# Driving after a first seizure

## New evidence supports the relaxing of the rules

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**RESEARCH, p 1260**

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The number of people killed or seriously injured in road accidents in the United Kingdom is low by international standards—about 27 000 in 2009.[1] Part of the reason, albeit one that is difficult to quantify and probably not very large, is that some people are prevented from driving on the basis of their medical condition, a regulatory function carried out by the drivers' medical group of the Driving and Vehicle Licensing Agency. This group also publishes and regularly updates the At a Glance Guide to the Current Medical Standards of Fitness to Drive,[2] which sets out the rules. The linked study by Bonnett and colleagues provides data on the risk of recurrence after a first seizure and the implications for driving.[3]

Driving restrictions may be imposed because of a fixed disability (such as after head injury), a progressive disability (such as dementia), or an intermittent disability (such as epilepsy). For all disabilities, and particularly epilepsy, the size of the risk that society is prepared to take needs to be decided and weighed against the rights of the individual to drive and be mobile. In the past few years the Driving and Vehicle Licensing Agency's neurology panel decided that anyone with an estimated risk of an epileptic seizure, or any other kind of sudden unexpected "attack," of more than 20% (or more than 2% for a heavy goods vehicle licence) in the next 12 months should not hold a driving licence. This does not and cannot take account of how much time the person is likely to spend driving or how likely a future event is to cause the driver to lose control of the vehicle during that event.

But how can the risk of an intermittent disability, such as epilepsy, be estimated? It cannot be done by reacting to unusual events as happened in the 1930s after a man with epilepsy had a seizure at the wheel that caused him to drive into the crowd watching the Changing of the Guard at Buckingham Palace, killing an onlooker. This resulted in epilepsy being the first medical condition to be declared an absolute bar to driving. Nor as in the 1960s when this draconian rule was relaxed after a driver with undeclared epilepsy crashed into the car of Barbara Castle who was the minister of transport at the time. Robust data are needed to estimate the future risk of a seizure, which is where Bonnett and colleagues' study is useful.[3]

The authors selected adults with just one seizure at baseline from a large completed randomised controlled trial of immediate versus deferred treatment for newly presenting unprovoked seizures. These people are probably representative of patients who present to UK neurology clinics after a first seizure, inevitably after the very early risk of a recurrent seizure has passed. It can also be assumed, although with less certainty, that during follow-up any further seizures were recognised and reported by the patients. Notwithstanding these caveats, it is reassuring that for those who started antiepileptic drugs within six months of the initial (single) seizure the risk of another seizure over the subsequent 12 months was below 20% (14%), as was the upper 95% confidence interval of that estimate (18%). But not everyone wants to or should start antiepileptic drugs after a single seizure. For those who did not start treatment, although the 12 month risk was still below the 20% cut off (18%), the upper confidence interval was 23%; if the clock was started at 12 months rather than six months after the first seizure, however, even the upper confidence interval was well below the 20% cut off (at 15%).

Currently, patients who have had a single unprovoked seizure (whether taking antiepileptic drugs or not) are banned from driving for six months; this was reduced from 12 months in 2009. The rule applies to patients who have no clinical factors or investigation results that suggest an unacceptably high risk of a further seizure (20% or greater in the next 12 months) but it does not specify what these might be.[2] So, is this rule reasonable? There are no other data to go on; indeed, the Liverpool risk estimates are the first available to help us decide who should and should not be allowed to drive.

The decision is ideally up to society, presumably through elected representatives, but how well do they understand that estimates of risk have confidence intervals? How often does an epileptic seizure actually cause an accident? And how well do doctors understand the complexities of multivariable analysis and prognostic models to estimate risk in individual patients. Such models are unlikely to be available in practice or indeed affordable by the Driving and Vehicle Licensing Agency in the near future. Bonnett and colleagues have made a start on risk modelling, but they recognise that external validation is necessary before prognostic models are used in practice.

Finally, everyone should realise that data from randomised controlled trials (and large observational cohorts) can, as here, be used years later and still be useful for public health, provided there is sufficient funding to do the work.

