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Medicinal Products Liability of the Pharmacists:
An Overview of Some Emerging Legal Issues in Nigeria

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haematobium-Infected Adults in a Rural Fishing Community in Nigeria

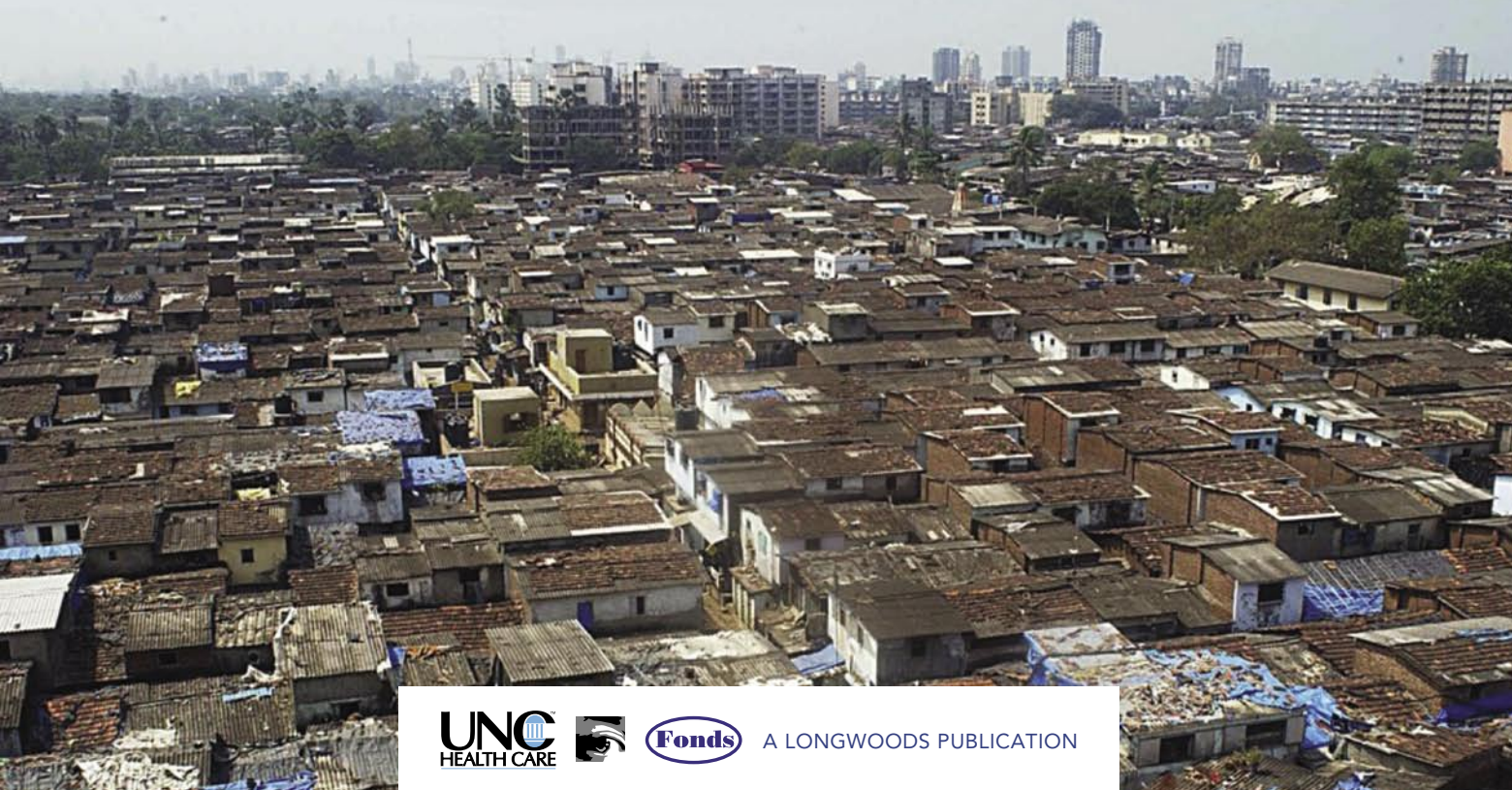
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Dianne Foster-Kent
E-mail: dkent@longwoods.com

Managing Editor
Rebecca Hart
E-mail: rhart@longwoods.com

Publisher
W. Anton Hart
E-mail: ahart@longwoods.com

Associate Publisher/Administration
Barbara Marshall
E-mail: bmarshall@longwoods.com

Associate Publisher/Media
Susan Hale
E-mail: shale@longwoods.com

Director, Design and Production
Yvonne Koo
E-mail: ykoo@longwoods.com

Graphic Designer, Design and Production
Jonathan Whitehead
E-mail: jwhitehead@longwoods.com

Graphic Designer, Design and Production
Dzeneta Zunic
E-mail: dzunic@longwoods.com

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From the Editor-in-Chief

This volume of *World Health & Population* presents papers which have recently been published online by *WHP* and are selected here as representative of the diversity and focus of the journal. The papers in this issue include four from Africa, one on Afghanistan, and a book review

In the first paper in this issue, Henry Okeri and Efe Okeri, respectively members of the Faculty of Pharmacy and Faculty of Law at the University of Benin in Nigeria, present an overview of product liability issues with regard to pharmaceuticals. Such issues are important from many dimensions, and demonstrate the intersection of health care with the social and legal structure of countries. First, in many resource-constrained economies pharmacists and compounders fill the health manpower gap by becoming prescribers as well as fillers of prescriptions. What should be the proper role and liabilities associated with such responsibilities? The second major issue is the ongoing and quite visible concern about conduct of multinational clinical trials in developing countries. There are a number of pressing ethical issues, most importantly including informed consent, which is a concept that needs strong cultural adaptation and validation before blindly applying the forms and procedures developed for trial sites in North America or Europe.

Akinwale and colleagues provide a short clinical note in our second paper, also from Nigeria, on a study examining urine samples for cell abnormalities associated with schistosomiasis infection. Schistosomiasis is second only to malaria among parasitic diseases affecting people in developing countries, and it is hyper-endemic in Nigeria. Beyond the significant primary morbidity caused by the disease, however, schistosomiasis is linked to serious long-term sequelae such as bladder cancer. This note describes field research necessary to better understanding the indicators and linkages.

Sociologist Ezebunwa Nwokocha from the University of Ibadan is the author of the third paper from Nigeria presented in this issue of *WHP*. Nwokocha examines the role of traditional medicine in Nigeria, in the context of “introduced”, or 21st century medicine brought on initially by colonization, but now made more accessible through the forces of the information age and globalization. The article describes six functions and modalities of Nigerian traditional medicine, and offers several theoretical models for understanding the choice of traditional medicine, including the well-known Health Belief Model. Nwokocha notes an uptake of interest in traditional medicine in Nigeria, and argues for the better integration of traditional medical approaches, along with introduced approaches, for the improved health of the population.

The fourth paper in this issue, by Jossy van den Boogaard and colleagues in Netherlands and Lukulu, Zambia, presents an interesting study on the choice by mothers of skilled birth attendants (SBAs) versus traditional birth attendants (TBAs) in a rural African community. The UN Millennium Development Goals specifically target reduction of maternal mortality by 75% by

the year 2015 (MDG Goal #5). Due to the overall shortages of health care providers, and SBAs in particular, it is critical to identify the appropriate continuing role of TBAs in addressing this goal. The authors point out important socio-cultural issues, as well as the training and access (transportation) issues, involved in the choice of a birth attendant. Policy implications include the allocation of scarce training resources for training of TBAs, versus excluding them from training in favor of more formally-educated and trained skilled birth attendants.

The only manuscript outside of Africa in this issue is from Shannon Doocy and colleagues from Johns Hopkins University, the University of California at San Diego, and the International Rescue Committee in Kabul. This team of researchers took on the very difficult task of updating tuberculosis (TB) prevalence rates and annual risk of TB infection in Afghanistan, which has reportedly the highest number of TB cases in Asia. Doocy et al. apply rigorous population-based survey sampling techniques under extremely challenging circumstances, with apparent reasonable success. Interestingly, their results show a substantially lower TB prevalence rate and annual risk of infection than the previous, very outdated 1978 data upon which WHO estimates have been based. Rates and risks are higher in rural areas than urban, and in provinces still experiencing the greatest violence and political unrest. As the health care system in Afghanistan struggles to recover, continued efforts need to be made to strengthen data and information on disease prevalence, to guide priority setting in this terribly resource-constrained country.

Finally, this issue includes a book review prepared by *WHP* Associate Editor Amir Khaliq, PhD, from the University of Oklahoma Health Sciences Center. Khaliq reviews Sandra Lane's 2008 book "*Why are our babies dying? Pregnancy, birth and death in America.*" Although outside the typical focus of *WHP*, the book's examination of factors impacting infant mortality in the U.S. sounds remarkably familiar with circumstances in other resource-constrained and challenged areas in the world. Views of affected U.S. populations after Hurricane Katrina could have easily been from the most impoverished areas of sub-Saharan Africa as from Mississippi or Louisiana, and the "socio-economic inequities" driving differential infant mortality in the U.S. are distressingly similar. Dr. Khaliq identifies and reviews an important book for our consideration, regardless of the geographic focus of our research or interests.

In summary, we hope that you find these articles and the book review of interest and value, and that you will additionally consult other papers recently released online at www.worldhealthandpopulation.com. *WHP* remains committed to its mission to provide a forum for researchers and policy makers worldwide to publish and disseminate health- and population-related research, and to encourage applied research and policy analysis from diverse international settings. As announced in the previous printed issue of *WHP*, we are also extremely pleased that the journal is now indexed on MEDLINE and accessible through PubMed. The reach and impact of *WHP* will be greatly enhanced, and we look forward to continued strong submission for consideration and publishing. Finally, the editors and publishers of *WHP* are always interested in any comments or suggestions you might have on the articles or journal. Please feel free to write or e-mail us.

John E. Paul, PhD
Editor-in-Chief, *World Health & Population*
paulj@email.unc.edu

Medicinal Products Liability of the Pharmacists: An Overview of Some Emerging Legal Issues in Nigeria

Henry Akpobor Okeri, Faculty of Pharmacy, University of Benin, Benin City, Nigeria.

Efe Okeri, Faculty of Law, University of Benin, Benin City, Nigeria.

Correspondence: H.A. Okeri, Faculty of Pharmacy, University of Benin, Benin City.
Tel: 08023112394, E.mail: hokeri1@yahoo.com

Abstract

There is no doubt that medicinal products are under strict control and regulation with the aim of protecting the consumers and hence promoting public health. However, there have been incidences in Nigeria where the use of some of these products have resulted to injury and even death. And in view of the alarming rate of adulteration of drugs and other related products and especially with the increase in the resort to numerous herbal products in Nigeria now, manufacturers, physicians, pharmacists as well as the consumers of medicinal products need to be abreast with their obligations, rights and remedies as the case may be. Also, the increased complexity and expanded role of the pharmacists in the drug-use process may bring about an increased exposure to liability as a result of injuries arising from their actions. This paper aims to highlight the potential liability of the pharmacist and educate the pharmacy community about product liability laws that have arisen from the expanded role of pharmacists in the healthcare delivery system.

Introduction

It is interesting to note that litigation prompted by consumer dissatisfaction with medicinal products and health practitioners has drastically increased over the years especially in the developed countries, with injured consumers and patients seeking compensation based on the available remedies in law.

Now that product-related bills in Nigeria are increasing and surveys are showing that many medicinal and regulated products are ineffective, fake, substandard or adulterated, the rights and remedies of the injured consumer need to be specified as does the liability of the manufacturer, medical professionals etc., for damages when the use of a defective product causes injury to a person or property. This will help to stabilize and improve people's lives and promote the sound development of the national economy.

Until recently, there was ample evidence of the poor state of regulatory activities in Nigeria. For example, the market was flooded with expired products, products with no expiry dates, products relabelled with the intention of extending their shelf life, toothpastes containing little or no fluoride, non-iodized or insufficiently iodized salt, improperly processed and unregistered packaged water (popularly called "pure water"), and beer and other alcoholic drinks containing high nitrosamines and with inappropriate labels that did not disclose the alcohol content.

Nigerian bakers continued to use potassium bromide as an enhancer (a product banned since the early 1990s for its implication in cancer, kidney failure and loss of hearing, as well as breakdown of vitamins). Others continued to deal in counterfeit cosmetics, banned chemicals, unsafe medicinal products and goods brought into the country as "export only" products. It is a fact that countries that produce such products do not actually distribute them to their own people. Thus, most importers (marketers who may be professionals or nonprofessionals) have become merchants of death in the quest to make quick money (Akunyili 2003).

Some Nigerians pay no attention to expiry dates, and storage conditions of medicinal and regulated products are so poor that even genuine products deteriorate. It is important to note that even when these medicinal and regulated products are properly stored they degenerate and the rate of spoilage is directly related to time.

The major problem in Nigeria is that of counterfeit or fake of products. Every useful product can be faked or counterfeited, and consumers are either deceived into buying the counterfeits as the originals or out of financial constraints and sundry reasons, buy the counterfeits because they are cheaper (Erhun 2001).

Fake and counterfeit products occur in many forms, but the common denominator remains the suffering, injury, pain and even death that they cause to the consumers. Regulated products for the promotion of good health and safety now result to grave danger or even death of consumers.

The truth is that the evil of fake and counterfeit products is worse than the scourge of malaria, HIV/AIDS and armed robbery put together. Malaria can be prevented, HIV/AIDS can be avoided, armed robbery may kill a few at a time, but fake and counterfeit products kill en masse. Anyone can be a victim at any time because we all need these products in our day-to-day life. It is also important to note that the social problems posed by hard drugs (e.g. cocaine and heroine) cannot be compared with the damage done by fake drugs (Akunyili 2004).

Consumers who have been injured by using defective medicinal products or received substandard professional services can seek redress to enforce their legal rights and obtain remedies by taking courts actions. The injured consumer is entitled to have remedies flowing directly or indirectly from civil or criminal law. As far as civil law is concerned, the remedy may be for breach of contract against the professional (e.g. a pharmacist) who has not fulfilled obligations imposed upon him or her by law, or the remedy may be in tort for negligence to show a reasonable standard of care. Additionally, where the professional's activities involve a criminal offence (such as unlawful dealings with hard drugs) resulting in a successful prosecution, the consumer may seek compensation under criminal law.

Some medicinal products may be considered safe, and administered, but eventually result in injuries to potential consumers or patients, for example, saccharin (for its carcinogenic potential). Other examples include thalidomide (an otherwise excellent sedative drug) and diethylstilbesterol (or DES, a hormonal drug used to treat threatened abortion and to prevent habitual abortion) were administered to pregnant women and both caused birth defects (Harvey 1973).

At times, pharmaceutical companies even push their products (e.g. Celebrex) into the market

before assessing their full side effects and subsequently become liable for damages. In Nigeria, 14 children died after receiving chloroquine phosphate injections in 1947 (Erhun 2001) and another 109 children died after taking paracetamol syrup (Daily Times 1990).

Recently, the Federal Government of Nigeria has instituted an action against Pfizer, Inc., a pharmaceutical company headquartered in New York, for the use of trovafloxacin mesylate (Trovan) in an impoverished region (Tudun-Wada) of Kano in northern Nigeria in 1996. In the study by Pfizer, 100 meningitis-infected children were treated with (Trovan) and another 100 children (used as control patients) received an approved antibiotic, ceftriaxone. It was reported that 11 of the children who received Trovan died, while others suffered physical disabilities and brain damage.

Although the pharmaceutical company is insisting that the drug was used to provide humanitarian relief, the investigation committee report indicted Pfizer for illegal experimentation by using an unapproved drug on human subjects. The Federal Government of Nigeria is asking for \$7billion US damages as compensation for damages (Wise 2001; Anaba 2007).

To avoid litigation and hence liabilities resulting from injuries caused by the use of medicinal products, pharmaceutical manufacturers, marketers of medicinal products and all health professionals who serve as learned intermediaries (one who takes into account the propensities of the drug as well as the susceptibilities of the patient and makes decisions regarding the usage of a drug), owe the potential consumers of these medicinal products a duty of care. Duty of care is an obligation to conform to a particular standard of conduct and ensuring that the person receiving care is given is not injured.

What Is Product Liability?

Product liability refers to the liability of any or all parties along the chain of manufacture of, and distribution (wholesale and retail) of any product, for damage caused by that product to a consumer. This includes the manufacturer of component parts (at the top of the chain), an assembling manufacturer, the wholesaler and the retailer (at the bottom of the chain).

Products containing inherent defects that cause harm to a consumer of the product, or to someone to whom the product was loaned, given, etc., are the subjects of product liability suits.

While products are generally thought of as tangible personal property, product liability has stretched that definition to include intangibles (e.g., gas), naturals (e.g., pets), real estate (e.g., houses), and writings (e.g., navigational charts). The term "product" is no longer limited to food and drink. It now includes cases in which the injurious element is not a foreign body but something intrinsically part of the product itself. It may cover areas in which there is no allegation that the product has been carelessly made, but that it is dangerous to use without proper warnings or instructions.

Therefore, products subject to the law cover a broad spectrum that includes food, drugs, appliances, automobiles, medical devices, blood and tobacco.

Product liability claims can be based on negligence, strict liability or breach of warranty of fitness, depending on the jurisdiction within which the claim is based. In any jurisdiction, one must prove that the product is defective.

When Is a Product Defective?

