Further, officials and ex-officials have accused the FDA of being overly biased in favor of the pharmaceutical industry, despite complaints within the industry that the FDA’s vetting process for new drugs is overly stringent and hurts the industry. Both David J. Graham, the associate director of the Office of Drug Safety in 2005, and Herbert Lay, the FDA commissioner who resigned in 1969, have been vocal in their warnings along these lines.

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See Also: Advertising: Over-the-Counter Drugs; Advertising: Prescription Drugs; Advertising, Government Regulation of; Cancer: Risk Communication; Chronic Diseases; Depression; Risk Communication; Warning Labels: Prescription Drugs.

Further Readings

Disclosure: Family Health History

Communication in families about family health history is important for health decision making for the individual, couples, and the broader family unit. Disclosing family health history may be necessary for family members to become aware of health conditions including genetic diseases (e.g., Huntington’s disease) and hereditary illnesses (e.g., predisposition to breast cancer), and individuals and couples who know their family health history may make specific life choices based on the information. Genetic testing also continues to advance its ability to identify the risk of carrying or developing an increasingly broad array of diseases. Several types of testing include prenatal (e.g., testing a fetus for Down syndrome), newborn (e.g., phenylketonuria), and late onset (e.g., breast cancer or Huntington’s disease). These genetic diseases may be distinct from conditions such as high blood pressure, alcoholism, prostate cancer, and some autoimmune disorders that have hereditary links.

All patients encounter parts of their family health history process when filling out patient intake forms at an initial consultation with a medical provider. These forms often ask about parents’ and grandparents’ medical histories, reinforcing the need for attention to hereditary connections for some health conditions. Genetic information is found in DNA, and patients increasingly have options to pursue genetic testing to facilitate decisions about their lives. This information could, for example, relate to a person’s decision to have children (or adopt). Additionally, testing can sometimes reveal unintended information such as paternity. An emerging field of genetic counseling prior to testing could take place for an individual, couple, or family for conditions such as sickle cell, cystic fibrosis, or hemophilia. There are many challenges related to genetic testing that may be addressed in counseling such as emotional turmoil, and those considering testing must reflect on the moral and religious implications of such knowledge prior to being tested. In a practical sense, for example, if the fetus tests positive for a particular condition, what would the parents do with this knowledge? Do the parents want to know if they will develop a degenerative and untreatable condition later in life?

Many people assume that health history will be shared within the family, but there are several reasons to disclose or not to disclose family health information. Families also may or may not agree on sharing family health history. If disclosure is made, family members must also determine the process, source, and setting/timing for delivering information.

Reasons for Disclosing Family Health History
Reasons for disclosure of family health information include relationship factors, potentially
improving health outcomes, and the potential for third-party disclosure. Relationship factors that affect sharing family health history include the feeling of responsibility to share important information that may affect another person. For example, if young women inherit specific BRCA1 or BRCA 2 genes, then parents may wish to share this information so the women are aware of the potential heightened risk for breast or ovarian cancer and can be tested for gene mutations. Additionally, the traditional family hierarchy places the responsibility with parents or family elders to share family health history with their children. Cultural norms regarding sharing family health history may influence decisions to disclose, with some groups expecting total openness, while others will not share any information (as in cultures in which a cancer patient is not told his or her diagnosis).

Children may be unaware of health conditions to which they might be susceptible, and in some rare cases they must acknowledge risk if they marry another carrier (e.g., Tay-Sachs disease). This accountability may lead parents to share family health information. This shared information is considered family-level and not individual-level information. An additional relationship factor is the relational quality in the family. A close-knit, supportive family will likely have an easier time sharing health as part of normal family history compared to dysfunctional and distant families or a family in which one member is estranged.

The second reason for disclosure of family health information is to improve health outcomes. Lack of awareness about a hereditary condition can negatively affect some outcomes, and family members who are aware may be able to alter some diet and exercise choices to increase chances of avoiding or delaying the onset of some conditions. Knowing what treatment options are available and when to best intervene can significantly improve health outcomes. The severity of the health condition may also affect disclosure. Consider sickle-cell disease and the risk of various complications (e.g., stroke, infection, kidney failure), especially when the condition is unknown. Early diagnosis of sickle-cell anemia can help patients learn to manage their condition and improve chances of longer life expectancy.

The final reason for disclosing family health history is potential third-party disclosure. If parents (or owners of the information) decide to keep health information private from their children but share it with others, they risk others sharing this information at some point. If grandparents, aunts, uncles, or family friends know about the health condition, they may share this information if they feel it is necessary. Take, as an example, Tay-Sachs disease. If adult children are carriers and are planning their own families, then they need to know about the potential for giving birth to an infant with the disease. Parents may assume that because their child is an unaffected carrier, their grandchildren will also be unaffected carriers, thus negating their reason to disclose the information. However, in such a case other parties may deem it necessary to share. Others may also not realize the information is secret and violate the decision not to share. This risk of third-party disclosure could be a reason for families to disclose a health condition sooner rather than later.

**Reasons Against Disclosing Family Health History**

Balanced against reasons to disclose, reasons against disclosure of family health information include anticipated negative reactions, protecting the family member, and the perception that disclosure is not necessary. Anticipated negative reactions to the information may prevent people from sharing family health history. For example, Huntington’s disease is a genetic disorder that causes neurodegeneration. Because of the severity of the disease, learning about risk can result in intense emotional responses. Emotions could include feelings of betrayal (“Why didn’t you tell me sooner?”), hopelessness (“There’s nothing I can do to avoid getting it”), anxiety (“When will I start to notice symptoms?”), and depression (“I’m not even going to get tested because I know I’ll develop the symptoms”). These potentially adverse reactions may cause nondisclosure in families. If the condition is untreatable or stigmatized (e.g., alcoholism or mental health disorders) the discloser can anticipate particularly negative responses.

