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# Ethical Concerns on the Study

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# Ethical Concerns on the Study

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## Review

**Introduction:**

The study by Roca et al1 of the effects of community wide vaccination with PCV-7, on pneumococcal nasopharyngeal carriage in The Gambia, raises a large number of ethical concerns. In addition there is concern that the long term beneficial effects of pneumococcal conjugate vaccines (PCVs) may be reduced by proliferation of non-vaccine (NV) strains. The study involved the administration of PCV-7 to a population of adults and children over 2 years (groups who are not the primary target for vaccination and who are not likely to benefit much from the vaccine) to determine the community-wide impact of PCV-7 vaccination of the population on pneumococcal carriage in rural Gambia. The benefits to the study participants from the vaccine are minimal, while at the same time it exposed the population (at least hypothetically) to some risk from the increased proliferation of NV strains. As discussed in the subsequent paragraphs, this study apparently breaches each of the basic ethical principles of clinical research (autonomy, beneficence, non-maleficence, and equity.

**Autonomy**

In the legendary Hindi movie, “Sholay” of yesteryears, considered by many including the British Film Institute to be among the greatest films of Indian cinema2, Gabbar Singh (the autocratic chief of the Dacoits) wants to punish three of his men for a failed mission. While pointing the loaded pistol to the head of the first of the offenders he realizes that there are three men and six bullets in the pistol and comments that this is not fair – so he randomly fires off three rounds after rotating the magazine chamber – leaving three bullets for three men in the 6 chambers. Thus each time the pistol is fired it could be either “khali” (empty) or it may be having “goli” (bullet) and neither Gabbar Singh nor his hapless victims know which is which. There was thus an equal chance of the victim either getting a live bullet through his head or escaping death. As he points the gun to his once faithful man named “Kalia” and asks what his fate will be, Kalia reminds his master that he has eaten Gabbar’s salt (which in the Indian tradition implies he will always be loyal to the master) to which Gabbar replies – now eat “goli” which in Hindi means bullet as well as a “medicine pill.”

The randomized placebo controlled trial by its very design is reminiscent of the Gabbar method. In developing countries, neither the participant nor the physician knows which arm will get “goli” (medicine pill) and which arm will get “khali” (the placebo). Just like in the Gabbar story the population must hope they receive the placebo because the “goli” may well result in the spread of non-vaccine pneumococcus in the community. In clinical trials in areas of poverty and desperation study participants in poor countries consent to such studies as, taking part in a trial is the only way to receive any form of allopathic health care.

The ethical principle of autonomy cannot be considered in a vacuum First comes a full stomach, and then comes ethics. Bertolt Brecht (1898 – 1956).

Ethical issues cannot be considered in a vacuum. The social, economic and cultural contexts dictate how the principles of ethics are interpreted and applied. That many researchers are exploiting these social, economic and cultural factors which lead to compromising of many of the ethical principles particularly autonomy is a matter of concern.
For giving informed consent, the subject should be knowledgeable about the research question, in a balanced frame of mind, without any overt or hidden incentive to participate in the trial – this is autonomy in letter and spirit. Vulnerable populations with poor access to health care may lack the capacity to make informed choices about participating in research.

Developed countries have a high adult literacy rate. They have a high per capita income and health insurance. The population in these countries are also more likely to be aware of some of the medical misadventures. These conditions are pre-requisites for “autonomy” to be exercised in the real sense. More often than not, people from these countries would be reluctant to give consent for clinical trials where they are uncertain of the risks and benefits. In the study under consideration, the benefits to the study participants from the vaccine are minimal to nonexistent because the risk of invasive pneumococcal infection is less common in this age group, and this conjugate vaccine is currently not

recommended for administration to adults. A 23-valent non-conjugate vaccine is what is usually prescribed for high risk groups in this age range. In such a scenario, it is not difficult to guess that an average citizen from a developed country is not very likely to give voluntary consent to such a trial.

On the other hand, developing countries have low adult literacy rate, and many are below the poverty line. Even if they are literate, they may not be enlightened enough to understand the intricacies of clinical trials including potential risks and minimal benefits. Most, particularly rural village folks have implicit faith in allopathic doctors and worship these medical persons as gods.