A product is defective if it does not provide the level of safety that the general public expects. Also, a defective product is the item that causes injury and, as such, an injured consumer can bring an action for damages against any party involved in the manufacture and distribution of the product.

Factors that determine whether a product is defective are:

- (1) Design defects that are inherent and exist before the product is manufactured. This type of defect affects every unit and includes provision of adequate warnings and instructions on using the product. The case of *Gall v. Union Ice Co.* involved the absence of sufficient warning labels on drums of sulphuric acid that eventually exploded. The Californian court held that the company was negligent in failing to place proper warning labels on their product (*Gall v. Union*

Ice Co. 1952). Similarly, in the case of *Toole v. Richardson*, the plaintiff's eye was damaged as a result of inadequate warning given with a prescription drug, MER/29. Justice Salsman found that the product was marketed without proper warning of its known dangerous effect (*Toole v. Richardson* 1967).

- (2) Manufacturing defects that occur during the construction or production of the item. Pharmaceutical industries are involved in the production of medicinal products and must avoid introducing defects during the manufacture of their products. Normally, there is an implied warranty (assumption) that a medicinal product is safe for what it is sold for. Manufacturing defects are limited in number and easy to prove, for example, improper sterilization of injectables.
- (3) Defects in marketing that result from improper instructions and failure to warn consumers of latent dangers in the product. Pharmacists are either direct marketers (wholesalers or retailers) of medicinal products or at least dispensers of medicinal products. Care must be taken to not introduce defects during repackaging, labelling or dispensing medicinal products. For example, where there is a representation that a packaged product is the same as that on the patient's prescription, then liability will be found against the pharmacist if the substituted product causes injury to the patient (*Jacobs Pharmacy and Co. v. Gibson* 1967).

Generally, product liability is considered a strict liability offense. Strict liability wrongs do not depend on the degree of carefulness by the defendant. Translated to product liability terms, a defendant is liable when it is shown that the product is defective. It is irrelevant whether the manufacturer or supplier exercised great care; if there is a defect in the product that caused harm, the defendant will be liable for it.

Who Is a Consumer?

A consumer has been defined as any person to whom goods and services or credit are supplied by another person for personal or household use (Section 32 of the Consumer Protection Decree No. 66; Ajai 1993).

There is always an imbalance between consumers and producers which often leads to the exploitation of the consumer. Being in a weaker position, the consumer is exposed to problems of product safety, fair trade practices, and product or services quality and ought to be protected. This was the position of Justice Aniogulu in the case of *Ngonadi v. Nigerian Bottling Co. Ltd.*

The aim of the manufacturer and entrepreneurs is to maximize profit, but they must be cautious and not cause injury to consumers. A manufacturer is required by law to take reasonable care to ensure that his or her products do not injure the ultimate consumer.

Who May Be Liable for Supplying a Defective Product?

Liability is not restricted to the ultimate supplier of a product, and this creates a liability chain and possibly increases the number of potential defendants to any claim.

It often becomes difficult to prove liability arising from the use of medicinal products, since so many people (manufacturer, distributors, prescribing doctor, dispensing pharmacists and even the nurse who administers the medicinal products) are responsible for the medicinal product reaching the patient. However, a pharmacist becomes liable if a medicinal product that is prescribed or dispensed by him or her causes injury to a patient.

From the above, four categories of persons may face liability for a defective product: the manufacturer, the importer, any person who holds or presents him- or herself out as the manufacturer and the person supplying the product to the victim.

The first three groups have primary liability, whereas the supplier of the product has a secondary liability. The supplying pharmacist should therefore ensure that he or she has adequate systems and records to identify with certainty the manufacturer of the medicinal products that he or she supplies.

This is because, unlike the general duty of care imposed on all vendors of goods, the pharmacist as an expert on and custodian of drugs, he or she is in a fiduciary relationship with the patient in respect of transactions involving pharmaceutical knowledge. Reliance is placed upon the special skill and knowledge of the pharmacist when manufacturing, selling, prescribing or dispensing medicinal products (Appelbe and Wingfield 1998).

The general duty of pharmacists when dispensing medicinal products involves product selection, recommendation of alternatives, counselling on the use of the product, monitoring drug therapies and evaluation of product utilization. It is important to state that the expanded role of the pharmacist resulting from the evolution of pharmacy practice to include clinical pharmacy and pharmaceutical care has also exposed pharmacists to liabilities arising from injuries caused by medicinal products.

Who Can Bring an Action?

Any consumer or patient who is directly or indirectly injured after using a product can institute an action of compensation in any court of competent jurisdiction. Second-generation injury enabled daughters of consumers of diethylstilbestrol (DES) to succeed in their claims even when it was their mother who had taken the drug. The drug caused impairment of their prospect of motherhood, propensity to develop cancerous tumours, malformation of bodily organs and some other effects that required lifelong monitoring and possibly surgery (Harvey 1973). It is important to note that the purpose of litigation is to compensate for injuries caused to an injured consumer of a product and then to forestall and prevent future occurrences.

What Type of Compensations Are Available?

The legal term for the type of award that an injured person can obtain after winning a law suit is “damages”. In product liability cases, damages are termed “compensatory damages.” They may be for economic loss (e.g., compensation for monies spent on medical bills and lost wages as a result of inability to perform usual duties) or non-economic loss, which includes monies awarded to compensate for the pain, suffering and inconvenience caused by the defective product.

Statutory Provisions and Case Law Position on Product Liability

In Nigeria, case law position on product liability is rare, and most court decisions are premised on foreign law positions as enunciated below. This is true where there is no legislation governing a specific matter or where ambiguity is occasioned and it may be necessary to have recourse to laws and practice elsewhere, especially English law and practice. Consequently, Nigerian product liability law cannot be discussed in isolation of the source and development of English law. English common law, doctrine of equity and statutes of general application were received into the Nigeria law by virtue of court ordinances. There are also international laws, conventions, agreements and treaties to which Nigeria is signatory, and they are increasingly having considerable impact on pharmacy laws in Nigeria.

Although these foreign laws operate in Nigeria, Nigerian cases, by their own nature, reflect the Nigerian interpretation and application on peculiarly Nigerian facts and situations. For example, Section 303 of the Nigerian Criminal Code imposes a duty of care on health professionals for the health of their patients, while Section 304 imposes duty on persons in charge of dangerous things, which include drugs as poisons. Section 305 states that a person who undertakes a duty, is so held to owe it, so that a pharmacist who dispenses medicinal product inexcusably owe a standard duty of care to patients based on his or her training.

As stated before, there are a number of overlapping counts upon which an injured party can bring an action in product liability law. These counts are negligence, breach of warranties (implied or express) and strict liability (Pasley 1969).

Some drug products undoubtedly cause harm and the initial law that governed the use of products was the English common law that devolved from the position of *caveat emptor* – let the

buyer beware. But currently, the position of the law offers considerable protection to even the most unwary buyer, and indeed, some would argue that it has reached the point of *caveat vendor* rather than *emptor* in developed societies.

Traditionally, a consumer or patient may have remedy in contract if the terms, (express or implied) have been breached. A good example is the famous old case of *Carlill v. The Carbolic Smokeball Company*, in which the defendant manufacturers of a product “The Carbolic Smoke Ball” (price 10/-, refills 5/-), issued an advertisement in which they offered to pay £100 to anybody who succumbed to influenza after using the smoke ball in the specified manner for a specified period. They added that they had deposited the sum of £1000 with the bankers “to show their sincerity.”

The plaintiff, Miss Carlill, relying on the advertisement, bought and used the smoke ball as prescribed but caught influenza nonetheless. She sued for her £100. The defendant company predictably and vigorously defended itself by arguing ingeniously that the claim was a bet within the meaning of the Gaming Act that the offer was a mere advertising “puff” never intended to create a binding obligation, that there was no offer made to an individual person and that, if there were, Miss Carlill had failed to notify the company of her acceptance (*Carlill v. The Carbolic Smokeball Company* 1892).

The Court of Appeal, upholding the decision of the trial judge (Justice Hawkins), found no difficulty in rejecting the argument that an offer cannot be made to the world at large. In that case Lord Justice Bowen stated that:

It is an offer made to the world which is to ripen into a contract with anybody who comes forward and performs the condition. Although the offer is made to the world, the contract is made with the limited portion of the public who comes forward and performs the condition on the faith of the advertisement (*Carlill v. The Carbolic Smokeball Company* 1892: 484).

None of the judges, however, saw fit to comment on the peddling of bogus or ineffective medical products, and it was only on a narrow contractual point that Mrs. Carlill was able to obtain satisfaction. Now, however, the tortious liability of regulated products has become a relevant concept when a consumer suffers damages or sustains injury occasioned by the use of a product.

It was not until 1932, with the House of Lord’s landmark decision in *Donoghue v. Stevenson*, that a general duty of care was actually formulated and generally accepted. The facts in the *Donoghue v. Stevenson* case were as follows. The defendant (a manufacturer of ginger beer) had supplied his products in a sealed, opaque glass bottle to a retailer who ran a café in a park in Paisley, Scotland. In August 1928, the plaintiff and a friend visited the café and Miss May Donoghue’s friend bought the bottle of ginger beer to be served with a slab of ice cream. The ice cream was served up in a tumbler; the ginger beer was poured over it. Miss Donoghue drank some of the concoction, and her friend was topping up her glass with the remaining ginger beer when the remnant of a decomposed snail floated out of the bottle. The plaintiff was upset and claimed that she suffered shock and gastroenteritis. She sued for damages from the manufacturer of the ginger beer but was not able to sue the café owner in contract owing to the rules of “privity” of contract, as her friend had bought the drink. She claimed that the defendant was in breach of the duty of care, which he owed her (*Donoghue v. Stevenson* 1932).

The manufacturer denied liability, as there was no contract between himself and the plaintiff. But the House of Lords ruled by a narrow majority of 3:2 that the defendant was liable for negligence on the grounds of a breach of legal duty of care owed the plaintiff as the ultimate consumer of his products. The case has formed the common law basis of our developing consumer law and gave rise to Lord Atkin’s famous statements (*Donoghue v. Stevenson* 1932).

Lord Atkin in the course of his speech stated

The duty which is common to all cases where liability is established must logically be based upon some elements common to cases where it is found to exist. In English Law, there must be, and is,

some general conception of relations giving rise to a duty of care, of which the particular cases found in the books are but instances. The liability for negligence ... is no doubt based upon a general public sentiment of moral wrongdoing for which the offender must pay. But acts or omissions which any moral code would censure cannot in the practical world be treated so as to give a right to every person injured by them to demand relief. In this way, rules of law arise which limit the range of complaints and the extent of their remedy. The rule that you must love your neighbour becomes, in Law, you must not injure your neighbour; and the lawyer's question: Who is my neighbour? receives a restricted reply.

You must take reasonable care to avoid acts or omissions, which you can reasonably foresee would be likely to injure your neighbour. Who, then, in law is my neighbour? The answer seems to be persons who are closely and directly affected by my act that I ought reasonably to have them in contemplation as being so affected when I am directing my mind to the acts or omissions which are called in question (*Donoghue v. Stevenson* 1932: pp. 580).

Lord Atkin also established and enunciated the manufacturer's duty of care in the following words:

A manufacturer of products, which he sells in such a form as to show that he intends them to reach the ultimate consumer in the form in which they left him with no reasonable possibility of intermediate examination, and with the knowledge that the absence of reasonable care in the preparation or putting up of the products, will result in injury to the consumer's life or property, owes a duty to take reasonable care (*Donoghue v. Stevenson* 1932).

Therefore, Lord Atkin reduced the concept of the consumer of products to what has been described as the "neighbour principle," consumers being persons who are closely and directly affected by the acts or omissions (negligence) that are called in question. He did not consider the relationship of the consumer and the manufacturer as arising only through contract but focused on the impact of the product on the consumer.

The duty of care according to the neighbour principle is an obligation to which law will give recognition and effect; to comport to a particular standard of conduct toward another, one must conform to legal standards of reasonable conduct in the light of apparent risk. A duty of care will be owed whenever, in the circumstances, it is foreseeable that if the defendant does not exercise due care, the plaintiff will be harmed.

In a negligence claim, a plaintiff must show that a manufacturer, seller, wholesaler or other party involved in the distribution chain had a duty to exercise reasonable care and failed to fulfill that duty, resulting in injury to the plaintiff. Negligence consists of doing something that a person with normal degree of prudence would not do under the same conditions, or of failing to do something that a person of normal prudence would do under the same conditions or circumstances. This may include negligence in drawing up plans for a product, in maintaining the machines that make the component parts of the product, in failure to anticipate probable uses of the product, in failure to inspect or test the product adequately, in issuing no warnings or instructions or adequate warnings or instructions, in releasing the product into the stream of commerce where due care is not used, and so forth.

The foreseeability test established by Lord Atkin in the celebrated case of *Donoghue v. Stevenson* and known as the neighbour principle is very important. The greater the likelihood that the defendant's conduct will cause harm, the greater the amount of caution is required (*Donoghue v. Stevenson* 1932).

Needless to say, if the condition of a product changes so as to render the product unreasonably dangerous after it has left the control of a defendant, that defendant cannot be held liable unless the change was reasonably foreseeable within the scope of the product's intended use.

To succeed in a claim of negligence, the plaintiff will have to prove that the injuries or damages sustained were reasonably foreseeable at the time, and any claim will be judged by reference to prevailing standards of knowledge and practices, i.e., the state-of-the-art.

The leading English case of *Roe v. Minister of Health* illustrates the protection that the state-of-the-art defense offers. TA patient, Mr. Roe, was admitted to hospital for a minor operation. An anesthetist injected his spine with nupercaine that had been stored in glass ampoules that were kept in a jar of phenol. Unfortunately, and unknown to the anesthetist, the glass ampoules had developed visually undetectable cracks through which the phenol seeped and contaminated the nupercaine. Mr Roe sued for negligence, but failed, because the dangers were not at that time appreciated by doctors (*Roe v. Minister of Health* 1954: 66).

As Lord Denning pointed out, the evidence at trial was that this risk was first pointed out in 1951 and would not have been appreciated by an anesthetist in 1947: “Nowadays it would be negligent not to realize the danger, but it was not then.” (*Roe v. Minister of Health* 1954).

However, under the breach of warranty and strict liability counts, while a plaintiff need not prove negligence, proving medical causation of injury is a crucial element. Under the warranty count, a plaintiff was required to be in “privity” of contract with the defendant, meaning that a contractual relationship had to be established between the injured party and the defendant sought to be sued. When viewed from the angle of the warranty theory, a pharmacist will be held liable if he or she takes steps without the consent of the patient. But where a patient is notified about, for example, a generic substitution and he consents to it, no liability will lie against the pharmacist. Under the strict liability theory, a plaintiff is not required to prove negligence or that he was in privity of contract with the manufacturer or the other seller. The strict liability was introduced with a California Court decision in the case of *Greenman v. Yuba Power Products, Inc.*, where the plaintiff was not required to prove negligence or privity of contract (*Greenman v. Yuba Power Products Inc.* 1963).

Strict liability theory holds suppliers of defective products liable for injury caused to consumers, especially where the product left the manufacturer and was expected to reach the consumer without any substantial change in condition. The liability is strict because it exists even when the supplier of the product has exercised reasonable care.

In the case of *Grant v. Australian Knitting Mill Ltd*, the Privy Council held that the defendant manufacturers were liable to the ultimate purchaser of the underwear that they had manufactured and that contained a chemical that gave the plaintiff a skin disease when he wore them (*Grant v. Australian Knitting Mill Ltd* 1936).

In *Osemobor v. Niger Biscuits Company*, the plaintiff purchased a packet of biscuits manufactured by the defendants. While eating a biscuit, she felt something hard in her mouth and it turned out to be a decayed tooth. The Court held the manufacturers liable (*Osemobor v. Niger Biscuits Company* 1973).

In the case of *Kubach & Anor v. Hollands & Anor*, a schoolgirl was injured while carrying out an experiment with chemicals supplied by her chemistry teacher. Under normal circumstances, the experiment would have been harmless. The teacher had brought the chemicals from the second defendant who had purchased them from a third party. The second defendant was held liable in negligence because a distributor or retailer may be liable for defects in products in appropriate cases (*Kubach & Anor v. Hollands & Anor* 1937). The law treats both the manufacturer and distributor/retailer as joint tortfeasors and holds them liable, as in the dictum of Judge Pemu in *Dumuje v. Nigerian Breweries Plc.* (Pemu 2000).

As part of this duty of care, a manufacturer must supply adequate information with those products, including any relevant warnings, and failure to do so will amount to negligence if the manufacturer knew or ought to have known of any latent dangers inherent in the product. There is a continuing duty on the part of manufacturers and suppliers of medicinal products to monitor their safety and to ensure that they are fit for their purpose and are reasonably safe. On occasion, a medicinal product or a particular batch of the product may have to be recalled, and/or there may be a duty to issue further warnings or information about the product in the light of emerging

knowledge and surveillance data.

Only in exceptional cases are products defective due to design and that is why the product liability rule focuses not only on the manufacturer, but on all those who are interposed between manufacturers and the ultimate consumers. In the case of drug products, health workers such as physicians, pharmacists, nurses and others who are termed “learned intermediaries” make the decisions on product use or application.

A learned intermediary is the expert who can take into account the propensities of the drug as well as the susceptibilities of the patient. He or she takes the risk of weighing the benefits of medicines against their potential dangers. The choice is an informed one, an individualized medical judgement based on knowledge of the patient and of drugs (Ovbiagele 2000).