In such cases, families may not share the information, even within the family. For example, some families are unaware that a member is
HIV-positive, and although this is stigmatized and potentially family health information, it is not hereditary.

Parents may also perceive that nondisclosure is a way of protecting children, balancing protection with causing worry. If the diagnosis is quite severe or the condition is untreatable, others may not want children to worry about whether or not they will develop the condition. In this case, the desire to avoid stress for the other would lead to not sharing family health information.

Disclosure may also be perceived as unnecessary if there is a small or moderate risk of developing or having the disease. For example, if there is a 25 percent chance, then parents may perceive the probability to be too low and therefore decide not to share. For adoptive or blended families, some of these family-health-sharing decisions are complicated because the inherited risk is different.

**Family Health Disclosure Message Enactment**

When balancing reasons for and against sharing, many families decide to share the information and must make decisions about how to enact the disclosure message or how to share the information. Approaches to family history disclosure include considerations of how to tell, who should tell, and the setting/timing in which to tell. How to share includes decisions about whether the disclosure is an ongoing interaction or a one-time discussion about the disease. Open communication about the disease can open the possibility for future communication about the risk for others, for genetic testing, and for treatment options. Continued discussions can also facilitate support for lifestyle changes such as exercise and nutrition. When considering message strategies, family members may also plan what to say and perhaps rehearse or even search for additional information online to be best prepared.

Families must also make decisions about who should share the information. Family members may be the most appropriate disclosure sources. Health information is private and even considered sensitive information that may be best received from close members of an individual’s social networks. Some may believe it is the family’s responsibility to inform other members of hereditary conditions. The language that the family uses may be targeted more toward laypersons and therefore easier to understand. However, medical professionals such as physicians or genetic counselors may supplement disclosure from family members in order to provide content expertise. Medical providers may be perceived as more credible sources of medical information and have the ability to respond to more specific questions about the health condition, treatment, and disease progression.

Setting and timing are additional decisions about when and where to disclose the family health information. Finding the appropriate setting is a consideration that may affect sharing. If the timing never feels right or plans for disclosure are consistently interrupted, this may lead to nondisclosure. Family gatherings may be a practical time to share, when all family members are likely to be present. A family gathering may also be too public, and a one-on-one setting may be preferable. People may also schedule a time and place to meet with a medical provider to discuss risk.

Finally, there is the consideration about the right time to share information. At what age or life stage is it appropriate to share a family health risk with children? Children should be old enough to understand and process the information. Children (and others) will process family health information not simply in terms of their own personal risk, but they may also have exaggerated concerns for the health of the other family member(s) (e.g., “Grandpa is sick and going to die this week!”). There may also be an appropriate time to tell a family member, such as when a major life transition occurs (e.g., marriage or family planning) and the information becomes more salient. Finally, people factor in the timing related to disease course, such as sharing information when symptoms become visible or when an elderly relative is beginning to show signs of dementia.

Choosing to disclose family health history is a complex process that includes many considerations. Sharing such sensitive information requires planning and preparation, and there are generally more reasons to share than to not share the information within the family. If disclosing, considerations include the process of disclosing (how the information will be shared), the discloser (who
Disclosure: Medical Errors

The investigation of communication competencies in the context of medical error disclosure has attracted significant research interest in numerous academic disciplines since the publication of the renowned Harvard Medical Practice Studies in 1991. Preliminary empirical evidence has successfully associated numerous therapeutic and relational benefits with effective disclosures. However, the results remain inconclusive until severe methodological limitations of the research findings are addressed. Furthermore, communication theory will be needed to integrate the data and translate the findings to frontline medical practice. Thus, medical error disclosure is an important new area for health communication inquiry that offers great potential to affect health outcomes and enhance quality of care.

At least 98,000 patients die and more than 1.3 million patients are injured in U.S. hospitals every year by medical treatments that are intended to help them. This count equates to fatalities that would be incurred by three jumbo jets crashing every two days, and exceeds the combined number of injuries and deaths that result from motor and air crashes, suicides, falls, poisonings, and drownings. About two-thirds of such adverse events are estimated to result from human error, making preventable adverse events the eighth-most common cause of death in the United States. Meanwhile, studies in Australia, the United Kingdom, Switzerland, and Denmark have suggested similar results, evidencing that medical errors are an international epidemiology.

Benefits of Disclosure

The competent disclosure of such medical incidents can drive quality improvement, reduce cost, and promote positive health outcomes. For example, honesty and compassion along with an apology can decrease patient distress after the disclosure of a medical error. Patient trust can be regained if providers play an active role in error discovery and disclosure. Improved physician communication can mitigate harm and reduce the likelihood of future errors. And about one-third of patients could be deterred from pursuing litigation if they received an error disclosure. Thus, disclosure is a marker of patient-centered medicine, a professional obligation of providers and health care institutions, and a prerequisite for safer medical care.

Systematic empirical assessments that account for the causal outcomes of insufficient disclosures are sparse. Preliminary data evidences that full disclosure reduces the likelihood of doctor-switching and improves the provider–patient relationship. Full disclosure also increases patient satisfaction, trust, and the likelihood of a positive emotional experience. In addition, error disclosures that are nonverbally involved evoke higher patient ratings of closeness, trust, empathy, satisfaction, and forgiveness, and lower ratings of patient emotional distress and avoidance. Nonverbally involved disclosures also directly predict patients’ perceived sincerity of the provider’s apology, severity of the error, fault attributions, and intentions to switch physicians. Accumulating evidence implies that...