The principle of autonomy is compromised further in "cluster randomized trials" in which consent may be given by village leaders or other decision makers. In traditional rural societies of developing countries individual will and choices are subjugated to the community wishes as expressed by the village elders. In such a scenario does "autonomy" which puts the interest of the individual before that of the community really exist? In such societies even "individual consent" may not be truly autonomous but influenced by community pressures. Weijer and colleagues have argued that the ethical issues related to autonomy are compounded in "cluster-randomized trials" as these trials only partly fit within the current paradigm of research ethics. They pose difficult ethical issues for two basic reasons. First, cluster trials involve groups rather than (merely) individuals, and second, our understanding of the moral status of groups is often incomplete.3

Another grey area in the present study regarding informed consent is that it is not easy to conceive "informed consent" was obtained in the present trial from each individual as mentioned by the authors? It would imply that each participant would have to be told about the possible benefit of the PCV – 7 vaccine to that participant (since it was given to the older age groups one really wonders what benefit would have been conveyed to the study participants) and the potential risks involved (i.e. adverse reactions to the vaccine and a possible increase in spread in the community of non-vaccine strains of the organism which could well be less sensitive to antibiotics than the local strains prevalent in the community) Secondly, though the authors have mentioned that individual informed consent was taken but nowhere is it indicated how many villagers declined to consent to the trial. One presumes from the data that all agreed to the trial (a rather strange situation). No wonder such docile populations are happy hunting ground for researchers.

**Beneficence (benefit to study participants and society)**

The present trial belongs to the category of investigation in which the intervention (PCV-7) is given to people who are not suffering from any illness. In such trials, the intention should be to benefit an individual by protecting him from a future hazard. According to the present medical consensus, infants are the main target group of PCV4. To date there is no evidence that conjugate vaccines are as, or more immunogenic than polysaccaharide vaccines in adults. Also there is currently insufficient evidence to suggest whether conjugate vaccine (PCV-7) will be superior to the 23-serotype polysaccharide vaccine in healthy children over 5-years old.5 The wider serotype coverage of the polysaccaharide vaccine (containing 23 serotypes) might be more appropriate in children older than 5 years, and in adults where indicated because, the serotypes covered by the PCV-7 are responsible for a smaller proportion of pneumococcal disease in these older groups.

**Benefit to study participants**

In view of the different serotypes responsible for majority of pneumococcal diseases in older children and adults, in the present study, all participants older than 5 years who were given the intervention, i.e. PCV-7, would not derive any worthwhile benefit from the vaccine. So the study violates the ethical principle of possible beneficence to the participant.

**Benefit to society**

Even if the conjugate vaccine were to be used in the population in which it is indicated i.e. children below 2 years, one has to work out the economic evaluation of such a policy. Vaccine cost-effectiveness is dependent on many factors, including the incidence of disease, the efficacy of the vaccine, the sequelae of the disease, and the cost per dose of the vaccine, as worked out by Lieu et al.5 The analysis was based on comparison of "vaccination" with "no vaccination," assuming use of four doses for routine vaccination of healthy infants and one dose for catch-up vaccination of children older than 2 years. In addition, the conservative assumption was made that a vaccinated infant would experience reductions in pneumococcal infections only until the fifth birthday, and that vaccine efficacy against invasive disease would decrease from

100% in children less than 2 years old to 93% in children 2 to 5 years of age. The cost-effectiveness of conjugate vaccines, from the perspectives of both society (medical and non-medical costs) and health care payers (medical costs only) were calculated. From the societal perspective, vaccination of healthy infants would result in savings if the vaccine cost $46 or less per dose. From the health care payer perspective, net saving would occur if the vaccine cost $18 or less per dose. It is unclear at this point whether these costs per dose can be achieved. As of 2001, the private sector cost for conjugate vaccine was $58.75 and the public sector cost was $45.99.6 At these prices, a full series of conjugate vaccine is much more expensive in the United States than two other new vaccines, the vaccines against varicella and hepatitis A. Moreover, in most developing countries like Gambia where the study has been carried out, a single dose of conjugate vaccine would substantially exceed the total cost of administering the nine antigens currently in use during the first month of life.

According to the Helsinki declaration, medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research. Every medical research study involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and communities involved in the research in comparison with foreseeable benefits to them and to other individuals or communities affected by the condition under investigation

Judged against these criteria, the present trial offers no real benefit either for the study participants or for the society in a poor country such as Gambia with competing health priorities.