In the case of a prescription drug, the manufacturer is required to convey warning information to an intermediary and not necessarily to the consumers or patients, while for over-the-counter (OTC) drugs, the information is conveyed directly to consumers.

Applying the learned intermediary rule, the burden on the manufacturer is discharged once a responsible intermediary has been informed, as in the case of *Holmes v. Ashford* (Holmes v. Ashford 1950).

A doctor or pharmacist who fail to provide a patient with adequate information or omits to convey important warnings may be found liable in tort for negligence. This is because consumers will, of course, expect that drugs prescribed to them by doctors and dispensed by pharmacists will be reasonably safe to take as illustrated by the case laws below.

In the American case of *Kaiser v. Suburban Transportation System*, a bus driver fell asleep while driving his bus and a passenger was injured in the resulting accident. The passenger sued the doctor who had prescribed Pyribenzamine (a sedating antihistamine) to the driver and had failed to warn him of its side effect - a tendency to cause drowsiness. After taking the first dose of the medication the following morning, the driver went to work and fell asleep while driving. The injured passenger sued the doctor, and would have been able to sue the manufacturers of the drug if they had not fulfilled their duty of care by informing the physician of the dangers. In this case, the Washington Supreme Court held that the doctor was liable for negligence because he was considered to be a person with knowledge of both properties of the medication and the relevant characteristics of the patient (*Kaiser v. Suburban Transportation System* 1965).

The pharmacist as an expert on drugs is expected not only to advise the patient but also to provide drug information for the physician. In *Dooley v Everett*, the Tennessee Court of Appeal found a violation of a pharmacist’s duty of care when the defendant pharmacy gave no warning to the physician or patient that a drug it dispensed was contraindicated for asthma medication the patient was taking (*Dooley v Everett*, 1990). Also, a pharmacist was held liable for failing to instruct or counsel a patient on the maximum dosage and possible risk of exceeding that dosage (*Riff v. Morgan Pharmacy* 1986; *Lasley v Shrake’s Country Club Pharmacy Inc.*, 1994).

In the case of *Dwyer v. Roderick* in the United Kingdom, a woman who suffered gangrene in both feet required extensive surgery as a result of receiving an overdose of Migril that has been prescribed for migraine. She was awarded £100,000 (\$200,000 US) damages in a High Court in London. The court tried to apportion blame for the error between the doctor who prescribed the drug and the pharmacist who dispensed it. The doctor admitted negligence by agreeing that the dose of Migril prescribed was wildly incorrect. He added, however, that the liability should be equally shared with the pharmacist because pharmacist’s duty to the patient is as strong and clear as that of the doctor. The doctor argued that the pharmacist even visited the patient three days after she had started the course of drugs and should have checked the drugs the patient was taking. After proving the negligence of the pharmacist, Justice Stuart-Smith held the pharmacy liable for 45% (£45,000 or \$90,000 US) of the damages awarded. The premise was that the pharmacist owed a duty to the patient to ensure the drugs were correctly prescribed and that the pharmacist should have spotted the doctor’s error and queried the prescription with the prescriber. It is therefore clear that a pharmacist has both a legal and a professional duty to query prescriptions with the prescriber

and should not be deterred by any adverse response or resentment on the part of the prescriber, because the pharmacist can be held as a joint tortfeasor if the dispensed product causes injury to a patient (Dwyer v. Roderick 1982).

In another case, *Prendergast v. Sam Dee Ltd*, a patient was prescribed Amoxil for a chest infection, but the pharmacist misread it as Daonil mistaking the “A” for “D” and the “x” for “n.” The patient took the drug and suffered irreversible brain damage. Mr. Justice Auld of the London High Court, in awarding £139,000 damages (75% against the pharmacist and 25% against the doctor), said that even assuming the prescription was unclear, the pharmacist should have been alerted to the fact that Daonil was being recommended in the wrong dosage. It was not enough for the pharmacist to blindly dispense drugs without giving it a second thought (Prendergast v. Sam Dee Ltd. 1988).

Although the doctor has a duty to his or her patient to write a prescription sufficiently legibly to avoid its being misread by the busy and careless pharmacist, the pharmacist is also under duty to give some thought to a prescription he or she is dispensing, and to refuse to dispense such a drug if there is any ambiguity, until satisfied that it was the correct one.

It is also important to note that the pharmacist may or may not be liable for injuries resulting from product selection, depending on whether he or she chose the product with or without the consent of the patient and physician. In the American case of *Ullman v. Grant*, a pharmacist substituted a generic drug as equivalent, and the doctor had not prohibited substitution. The court held that the pharmacist was not negligent since it was not proved that the product dispensed was defective and inferior to the other brands. However, where a physician prohibits generic substitution, a pharmacist be in breach of duty and hence will be held liable (Ullman v. Grant 1982).

From the foregoing, the liability when a consumer suffers damages or sustains injury occasioned by the use of any medicinal products could be that of the manufacturer or entrepreneur, or the distributors or retailers, as well as the learned intermediary. However, if the consumer fails to adhere to the instructions provided by the manufacturers and the learned intermediaries, the consumer has voluntarily undertaken the risk. The position of the law is that no wrong is done to one who consents. Consent renders a person “*volenti*” and gives a defence of *volenti non fit injuria*, which means, that to which a person assents is not regarded in law as injury; therefore, the learned intermediaries will be protected from liability.

Another major act of negligence especially in the developing countries, is predicated on the failure of pharmacists to observe the pharmacy laws by leaving their pharmacies (stores) in the sole charge of an unregistered person such as clerks. Obviously, this is a charge of statutory negligence and were the unregistered person a clerk dispenses and drug that injures a defendant, the pharmacist will be held liable (Goodwin v. Rowe 1913).

The Government versus Pfizer lawsuit

Initially, three bereaved Nigerian families were given permission by the Kano High Court in March 2001 to sue Pfizer after 11 children died; the families sought \$1,000,000,000 US as compensation. In May 2007 (11 years after the completion of the clinical trial), the Government instituted a criminal charge (FHC/ABJ/CR/47/07) against the pharmaceutical firm at the Federal High Court in Abuja.

The government alleges that the drug makers did not seek the consent of the children’s parents, did not explain to the families that the antibiotic was experimental and that they could refuse treatment for their children, did not explain to them that other medicines were available and did not allow the parents of the children into the wards during the administration of the drug. The government alleges that the researchers administered Roche-made ceftriaxone, used as the control drug, in dangerously low doses to make Trovan look more effective, and, after the completion of the trials, that Pfizer took all medical records and obliterated any evidence. The government also claims that the approval letter obtained from a Nigerian ethics committee was falsified. They summarize that these acts violated Nigerian laws, the International Declaration of Helsinki (Declaration of Helsinki 1964) and the UN Convention on the Rights of the Child.

Pfizer on their part has vehemently denied the allegations of misconduct surrounding the drug trial and claims that the suit has no merit, is frivolous and is a gross abuse of court process. They argue that at the time of the Kano clinical trial, Trovan, which was in the last stage of development, had been tested clinically in more than 5000 patients and showed excellent activity against all meningitis pathogens. Pfizer said they used the best medical knowledge available at the time and acted in the best interest of the approximately 200 children involved in the trial. They also claim that they sought and obtained all necessary approvals from relevant federal and state government agencies in Nigeria and that an approval letter was obtained from the National Agency for Food and Drugs Administration and Control (NAFDAC) in March 20, 1996.

A US federal court had dismissed a previous lawsuit filed against Pfizer in 2005 concerning the Kano clinical trial, but the trial Judge (Justice Anwuri Chikere) in Abuja has refused to dismiss the case as submitted by the Counsel to Pfizer.

Use of Trovan was severely restricted by the US Food and Drug Administration agency in 1999 because the drug was associated with reports of liver damage and deaths. European regulators also banned the drug.

In my view, a pharmaceutical company should be able to accept responsibility for the efficacy and safety of its product and the clinical investigations used to justify that the therapeutic value of the product outweighs the foreseeable inherent risks to the subjects or others. The question that comes to mind, even after fulfilling all ethical obligations is whether legal issues can arise from a particular action. In the treatment of a sick person, one is free to use a new therapeutic measure if, in one's judgement, it offers hope of saving life, re-establishing health or alleviating suffering. There is also the need for clear protocols, procedures and supervision in trial stages. The effect of inadequate protocol and proper duty of care was observed at a Liverpool inquest in 1984, where there was evidence that during a trial for oral morphine tablets given following a routine gynecological operation, a woman had died of unexpected side effects. The researchers were held liable (Brahams 1984).

Conclusion

Pharmacists have a duty to fill prescriptions correctly and to warn patients or notify prescribing physicians of an excessive dosage or of obvious inadequacies in prescribing that creates a substantial risk of harm to the patient.

It is hereby recommended that statutes and regulations such as the Nigerian Consumer Protection Act and other laws relating to product liability be updated to reflect the contemporary pharmacy practices and to provide stricter liability provisions as well as additional basis for a claim for damages for personal injuries to an action in negligence (tort) or contract. Although it is argued that truly strict liability would seriously hamper the development of new products, it is important to safeguard the health of the Nigerian public especially since most of these products are imported.

In the Pfizer case, the main issue is to establish if it was actually Trovan that caused the death and/or damages to the children involved in the Kano clinical trial. To not be prejudicial, this paper will only raise some questions that will need to be addressed. These are as follows: Before the Kano clinical trial, had Pfizer tested the drug in children with meningitis? Is there evidence that the drug (and not the disease) played a part in the death of the children? Did the experimentation conform to generally acceptable scientific principles such as dosage in children (e.g., compliance with *Bolam v. Friern Barnet HMC 1957*)? Did the experimentation conform to the laws and regulations of the country in which the research was performed? Was the research carried out by scientifically competent personnel following approved procedures? Was a higher standard of care required in the situation? Are there inherent risks associated with the use of the drug, and what procedures were followed to warn patients and what procedures were taken to manage those risks? Are the reasons (e.g., illiteracy) for not obtaining consent tenable? Is the allegation of malpractice in the dosage of ceftriaxone (Rocephin) used true?

Answers to these questions are necessary, and evidence should be examined to establish a link between the alleged breach of the duty of care and the resulting harm before liability can arise.

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Squamous Cell Abnormalities in Exfoliated Cells from the Urine of *Schistosoma haematobium*-Infected Adults in a Rural Fishing Community in Nigeria

O. P. Akinwale BSc, MSc, PhD, Public Health Division, Nigerian Institute of Medical Research, P.M.B. 2013, Yaba, Lagos, Nigeria

G. C. Oliveira BSc, PhD, Centro de Pesquisas René Rachou – Fundação Oswaldo Cruz, Av. Augusto de Lima 1715, Belo Horizonte, MG, 30190-002, Brazil

M. B. Ajayi AMLSCN, FMLSCN, MSc, Public Health Division, Nigerian Institute of Medical Research, P.M.B. 2013, Yaba, Lagos, Nigeria

D. O. Akande AMLSCN, MNIST, Public Health Division, Nigerian Institute of Medical Research, P.M.B. 2013, Yaba, Lagos, Nigeria

S. Oyebadejo AMLSCN, FMLSCN, MSc, Department of Medical Microbiology, College of Medicine, University of Lagos Teaching Hospital, Idi Araba, Lagos, Nigeria

K. C. Okereke MBBS, FWACP., Department of Medical Microbiology, College of Medicine, University of Lagos Teaching Hospital, Idi Araba, Lagos, Nigeria.

Address for correspondence: Dr. Olaoluwa Pheabian Akinwale, Public Health Division, Nigerian Institute of Medical Research, P.M.B. 2013, Yaba, Lagos, Nigeria. Phone: 234-805-514-6173, E-mail: pheabian@yahoo.co.uk

Abstract

Schistosoma haematobium infection is endemic in Nigeria, with substantial transmissions in all the states of the federation and a high prevalence rate in schools. Literature has linked bladder cancer, mostly squamous cell type, with long-term *S. haematobium* infections. The objective of this descriptive study was to screen exfoliated cells in the urine of *S. haematobium*-infected patients for squamous cell abnormalities through cytopathological examinations. Study participants were drawn from Imala Odo, a community near Oyan Dam in Abeokuta North Local Government Area, Ogun state, Southwest Nigeria. Due to a considerable day-to-day variation of *S. haematobium* eggs in urine, 3 rounds of 200

ml of urine samples were collected on 3 different days from 32 infected patients and 10 uninfected controls and examined. Cytological preparations of the infected 15 males and 8 females and 10 controls (5 males and 5 females) were screened for squamous cell abnormalities. Severely dysplastic to frankly malignant squamous cells were observed in 1 (3.1%) male and 2 (6.3%) females, while no abnormality was observed in the controls.

Introduction

Schistosomiasis ranks second to malaria among parasitic diseases of socio-economic and public-health importance. It afflicts more than 200 million people living in developing countries, with at least 600 million people at risk of infection and 1.7 million Disability Adjusted Life Years (DALYs) lost annually (Chitsulo et al. 2000). In many African countries, there occur both urinary and intestinal schistosomiasis caused by *Schistosoma haematobium* and *Schistosoma mansoni*, respectively. Schistosomiasis is hyper-endemic in Nigeria, with substantial transmissions occurring in all the states of the federation and a high prevalence rate in school children (Mafe et al. 2000). Transmission is largely confined to water development project areas and along the main rivers and streams. Haematuria and egg counts are the only indicators of morbidity currently being used for surveillance, but Poggensee et al. (1998) reported urinary tract morbidity in some infected Tanzanian women with negative haematuria and scant or no egg output in their urine.

Bladder cancer, mostly squamous cell-type, has been associated with long-term infection with *S. haematobium* (Muscheck et al. 2000). The epidemiologic association is based both on case-control studies and on the close correlation of bladder cancer incidence with prevalence of *S. haematobium* infection within different geographic areas (Bedwani et al. 1998). A parasite-tumour linkage is further suggested by the predominance of squamous cell morphology of bladder carcinomas seen in *S. haematobium*-endemic areas, and by the frequent association of tumours with parasite eggs and egg-induced granulomatous pathology in involved bladder tissues (Christie et al. 1986). Bladder cancer caused by *S. haematobium* is difficult to diagnose without invasive measures such as cystoscopy; consequently there is little information on its epidemiology.

The objective of this descriptive study was to screen exfoliated cells in the urine of some *S. haematobium*-infected patients for the presence of squamous cell abnormalities. Our work focused on using evaluation of Papanicolaou-stained urine sediment cytology to show an association between squamous cell abnormalities and *S. haematobium* infections in a group of infected adults from a rural fishing community in Nigeria, where the infection is endemic. This study was part of a just-concluded pilot project designed to characterize exfoliated cells in the urine of *S. haematobium*-infected patients in order to generate specific genetic markers that could be used to detect bladder cancer in *S. haematobium* through a noninvasive diagnostic method.

Methodology

Study Site

Study participants were drawn from Imala Odo, a community with a population of about 780 located in Abeokuta North Local Government Area of Ogun state, Southwest Nigeria. The community lacks basic infrastructure such as pipe-borne water, safe waste disposal, electricity and a health centre, although it has a primary school. It is about 10 km from a major asphalt road, while the road approaching and within it is a laterite bush road. The community is inhabited by migrant fishing families, mainly from the middle belt area of Nigeria, who depend largely on fishing in the Oyan River, located within the community. The river also meets all their water needs and the needs of their domestic animals. The nearest health centre is about 12 km away and serves the population of about 4895 people of Imala, a predominantly rural farming community that is also hyper-endemic for urinary schistosomiasis (Mafe et al. 2005). The community was selected for this work based on the previous urinary schistosomiasis survey, which showed that the disease was hyper-endemic (Sulyman et al. 1998; Mafe et al. 2005). Previous treatment with praziquantel about 4 years ago (Mafe et al. 2005) targeted only school children aged 5 to 19 years.

Study Subjects, Selection Criteria and Ethical Considerations

The baseline examination included adult males and females aged between 40 and 70 years, with a mean age of 47.5 years. This age group was chosen for the study based on the observation of Muscheck et al. (2000) that bladder cancer caused by *S. haematobium* infection occurs especially in the fifth decade of life. Other selection criteria used for this study were haematuria and presence of *S. haematobium* eggs in all the three rounds of urine collected from each patient. Thirty-two of a total of 73 infected patients, made up of 21 (65.6%) males and 11 (34.4%) females, met the selection criteria. Ten controls – five males and five females – within the same age group took part in the study. The study was approved by the Institutional Review Board of the Nigerian Institute of Medical Research, while permission to carry out the study in the village was granted by the Ogun State Ministry of Health. Informed consent was obtained from each participant under a protocol approved by the Ethical Review Committee of the World Health Organization.

Parasitological Investigations and Treatment

The study population was registered on household forms, and the name, surname, age, sex and weight of all participants were recorded. Every participant was allocated a unique code of six digits representing village, household and individual numbers. For maximum egg yield, mid-stream urine was collected between 10:00 am and 2:00 pm on each collection day, following the observations made by Weber et al. (1967). Due to a considerable day-to-day variation of *S. haematobium* eggs in urine, three rounds of 200 ml of urine samples were collected into sterile containers on 3 different days. Containers were labelled with the study number of each participant and taken immediately to the laboratory in an icebox at 4°C. *S. haematobium* infection was detected by centrifugation of 100 ml of the urine samples and examination of the sediment under the microscope, while haematuria was detected using commercially prepared reagent strips (Hemastix; Boehringer Mannheim, Germany). All infected participants were treated with a single dose of praziquantel at 40 mg/kg body weight at the end of the investigation.