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# Drug treatment for users of smokeless tobacco

## Varenicline has the strongest evidence base but is not yet licensed for this indication

RESEARCH, p 1259

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The linked randomised controlled trial of varenicline reported by Fagerström and colleagues is the first to show that a drug can help patients who do not smoke but are dependent on smokeless tobacco to give up their habit.[1] The participants were dependent on "snus", moist smokeless tobacco that is placed under the upper lip and sucked. The trial found that varenicline significantly increased abstinence at the end of treatment compared with placebo (weeks 9-12: 59% *v* 39%; relative risk 1.60, 95% confidence interval 1.32 to 1.87; number needed to treat 5). The benefit was still significant at follow-up 14 weeks after the end of treatment. Adverse events resulting in treatment discontinuation were of similar frequency (varenicline 12%, placebo 8%).

Although banned in the European Union, snus is widely used in Sweden and Norway. Other forms of smokeless tobacco are chewed or inhaled. Although the popularity of smokeless tobacco varies by region, it is used worldwide—a prevalence of 20% is reported in India and, in 2005, 7.7 million Americans were users.[2]

Increasing evidence shows that the partial nicotinic agonist varenicline is as good as or better than nicotine replacement or the antidepressant bupropion in helping people to stop smoking.[3] People who use smokeless tobacco absorb similar amounts of nicotine and have similar levels of dependence as those who smoke. This is the rationale for treating smokeless tobacco use with drugs that attenuate nicotine withdrawal. A systematic review of randomised trials found that, as with smoking, advice to stop and behavioural interventions can help users of smokeless tobacco to quit.[2] The review found no effect of nicotine replacement or bupropion, both of which have been shown to increase quit rates in patients who smoke.

Why should varenicline reduce smokeless tobacco use when nicotine replacement and bupropion do not? Chance is one possible explanation. The systematic review found no significant effect of either treatment on quit rates after six months, but the number of participants included in the meta-analysis was small.[2] The confidence intervals do not exclude benefit—indeed they overlap with the confidence intervals reported by Fagerström and colleagues for varenicline.

Another possibility is that the pattern of nicotine intake with oral absorption may be different from that for smoking, and that this pattern responds to the mixed agonist and antagonist effects of varenicline on nicotine receptors. History suggests that chance is more plausible than a mechanistic explanation—the effects of nicotine replacement for smoking cessation were similarly uncertain before increasing numbers of trials enabled a reliable meta-analytical estimate of its effect.

What is the reason for helping people to stop using smokeless tobacco? The evidence about its health effects is conflicting, although it is certainly less dangerous than smoking. Systematic reviews found inconsistent evidence of links with cancer and cardiovascular disease.[4-6] A recent cohort study of Swedish men found that snus was associated with a relative risk of 2.0 for pancreatic cancer, but that it had no effect on the risk of oropharyngeal cancer.[7] Compared with snus, other forms of smokeless tobacco contain higher concentrations of carcinogenic nitrosamine, and thus may carry a higher risk of oropharyngeal cancer. In the absence of strong evidence of harm snus has been, albeit controversially, proposed as an aid to smoking cessation.[8] A survey of Norwegian smokers found that snus was more widely used by male smokers seeking to quit than medicinal forms of nicotine replacement, even though it is not promoted for this use in Norway.[9] People who quit using snus were, however, more likely to continue use after stopping smoking than those using medicinal nicotine replacement. Therefore, one reason for treating people is to help them break an unwanted dependence, even if the physical benefits of quitting are not well defined.

What are the clinical implications of this new trial? Few doctors in the United Kingdom will have encountered patients who use snus, and many may never have been asked by a patient to help with dependence on smokeless tobacco. In the UK, smokeless tobacco is used in the form of quid (chewing tobacco mixed with areca, slaked lime, and betel), mainly by members of the Bangladeshi community.

In the 2004 health survey for England, 9% of men and 16% of women from this community reported chewing tobacco.[10] Trials of varenicline in people who chew tobacco are in progress in India and the United States. Pending results of these trials, it is reasonable to assume that the effects seen in snus users will translate to other forms of smokeless tobacco. For those working in communities where use of smokeless tobacco is high, it is sensible to ask about its use and to advise quitting.[11] When considering drug treatment for patients who smoke and use smokeless tobacco, varenicline is the treatment with the strongest evidence base. Although we now have evidence that varenicline may help users of smokeless tobacco who do not smoke, it is not licensed for this indication. Guidance from the National Institute for Health and Clinical Excellence on treatment of smokeless tobacco use is in preparation and is expected by 2013.

