C&T of other populations as well.

CONCLUSION

The CDC guidelines are a carefully crafted attempt to simultaneously increase the numbers of individuals who know their HIV status, while maintaining the historical emphasis on extensive pretest counseling and consent procedures. They therefore reflect an attempt to balance the historical commitment to voluntarism and prevention with an increased focus on identification. Future research on the topics addressed will be needed to evaluate whether the guidelines can simultaneously achieve these goals.

Our analysis is meant to raise awareness and understanding about the C&T guidelines, not to provide simplistic “solutions.” The guidelines address difficult issues, and there are no easy answers to dilemmas such as whether to conduct routine or targeted testing. An observation made in the New England Journal of Medicine (4) a decade ago is still relevant: “Attempting to screen the entire population would simply be impractical; on the other hand, targeting only high risk groups would be unworkable, in part because it would entail making distinctions that are often impossible as well as invidious.” Testing practices and policies have been the result of a social negotiation to HIV that has evolved and continues to evolve. The decisions that need to be made about the most appropriate approach to C&T will continue to be challenging due to the changing nature of the epidemic. For example, the almost 10 years of debate over the approval of home collection HIV tests foreshadows the debates that are likely to continue as new technologies, such as true home HIV tests that would allow individuals to test themselves at home and receive the results immediately without counseling, allow the complete “delinking” of testing and counseling (8,46,55, 56) (Phillips KA and Chen J, unpublished data, 2002).

To conclude, the new CDC guidelines may reflect the only merger of the dual goals of C&T—increased identification and maintenance of approaches forged in the early years of the epidemic—that is feasible at this time, given political and practical constraints. However, it remains to be seen whether this carefully constructed compromise will endure. If the new guidelines prove to be unworkable, it is likely that there will be increased pressure for CDC to fully adopt the IOM model of universal, routine C&T, not only for pregnant women but also for other populations. Although counseling will undoubtedly continue to serve a vital role in controlling the epidemic, a paradigm shift toward routine testing without pretest counseling would signal the final delinking of testing from counseling, the death of HIV exceptionalism, and the end to an important chapter in the history of the social response to the AIDS epidemic.

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KEY RECOMMENDATIONS OF THE CDC GUIDELINES

General Population Guidelines

Primary Goals

To ensure that HIV-infected persons and persons at increased risk for HIV:

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Have access to HIV testing to promote early knowledge of their HIV status.
• Receive high-quality HIV prevention counseling to reduce their risk for transmitting or acquiring HIV.
• Have access to appropriate medical, preventive, and psychosocial support services.

To promote early knowledge of HIV status through HIV testing and ensure that all persons recommended and/or receiving HIV testing are provided information regarding transmission, prevention, and the meaning of HIV test results.

Testing Strategies

• HIV testing should be voluntary, preceded by informed consent, and provided in a way that ensures strict client confidentiality. HIV testing should be available in both confidential and anonymous formats.
• Routine offering of voluntary testing is recommended for all clients in settings where the client population is at increased behavioral or clinical risk of acquiring or transmitting HIV infection, regardless of setting prevalence.
• Routine offering of voluntary testing is recommended in settings where HIV prevalence is high (e.g., > 1%).
• Targeted HIV testing based on risk screening is recommended in settings where both the HIV prevalence and the behavioral or clinical risk for HIV of the client population are low (e.g., health care settings). Any client requesting an HIV test should be provided one, regardless of his or her risk.
• Routine offering of voluntary testing is recommended for clients with “prevention treatment potential” (i.e., pregnant women and clients with acute occupational or non-occupational exposure), given the existence of effective biomedical interventions to prevent HIV transmission.

Informed Consent and Information

• Written documentation of informed consent is recommended for HIV testing. Information about consent may be presented orally or written. State or local laws governing HIV testing should be followed.
• When HIV testing is offered, information should be provided about the HIV test, risks of transmission, importance of obtaining test results, meaning of test results, and where to obtain further information and services. Information can be delivered in the form of a pamphlet, brochure, poster, or video.

Counseling

• HIV prevention counseling should be conducted for all clients in settings where clients are at increased behavioral risk for HIV, regardless of HIV prevalence. Targeted prevention counseling based on risk screening is recommended in settings of high and low HIV prevalence, and for populations with low behavioral or clinical risk for HIV.
• Prevention counseling should focus on the client’s own unique circumstances and risk through an in-depth, personalized risk assessment. Counseling should help the client set and reach an explicit behavior change goal through use of an interactive rather than informational approach.

PRENATAL GUIDELINES

Primary Goal

• All pregnant women in the United States should be tested for HIV as a routine part of prenatal care because of the benefits of knowledge of HIV status for both women and their babies. HIV testing should be voluntary.

Informed Consent and Information

• Written documentation of informed consent is recommended for HIV testing. Information about consent may be presented orally or written. State or local laws governing HIV testing should be followed.
• When HIV testing is offered, information should be provided about HIV, risks of transmission, effective interventions, that testing is recommended for all pregnant women, services are available, and that women who decline testing will not be denied care. Although face-to-face counseling is ideal, other methods can be used.

Counseling

• HIV prevention counseling, including education about HIV and assessment of risks for HIV infection, should be provided to all pregnant women as part of routine health education during pregnancy. Reluctance to provide HIV prevention counseling should never be a barrier to testing. Women found at increased behavioral risk for acquiring HIV or who want more intensive client-centered counseling should be provided with or referred to HIV risk reduction services.