Cytological Evaluation

Within 4 hours of collection, the remaining 100 ml of each urine sample was prepared for cytological analysis as follows. The urine was centrifuged and slides were made from the filtrates from each round of urine samples per patient, fixed in 90% alcohol and stained with Papanicolaou stain. Slides were examined for exfoliated and reactive cellular changes by a consultant pathologist who was not aware of the parasitological results and infection status of participants. The cost of Papanicolaou stain for each specimen was about 40 US dollars.

Results

A total of 32 infected individuals and 10 uninfected controls aged between 40 and 55 years participated in the study. All 32 infected participants were positive for haematuria, and *S. haematobium* eggs were also detected in their urine samples collected on 3 different days. Some severely dysplastic malignant squamous cells were seen amidst a few normal squamous cells in two infected female participants aged 40 and 45 years and one infected male patient aged 48 years. Figure 1 shows a malignant squamous cell as seen in one of the cytological preparations of an infected participant, but in the cytological preparations of the controls, there were seen a few normal squamous cells against light backgrounds (Figure 2).

Discussion

This study was carried out in Imala Odo, a rural, isolated community in Abeokuta North Local Government Area of Ogun state, Southwest Nigeria, with no basic infrastructure. Our results support those from a study in Kenya that showed an association between urinary tract hyperplasia and *S. haematobium* infection (Hodder et al. 2000). Three (9.4%) of the 32 infected patients who participated in this study had malignant squamous cells of the bladder. Koss et al. (1985) noted

that the basis of inflammation in urinary schistosomiasis is chronic inflammation associated with egg deposition in the bladder wall.

Figure 1. Cytology of an infected participant showing (1) a malignant squamous cell, (2) a plasma cell, and (3) a lymphocyte

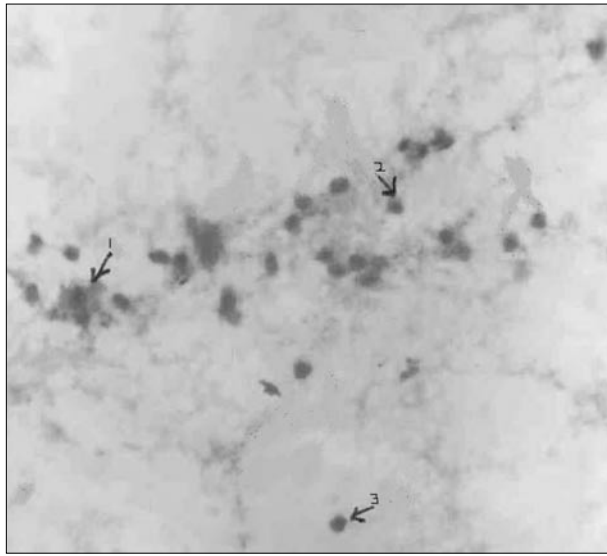
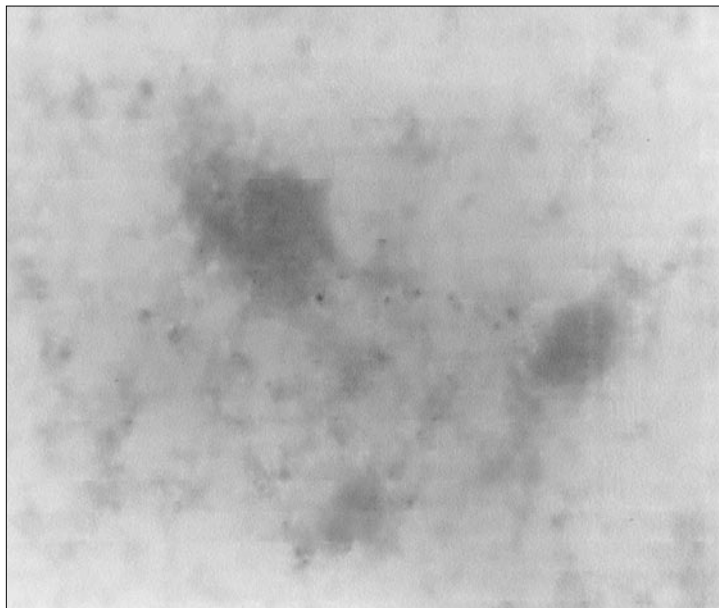


Figure 2. Cytology of one of the controls showing a cluster of normal squamous cells against a clear background



Cytology was used in this pilot study because the study was designed to characterize exfoliated cells in participants' urine. However, cytology can miss up to 50% of tumours, especially low grade and low stage ones, and bladder cancer detection at an early stage is crucial to patients' survival. We

recommend that these patients would benefit from a careful follow-up using a diagnostic method that is more efficient than cytology. We therefore suggest to the state Ministry of Health that efforts be made to follow up these patients using cystoscopy, which is the “gold standard” for diagnosis of bladder cancer, so as to be able to identify cases that might have been missed by cytology, the method used in this descriptive study.

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Traditional Healthcare Delivery Systems in the 21st Century Nigeria: Moving beyond Misconceptions

Ezeunwa E. Nwokocha, PhD,
Department of Sociology,
University of Ibadan, Ibadan, Nigeria

Ezeunwa E. Nwokocha, PhD, Department of Sociology, University of Ibadan, Ibadan, Nigeria,
Tel:+2348088863553, Email: miczeze@yahoo.com

Abstract

One of the most notable features of medicine in the later part of the preceding century were vigorous criticisms against traditional systems of healthcare delivery, almost to a point of suffocation. Although most of the issues raised to affirm the seemingly inadequate status of this system are compelling, its absolute undesirability has been difficult to establish. Part of the misconception derives from lumping Nigeria into one integrated and indivisible indigenous unit, notwithstanding differences in values, beliefs and practices among communities. Against this backdrop, this study invites a reassessment and possible integration of Nigerian traditional medicine with the introduced systems of healthcare delivery. This will ensure not only a holistic approach to dealing with complex health issues among Nigerians, but also the continued relevance of indigenous medicine. Critical issues examined include forms and factors affecting traditional medicine, and conflicts between indigenous and introduced systems of healthcare delivery. Consequently, a framework for explaining traditional medicine in the context of Nigeria was designed through a triangulation of Rational Choice theory, Ethnomethodology and the Health Belief Model.

Introduction

Traditional healthcare delivery systems are those channels through which individuals and groups seeking healthcare can obtain intervention by recourse to indigenous methods. Healthcare systems are products of both culture and society and derive from the experiences and dictates of a particular socio-cultural environment. This implies that health systems are relative to times and places. Nigerian society consists of peoples with different cultures, orientations and healthcare systems. Although the notion of “Nigerian tradition” exists, it is more realistic to view Nigeria as a collectivity of cultures or subsystems that share certain similarities, albeit not to a perfect extent.

The term “traditional” in the context of this paper is not used in a generic sense to mean Nigerian tradition as a whole, but rather to denote cultural activities in various societies within the country. A restatement is made, therefore, to the effect that there exists neither a common tradition universal to Nigeria nor a unifying healthcare delivery system. There is no contradiction in stating that the components of healthcare delivery systems in Nigeria derive from indigenous knowledge and technology that are contextualised. To simplify the matter, this paper will view what exists in any Nigerian community in terms of healthcare delivery systems as traditional systems of healthcare in the country, holding the systems in other communities constant.

Although several categories of traditional medicine and by implication practitioners exist in Nigeria (Owumi 2005), two main types of traditional healthcare systems are easily identifiable – general and specific systems. This paper argues that although components of each of these systems can be found in different communities within the country, their contents vary.

In our analysis of traditional healthcare delivery systems, especially in an era of globalization and knowledge explosion, it is pertinent to raise some crucial issues. The questions that readily come to mind include the following: (A) To what extent have Nigerian knowledge or technology and medical systems solved or achieved the medical needs of Nigerian peoples? (B) What factors militate against the proper functioning of traditional medicine? (C) Is “traditional” synonymous with inferiority? (D) To what extent can the traditional systems of healthcare delivery converge with the introduced systems in present day Nigeria? These questions invite a comprehensive analysis of the dynamics of Nigerian traditional medicine within the context of seeking relevance in the 21st century.

Forms of Traditional Healthcare Delivery Systems

There are basically two major forms of medical systems in Nigeria: the traditional or indigenous, and the Western (Agbolanhor 1996). The latter is also referred to as “introduced systems” in the present analysis. This paper will centre on only the traditional system. According to Owumi’s (1996b) analysis of a Nigerian community that is not radically different from most societies in Nigeria, six categories of traditional medical practitioners exist. Following from Owumi’s insight, this investigation classifies traditional medical delivery into two main forms: (1) the general healthcare delivery system and (2) the specific healthcare delivery system. In what follows, Owumi’s (1996b; 2005) classifications, which centred on the Okpe people of Delta State, Nigeria, are revisited to accommodate some other societies in Nigeria – the Igbo, Efik/Ibibio, Ibani, Igala, Nupe, Kalabari and Yoruba among others.

General Healthcare Delivery System

The general healthcare delivery system is an outlet that offers non-specific medical care to individuals seeking various forms of healthcare. Such a system has no limitation in the extent to which it can supposedly provide medical assistance to the “needy,” no matter what their needs. This type of system combines the attributes of divination, poison healing, birth attendance, bone healing or setting, and psychiatry. General practitioners are persons with diverse skills in the handling of different forms of problems (Owumi, 1996b; 2005). This comprehensive expertise is common in traditional medical practice in Nigeria. In some instances, two or three attributes are combined in a particular healthcare delivery system or individual practitioner. Investigation indicates that the explanation for such combinations is not clear, but some argue that its basis lies in economic

considerations and practitioners' predisposition to material wealth. This paper does not mean to clarify the veracity or otherwise of this assertion.

Specific Healthcare Delivery Systems

The concept of specificity is related to terms such as "specialty," "specialization," "concreteness" and "interest." In this paper, we shall be looking at specific areas of traditional healthcare delivery systems in most Nigerian societies, such as (1) divination, (2) poison neutralizing, (3) birth attendance, (4) bone setting or adjustment and (5) psychiatry. The intention of specializing in one major aspect of healthcare delivery systems is to enable practitioners who have adequate knowledge of the specific aspect of healthcare delivery to be experts. Notwithstanding the strength of the argument for general medicine, specialization offers a deeper knowledge to practitioners in their healing activities. Specialization is not popular among most traditional medical practitioners, although claims about specialties are made to attract individuals seeking traditional care. These practitioners ascribe to themselves varying statuses at different periods, depending on the desires of an individual or a group of individuals seeking healthcare. This seeming non-definite (shifting) posture explains the apparent failure at efficacy and the dwindling popularity of traditional medicine among some Nigerians. We now examine these specific healthcare delivery systems.

Divination

Diviners are practitioners who have power to see, through supernatural means, extraordinary activities of individuals pertaining to past or present events. They are believed to be particularly important in Nigerian medicine, given the notion among most Nigerians that every ailment and/or misfortune has a supernatural explanation. It follows that before any disease can be cured, its cause(s) should be known and properly understood. Owumi (1996b; 2005) referred to these diviners as oracle men/women believed to be specially endowed with uncommon divination skills. Although some individuals and groups still use the services of diviners, Christianity is strongly opposed to divination. Christians' opposition partly explains non-preference for the act, given their increasing numbers in Nigerian societies. Moreover, the gift of "deep sight" or vision expressed among some Christians dislocates the essence of divination among adherents of the Christian religion. Notwithstanding this waning posture, divination still remains a means of understanding past events and seeing into the future among traditional worshippers as well as nominal Christians.

Poison Neutralizing

This healthcare delivery system deals specifically with cases related to poisoning. There is a belief in some parts of Nigeria that both supernatural and physical substances that can affect part of or the entire body network could be administered to individuals by their enemies. There are two identifiable approaches to administering poison in Nigerian communities: (1) substances that enter through the mouth with food and are digested before they finally destroy the entire system, either almost immediately or over the long-term; this type of poisoning is difficult to neutralize because of its ability to affect the biological system in totality, and (2) substances that affect a particular part of the body but do not necessarily enter through the mouth. This method is common among individuals who are involved in land disputes in some Nigerian communities. There are instances when poisonous substances are kept for opponents on the plots of land in dispute, in order to kill or paralyse them and bring the dispute to a quick end. Thus, due to the possibility of poisoning and the likely consequences, the need for a healthcare delivery system that can provide intervention for poisoning is imperative and, perhaps, inevitable in safeguarding the lives of individuals in these communities.

Birth Attendance

The practice of attending to pregnant women, from conception to delivery and even during the postpartum period, is an important aspect of traditional healthcare delivery systems in Nigeria. Various factors justify the need for the system, such as the absence of Western maternal facilities,

including competent personnel and equipment, in some rural communities; affordable services; and accessibility and sensitivity of practitioners, among others. One study, for instance, found there were no introduced maternal facilities in most Ibani villages in Rivers State, Nigeria, leaving the people without an alternative to the traditional system (Nwokocha, 2004). In the absence of Western maternal facilities, the traditional system is inevitable. It means that traditional birth attendants (TBAs) must be equipped with significant knowledge to handle emergencies, given the number of complications that occur each year. Studies have shown that Nigeria has one of the worst records of maternal outcomes in the world, a situation explained mainly by the low percentage of births attended by skilled personnel (Erinosho, 2005; Nwokocha, 2006).

Bone Setting/Adjustment

This aspect of traditional medicine deals specifically with issues related to bones. Injuries and/or deformations related to bones can arise from natural causes or accidents. The duty of practitioners is to set and/or adjust these bones, using different techniques and materials, to meet the health needs of clients. Training in bone-healing processes requires carefulness, tact and hard work, given the inherent sensitivity associated with bone defects and injuries. It is important to note, however, that this particular system of traditional healthcare delivery is recognized as efficacious in dealing with bone setting and adjustment, even among patrons of introduced medicine. For some individuals, no matter what the level of treatment received from a Western bone-treating facility, assurance is only guaranteed when traditional bone healers give final approval. There is therefore collaboration between the introduced and traditional systems of healthcare delivery. Observation indicates an interesting pattern of convergence: whereas confirmation of complete bone adjustment is sought from the traditional system after initial contact with introduced medicine among most health seekers, the reverse is not the case when contact begins with the former. This scenario indicates the perceived efficacy of traditional bone-healing therapy. Consequently, bone healing is one aspect of traditional medicine that has remained consistent in terms of high patronage. The consistency derives from the perceived reliability in meeting the health needs of individuals and groups.

Psychiatry

This branch of traditional healthcare delivery systems deals with restoring individuals with both major and minor psychiatric problems to normal mental stability to the extent possible. The purpose of attempts to cure people with various forms of brain defects is to reintegrate them into conventional society as reasonable members who can contribute significantly to the development of their communities. Among Nigerians, there are two main sources of mental disequilibrium: (1) natural and (2) induced. The natural causes of mental imbalance derive from birth, while the induced arise from conscious or unconscious human design to harm self, enemies and/or individuals who are perceived as threats. Studies indicate that nutrition, alcohol and drug use, workload and hygiene during pregnancy are linked to low birth weight, hearing problems, learning difficulties and brain damage in children (UNICEF 2001; Hesperian Foundation 2001; Odebiyi and Aina 1998). Experience shows that traditional psychiatry is still relevant in most rural settings within Nigerian society. Some believe that an effective cure for brain defects related to supernatural causes can be achieved only after conjuring and appeasing ancestral spirits. As a result, any attempt to approach such defects from the introduced medical system is futile. In addition, traditional psychiatry deals with induced mental illness and as such has double relevance.

Framework for Explaining Traditional Medicine

In explaining traditional medicine, we shall focus on human beings who are inevitably the beneficiaries of medical practices. This emphasis on individuals derives from the fact that medical activities neither operate in a vacuum nor are enterprises that exist without focus. Interestingly, individuals have the capacity to weigh alternatives in order to minimize costs while striving to maximize benefits. It is within this understanding (that individuals are inherently rational) that three theoretical perspec-

tives are briefly examined. These are the Rational Choice theory of Friedman and Hechter (1988), Ethnomethodology by Garfinkel (1967) – both theories are explained by Ritzer (1996) – and the Health Belief Model (HBM) of Rosenstock and Becker (1966 and 1974, respectively).

According to Friedman and Hechter (1988), Rational Choice theory focuses on the individual actor as a purposeful being with some intentionality, and as such his or her actions are directed at ends or goals. The implication is that individuals have the privilege of making choices, given their resources and conditions as well as available alternatives. The individual, for instance, chooses between traditional and received health delivery systems in seeking healthcare at the macro-level, while further choosing among alternatives within the chosen system at the micro-level. A health-seeking person might decide to settle for traditional medicine and particularly “divination” or any other specific or general healthcare delivery system perceived as most appropriate in alleviating the effects of an illness condition. Appropriateness as conceived in this analysis involves weighing derivable benefits of using a particular health system against the costs of not using it. Nwokocho (2004), in a study among the Ibani found, for instance, that quick access to TBAs, encouragement and support of pregnant women and respect for cultural norms guiding disposal of the placenta were major reasons for patronizing TBAs.

Similarly, Ethnomethodology focuses on the actor’s adaptability to the social environment in his or her day-to-day activities without necessarily infringing on the collective goodwill. Ethnomethodology as noted by Heritage (1984: 4) is:

The body of common-sense knowledge and the range of procedures and considerations by means of which the ordinary members of society make sense of, find their way about in, and act on the circumstances in which they find themselves.