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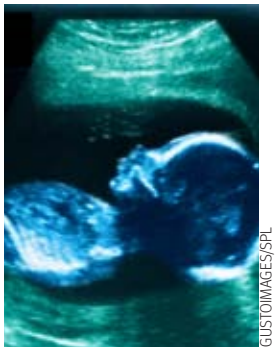
# Carbamazepine in pregnancy

## Has the best safety profile, and is therefore the drug of choice



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RESEARCH, p 1261

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Epilepsy is the most common neurological disorder seen in pregnant women. It often needs drug treatment, and it causes complications in about 0.25% of all pregnancies. Seizure control is the primary goal when treating a convulsive disorder. Epilepsy itself is not associated with an increased risk of major congenital malformations,[1] although some risk cannot be excluded. All first line antiepileptic drugs, such as valproic acid, carbamazepine, and phenytoin, are associated with a twofold to threefold increase in rates of major congenital malformations compared with the general population. In the linked review of observational data, Jentink and colleagues assessed major congenital malformations associated with the use of carbamazepine in the first trimester of pregnancy.[2]

The benefits of seizure control during pregnancy should not be underestimated. For many pregnant women, discontinuing antiseizure drugs is not an option. The choice of drug is challenging to patients and doctors because of the conflict between the optimal treatment of the mother and the wellbeing of the fetus. Women should plan their pregnancy, receive evidence based prenatal counselling, and be given the safest antiepileptic drug.

Several factors make the reproductive safety of antiepileptic drugs difficult to assess. It is hard to attribute congenital abnormalities to any single factor because of the interaction between genetic and environmental components and the lack of studies with sufficient power to control for them. Although a randomised controlled trial would provide the most reliable evidence, it would not be ethical. High quality observational studies are therefore the best source of evidence.

Carbamazepine is efficacious in the treatment of a variety of epileptic seizures and is widely accepted as the drug of choice in pregnancy. Large population based studies and registries have reported that rates of major congenital malformation after exposure to carbamazepine are almost the same as those in the general population. The Swedish medical birth registry reported an odds ratio of 1.86 (95% confidence interval 1.42 to 2.44) for having a major congenital malformation in those exposed to antiepileptic drugs.[3] Monotherapy with valproic acid compared with carbamazepine gave an odds ratio of 2.51 (1.43 to 4.68). Recently the North American registry found that the prevalence of malformations associated with carbamazepine monotherapy was 2.6%,[4] similar to that of the general population (1-3%). The United Kingdom epilepsy and pregnancy register reported an absolute rate of major congenital malformations of 2.2% with carbamazepine, 3.2% with lamotrigine, and 6.2% with valproic acid compared with 3.5% in untreated women with epilepsy.[5] On the basis of this report, the American Academy of Neurology and American Epilepsy Society subcommittee concluded that in utero exposure to carbamazepine does not substantially increase the risk of major congenital malformations in offspring.[6] The committee reported that there was no association between carbamazepine dose and major congenital malformations rates, but that the drug contributes to the risk of a posterior cleft palate.

Despite their importance, long term neurodevelopmental outcomes have received little attention. A systematic review found insufficient evidence to differentiate between the long term neurodevelopmental outcomes associated with different antiepileptic drugs.[7] Two subsequent studies found that valproic acid has a clear, dose dependent, adverse effect on children's neurodevelopment,[8 9] whereas six studies found no impairment of cognitive functions in children exposed to carbamazepine monotherapy.[10]

Jentink and colleagues reported the results of a review of all published cohort studies and a population based case-control study using the EUROCAT database. They compared carbamazepine monotherapy with five "signals of specific congenital malformations" derived from combined published cohort studies "as cases." They found no significant association between carbamazepine and cleft palate (odds ratio 1.3, 0.4 to 4.1), diaphragmatic hernia, hypospadias, and total anomalous pulmonary venous return (no exposed cases were found). Only spina bifida was significantly associated with carbamazepine monotherapy (2.6, 1.2 to 5.3), when compared with unexposed controls.[2]

Jentink and colleagues confirmed that carbamazepine is associated with a specific pattern of malformation: spina bifida. Although the study found a rate of neural tube defects that was 2.6 times higher than the general population rate of 1:1000 births, the absolute risk is still small. This should be clearly communicated to pregnant women and care providers. Importantly, carbamazepine has not yet been found to impair children's long term neurodevelopment, an outcome that cannot be screened prenatally.