Non-maleficence (do no harm)

The Helsinki declaration states that, physicians may not participate in a research study involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians must immediately stop a study when the risks are found to outweigh the potential benefits or when there is conclusive proof of positive and beneficial results. Medical research involving human subjects may only be conducted when the importance of the objective outweighs the inherent risks and burdens to the research subjects.

In the present study, whole communities have been subjected to mass vaccinations targeted at an age group least expected to benefit from the vaccine. Earlier studies including mathematical modelling and animal challenge data suggest that, for conjugate vaccines, like PCV-7, serotype replacement may occur after conjugate vaccination.7, 8, 9, & 10 Non-vaccine serotypes may or may not prove to be virulent when competition from vaccine serotypes is removed, and virulence may change in response to vaccine-induced selective pressure.4 Thus it is important to be vigilant whenever there is widespread use of a conjugate vaccines, where only a small fraction of the known strains are covered by the vaccine. Such vaccination programs require careful monitoring to determine whether serotype replacement is occurring in carriage of the disease-causing organisms and disease-related strains.

Because of these potential hazards associated with serotype (strain) replacement, caution has been advised in carrying out additional efficacy trials of pneumococcal conjugate vaccines, like PC-7, as such trials would be ethically questionable in developed countries.4 However, these cautions have been fully ignored when contemplating the present trial in a poor country such as Gambia. To add insult to injury, the subjects chosen for the study (older children and adults) do not derive any benefit from the PCV-7 vaccine as this vaccine is not indicated for this age group (since only 7 serotypes are covered). Currently, older children and adults are better served, where indicated (e.g. those who have undergone splenectomy) by the polysaccharide vaccine incorporating 23 serotypes.

Another issue was that, within the short follow-up period (which was further truncated by the mass administration of Azithromycin administration as a part of an attempt to control trachoma, a bacterial eye infection caused by infection with the bacteria Chlamydia trachomatis) repeated cross-sectional study did not show an increase in non-vaccine serotypes in the community. However, the shortness of the follow-up period and the biasing use of the antibiotic Azithromycin cannot predict the long-term changes in serotype patterns and virulence that, based on U.S. experience, are known to have occurred.

Equity or justice

The goals of research should always be secondary to the wellbeing of the participants. The Helsinki declaration states:

Concern for the interests of the subject must always

prevail over the interests of science and society...every patient – including those of a control group, if any – should be assured of the best proven diagnostic and therapeutic method.

Researchers sometimes may feel that obtaining an answer to the research question is the primary ethical obligation, so that they then "find themselves slipping across a line that prohibits treating human subjects as means to an end. When that line is crossed, there is very little left to protect patients from a callous disregard for their welfare for the sake of research goals."11 This has raised debates about possible "scientific imperialism" characterised by the performance of trials, sometimes with lower ethical standards, in communities which are unlikely to be benefited from the findings (like in the present study). These concerns have been expressed as: are poor people in developing countries being exploited in research for the benefit of patients in the developed world where subject recruitment to a randomized trial would be difficult?12 The reasons stated for conducting research in Africa rather than developed countries are lower costs, lower risk of litigation, less stringent ethical review, the availability of populations prepared to give unquestioning consent, and, tellingly, anticipated underreporting of side effects because of lower consumer awareness... in some experiments in developing countries it is difficult for patients to refuse to participate...participation in a trial may be the only chance of receiving any treatment.

The basic principle of equity is neatly summarized in the following exchange: 'Mr Ederer: "If you could give only one bit of advice to a clinician planning a clinical trial, what would you tell him?" Dr Davis: "A one word answer might be 'don't. If you are determined to do it, my advice would be from the beginning put yourself in the patient's position and develop the protocol so you would be happy to be one of the subjects. If you cannot do that, you'd better not start."13

As a corollary, in situation such as the present trial, to ensure equity, such community trials should be designed to concomitantly recruit, and conduct the trials, in communities in both the developed and developing nations, so that all ethical doubts about inequity and injustice towards the poorer countries are laid to rest. If the communities in the developed world do not agree to the trial or the individuals there do not give informed consent – it would be unfair to impose the trial on simple and vulnerable communities in developing countries.