Following from this view, individuals are expected to adapt to their socio-cultural environments by applying necessary sense in their activities. This perspective is similar to the Rational Choice theory at the point where emphasis is placed on the individual’s ability to make objective judgments about the social situation – what Haralambos (1980) would refer to as the application of common sense strategy. The use of common sense in an ethnomethodological explanation of phenomena implies that individuals have the capacity to adjust and adapt to varying situations – a kind of rationalization of situations.

The Health Belief Model explains health behaviour from a social–psychological perspective using the theories of value expectancy and decision making. The model focuses on dimensions affecting an individual’s control over a specific action and uses those same dimensions to predict behaviour. The position of this model by Rosenstock (1966; 1990) and Becker (1974), which focuses on the individual’s subjective assessment of the health situation, especially with regard to use of health services, is that by taking a particular action an individual’s susceptibility would be reduced or, if disease had already occurred, its severity would be ameliorated.

The model assumes that people’s beliefs and attitudes largely determine their health-related actions. Thus, while an individual could perceive a particular action as necessary to reduce an adverse health condition, that individual could reject the same action if it were perceived as more expensive, painful, inaccessible or more traumatic than an alternative and if it did not conform to the cultural expectations of a people. The model therefore provides a framework for understanding the potential influence of the cultural environment on an individual’s perception and decision to use available health services (Becker et al 1977). In what follows, an attempt is made to address the major questions that were raised earlier.

A. To What Extent Have Nigerian Knowledge or Technology and Medical Systems Achieved the Medical Needs of Nigerians?

Before Africa, and Nigeria in particular, were colonized, its peoples were solely dependent on indigenous medicine. However, with the introduction of Western culture that affected virtually all aspects

of life, Western medicine became an integral part of health seeking, even to the extent that some indigenes of Nigeria abandoned indigenous medicine. Some who stuck to the home-grown systems relied also on “foreign” medicine. Only a few Nigerians depended entirely on medicine that is rooted in Nigerian knowledge and technology. It is within the context of these two latter categories that an assessment of the sufficiency of Nigerian medicine in dealing with the medical needs of Nigerians will be made.

Among those who combine Nigerian medicine with Western, the former does not provide for all needs and, as such, the need for collaboration cannot be overstated. However, one is inclined to assume that the category of people who depend entirely on the indigenous and who may not have had reason to seek healthcare from the Western medical system can claim that traditional systems have sufficient capacity to deal with their health needs. This study argues that such conclusions are relative to individuals and may derive from their perceptions of and expectations from the thematic systems. As a corollary, perceiving any of these medical systems as either superior or inferior is a function of the benefits that may or may not have been derived from its use in the course of health seeking.

In addition, introduced medicine is traditional to Western societies, and what is indigenous to Nigeria becomes “introduced” in Europe, Asia, America and other continents. Does it then mean that Nigerian medicine would be perceived as superior to what exists in those societies just because it is introduced from outside those places? The same question can also be asked in examining the situation in Nigeria. Therefore, using the concepts of superiority and inferiority in the present analysis would not only be misleading but also a dislocation of the essence of objectivity in research.

B. Factors Affecting Traditional Healthcare Delivery Systems

This section deals with issues related to the actual practice of Nigerian indigenous medicine and the factors undermining it. The report is based on two sources: (1) the author’s several years of interaction (formal and informal) with different categories of people/stakeholders in rural and urban locations in Nigeria on indigenous medicine, and (2) unobtrusive observation of practices, which derive from beliefs and customs in some Nigerian communities. Data indicate that several factors affect the functioning of traditional healthcare delivery systems in Nigeria. These include (1) negative perception of traditional medicine, (2) lack of awareness, (3) the high level of gullibility among Nigerians, (4) dwindling involvement of young Nigerians in traditional medicine, (5) stiff competition from introduced medicine, and (6) government policy.

Negative Perception of Traditional Medicine

In parts of Africa, Nigeria in particular, traditional medicine is viewed as taboo by some individuals and groups. Among the elite, for instance, this perception is manifestly common, except in cases where the received system could no longer provide remedy for certain health conditions. For this category of people, Nigerian medicine is conceived only in terms of its relevance as the last resort. This attitude derives from the notion that traditional medicine lacks the consistency, reliability and replicability that characterize scientific knowledge. The extent to which the latter assertion is correct will not be examined in this paper. Some individuals perceive non-patronage of traditional health systems as elitist. While this paper views that perception as erroneous and misleading, it at the same time suggests that a re-orientation against this xenocentric (seeing one’s ways as inferior to another’s) view be vigorously undertaken across identifiable social strata in relevant contexts.

Lack of Awareness

One of the major factors militating against the functionality of traditional healthcare delivery systems is ignorance among indigenous peoples about the efficacy of these systems. Some of these individuals are genuinely not aware of the extent to which traditional medicine is relevant, while others intentionally avoid traditional systems because of negative information ascribed to them. Some parents of the younger generation of Nigerians castigate African medicine to the extent that they see “nothing good” about it. This orientation has largely affected both improvement and sustainability of tradi-

tional healthcare systems. We note here that justification for sustaining traditional medicine has been weakened by the negative picture painted in indigenous Nigerian movies, to the extent that the system is conceived as wholly diabolic. While not absolving the system in entirety, it is argued here that a comprehensive exposure of the system be made by the Nigerian movie industry to counterbalance the lopsided, partial view of reality presented to date. In that way, a complete assessment can be made. We contend that beyond the fact that Nigerian traditional medicine is universal in the country and can be assessed promptly, divination has sustained “the spirit of saying the truth” in places where it is practised. This does not suggest, however, that outcomes of divinations are always valid and reliable; the mere fact that divination is feasible in investigating a particular uncertain situation or event discourages individuals and groups from deviant behaviour.

Gullibility of Nigerians

Nigerians’ negative attitude toward traditional healthcare delivery systems and the corresponding ignorance are a function of inconsistency and gullibility. This Nigerian attitude has links with colonialism introduced into the continent in the 19th century. Colonialism dislocated the norms, perceptions, attitudes and behaviour of individuals to the extent that the psyche of Nigerians was/is changed. We would even agree with Ekeh (1983 6) that colonialism “represents a congerie of events and consequences ... in its fullness.” We argue that the colonial era dislocated “Nigerian knowledge” and “Nigerian confidence.” It was an epoch that rewrote African views, entirely, as inferior to those of the West. The period was marked by forceful enthronement of the spirit of xenocentrism among Africans, and Nigerians in particular. This lack of courage to sustain African culture, views, knowledge and technology has implications for what persists in the continent, including the functioning of traditional healthcare delivery systems in relevant societies.

Dwindling Involvement of Young Nigerians in Traditional Medical Practice

One of the greatest challenges facing traditional medicine in Nigeria is the threat of extinction. This fear stems from the observation that aged practitioners are not being replaced by a younger generation. The implication is that if lack of interest in traditional medical practice persists among young Nigerians, patronage of traditional healers will wane and, by extension, so will income and prestige. When these attractions diminish significantly or no longer exist, fewer people will join the profession. Moreover, it is highly likely that younger people who join the traditional medical practice would be ridiculed, stigmatised and even discriminated against by peers. This perception and attitude among individuals and groups in contemporary Nigeria portends problems for traditional medicine unless genuine efforts are made change attitudes to indigenous medicine.

Stiff Competition from Introduced Medicine and Practitioners

The quest to establish superiority between traditional and introduced healthcare systems has given and is still giving rise to conflicts between these systems. Although the former is indigenous, the latter, notwithstanding that it was inherited from the colonial experience, is enjoying more confidence from some people in the country. This situation is similar to saying that the systems are “two sides of the same coin” and supposes that improvements in one would ultimately retard the fortunes of the other. It has been argued, for instance, that the scientific basis of the Western medical system is lacking in the traditional system.

The above position arises from a perception in most quarters that the traditional system operates on the “trial and error” principle that negates scientific norms and procedure. This view is seen among traditional health practitioners as a misconception derived from ignorance because, as they argue, indigenous medicine is characterized by exactitude and rigor consistent with the scientific enterprise. There is a need to correct the impression that the development of one of the systems would automatically lead to underdevelopment of the other. The position of this paper is that these systems could be complementary without demeaning their individual strengths.

Government Policy

Part of the problem facing traditional health delivery systems in Nigeria is the lack of political will by governments to introduce policies that sustain the existence of indigenous medicine. It can be argued that the major reason for this deliberate indifference is to satisfy the requirements for international agencies' support for various programs. In fact, grants and aid to the less-developed countries are, for the most part, tied to their readiness to accept "hook, line and sinker" the definitions of these agencies. The implication is that instead of protecting indigenous medicine, there are obvious efforts to either ignore traditional systems or debase them completely. Feasible solutions can evolve only when governments genuinely appreciate the problems facing traditional medicine and muster enough courage and political will to introduce policies that are both culture and people oriented. Ghana realized the essence of indigenous medicine immediately after political independence and made attempts to emphasize its use (Dokosi, 1998). Governments in some other African countries, such as Ethiopia, Tanzania and very recently Nigeria, are making efforts to mainstream indigenous medicine (Owumi, 2005). These efforts are timely in view of the increasing patronage of traditional healthcare system.

C. To What Extent Can the Two Systems Converge?

Convergence of the introduced and traditional systems of healthcare delivery is visible in psychiatry, bone setting and poison neutralization. Experience has shown that people who need medical attention in these three areas experience the collaborative effects of the two major systems. For instance, mental defects that are conceived as induced rather than natural are treated at two levels. The first is through divination as a means of ascertaining the latent source of the illness condition so as to apply the most appropriate approach to spiritual cure. The second, given that mental illness has physical and psychological implications, is the treatment from introduced systems to cater for the manifest effects of psychiatric disorders.

The collaboration is also evident in bone setting. Most Nigerian peoples who access introduced medicine as initial therapy still undertake treatment based on traditional medicine. The justification for the convergence is to concretize the benefits of each system while diminishing their weaknesses at the same time. A notable feature of this collaboration is that whereas it is rare among people who have access to traditional bone setting to seek further treatment from the introduced system, the reverse is usually the case among a large majority of Africans. This attitude derives from the perception that the introduced system lacks capacity for the comprehensive cure of fractured bones. The veracity of these views is not discussed in this paper.

Traditional and Introduced Medicines: Can the Code Be Broken?

Although the paper focuses on indigenous Nigerian medicine, there is a need to examine the relationship between the home-grown healthcare system and the Western type. This examination is necessary in view of their side-by-side existence; what happens in one affects the other, albeit not necessarily negatively. The traditional and introduced medical systems have had conflicts from the time the former was introduced into Nigeria. As with other activities forged by colonialism, Western medicine in Nigeria is an inherited legacy, first introduced by medical missionaries as early as the 1850s (Isamah, 1996).

Studies indicate that practitioners of traditional medicine in Nigeria are operating in a difficult environment. This, according to Alubo (1995) and as highlighted by Owumi (1996), is due partly to government attitude and policy, and to the low educational status of traditional medicine practitioners. It is thus argued that the introduced healthcare system enjoys higher patronage and supremacy over the traditional, (Imogie et al 2002). However, for some healthcare seekers, particularly pregnant women, traditional beliefs surrounding childbirth coupled with misconceptions about and fear of medical institutions sustain women's reliance on home delivery (Griffiths and Stephenson 2001), particularly with the assistance of TBAs.

In a "cold war" between practitioners of these medical systems that had existed over several

decades, Western medical practitioners denigrated and deprecated traditional healers. For their part, practitioners of traditional medicine argue that their practice is superior to the introduced practice. According to one herbalist, “modern doctors are good, but there are some ailments and conditions that the white man’s (Western) medicine can not handle” (Okolocha et al. 1998: 295). Hence, the local belief that some “indigenous diseases” are not likely to be understood or treated successfully by introduced or Western medicine, but by traditional medicine, is reinforced (Njikam 1994). Even though concrete data are not available, Owumi (2005) has noted that literature indicates 70% utilization of traditional medicine among Nigerians. This does not suggest that only 30% patronize the introduced system; rather, the 30% constitutes individuals who do not rely on the traditional in any way. It also means that some of those in the 70% category rely on the introduced system in some way in dealing with their health needs.

Considering the acceptance of each of the medical systems at various quarters, the need for understanding of traditional health practices and possible integration with the introduced system has been both acknowledged and emphasized (Addai 1998). Sophie (2000) observed that alternative care providers have always existed in most less-developed countries in the form of traditional medicine. While the latter observation is correct in most parts of Nigeria, there are, however, scepticisms about and divergences between the two types of healthcare delivery systems in Nigerian societies. This division results from both the differences in orientation and the perceived practical significance of each of the systems against the other. Gureje (2005), for instance, highlights the difficulty in integrating the two systems by discrediting, in part, indigenous medicine as embedded in secrecy and risk.

Nigeria in the 21st century is characterized by a high rate of migration and urbanization that necessitates interaction of perceptions, knowledge and behaviour among different peoples. Moreover, the economy of most societies in sub-Saharan Africa compels individuals to deviate from normative values to innovative activities, most of them negating traditional expectations, in a bid to survive. This “survival of the fittest” approach accounts to a large extent for the high prevalence of sub-standard and fake drugs in countries on the continent and in Nigeria in particular. These reasons further signal a need for the convergence of traditional and introduced systems of healthcare delivery. The implication of such collaboration is that the limitations of one system can be bridged by the strength of the other and could lead to the evolution of a comprehensive healthcare system. Owumi (2005) observed that the Alma Ata conference of 1978 provided a platform for highlighting the limitations of Western health systems in terms of equitable and adequate healthcare delivery.

Consequently, it became necessary to promote indigenous medicine to enhance accessibility and cost reduction, critical factors in utilization. It is argued here that while access can be canvassed as a factor in the effort to develop traditional medicine, cost may not suffice; in some instances, the traditional system of healthcare delivery is more expensive, especially when treatment involves material sacrifices and appeasement of gods.

Conclusion

This paper has examined traditional healthcare delivery systems in the Nigerian context as a way of understanding the prospects of Nigerian medicine in the 21st century. Our analysis indicates clearly that although scepticism still surrounds the proof of efficacy of traditional medicine, it has a high degree of relevance, at least within the context and peculiarities of contemporary Nigerian societies. This paper has shown that recourse to indigenous medicine is beginning to increase once again among the peoples of the country, after several decades of denigration and castigation. This change in perception and attitude arose out of inquiry and experiences that had consistently revealed the inseparability of the medical system from its peoples and cultures.

Toward the end of the 20th century, it became apparent in medical literature that viewing the introduced medical system as possessing the ability to take care of every aspect of Nigerians’ medical needs was deceptive and unnecessarily pretentious. Consequently, a synthesis of these systems has become paramount. This collaboration will ultimately take care of the health needs of Nigerians

in an era that is becoming medically more complex and for which the essence of both micro and macro linkages cannot be overstated.

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Skilled or Traditional Birth Attendant? Choices of Communities in Lukulu District, Rural Zambia

Josy van den Boogaard, APRIORI (African Poverty Related Infection Oriented Research Initiative), Radboud University Nijmegen Medical Centre, the Netherlands, and Kilimanjaro Christian Medical Centre, Moshi, Tanzania

Bart Arntzen, General Practice Medicine, University Medical Centre Groningen, The Netherlands

Junist Chilwana, Lukulu District Health Office, Lukulu, Zambia

Martin Liyungu, Lukulu District Health Office, Lukulu, Zambia

Albert Mantingh, Department of Obstetrics and Gynaecology, University Medical Centre Groningen, The Netherlands

Jelle Stekelenburg, Department of Obstetrics and Gynaecology, Medisch Centrum Leeuwarden, The Netherlands

Jelle Stekelenburg, Henri Dunantweg 2, 8934 AD Leeuwarden, The Netherlands, Tel: +31 58 2866666, Email: jelle.stekelenburg@wanadoo.nl

Abstract

Objective: To analyse factors that contribute to the choice of either traditional birth attendants (TBAs) or skilled birth attendants (SBAs) by inhabitants of Zambia's Lukulu District.

Design: Cross-sectional descriptive survey.

Settings: Lukulu District, Western Province, Zambia.

Population: 1413 participants: parous women, their husbands, village headmen and elderly women.

Main outcome measures: Preferred and actual place of birth.

Methods: Questionnaires, structured interviews and focus group discussions

Results: 42% of women gave birth in a health facility, assisted by SBAs; 75% prefer to give birth in a health facility; many barriers are to be passed for women to reach a skilled attendant in time.

Conclusion: Skilled birth attendants are preferred to assist at childbirth in Lukulu District. Transportation problems, sociocultural reasons and unpreparedness still cause the majority of women to turn to traditional birth attendants. Traditional birth attendants should not yet be excluded from safe motherhood programs.

Introduction

By the year 2015, the number of women dying because of pregnancy-related complications should be reduced by 75% worldwide, as is stated in the United Nations Millennium Project (2006).

The current international policy on reducing the maternal mortality ratio (MMR) is to train more skilled birth attendants (SBAs), who should assist all pregnant women at childbirth. SBAs are people with midwifery skills (e.g., doctors, midwives, nurses) trained to proficiency in the skills necessary to manage normal deliveries and diagnose, manage or refer complications (Starrs 1998). The definition excludes traditional birth attendants (TBAs), because they lack the resources to manage obstetric complications. Investing in the training of TBAs therefore no longer has priority (Kruske and Barclay 2004).