Proper prenatal counselling and the recommendation of folic acid supplements may help to prevent major congenital malformations.[11] The screening tests used, which include α fetoprotein in maternal blood and two dimensional or three dimensional ultrasound, are highly sensitive for the prenatal diagnosis of neural tube defects. Detection rates for some of these defects approach 100%.[12]

Patients should be informed and understand the risks associated with uncontrolled seizures and the teratogenicity of anticonvulsive drugs. Of all the anticonvulsant drugs, carbamazepine is associated with the lowest rate of morphological defects and has not been found to be neurotoxic. Carbamazepine should therefore be considered the drug of choice in pregnancy. Proper seizure control and judicious perinatal counselling and management will produce favourable outcomes in more than 95% of pregnancies.

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# The new public health strategy for England

## Has great potential but implementing it will be challenging

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The government's new public health strategy for England, *Healthy Lives, Healthy People*,[1] is a welcome commitment to protecting and improving health and reducing health inequalities. Action is clearly needed. Although people are generally living longer, the overall burden of chronic physical and mental ill health is increasing,[2] and the poor are worse off than the rich. If, as some have predicted,[3] the recent comprehensive spending review affects the poor more than the rich, this is likely to be exacerbated.[4]

The strategy, which promises to be radical and new, is evidence based and rooted in an approach that engages and integrates the efforts of national and local government, the NHS, charities, schools, higher education, voluntary groups, businesses, and employers. The strategy accepts a place for government leadership and, albeit when other approaches have failed, for regulation. However, it takes the view that the balance of responsibility and action should shift from central government to local communities, and that people should be "nudged" towards taking on more responsibility for their health by living more healthily. A cabinet subcommittee has been established to engage relevant government departments, and the strategy includes an encouraging list of related initiatives.

In the spirit of national engagement, county and unitary local authorities will employ the local directors of public health and their staff and will be given increased powers and responsibilities for health, supported by ring fenced public health budgets. Local authorities will be required to set up multiagency health and wellbeing boards to review local needs and coordinate responses, informed by their director of public health's independent annual report. A new organisation, Public Health England, will be established within the Department of Health and will combine the current functions of the Health Protection Agency, National Treatment Agency, and regional public health teams and observatories, together with some existing national policy and response functions. Directors of public health will be "jointly appointed" by and accountable to the local authority and the secretary of state for health through Public Health England, and they will work at the interface of national and local agendas.

The aim of these reforms is to place public health leadership and expertise at the heart of local and national decision making. Opportunities for making a sustained impact on health exist but the risks are high. Local authority budgets are under pressure, and the current changes must take place alongside what is arguably the biggest NHS reorganisation since 1948. Successful public health work depends heavily on effective working relationships between key local players and on a clear understanding of local contexts. The new arrangements will take a while to achieve their full potential, during which time serious disruption to public health activities could occur. The implementation timetable extends over more than two years. Local authorities' budgets will not be ring fenced until 2013, and despite the government's expressed intent to protect public health, cost reductions that are currently being implemented through existing systems could result in a greatly depleted public health workforce before then.

Public health is "the science and art of protecting and promoting health and wellbeing, preventing ill health, and prolonging life through the organised efforts of society" (www.fph.org.uk/what_is_public_health). It takes a multifaceted approach and a societal perspective, and it must be rooted in coherent coordinated action that is focused on the population rather than the individual. Some public health initiatives, such as slum clearance and ensuring clean air and water, work exclusively at a population level. Others, such as those targeting smoking or infectious disease, require a suite of synergistic interventions from government regulation to clinical advice and treatment. The good health of the population requires action in each of the three "domains" of public health: health protection, which is concerned with infectious disease, disasters, and environmental hazards; health improvement, which deals with lifestyle and the wider determinants of health and wellbeing; and the provision of effective, appropriate, and accessible health services.