Overview – Ethical issues in pneumococcal vaccine trials

The complex nature of pneumococcal disease presents special technical and ethical problems for evaluating pneumococcal vaccines.14 The most common manifestation of pneumococcal disease is pneumonia. But the burden of pneumococcal disease is difficult to quantify, as the bacteriological cause cannot be established in most situations. In addition, the pneumococcus causes a range of other conditions from meningitis to bacteraemia with fever and otitis media. While gross manifestations such as pneumonia and meningitis may be easy to detect, the more common but and less serious manifestations are difficult to identify as pneumococcal in origin, and as a result, the epidemiology of these conditions in developing countries is poorly understood. To make matters more complex, there are more than 90 different serotypes of pneumococcus, with varying virulence. Existing vaccines are serotype specific, covering the most important 7 to 13 serotypes (for the conjugate vaccines) or 23 serotypes (for the polysaccharide vaccines). Uncertainty as to the true burden of vaccine-preventable disease is a major obstacle to the introduction of pneumococcal vaccines. Future studies should focus on quantifying the vaccine-preventable burden of disease rather than the efficacy of vaccines.

**Types of pneumococcal vaccines.**

Presently, there are three types of vaccines available/under development.

a. Pneumococcal polysaccharide vaccine. These vaccines have been available for 20 years and cover the most important 23 serotypes. They are inexpensive, are only used at present for high risk individuals and the elderly in industrialized countries, are poorly immunogenic in young children, and have uncertain benefit for children in developing countries.

b. Pneumococcal conjugate vaccine. These vaccines have been designed to overcome the poor immunogenicity of the polysaccharide vaccine in young infants. One conjugate vaccine is licensed (7-valent Pnc-CRM, Wyeth's Prevenar) but lacks two important serotypes for developing countries (types 1 and 5) and is expensive (currently $50 per dose for four doses). Newer pneumococcal vaccines cover 9 to 13 serotypes, potentially preventing a larger proportion of pneumococcal disease in developing countries.

c. Pneumococcal common protein vaccine. This new class of vaccines, which is currently under development, aims to prevent pneumococcal disease by raising antibodies against the capsular protein. These vaccines would not have the problem of serotype specificity, as these proteins are represented

on all serotypes. Furthermore, they could be produced relatively simply in large volumes at low cost. At an individual level, the degree of protection offered by these vaccines is likely to be less than for the conjugate vaccine, but their public health impact is likely to be greater.

**General ethical considerations**

The most profitable market for pneumococcal vaccines is in developed countries, paradoxically, where they are least needed. This has potential for serious ethical concerns due to two conflicting goals:
a. to make profits in the developed countries and
b. to make vaccines available in the developing countries at low costs. Many would consider it unethical to evaluate a vaccine in a developing country with the aim of licensure and distribution in the industrialized world. At present, trials of new conjugate vaccines are being conducted in developing countries. This strategy may be motivated in part as a means of bypassing the problem of evaluation in the developed countries, and therefore raises serious ethical issues.

In the Gambia, which maybe typical of many of the poorer countries, rates of pneumococcal disease, pneumonia and mortality are high. However, except for children below 2 years, PCV-7 is not considered ideal or suitable for the country because of its limited serotype coverage, and its unknown value for the prevention of pneumonia in adults. It is not understood, how the present study was allowed in a group of participants comprising whole communities, in which the intervention was of no benefit. On the other hand, it could hypothetically lead to the proliferation of non-vaccine serotypes (serotypes which cause disease in adults) – surprisingly exploring this phenomenon was one of the study objectives!! Perhaps mass drug administration in form of Azithromycin (given for trachoma control) to these communities may have averted a major disaster in form of outbreaks of pneumococcal disease caused by the non vaccine serotypes. Whatever, the actual situation, one fails to understand how different ethics committees approved the study – where there was no benefit whatsoever to the participants and all the risk for harm and adverse events.

Minimizing exploitation An ethical framework for multinational research should minimize the possibilities of exploitation.15 A exploits B when B receives an unfair level of benefits or unfair risks as a result of interaction with A. In the study under consideration, the study participants (B) did not receive any benefit as the vaccine is not indicated in their age group and had potential for all risk (due to increase prevalence of non-vaccine strains, which are more likely to cause disease in the age group they belonged). Perhaps the concomitant mass administration of the antibiotic Azithromycin in a program to control trachoma saved them!!