Like many African countries, Zambia is facing a human resource crisis in health. In rural areas, 60% of women are assisted by TBAs at childbirth (Central Statistical Office Lusaka 2001–2002). Increasing the number of SBAs so that every Zambian woman can be assisted by one at childbirth does not seem realistic in the short term. Besides, factors such as distance and transportation difficulties, socio-cultural ideas about childbirth and fear that SBAs could have a poor attitude may keep women from turning to them (Thaddeus and Maine 1994, Walraven et al. 2000, Kruske and Barclay 2004, Cham et al. 2005, Osubor et al. 2006).

Objectives

Our objectives in this paper are twofold: to analyse the factors that contribute to the choice of either TBAs or SBAs by inhabitants of Zambia's Lukulu District and to evaluate whether current international policy to exclude TBAs from safe motherhood programs is suitable for the district (and comparable poor rural districts).

Methodology

Study area and Population

Lukulu District is a rural district in the northern part of Zambia's Western Province. The total population is estimated at 78,737 and the district covers about 16,000 square kilometres (Lukulu District Health Office 2005). The majority of the population have no substantial source of income, and the district has no major industries that provide formal employment. Subsistence farming and small-scale fishing are the main ways of making a living. The western part of the district is flooded by the Zambezi River half of the year and is inaccessible during the rainy season. The district can only be crossed on dirt tracks.

Lukulu District Hospital is the only hospital in the district and meets the criteria for provision of comprehensive emergency obstetric care (EmOC) on most occasions. The distance from the 13 health centres to the hospital ranges from 12 to 127 kilometres. Health centre staff are supposed to provide basic EmOC.

Seventy-nine TBAs have been trained by the district's midwives and clinical officers. The training was based on a World Health Organization training program (Cabral et al. 1992), adjusted to national and local circumstances. Trained TBAs are supposed to assist women who choose to give birth in the village. The number of untrained TBAs in the district is not known, since they are not registered by the district's health board.

The exact number of maternal deaths in Lukulu District is also not known. The MMR in neighbouring Kalabo District, which has comparable features, was estimated at 1238 deaths per 100,000 live births (Vork et al. 1997), in a sisterhood method (a method to obtain information from a large population by interviewing respondents about the survival of all their adult sisters). Calculations using hospital-based data for Kalabo District showed an MMR of 1359 per 100,000 live births (Stekelenburg & van Roosmalen 2002).

Methods

Eight health centres and their catchment areas were selected for convenience. Data were collected by means of standardized, structured interviews from women who had given birth at least once in the past 5 years (abortions excluded, stillbirths included), husbands of parous women, and elderly women who had not given birth in the past 5 years. Village headmen of all selected villages were also interviewed.

Sample-size calculation was based on finding a significant difference of 60% in preference for either a TBA or an SBA (two-tailed, 95% confidence interval, 95% power). Sample sizes for parous women, husbands and elderly women had to be at least 369 each.

Motives for the choice of birth attendant were categorized (after interviewing). A *medical reason* was defined as a medical problem (in the respondent's view). Unexpected, fast progress of labour, making it impossible to reach the health centre in time, was called *fast delivery*. To *economic reasons* belonged financial and/or transportation problems. Motives such as expected witchcraft and gender of the birth attendant were grouped as *socio-cultural reasons*. When the respondent explicitly appreciated the fact that the chosen birth attendant was trained, the reason *trained staff* applied. Other reasons or unknown reasons were grouped as other.

Eight interviewers, all health centre staff members fluent in English and the two major local languages (Lozi and Luvale), were selected for data collection. The interviewers were trained in a 1-day session, during which questions and interviewing strategies were discussed.

The interviewers conducted their interviews in villages selected for convenience, divided in three categories:

Villages within a 30-minute walk from the health centre (category I)

Villages more than a 30-minute walk but less than a 2-hour walk from the health centre (category II)

Villages more than a 2-hour walk from the health centre (category III)

The included villages all consisted of at least three different households. Interviewing occurred in private to avoid getting copied answers. The anonymity of participants was guaranteed. Four focus group discussions (two with women only, two with men only) were done to obtain additional information.

Data were coded and recorded on data master sheets, using the software program Epi Info version 3.3.2 (Centres for Disease Control, Atlanta). Significant differences, bivariate odds ratios (OR) and 95% confidence intervals (95% CI) were calculated using ANOVA and chi-square tests. Results of the focus group discussions were used to complement interview data.

Three levels of obstetric care are distinguished in this survey: care by untrained TBAs, by trained TBAs and by health centre or hospital staff (SBAs).

Definitions

Skilled birth attendants are people with midwifery skills (e.g., doctors, midwives, nurses) trained to proficiency in the skills necessary to manage normal deliveries and diagnose, manage or refer complications.

Traditional birth attendants are community-based providers of care during pregnancy and child-birth. TBAs are not trained to proficiency in the skills necessary to manage or refer obstetric complications. TBAs are not usually salaried, accredited members of the health system.

Limitations

Bias might have been introduced by the selection of interviewers, health centres and respondents. Interviewers were recruited from health centre personnel. Health centres and their catchment areas were selected for convenience, taking into account compromised accessibility during the study

period, which was the flood season. Only healthcare clients and their husbands were interviewed, not healthcare providers.

Results

Characteristics of the participants of 162 villages are summarized in Table 1. Overall, 444 parous women, 429 husbands, 378 elderly women and 162 village headmen were interviewed.

Age, parity, marital status and educational level of the women did not influence the choice of birth attendant. Trained TBAs were more present in category III than in category I and II villages ($p = .03$). Untrained TBAs were present in more category II and III than in category I villages ($p = .002$). Parous women from category I villages had a higher level of education than women from category II and III villages ($p < .001$). Husbands, elderly women and village headmen showed no differences in characteristics.

Table 1. Characteristics of the study population in total and per category of villages

Parameter	All villages together	Per village category*			p-value
		I	II	III	
Villages (n)	162	49	54	59	
Inhabitants per village (mean)	66	60	53	82	> .05
% of villages in which t-TBA† present	40	33	34	50	.043
% of villages in which TBA‡ present	68	51	77	75	.002
Parous women (n)	444	136	148	160	
Age (mean, years)	29.4	29.8	28.7	29.5	> .05
Parity (mean)	4.3	4.5	4.0	4.3	> .05
Number of children (mean)	3.5	3.7	3.3	3.4	> .05
% married	74	71	77	75	> .05
Education:% not educated	16	15	14	20	> .05
% grade 1–4	32	18	42	34	< .001
% grade 5–8	47	56	43	41	.007
% grade 9–12	5	11	1	5	.001
Husbands of parous women (n)	429	136	155	138	
Age (mean, years)	35.6	35.8	35.6	35.3	> .05
Number of children (mean)	4.5	4.5	4.1	4.8	> .05
Number of women married to (mean)	1.1	1.1	1.1	1.1	> .05
Education:% not educated	12	9	11	15	> .05
% grade 1–4	23	22	26	19	> .05

Table 1. Continued

% grade 5–8	47	53	45	45	> .05
% grade 9–12	18	16	18	21	> .05
Elderly women (n)	378	107	135	136	> .05
Age (mean, years)	56.6	58.4	56.8	54.9	> .05
Parity (mean)	7.2	7.4	7.4	6.8	> .05
% married	54	49	56	56	> .05
Education: % not educated	43	45	39	45	> .05
% grade 1–4	34	36	37	29	> .05
% grade 5–8	20	18	20	23	> .05
% grade 9–12	3	1	4	3	> .05
Village headmen (n)	162	49	54	59	
Age (mean, years)	63.5	62.6	65.6	62.3	> .05
% married	88	89	89	86	> .05
Education: % not educated	21	20	22	20	> .05
% grade 1–4	38	35	35	42	> .05
% grade 5–8	28	27	35	22	> .05
% grade 9–12	13	18	8	16	> .05

*Category I: villages within a 30-minute walk from the health centre; category II: villages more than a 30-minute walk but less than a 2-hour walk from the health centre; category III: villages more than a 2-hour walk from the health centre.

† t-TBA = trained traditional birth attendant.

‡ TBA = untrained traditional birth attendant.

Table 2 shows that the latest delivery of parous women between 2000 and 2005 was assisted by SBAs in 42%, trained TBAs in 28% and untrained TBAs in 29% of cases. Three women (1%) gave birth without any help. Distance influenced the choice of birth attendant: more women from category I villages gave birth in the health centre than women from more remote villages ($p < .001$, $OR=2.06$, 95% CI 1.34–3.16). Fewer women from category I villages were assisted by untrained TBAs than women from category II and III villages ($p < .001$, $OR=0.31$, 95% CI 0.17–0.53). The educational level of parous women did not influence the choice of birth attendant (data not shown).

A multivariable logistic regression analysis (binominal, i.e., SBAs versus trained and untrained TBAs) was performed to investigate whether age, marital status and education of women, and the distance from their village to the health centre, were independently affecting the choice of birth attendant. Only distance to the health centre was significantly associated with the choice of birth attendant ($p = .003$).

Table 2. Birth attendant at previous childbirth per category of villages

	All villages	Cat I	Cat II	Cat III	p-value (2)
SBA	42%	54%	38%	34%	.002
Trained TBA	28%	30%	24%	31%	> .05
Untrained TBA	29%	15%	38%	34%	< .001
No one	1%	1%	0%	1%	> .05
Total	100% (n = 444)	100% (n = 136)	100% (n = 148)	100% (n = 160)	

Table 3 shows the motives for the choice of birth attendant at the previous birth: 44% of women who gave birth in the health centre or hospital mentioned confidence in the skills of birth attendants in these facilities, and 54% of women who were assisted by a trained TBA had the same motive. When labour progressed fast, untrained TBAs were called for help (38%). TBAs, both trained and untrained, were chosen for socio-cultural reasons (24% and 31%, respectively).

Economic reasons were more often mentioned as a motive for choosing an untrained TBA, and socio-cultural reasons were more often mentioned to explain the choice of a TBA. Fast delivery was mainly a motive of women who were assisted by untrained TBAs.

Table 3. Motives for choice of birth attendant at previous childbirth per chosen birth attendant

	SBA (1)	Trained TBA (2)	Untrained TBA (3)	Pair-wise analysis of:	p-value of pair-wise analysis	OR of pair-wise analysis	95% CI of pair-wise analysis
Medical reason	11%	0%	1%	1 versus 2+3	< .001	31	5–1281*
Fast delivery	4%	7%	38%	1+2 versus 3	< .001	0.09	0.05–0.17
Economic reason	7%	10%	16%	1 versus 2+3	.045	0.51	0.25–1.04
				1+2 versus 3	.01	0.46	0.23–0.89
Socio-cultural reason	14%	24%	31%	1 versus 2+3	< .001	0.43	0.25–0.73
Trained staff	44%	54%	1%	1+2 versus 3	< .001	119	20–4783*
Other	20%	5%	13%	1+3 versus 2	< .001	4.1	1.7–12.0*
Total	100% (n = 185)	100% (n = 125)	100% (n = 130)				

* Exact confidence limits, because of small numbers in some cells.

OR = odds ratio; 95% CI = 95% confidence interval.

Table 4 shows the preference of birth attendant for the next childbirth. Ninety percent of women who gave birth in a health facility prefer to give birth in this facility again. Forty-seven percent of women assisted by a trained TBA wish to be assisted by the trained TBA again, and 9% of women again prefer the help of the untrained TBA.

Table 4. Birth attendant preferred at next childbirth compared to birth attendant at previous childbirth

Previous delivery Next delivery	SBA	Trained TBA	Untrained TBA
SBA	90%	52%	74%
Trained TBA	10%	47%	17%
Untrained TBA	0%	1%	9%
Total	100% (n = 185)	100% (n = 125)	100% (n = 130)

Table 5 shows that the majority of women prefer an SBA to assist their next delivery. No significant difference was found in preferences between the different groups of participants.

Table 5. Preferred birth attendant at next childbirth

	Survey population (total group)	Parous women	Husbands	Elderly women	Village headmen
SBA	75%	74%	76%	77%	70%
Trained TBA	22%	23%	22%	20%	23%
Untrained TBA	3%	3%	2%	3%	7%
Total	100% (n = 1413)	100% (n = 444)	100% (n = 429)	100% (n = 378)	100% (n = 162)

Table 6 shows that 69% of parous women prefer to give birth in the health centre or hospital, because of the presence of trained staff; 75% of women who prefer an untrained TBA have socio-cultural reasons for doing so.

Table 6. Motives of parous women for preferred birth attendant

	SBA	Trained TBA	Untrained TBA
Economic reason	1%	15%	8%
Socio-cultural reason	23%	32%	75%
Trained staff	69%	46%	0%
Other	7%	7%	17%
Total	100% (n = 328)	100% (n = 102)	100% (n = 13)

Discussion

Whereas 75% of study participants would prefer to give birth in a health facility, only 42% of women actually did so for their previous delivery. Although 29% of women were assisted by untrained TBAs at the last delivery, only 3% prefer assistance of an untrained TBA at their next delivery. In other words, there is a difference between preference and actual choice. This was also found by Voorhoeve et al. (1982) and Stekelenburg et al. (2004). All villagers participating in the focus group discussions explained the difference by referring to the lack of transportation from their village to the health centre.

The distance from village to health centre contributes to phase-one and phase-two delay in receiving adequate obstetric care (Thaddeus and Maine 1994). Distance may delay or postpone the decision to go to the health facility (phase one), and it determines travel time from village to health centre (phase two). During the rainy season, some health centres are not accessible at all due to heavy floods.

To overcome transportation problems and reach a health centre when labour has already started, mothers' shelters (maternity waiting homes), places where women can wait for labour during the last few weeks of pregnancy, were constructed near some health centres. Although practical problems such as the provision of food and care for other children need to be solved (Figa' - Talamanca 1996), maternity waiting homes can function well, as long as basic elements are provided (Stekelenburg et al. 2006).

Women who were assisted by SBAs or trained TBAs value highly that these birth attendants are trained to conduct "a clean and safe delivery." The presence of a radio system to communicate with the hospital in case of complications was important to women who gave birth in a health centre. Most inhabitants of Lukulu District seem to be aware of some of the dangers of pregnancy and delivery. They express overwhelming confidence in the capacity of health centre staff. Trained TBAs belong to the same category as trained, qualified staff according to many villagers. They are seen as "the eyes of the health centre."

This comparison of the skills of trained TBAs with those of health centre staff is realistic. At least half of the deliveries in health centres are attended by classified daily employees (CDEs) who, like trained TBAs, have no formal medical education. Only female CDEs were trained in obstetrics, during a 3-week course comparable to the training given to TBAs. So, whereas all health centre staff were referred to as SBAs in this survey, the term applies to half of them at most. This illustrates the current worldwide discussion about the definition of a skilled attendant. Some attendants who are supposed to be skilled are not (Harvey et al. 2007), and trained TBAs might be more skilled than expected.

A remarkably high number of women described an emergency situation (fast delivery) to explain why an untrained TBA conducted the delivery. Apparently untrained TBAs are rescuers for those who cannot reach the health facility in time. They are present in most villages.

The socio-cultural role of trained and untrained TBAs should not be underestimated. Their practices often stem from deeply rooted cultural ideas (Lefèber 1994), and they are highly respected in rural communities for socio-cultural reasons (Kruske and Barclay 2004). Trained TBAs could therefore play an influential role in linking communities to health facilities, for example, by educating communities about risks of pregnancy and delivery, informing women about their estimated date of delivery, assisting them in being well prepared and providing them with continuous emotional support (van Roosmalen et al. 2004).

While national and regional programs should focus on increasing the numbers of properly trained midwives, in certain districts where serious shortages of trained health workers exist and investments have been made in the past to empower and train TBAs, continuation of TBA-support programs should be considered. A short-term additive value can be expected. This strategy will succeed only if both TBAs and health workers are willing to co-operate. Regular training should be organized for TBAs, and they should be compensated for the work they do. Providing them with a regularly replenished delivery kit and a mode of transportation (e.g., a bicycle), or a small salary, is worth

considering. On these conditions, TBAs could be of great value at improving pregnancy outcome in developing countries. Indicators to evaluate the effect of such programs should be developed, for example, the number of referrals or percentage of skilled attendants (including trained TBAs) present during delivery. Maternal mortality ratios are not appropriate indicators to evaluate the effect of TBA support programs at the district level.

Conclusion

Although TBAs conduct more deliveries than SBAs in Lukulu District, the majority of women prefer SBAs to TBAs. The closer women live to a health facility, the more likely they are to choose to give birth there. Whereas trained TBAs and SBAs are preferred because of their skills acquired by training, untrained TBAs assist when lack of time, transportation or money keep women in labour from reaching the health centre. As long as there is no improvement in the district's poverty level and infrastructure, women will continue to give birth in the village without the assistance of SBAs. Socio-cultural reasons for assistance from TBAs will not be easy to overcome. Besides, the current number of SBAs in Zambia is too small to assist all women in labour. Therefore, TBAs cannot yet be excluded from safe motherhood programs.

Authors' Contributions

Josy van den Boogaard, MD, former research officer Lukulu District. Initiated and carried out the survey. Drafted first version of the manuscript.

Bart Arntzen, MD, former MD Lukulu District Hospital. Initiated the survey. Revised the manuscript critically for substantial intellectual content.

Junist Chilwana, health worker Lukulu District, participated in the survey.

Martin Liyungu, health worker Lukulu District, participated in the survey.

Albert Mantingh, MD, PhD, consultant obstetrician. Supervised the survey and revised the manuscript critically for substantial intellectual content.