Although the new strategy acknowledges the importance of the healthcare domain to public health it makes few solid proposals. A public health outcomes framework which is, as proposed, separate from those for the NHS and social

care, is unlikely to stimulate collaborative working unless outcomes are common to all three. The strategy recognises and encourages primary care's contribution to the public health agenda but says little about the enormous potential contribution of other medical specialties. The new general practitioner commissioning groups will need public health advice, and directors of public health will be expected to support them. Detailed arrangements will have to be negotiated soon, at a time when the local public health landscape will be far from clear.

The director of public health, sitting at the local authority's top table and working closely with colleagues from the NHS, other authorities, and the private and third sectors, should be a powerful force driving changes that improve people's health. However, they will have limited power if their position is too junior and if they have few supporting staff. The strategy is, so far, silent on the nature and scale of the infrastructure likely to be available to directors of public health. The success of local initiatives could be enhanced greatly if the proposed national "responsibility deal" between government and the private sector has tangible relevant outcomes. Precious time could be wasted and confidence lost however, if—as seems to have happened in the United States[5]—industry does not take its voluntary agreements seriously.

Will the strategy achieve its overall objective of streamlining the system and providing a "clear line of sight" from the government to the front line in emergencies? As yet, it is not clear who is accountable and who will be in charge in the new system, particularly regarding health protection issues, where success depends so heavily on clarity of responsibility. Further discussion is urgently needed.

*Healthy Lives, Healthy People* has huge potential. But the step changes it is hoping for will depend on determined implementation and strong leadership, sustained over time, and on each individual being inspired and enabled to make his or her own contribution.


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# Training programmes in global health

## New guidelines outline best practice and the ethics of working abroad

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On 30 November, the Working Group on Ethics Guidelines for Global Health Training (WEIGHT) published guidance for institutions, trainees, and sponsors of field-based global health training on ethics and best practices in this setting.[1] The working group included a wide swath of trainees in their discussion, from students to postgraduates, who might go abroad for days, weeks, or up to one year of training before returning home. The benefits for trainees include inspiration, education, and career guidance; for institutions, they include building overseas partnerships and recruitment of trainees (box).[1] The risks include burdens on the host institutions, failure to compensate host institutions for costs incurred on behalf of trainees (especially relevant for low resource institutions), the use of underqualified trainees, and competition between trainees for mentorship or co-author opportunities (box).[1] Although short term exchanges of trainees may occur between institutions, higher resourced universities or hospitals invariably send more short term trainees abroad than lower resourced institutions.

The challenge of implementing guidelines is that the people and institutions for whom they are intended often assume that the guidelines do not apply to them, especially when costs are involved. The WEIGHT report argues that trainees going from an institution in a high income country to one in a lower income country should take funding with them. This is because university fees or tuition fees are collected by the home institution, but a host institution is providing the short term training free of charge; an appropriate fraction of that tuition money should, fairly, go to the host institution. If no such arrangement exists, then the host should receive other explicit and agreed benefits that justify the investment of time and effort for trainees. The report articulates these issues, from both the institutions' and the trainees' perspectives.[1]

The guidelines highlight that adult education should be based on certain key principles.[1] Among these is the need to learn through experience, because this creates deeper understanding and self awareness. Learning through experience emphasises the learning process, so that healthcare students and teachers develop applied skills and critical thinking capabilities that are suitable for the circumstances facing the healthcare professional in the workplace.[2]

International educational exchanges may include internships, preceptorships (training through professional mentorship or supervision), clinical rotations, service learning (integrated community service with academic learning), and other forms of "on the job" training.[3] Encountering and solving field based problems during such forms of learning mean that students link teaching to practice. Cross national training can engender mutual cultural and ethical understanding, which is essential to the training of global health professionals. One of the largest and most compelling studies on medical internships recently found that medical students who have engaged in cross national training are more able to treat patients from diverse backgrounds.[4] Experience based education in global health serves to increase the knowledge and self efficacy of local populations who are being served.