**Ethical guidelines**

Ethical principles governing research with human subjects have evolved over the years from the Nuremberg Code,16 the Declaration of Helsinki,17and the Belmont Report.18 As enunciated in the Belmont Report, these principles are based on respect for persons (the principle that participation in research is voluntary and requires informed consent), beneficence (the principle that subjects must be protected from harm and that potential benefits must be weighed against the risks incurred), and justice (the principle of equitable selection of research subjects). Drawing on these sources, Emanuel et al15 note that application of these principles has generated controversy in the past because of differences in their interpretation. They suggest that individual ethical principles are rarely absolute and that balancing competing principles require discerning judgment. That resources in many developing countries are limited raises special concerns with regard to exploitation of research subjects, appropriate standards of care, and subsequent availability of measures established to be useful by the studies in question. Perhaps the most important contribution by Emanuel et al's15 paper is the call for dialogue and debate among individuals holding reasonable but differing points of view. Such dialogue is essential if we are to avoid the acrimony and moral absolutism that has sometimes characterized debate in this highly charged arena.19
Comments of others and the response of the authors.
Vashisht and Jain have raised some of these issues in a comment published on the PLoS Medicine web site20
1. They were concerned a trial to investigate emergence of new strains (possibly penicillin resistant strains) was performed in a poor country where villagers may not easily afford antibiotics for the treatment of the consequence – the emergence in the community of penicillin resistant strains. They wonder if it was correct to subject this population to such selection pressures that could have resulted in the spread of penicillin resistant pneumococci in the community.
2. They asked if it was appropriate to vaccinate adults, who are not the primary target of a conjugate vaccine and so with little chance of benefit.

3. They wondered whether informed consent included disclosure of the study-aim to look for strain shifts and an increase in resistant bacteria in the community. They specifically ask how many refused consent to participate in the study
4. Vashisht and Jain were also concerned that the duration of follow-up described in the paper (two years) was too short to detect serotype replacement which sometimes takes 6 years.
Authors Response
The lead author A Roca has responded to the journal to these observations and the comments of Vashisht and Jain.21 The response of the author did not address the ethical question about the appropriateness of doing this study (that risks emergence of potentially new and possibly antibiotic resistant strains) in an economically poor country – namely The Gambia.
The response has clarified that the consent form states “MRC would want to know whether or not there would be changes in the types of this germ in the throat when the vaccine is used in a large scale in the future” and the community consent form stated “Therefore it is important to find out whether or not these other similar germs that are capable of causing pneumonia can replace the germs, which have been eliminated”.

To the pointed question about how many persons felt empowered to refuse consent the author says simply that there were some individual refusals, without specifying the numbers. One has to assume that the answer suggests the numbers were miniscule. The response instead states that vaccine coverage in the vaccinated arm oscillated between 85% and 92%. This in no way answers the question because incomplete vaccine coverage cannot all be attributed to numbers of persons who felt empowered to refuse consent to participate.

To the question of the wisdom of vaccinating adults who were unlikely to benefit but were at risk of harm from replacement strains they were not immune to, Roca quotes a study of the use of 7-valent pneumococcal conjugate vaccine in HIV-infected adults22 and another in elderly adults23 to suggest that all adults would have got some benefits. The benefits in immune-deficient patients with HIV infection and the elderly do not exactly translate to justification for administering the vaccine to all adults.

Further the author says in defence of the study that “that adults who received the pneumococcal conjugate vaccine did obtain some benefit is strongly suggested by our detection of a lower prevalence of carriage of pneumococci of vaccine-type in adults in pneumococcal vaccinated communities”. Here the authors confuse asymptomatic carriage with harm, which is a non-scientific response to the question raised. There is no scientifically or medically sound reason to reduce asymptomatic carriage of a bacterium. On the other hand, the presence of these commensals yields a measure of protection to the individual from more pathogenic strains.

Regarding the duration of the follow-up the lead author of the study in question, agreed that this was too short to be meaningful, but they promises to provide data from a follow-up study. However the validity of such follow-up, after Azithromycin has been given to the community, is questionable.