Jelle Stekelenburg, MD, PhD, consultant obs & gyn. Initiated and supervised the survey, revised the first manuscript critically for substantial intellectual content and drafted the manuscript for *Journal of World Health and Population*.

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Population-Based Tuberculin Skin Testing and Prevalence of Tuberculosis Infection in Afghanistan

Shannon C. Doocy, PhD

Department of International Health, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, Maryland, United States

Catherine S. Todd, MD, MPH,

Division of International Health & Cross-cultural Medicine, University of California at San Diego, La Jolla, California, United States

Yolanda Barbera Llainez, PharmD

International Rescue Committee, Kabul, Afghanistan

Ahmadullah Ahmadzai, MD

International Rescue Committee, Kabul, Afghanistan

Gilbert M. Burnham, MD, PhD*

Department of International Health, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, Maryland, United States

* Corresponding author: Gilbert M. Burnham, MD, PhD, Johns Hopkins Bloomberg School of Public Health, 615 N Wolfe St, Suite E8132, Baltimore, MD 21205. Tel. 410-955-7934, Fax 410-614-1419, email gburnham@jhsph.edu.

Abstract

Objective. A tuberculin skin-test survey was conducted in eight provinces of Afghanistan to estimate the prevalence and annual risk of tuberculosis infection among the Afghan population.

Methods. A cluster survey in eight Afghan provinces, chosen based on population density and geographic distribution, was carried out between October and February 2006. Interviews were conducted and tuberculin skin tests were administered and read.

Findings. 11,413 individuals participated in the study. Using the international standard cut-off of ≥ 10 mm, tuberculosis prevalence and annual risk of infection in the population were 15% (CI: 14.4–15.7) and 0.80 (CI: 0.76–0.84), respectively. Tuberculosis prevalence was higher in rural than in urban areas. Other risk factors included age, prior tuberculosis treatment or contact, productive cough or cough >3 weeks, no prior bacille Calmette Guérin (BCG) vaccination and a cooking fire in the sleeping room.

Conclusions. The survey documented a lower prevalence and risk of tuberculosis infection than the 1978 national survey and a substantially lower estimate of incidence of new smear-positive tuberculosis cases than World Health Organization estimates. However, other findings suggest that active tubercu-

losis may remain widespread and undiagnosed, and indicate a need for both additional research and continued investment in tuberculosis treatment and prevention, and in health infrastructure.

Introduction

Tuberculosis is a leading infectious cause of morbidity and mortality globally, resulting in an estimated 1.7 million deaths annually, and disease burden is expected to increase as a consequence of interaction with the HIV epidemic (World Health Organization [WHO] 2006). Afghanistan is among the 25 countries with the greatest tuberculosis burden and has the highest number of cases in Asia: the WHO estimates the annual tuberculosis incidence is 333/100,000/year, and tuberculosis mortality is 92/100,000/year (WHO 2004). During three decades of instability in Afghanistan, the health system has deteriorated, though substantial improvements have occurred since 2002. In spite of recent changes, facilities providing tuberculosis diagnosis and treatment are unevenly distributed and are concentrated in urban areas (Management Sciences for Health 2006).

Tuberculin skin testing is a method commonly used to estimate prevalence of tuberculosis infection and annual risk of tuberculosis infection (ARTI) and is suitable for populations receiving bacille Calmette Guérin (BCG) vaccinations (Salanipioni et al. 2004; Shashidhara et al. 2004; Norval et al. 2004). The last national tuberculin skin-test survey in Afghanistan was conducted in 1978 and estimated prevalence of tuberculosis infection at 46% and ARTI at 3.53% (Japan International Cooperation Agency [JICA] 1978). More recently, a tuberculin skin-test survey among 6575 school-age children in Kabul noted a 4.3% prevalence of tuberculosis infection, with a corresponding ARTI of 0.62% (Dubuis 1999).

Available data do not provide a clear picture of current tuberculosis infection prevalence or disease incidence in Afghanistan. WHO estimates are based on the 1978 survey and data from those currently on tuberculosis treatment (WHO 2004). With the global tuberculosis pandemic and the increasing prominence of multiple-drug-resistant (MDR) tuberculosis, quantification of the epidemic in high-prevalence areas such as Afghanistan is essential for adequate management. The present study aimed to determine prevalence of tuberculosis infection and ARTI in selected provinces of Afghanistan using population-based survey methods.

Methods

Sample-size calculations were performed at the province level and with the objective of determining a sample sufficient to detect a 10% change in the proportion of skin-test-positive individuals from a hypothesized 1978 rate of 46% (95% CI: 41–51) with 80% power and $\alpha = 0.05$ (JICA 1978). Sample size was doubled to 390 per province to account for loss of efficiency in the cluster survey design. Allowing for a 10% loss to follow-up after the skin test, and a design effect of 2, required 906 individuals per province or 7246 in total. To account for potentially underestimating differences between urban and the other, predominantly rural, sites, an additional 1812 persons were included to increase specificity of urban estimates, yielding a minimum sample of 9058. A sample of 11,970 was planned to allow for variation in household size and potential loss or inaccessibility of clusters due to lack of security. Each cluster contained five households, and average household size was assumed to be seven, so cluster size was approximated at 35 individuals (Asscfa et al. 2001). Based on estimated cluster-size and sample-size calculations, 329 clusters were required and 342 clusters were planned. Rural clusters were equally distributed among the eight provinces ($n = 36$ clusters per province), and urban clusters ($n = 54$) were apportioned according to the relative size of the urban population centres.

Of Afghanistan's 34 provinces, eight (Bamiyan, Herat, Jawzjan, Kandahar, Kapisa, Khost, Kunduz and Wardak) were selected as representative of the country on the basis of population density, geographic location and accessibility (Figure 1). Sampling employed a probability proportional to size methodology that was modified for use in conflict settings where insecure districts were excluded from the sampling frame; within each province, districts were eligible to be sampled only if security was adequate. Within each district, rural villages or urban neighbourhoods were randomly selected

as cluster sites using probability-based sampling that employed pre-census data from the Central Statistics Office (CSO) as the reference population (Central Statistics Office 2005). Cluster numbers in both urban and rural areas were adjusted after the first month of enrollment to accommodate variability in cluster sizes in each province.

Once an area was identified as a cluster site, the survey team met with community leaders to obtain permission to approach households. The community centre, usually the mosque, was used as the starting point for cluster identification. The survey team then proceeded in a random direction numbering houses and then randomly selected five households to participate. Permission from the household head was obtained prior to approaching household members for enrollment. Household members were defined as those who slept in the same dwelling and shared at least one meal per day. Few households refused to participate, though this information was inconsistently recorded. For consenting households, all members older than 1 year of age were eligible. Parental consent was obtained for all members under the age of 18 years, and subject assent was secured for children aged 7 and older.

Figure 1. Map of Afghanistan provinces and survey area



The survey was conducted between October 2005 and February 2006. After consent had been given and questionnaires administered, tuberculin dosing was performed according to WHO/IUATLD recommendations, where 1 mL of PPD RT23/Tween 80 (Statens Serum Institute, Copenhagen, Denmark) was administered to people 1 year or older who were not pregnant. Transverse and vertical induration widths were measured within 48 to 72 hours to the nearest millimeter using metal calipers, and recorded. Prior to the survey, study teams completed competency-based training in administering and interpreting tuberculin skin tests. Supervisors and field managers conducted routine spot checks to assess accuracy of placement and induration measurement using standard messages from the Afghanistan National Tuberculosis Program (NTP). People with symptoms suggestive of active tuberculosis disease were referred to the nearest tuberculosis clinic for evaluation.

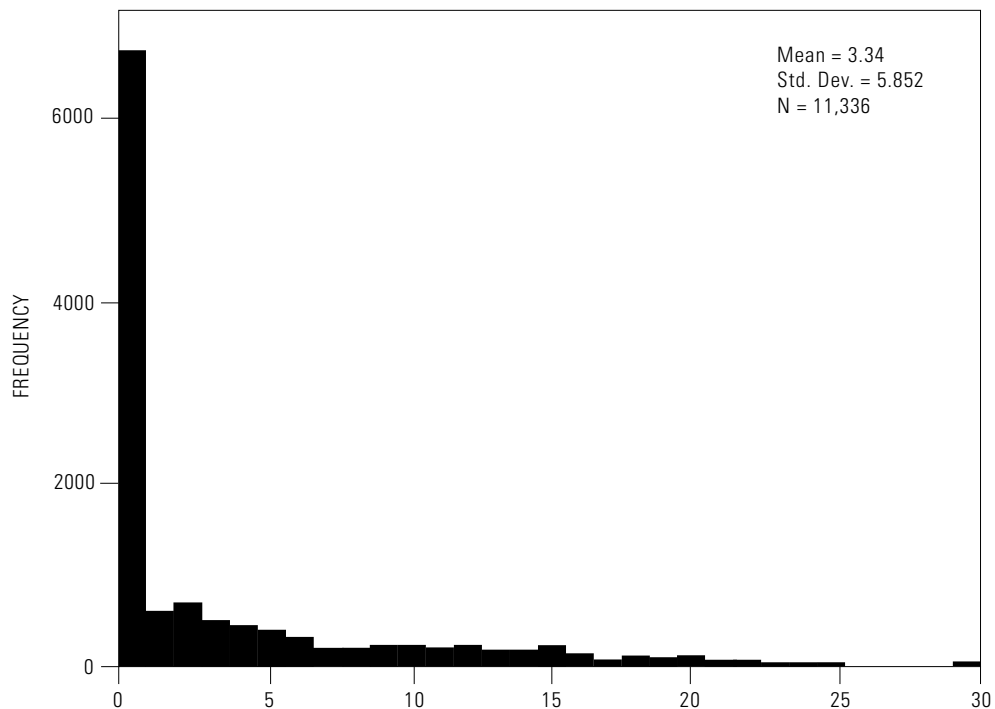
Data analysis was performed using Excel, STATA Version 8.0 (College Station, TX), and SPSS Version 14.0 (Chicago, IL). The design effect from cluster sampling was calculated at 1.97 such that confidence intervals did not subsequently need to be adjusted. Risk factors for tuberculosis were assessed using chi-square tests and logistic regression. Nagelkerke R² was used to examine the proportion of variance accounted for by predictors in multivariate models, and the Hosmer–Lemeshow test was used to assess goodness-of-fit. Prevalence of tuberculosis infection was estimated based on a transverse induration diameter of ≥ 10 mm, a criterion commonly used to determine latent or active tuberculosis in high-prevalence countries. The cut-off is applicable to all age groups and has been used in multiple international settings in population-based studies to approximate tuberculosis prevalence (American Thoracic Society 2000). Annual risk of tuberculosis infection is a mathematical calculation used to indicate the proportion of the population that will be primarily infected or re-infected with tubercle bacilli in 1 year. The trend in change of risk of infection is calculated based on prevalence of infection rates using the standard of ≥ 10 mm to classify a person as positive (Reider 1999; Spinaci et al. 1989).

Ethical review and approval was obtained from review boards of the Ministry of Public Health of the Islamic Republic of Afghanistan, the University of California at San Diego and Johns Hopkins School of Public Health prior to data collection.

Results

The sample comprised 11,413 individuals, and skin-test results were recorded for 11,336 or 99.3% of subjects. The sample population was 55.5% male and 44.5% female and had the following age distribution: 0–4 years, 13.8%; 5–9 years, 20.3%; 10–14 years, 15.2%; 15–19 years, 10.5%; 20–29 years, 13.0%; 30–39 years, 10.6%; and 40+ years, 16.5%. Of participants, 52.2% (CI: 51.2–53.1) had received a BCG vaccination, and 13.3% (CI: 12.7–14.0) reported prior tuberculosis treatment or contact with an individual with active disease.

Figure 2. Frequency of induration size



Induration Characteristics

The distribution of induration width among participants is presented in Figure 2. Of all participants, 60% (95% CI: 59–61) had a reaction of 0–5 mm to the tuberculin skin test. The distribution of induration was: 78% negative reaction (0–5 mm); 7% some reaction (6–9 mm, defined by the WHO as a negative reaction and by the manufacturer as a weak positive reaction); 7% positive reaction (10–14 mm); and 8% strong positive reaction (15+ mm). Among those with any induration ($n = 4564$), mean and median transverse diameters were 8.3 mm (standard deviation [SD] = 6.6) and 6.0 mm, respectively, and the distribution was somewhat skewed as reflected by the 25th and 75th percentile values of 3 mm and 13 mm, respectively. In general, induration size increased with age: diameter increased on average 0.14 mm (95% CI: 0.13–0.15) per year ($p < .001$).

Prevalence of Tuberculosis Infection and Annual Risk of Infection

At the standard 10 mm cut-off, prevalence of tuberculosis infection was 15% (95% CI: 14.4–15.7) and ARTI was 0.80 (95% CI: 0.76–0.84) for the survey population. Prevalence of tuberculosis infection rates by sex, age, prior BCG vaccination, urban/rural residence and province are presented in Table 1. Prevalence of tuberculosis infection was similar between the two sexes. Skin-test positivity increased with age and was significantly greater among those without prior BCG vaccination. Prevalence of infection varied widely between provinces, with the lowest in Wardak (5%) and the greatest in Kandahar and Bamiyan (25%). While Bamiyan and Kandahar had the highest prevalence rates, the odds of having BCG scars differed appreciably between the two areas, at 1.9 (95% CI: 1.6–2.2) and 0.5 (95% CI: 0.5–0.6), respectively. Prevalence of infection was significantly greater in rural than in urban areas, although there was no significant difference in BCG vaccination rates between urban and rural areas ($p = .202$).

The ARTI is the proportion of the population that will be primarily infected or re-infected with tubercle bacilli in 1 year and is usually expressed as a percentage. The risk of contracting tuberculosis may change over time; thus, ARTI represents the midpoint in time between the year the cohort was born and the year of the survey. Annual risk of infection by age, sex, BCG status, urban/rural residence and province are presented in Table 1. The risk of infection is directly related to prevalence, and a higher prevalence of infection is associated with a greater ARTI. For the eight provinces surveyed, ARTI was 0.80% (CI: 0.76–0.84).¹ ARTI was similar for men and women, and higher among those without prior BCG vaccination. In general, ARTI increased with age; however, the greatest ARTI was observed in two groups, those 0–5 years and 30–39 years of age, where the point estimate for ARTI in both groups was 1.0%. ARTI varied widely by province and was significantly higher in rural areas.

Risk Factors for Tuberculosis Infection

Risk factors for tuberculosis infection assessed included location (province, urban/rural residence); demographic characteristics (age, sex); tuberculosis prevention, exposure and symptoms (prior BCG vaccination, history of TB treatment or contact with infected individual, cough >3 weeks in duration and productive cough); and environmental risk factors (crowding, defined by the number of people sleeping per room and presence of a cooking fire in the sleeping room). The odds and adjusted odds of tuberculosis infection for risk factors are presented in Table 2. All predictors were significantly associated with tuberculosis infection in univariate models, and, with the exception of sex and crowding, the observed relationships remained statistically significant in multivariate models.

The adjusted odds ratio of tuberculosis infection was 1.56 (CI: 1.29–1.87) times greater in rural than in urban areas and varied between provinces. An age-dependent increase in risk of 1.47 (CI: 1.42–1.52) was associated with each additional 10 years of age. The adjusted odds ratio of tuberculosis infection was significantly greater among those with prior TB treatment or exposure (13.3%, CI: 12.7–14.0; OR = 2.46, CI: 2.10–2.88), cough greater than 3 weeks in duration (17.1%, CI: 16.4–17.8; OR = 2.36, CI: 1.95–2.87) and productive cough (10.1%, CI: 9.5–10.6; OR = 2.84, CI: 2.27–3.54). A BCG scar was noted in 52% (CI: 51.3–53.1) of subjects and was protective against

tuberculosis in the univariate model; however, in the adjusted model this finding was reversed, and those with no prior BCG vaccination were significantly less likely to be identified as having tuberculosis infection (OR = 0.86, CI: 0.75–0.99). A positive association between the presence of a BCG scar and age was observed and is a potential confounder.