A key focus of the WEIGHT guidelines is cultural competency, which refers to a person's ability to function effectively and appropriately within a particular social, linguistic, and religious environment.[5] However, few measures can assess a trainee's preparedness for or ultimate proficiency in cultural competency. Compounding this challenge, institutions often

**Benefits and risks to trainees and institutions of global training programmes**[1]

**Benefits**

Inspiration for trainees:
- Care for the poor, ethnic minorities, and the underserved
- Embrace primary care medicine
- Improve diagnostic and interpersonal skills
- Volunteer in humanitarian work
- Consider global health careers
- Long term commitments to tackling the challenges that they confronted in their training
- Appreciate interdisciplinary and multidisciplinary approaches
- Engage in a different cultural milieu

Education for trainees in the following areas:
- Specific topics, such as tropical and neglected diseases; HIV, tuberculosis, and malaria; chronic diseases; diseases of poverty; maternal and child health
- Socioeconomic issues in health
- Foreign languages
- Cultural competency
- Diagnosis, treatment, and clinical monitoring

Cost effectiveness of various medical or public health strategies:
- Recruit trainees interested in global health
- Benefit from programme appeal to funders or philanthropists
- Meet trainee demand
- Build partnerships with overseas institutions
- Enhance research or service with short term trainee labour
- Partner trainees from high income nations with those from lower income nations with the aim of sharing experiences, training each other in areas of personal competence, and building friendships across nations

**Risks**

Burden on hosting institution:
- Host may provide training without reimbursement for time
- Host may use resources intended for local trainees
- Visitors may provide health services without proper credentials
- Extra trainees may crowd ward rounds or other settings
- Trainees may get sick (physically or mentally) and need care

Risks taken by home ("sending") institution:
- Trainees may engage in high risk activity overseas—for example, risky vehicular travel, sexual activity, or failure to take prophylactic antimalarial drugs
- Trainees may fail to secure protective services for travel—for example, vaccinations, necessary drugs, and condoms

Unbalanced relationships between institutions:
- Higher income trainees go overseas without reciprocity
- Tuition or faculty salary support retained by home institution
- Poor sustainability
- Ethical review may be inconsistent with that of the institution in the home country
- Trainee may not be competent to communicate effectively with patients, staff, or community members
- Problems regarding the research trainee's expectations about authorship and competition for credit with local trainees or investigators
- Negative impact on patients when visiting trainees are underqualified

have too few people qualified to teach cultural skills for a given societal context. Some programmes have little or no pre-orientation preparation, and trainees end up learning the local culture "on the ground." Although cultural competency is a process, [6-8] learning local customs through trial and error may reflect poorly on the home and host institutions, and, most importantly, can compromise patient care.

The guidelines propose that training to improve cultural competency should begin at the home institution and should encompass cultural awareness of the trainee's own background and perspectives; cultural knowledge of the group he or she plans to serve; encouragement of the trainee's desire to learn and respect a different worldview; and the skills necessary to take a patient history or personal narrative from someone with a different cultural background.[6 9] Once training in a foreign location has begun, trainees should continue to hone their skills and beliefs through individual and collective encounters.[6] Partnering local and foreign trainees at host institutions can facilitate this process.

Institutions and trainees in higher income nations should try to deal with these problems when sending short term trainees abroad. Perhaps an ideal model to follow is the Fogarty International Center's International Clinical Research Scholars and Fellows program (FICRS-F, www.fogartyscholars.org).[10] In the component of this programme that covers students, each US predoctoral scholar is paired to a counterpart from one of the 25 institutions in the 23 participating developing countries. Both US and foreign trainees receive training at the National Institutes of Health, stipends to enable protected time in research venues in the developing country they will work in, and modest support for their work. Resources are provided to support the host institution, acknowledging the expenses incurred in the support of trainees. Of the 475 trainees in the seven annual cohorts that have been supported by this programme to date, half have come from the host developing nations.

"Parachute research" refers to the resource rich investigator who comes to a developing country, "parachutes" in for a research study, extracts the data needed, and returns home. This investigator does the data analysis and laboratory work back home and builds little to no local research capacity. Such models of "collaboration" are now acknowledged to be inappropriate, as investigators and institutions in developing countries have spoken out for fairness and benefit to their institutions and communities.[11 12] Avoiding superficial "parachute training" with true partnerships between home and host institutes depends on mutual efforts and fair agreements that result in mutual benefit.[13]

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