**Responsibilities of the Ethics Board**

It is interesting that there is no response from the Ethics boards that sanctioned this study where they must take equal responsibility for what was done. This acceptance of responsibility by the Ethics boards who approve studies is currently not the norm, but it should become a requirement in the future. Two ethical boards were involved. The two ethics committees involved in approving the study were: the Joint Medical Research Council (MRC)/Gambia Government Ethics Committee and also the ethics committee of the London School of Hygiene and Tropical Medicine. The question that the ethics committee members should be required to answer is: whether such a study would be considered ethical to be performed in their own countries.

**Conclusion**

There are grave concerns about the ethics of this study. We hope all concerned including the ethics committees involved will take responsibility for what has happened and draw appropriate lessons from it, so that the continued exploitation of poor and vulnerable communities ceases to be perpetrated in the name of medical research.

# Original Study in a Nutshell

The study in a nutshell

**Background:** It is estimated that each year 0.8 million children die of pneumonia particularly in poor countries. The most common agent of pneumonia is

Streptococcus pneumoniae of which there are over 90 serotypes. These organisms may colonise the nose and throat without causing any disease. A few children suffer from invasive disease. Vaccines are available which cover some of the serotypes. Two types of vaccines are commonly in use – the conjugate vaccine which is useful in children under 2 but less useful because they protect against 7 to 13 serotypes only, and a polysaccharide vaccine which cover 23 serotypes but not useful in children under 2 years. The conjugate vaccine given in children under 2 has been successful in reducing the incidence of vaccine strain invasive pneumococcal disease, in both vaccinated children and in the non-vaccinated older population. However widespread use of the 7 valent vaccine in some countries has resulted in an increase in infections with non-vaccine strains (replacement strains) some 6 years later. Some of the replacement strains are resistant to the relatively inexpensive antibiotics like penicillin.

The research question: The investigators wanted to explore whether further vaccine pressure, from mass vaccination with PCV-7 of the whole population (including adults who are not usually the target population for the conjugate vaccine), would cause proliferation of replacement strains in the community.

**Methods:** They performed a cluster randomized trial. PCV was given to all children under 30 months of age. Older children and adults in some communities selected randomly received one dose of PCV-7 vaccine as study drug and control communities received meningococcal serogroup C conjugate vaccine. Cross-sectional surveys to collect nasopharyngeal swabs were conducted before vaccination and periodically after vaccination. Azithromycin (a drug also effective against pneumococcus) was given to this population in an unrelated programme and so this study was truncated after 2 years.

**Findings:** The authors did not find any significant serotype replacement as a result of mass vaccination with PCV-7 over the 2 year study period. The ethical issue considered is whether a trial of this nature, that increases the chances of the spread of resistant strains in the community can be justified in a poor country like The Gambia

# The Context

The social, economic and cultural context

The Gambia is the smallest nation on the continent of Africa, smaller than Connecticut. It is a narrow strip of land on the Western Coast of Africa. It is surrounded by the Republic of Senegal, except for the coastline on the Atlantic Ocean. The country extends about 320 km inland along either side of the Gambia River, but it is only about 32 km wide. Gambia has a hot humid climate, temperature often reaching 43?C. The land is low-lying and largely prone to flooding. Most Gambians are poor and earn their living from farming. They grow rice, maize (corn), sorghum, and peanuts (The Gambia's most important crop and chief export). In recent years tourism has increased. The total population is about 1.7 million. In spite of free primary education, illiteracy remains high.

Economy is characterised by traditional subsistence agriculture, and a historic reliance on peanuts for export earnings. Average wages hover around $ 1 – 2 per day. Agriculture accounts for 23% of GDP and employs 75% of labour force. Mean wages were around$ 0.57 per man hour in 2009 with 61% below poverty line. A Gini coefficient of 0.5 indicates inequitable distribution of health care and other resources. Infant mortality rate over 70 per 1000 live births indicates the poor health status of the country. Short run economic progress remains highly dependent on sustained bilateral and multilateral aid.
Of the different Negro tribal groups which make up the greater part of The Gambia's population, by far the largest group are the peanut-farming Mandingo (40%), next are the cattle-raising Fulani(13%). In recent decades there have been political upheavals and there have been curbs on journalists. Reporters without Borders have accused the government of human rights violation.

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