Table 1. Prevalence and annual risk of tuberculosis infection

	Prevalence of infection (transverse diameter ≥ 10 mm)		Annual risk of tuberculosis infection			
	<i>n</i>	Percent (95 CI)	Point Estimate	95 % CI		
Overall (<i>n</i> = 11,336)	1701	15.0 (14.4–15.7)	0.80	0.76	–	0.84
By sex						
Males (<i>n</i> = 5023)	714	14.2 (13.3–15.2)	0.76	0.71	–	0.82
Females (<i>n</i> = 6306)	987	15.7 (14.8–16.6)	0.83	0.78	–	0.88
By age						
0–4 yrs (<i>n</i> = 1569)	42	2.8 (1.9–3.6)	1.01	0.68	–	1.30
5–9 yrs (<i>n</i> = 2310)	110	4.8 (3.9–5.7)	0.72	0.58	–	0.86
10–14 yrs (<i>n</i> = 1730)	140	8.1 (6.9–9.5)	0.71	0.60	–	0.84
15–19 yrs (<i>n</i> = 1194)	144	12.1 (10.3–14.0)	0.77	0.65	–	0.90
20–29 yrs (<i>n</i> = 1470)	255	17.3 (15.4–19.4)	0.80	0.71	–	0.91
30–39 yrs (<i>n</i> = 1194)	341	28.6 (26.0–31.2)	1.01	0.91	–	1.12
40 + yrs (<i>n</i> = 1869)	669	35.8 (33.6–38.0)	0.86	0.80	–	0.93
By BCG status						
Prior BCG (<i>n</i> = 5934)	723	12.2 (11.4–13.0)	0.73	0.68	–	0.78
No BCG (<i>n</i> = 5402)	978	18.1 (17.1–19.2)	0.86	0.81	–	0.91
By location						
Urban (<i>n</i> = 1919)	232	12.1 (10.7–13.6)	0.66	0.58	–	0.74
Rural (<i>n</i> = 9417)	1469	15.6 (14.9–16.3)	0.83	0.79	–	0.87
By province						
Bamiyan (<i>n</i> = 1076)	264	24.5 (22.0–27.2)	1.26	1.11	–	1.42
Herat (<i>n</i> = 2313)	277	12.0 (10.7–13.4)	0.65	0.58	–	0.74
Jawzjan (<i>n</i> = 1491)	214	14.4 (12.6–16.2)	0.68	0.59	–	0.78
Kandahar (<i>n</i> = 1566)	399	25.5 (23.3–27.7)	1.52	1.37	–	1.68
Kapisa (<i>n</i> = 1191)	161	13.5 (11.6–15.6)	0.69	0.59	–	0.81
Khost (<i>n</i> = 1213)	142	11.7 (10.0–13.7)	0.70	0.59	–	0.82
Kunduz (<i>n</i> = 1153)	176	15.3 (13.2–17.5)	0.75	0.64	–	0.86
Wardak (<i>n</i> = 1333)	68	5.1 (4.0–6.4)	0.28	0.28	–	0.35

Discussion

The present study of eight provinces represents the first population-based tuberculosis skin-test survey in Afghanistan since the national survey of 1978. Although smaller studies have been conducted in the interim, there are few reports with which to compare results. The distribution of induration diameters in the present survey was similar to that previously observed in Afghanistan (Reider 1999). Using a 10 mm standard for induration, the prevalence of tuberculosis infection was 15.0% (CI: 14.4–15.7) and ARTI 0.80 (CI: 0.76–0.84). These are substantially lower than the national prevalence of infection of 46% and ARTI of 3.53 observed in 1978 (JICA 1978). A recent tuberculin skin-test survey among children 7–8 years of age in Kabul estimated the prevalence of tuberculosis infection at 4.3% and ARTI at 0.34 (CI: 0.23–0.54) (Dubuis et al. 2004). If the cut-off used in the Kabul study (8 mm) in children 7–8 years of age were applied in the current study, tuberculosis prevalence across the eight provinces surveyed would be 8.3% and ARTI 1.15, both greater than the rates recently observed in Kabul. These comparisons should be made with caution because of the pronounced geographic variation in prevalence of infection (where infection rates appear to be higher in rural areas) and because Kabul was not included in our survey.

The 2004 WHO estimates place Afghan active tuberculosis disease prevalence and incidence, respectively, at 661/100,000 and 333/100,000/year with a constant incidence rate (i.e., a trend in incidence rate change of 0.0% per year) (WHO 2006). To compare WHO figures and survey data, Styblo's rule was applied, where a 1% annual risk of infection corresponds to an incidence rate of 50/100,000/year (CI: 39–59) new smear-positive tuberculosis cases (Styblo 1985). Using the ARTI estimate of 1.01 for the youngest age group (0–4 years) as a measure of current risk, the corresponding annual incidence rate would be 50/100,000/year, which is considerably less than WHO estimates. This could suggest that estimated prevalence of tuberculosis infection documented in the survey is biased toward lower values or that the Styblo rule may not apply in Afghanistan.

A primary cause of false-positive tuberculin skin tests is BCG vaccination (Menzies and Vissandjee 1992). Because of the large proportion of the population with BCG scars (52%), there was concern that tuberculosis prevalence rates may have been overestimated. Some prior surveys calculate prevalence and annual risk of infection only for the population that has not received BCG. However, in our study, mean induration size was significantly smaller among those with a vaccination, suggesting they were less likely to be categorized as a false positive. Among children who received BCG in infancy, almost all will have a reaction of less than 10 mm in diameter after 2 years of age; among those who received BCG between primary school age and adolescence, 15–25% have positive reactions up to 20 years later (Menzies and Vissandjee 1992; Jonson et al. 1995; Joncas et al. 1975). In most Asian countries and in other regions where tuberculosis infection is frequent, tuberculosis is a more likely cause of a positive skin test than BCG vaccination (Menzies et al. 1992; Menzies et al. 1999).

Another major cause of false-positive tuberculin skin tests is infection with nontuberculous mycobacteria, which is commonly present in soil and water in tropical and subtropical climates. Sensitivity is common among people in these areas, and cross-reaction may produce a false-positive tuberculin test. Nontuberculous mycobacteria are relatively rare in cold environments, such as mountainous areas of Afghanistan with their cold winters, and more common in tropical and subtropical climates (Menzies et al. 1999). In most of Afghanistan, nontuberculous mycobacteria are expected to occur rarely and are not likely to be an important cause of false positives; however, an exception might be the southern provinces bordering Pakistan, where mean annual soil temperature is 15°C or greater (United States Department of Agriculture 2001). The only southern province surveyed was Kandahar, which had the highest prevalence of infection of all provinces; continued conflict has limited access to health facilities in Kandahar, and this could also be associated with elevated infection rates.

Our survey found that risk of tuberculosis infection was 1.56 (CI: 1.29–1.87) times greater in rural than in urban settings. In contrast, higher prevalence of tuberculosis infection is anticipated in urban areas, where opportunity of exposure and risk of contracting infection are presumed

greater due to increased population density (Reider 1999). Larger household size, lower rates of care seeking, and more treatment failures may be associated with higher tuberculosis infection prevalence in rural areas.

Table 2. Risk factors for tuberculosis infection

Predictor variables	Unadjusted		Adjusted (all predictors included)	
	Odds (95% CI)	<i>p</i>	Odds (95% CI)	<i>p</i>
Location variables				
Bamiyan	6.05 (4.57–8.01)	<.001	5.57 (4.03–7.69)	<.001
Herat	2.53 (1.92–3.33)	<.001	2.76 (2.01–3.77)	<.001
Jawzjan	3.12 (2.35–4.14)	<.001	5.08 (3.65–7.06)	<.001
Kandahar	6.36 (4.86–8.33)	<.001	12.63 (9.12–17.48)	<.001
Kapisa	2.91 (2.17–3.91)	<.001	3.24 (2.34–4.49)	<.001
Khost	2.47 (1.83–3.33)	<.001	3.40(2.44–4.74)	<.001
Kunduz	3.35 (2.50–4.49)	<.001	3.05 (2.19–4.23)	<.001
Wardak (reference)	1.00		1.00	
Rural area (reference: urban)	1.34 (1.16–1.56)	<.001	1.56 (1.29–1.87)	<.001
Individual characteristics				
Age (per 10-year increase)	1.59 (1.54–1.63)	<.001	1.47 (1.42–1.52)	<.001
Male sex (reference: female)	0.89 (0.80–0.99)	.033	0.91 (0.80–1.03)	.117
Prior TB treatment / contact	3.33 (2.94–3.77)	<.001	2.46 (2.10–2.88)	<.001
No BCG scar	1.59 (1.43–1.77)	<.001	0.86 (0.75–0.99)	.003
Cough >3 weeks' duration	6.42 (5.73–7.20)	<.001	2.36 (1.95–2.87)	<.001
Productive cough	9.29 (8.14–10.60)	<.001	2.84 (2.27–3.54)	<.001
≥ 7 people sleeping / room	0.85 (0.74–0.98)	.023	0.88 (0.73–1.05)	.142
Cooking fire in sleeping room	1.50 (1.25–1.80)	<.001	0.81 (0.64–1.03)	<.001
	Nagelkerke R ²		.316	
	Hosmer Lemeshow		.109	

There are a number of limitations to this survey. First, the survey encompassed eight of 34 provinces, when a survey of all provinces would have been ideal considering the paucity of data on tuberculosis in Afghanistan. Although efforts were made to select representative provinces, there is no assurance that the eight are indeed representative of the country. Second, survey teams were unable to cover all districts in some provinces due to security concerns; this was particularly true in Kandahar. Populations in insecure areas may have restricted access to health services as well as higher infection rates than those in areas with better access; conversely, isolation may protect populations

from infections entering from other areas. Third, the smear-positive incidence rates derived from Styblo's rule are unexpectedly low, and there is a discrepancy between survey findings and anticipated incidence rates that suggests the survey may have underestimated the extent of tuberculosis in Afghanistan. False negatives, resulting from poor nutrition, improper storage of PPD, or incorrect application or reading of skin tests, could have biased survey findings toward lower prevalence rates. Lastly, the distribution of induration width shows no clear cut-off for classification of tuberculosis based on size of induration, thus it is possible that employing a 10 mm cut-off may have increased specificity. However, some true infections may have been misclassified as false negatives where other noninfections could have been classified as positives. This is an unavoidable problem that the authors attempted to address by providing prevalence rates and ARTI by multiple classification criteria.

Conclusions

The present eight-province survey documented a lower prevalence of tuberculosis infection and lower annual risk of infection compared to the 1978 national survey. The annual incidence of smear-positive tuberculosis cases calculated from survey data was also lower than disease incidence rates estimated by the WHO. These findings suggest that poor infrastructure coupled with several decades of instability may not have adversely affected the epidemiological situation; however, prevalence of tuberculosis infection as measured in the skin-test survey cannot be directly compared with prevalence of active disease reported by the WHO. Several other study outcomes, notably the high proportion of individuals reporting prior TB treatment or exposure and current TB symptoms, are causes of concern and suggest that active tuberculosis disease may remain relatively widespread and undiagnosed, despite increasing trends in diagnosis and treatment. While this is not unexpected in a country that has the greatest estimated tuberculosis burden in Asia, it illustrates the need for additional efforts to update national tuberculosis statistics and continued and expanded investment in the National Tuberculosis Program and reconstruction of the Afghan health system.

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Notes

¹When the international standard cut-off of 10 mm is applied.

Book Review

Why Are Our Babies Dying? Pregnancy, Birth and Death in America

By Sandra D. Lane
237 pages, \$68.85
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Reviewed by Amir A. Khaliq, PhD
Associate Professor
Health Administration & Policy
College of Public Health
The University of Oklahoma Health Sciences Center

It is well known to sociologists and public health professionals that infant mortality rates among people of colour in some parts of the US are similar to those in developing countries. Based on the author's involvement over many years with the Syracuse Healthy Start program, the book provides a thorough examination of factors that contribute to high rates of infant mortality and negative birth outcomes among young women of colour. Using the conceptual framework of structural violence theory, Lane provides overwhelming evidence of the role of socio-economic risk factors as predictors of infant mortality. In examining the role of factors associated with negative birth outcomes and infant mortality among women of colour, as opposed to that of personal responsibility, the author leans heavily on social and environmental factors to explain disparities in these public health indicators. This detailed case study of the Syracuse inner-city population underscores the role of socio-economic risk factors as generalizable determinants of infant mortality throughout the country and, in some respects, globally as well. The book also provides an example of the unintended and often undesirable effects of social and environmental restructuring programs such as urban renewal.

Lane uses the ecosystem approach to illustrate the impact of a host of social and environmental conditions on the health and well-being of affected communities at large and on specific health-

related outcomes such as infant mortality. A thread of “structural violence” that alludes to unequal distribution of power and resources through built-in societal injustice runs throughout the book. Each chapter is divided into sections that demonstrate with statistical evidence the significance of a variety of social and environmental conditions. These conditions not only affect the quality of life in a community, but also directly determine the odds of survival for babies born to women of colour in communities similar to the one examined in great detail in this book.

One notable aspect of the book is Lane’s frank criticism of the misguided and at times counter-productive social policy discourse in the US. For example, policies designed to provide incentives for single mothers to wed might be well meaning but seem uninformed by the demographic characteristics of inner-city African American communities. Lane argues that for most African American women, being a single mother is not a matter of preference but the result of statistical realities of African American demographics that stem from the disproportionate incarceration of African American men. The dearth of men leads to an unhealthy outlook in which African American women unduly accord a social advantage to their men. This situation not only engenders feelings of powerlessness and devaluation but leads to distorted relationships. Men simultaneously carry on more than one relationship, and women not only compete for their affection but also leverage pregnancy to seek greater commitment.

The author points out that race is neither a measurable biological construct nor an independent risk factor; it is only a source of discrimination or an identifier of social inequities. That is, there is no race-related gene that distinguishes whites from blacks, Latinos, Asians or Native Americans. The higher risk of infant mortality among inner-city African American women is related to socio-economic disparities and environmental risk factors that disproportionately affect African American women. Lane argues that racial classification is not an accurate measure of group homogeneity, since clinical and demographic records arbitrarily and inconsistently label individuals as white, black, Hispanic or Native American. Therefore, race does not have a valid biological or statistical explanatory value in discussions related to infant mortality – it serves only as a surrogate for socio-economic inequities. This is demonstrated by the fact that, adjusting for income, insurance status and education, race is found to be independently associated with reduced access to healthcare for African American women. Reduced access, in turn, leads to higher infant mortality rates.

Notably, factors such as poverty, malnutrition, lack of education or lack of access to healthcare are not only interrelated but are also consistently linked to a higher risk of infant mortality. As illustrated by Lane, pregnant women who face poverty, unemployment and limited access to healthcare are more prone to pregnancy-related health problems and negative birth outcomes. On top of that, the complexities of eligibility for social assistance programs such as Aid to Families with Dependent Children (AFDC) or Temporary Aid to Needy Families (TANF), and conditional or intermittent patterns of access to healthcare through Medicaid, take a heavy toll in terms of higher rates of complications and infant mortality among affected populations.

The book begins by describing the origin, growth and evolution of Syracuse to become the fifth largest city in the state of New York. The face and character of the city were transformed in the second half of the twentieth century by the urban renewal experiment that levelled unattractive minority neighbourhoods and caused social restructuring through uprooting individuals and families. Changed demographics around areas affected by urban renewal led to urban decay and a host of social problems including unemployment, poverty, drugs, prostitution, inadequate housing, substandard education, and low academic performance including high rates of school dropouts. Each of the subsequent chapters deals with a specific theme in terms of factors that contributed to high infant mortality rates among African American women in Syracuse between 1997 and 2002.

With a general readership in mind, earlier in the book Lane provides basic patho-physiologic information on pregnancy and factors that lead to negative birth outcomes. Another chapter deals with teen pregnancy issues that predominantly affect African American females. This includes a discussion of the negative effects of funding policies that promote abstinence rather than provide support for sex education and information on pregnancy avoidance. In other chapters, Lane examines the

effects of risk factors such as developmental delays, exposure to lead and teen smoking on negative birth outcomes such as premature delivery and low birth weight babies. In spite of significant reductions in teen pregnancy in the last two decades, the phenomenon of “babies having babies” is still a serious issue in African American communities. That the fathers of many of these babies are adult males and the mothers teenage girls seeking “sugar daddies” is troubling enough, but more troubling is a measure of community acceptance, indifference or resignation in this regard.

Every chapter and section in the book provides a lot of statistics to support the arguments. Many statistics, such as the increase in the number of female-headed households, the number of black teen arrests for minor infractions such as loitering or being in a park after sunset, the number of incarcerated black males and HIV seropositivity rates in correctional facilities, will be shocking even to well-informed readers or public health professionals.

While many of the problems are common to both developed and developing countries, because of the text’s local focus and specific socio-cultural context, its findings and conclusions may not be very generalizable to developing countries. Indeed, the specific definition of poverty or access can be entirely different from one place to another. The example of a highly educated Egyptian woman for whom the notion of a planned pregnancy appeared to be completely alien perfectly illustrates this point. However, the value of the book to readers, irrespective of geography, is the fine way that Lane has combined ethnography methodology with skilful use of statistics to bring into sharper focus the multifactorial etiology of infant mortality and to draw attention to a host of socio-economic ills that are responsive to specific solutions or community-based initiatives. Studies in the developing world using a similar approach could only help to bring more insight to the problem of infant mortality and uncover solutions best suited to local contexts.

Dr. Lane, a Professor of Social Work and Anthropology at Syracuse University and a Research Professor of Obstetrics and Gynecology at SUNY Upstate Medical University, has brought her background in anthropology and nursing to the discussion of complex issues surrounding infant mortality in the vulnerable and disenfranchised population of young, mostly African American females in Syracuse. Her many years of work with the Syracuse Healthy Start program and other community-based initiatives have afforded her a richness of experience in maternal and child health issues and the ability to comment on this subject with authority. The author’s interactions with healthcare providers, law enforcement agencies, social service departments, policy makers and educators have also given her a multidimensional appreciation of the problems that plague the city of Syracuse.

Given this intimate knowledge and obvious care for the topic of her text, Lane was able to produce an easy-to-read book written in simple and frank language. She is direct and candid in pointing out the flaws and shortcomings of the health system and social service programs such as AFDC, TANF and Medicaid. The use of stories, individual experiences and opinions of those affected by the daily realities of a community tormented by a variety of social ills gives the book a very human element. In spite of the troubling subject matter, it makes for a fascinating reading experience.

By design, the book is neither tailored to any particular audience nor meant to serve as a textbook for students in any particular discipline. Instead, it should be of equal interest to public health professionals, social workers, policy makers and students in sociology, anthropology, health policy and health promotion programs. Healthcare professionals and social workers in the country will be able to relate to many problems, insights and observations offered throughout the book. Mostly, though, it is the uninitiated students of sociology, anthropology and public health who will greatly benefit from this book.

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