In an open letter to Guido Rasi, director of the European Medicines Agency, the AllTrials campaign urges the EMA to revise its trial data policy or risk losing the trust of patients and healthcare professionals.

**There is no good reason to introduce barriers to access clinical study reports, as the agency’s draft policy does**

- Excluded from even voluntary codes of practice.
- The “Redaction Principles” policy asks sponsors to submit two versions of a CSR from each trial: a standard version (CSR(a)) and a redacted version (CSR(b)). While this might be driven by a desire to lower the costs of transparency for the agency, it puts primary responsibility for redacting in the hands of sponsors. How close CSR(a) is to CSR(b), and which parts are missing, may never be known to researchers granted access to CSR(b). Will there be an audit to explore whether redactions are proportionate or risk patient safety, and will there be penalties for excessive redactions?
- The Terms of Use contract contains clauses that seem to prioritise trial sponsors’ legal rights over researchers’ need to scrutinise and use information from CSRs to improve the evidence base for patient care. These supposed rights given to sponsors have never been established in law and are currently being debated in court cases in which the agency is involved. Of greater concern, researchers will be asked to agree to a clause that allows trial sponsors to take direct legal action against the researcher for possible violation of the terms of use. Individual researchers are therefore being made vulnerable to protracted legal battles with large companies for infractions to these cumbersome rules. Since the rules themselves are poorly specified, these cases are likely to involve lengthy legal discussion. They will therefore introduce a new and unpredictable risk of high legal costs into routine academic work, effectively chilling researchers’ ability to use information relevant to patient care.
- You have probably heard from some quarters that information from clinical trials is confidential in law. We know you agree that allowing independent researchers to be free to scrutinise CSRs will have huge benefits for patients, doctors, pharmacists, regulators, and researchers and that these will inform treatment decisions now and decisions about future research.

AllTrials is a campaign for all clinical trials to be registered and results reported. It is supported by more than 78,000 people and 470 organisations worldwide. The numbers of European citizens and organisations supporting it are growing every day—and will continue to grow and press for change. We ask you to revise the policy to reflect your earlier support for the public interest in better medicine. We are entering a new era of medicine, one where medical practice is based on evidence that is openly available and critically appraised rather than on edicts and eminence. If the EMA allows its new policy to be based on out-of-date attitudes it risks losing the trust of patients, policy makers, and healthcare professionals. We urge you to revise your policy to reflect your earlier support for the public interest in better medicine.

Ben Goldacre research fellow in epidemiology, London School of Hygiene and Tropical Medicine; Fiona Godlee editor in chief, The BMJ; Carl Heneghan director, Centre for Evidence based Medicine, Oxford; David Tovey editor in chief, Cochrane Library; Richard Lehman general practitioner, Oxfordshire; Iain Chalmers coordinator, James Lind Initiative; Virginia Barbour medicine editorial director, PLOS; Tracey Brown managing director, Sense About Science.

**Correspondence to:** AllTrials campaign, c/o Sense About Science, 14a Clerkenwell Green, London EC1R 0DP, UK alltrials@senseaboutscience.org

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- Click on the data supplement to the online version of this article to read the response of Guido Rasi, executive director of the European Medicines Agency.

- Find out more about The BMJ’s open data campaign at bmj.com/open-data
LETTER FROM NEW ENGLAND  David Loxterkamp

Life after work: a doctor’s lonely hearts club

Social isolation is a substantial problem among older people, and helping them to overcome it may be as important as support for controlling diabetes or stopping smoking.

They shuffle into our cramped conference room this Monday morning, the nine members of the “life after work” group. They have arrived at my invitation (I am not only their doctor but their group facilitator). Today’s theme is “friendship,” and for some of the artists, journalists, teachers, line men, and managers in the room, it is in short supply. They have been coming for weeks now to explore what lies over the cliff of retirement, and what is left of them after the hat and coat of their career are hung at the door. What they don’t know is that I have no answers, and that they assuredly do.

Over the years, I have listened to male patients in this blue collar community grumble about troubles at home, boredom, loss of friendship, and the aggravations of ageing. Who, I would ask, did they commiserate with? For most, it was no one. Work had narrowed their social circles; few had hobbies, and there was no time or occasion to chum with friends. Retirement, it seemed, posed a bigger threat: reducing their income, peer group, and sense of direction and purpose in life.

I knew that social isolation and loneliness were associated with increased mortality. And I could see their adverse effects on the quality of life of my patients. So I sent an email to men aged 65 to 75, inviting them to join a conversation group. The first 10 respondents would be included in a nine session “course” on the issues of ageing. Membership filled immediately.

Our sessions began with a poem, followed by a “check-in” that allowed each member to reflect on his previous week. Then discussion around a chosen topic: family, community involvement, medical concerns, living wills, legacy. We had tears, anger, frustration, a comparing of each others’ predicaments, bonding through a sense of shared struggle and common space, and gratitude for the companionship more than the advice.

Before the work of Andrew Steptoe and colleagues, it was thought that both social isolation and loneliness were associated with increased risks of mortality related to heart disease, high blood pressure, infectious disease, cognitive decline, and a higher inflammatory response to stress. Social isolation is a quantifiable condition of a few social contacts and infrequent interactions. Loneliness is the perception that one has fewer meaningful social contacts than desired and is intensified by poverty, depression, and poor health. Although social isolation and loneliness intermingle, Steptoe’s landmark paper in 2013 showed that only social isolation increases the risk of mortality (hazards ratio 1.26) after demographic factors, baseline health status, mobility, and depression are controlled for. He followed over 6500 men and women in the English Longitudinal Study of Ageing from 2004-12.

Steptoe found equal rates of social isolation in men and women, but higher rates among those who were older, unmarried, less educated, and poorer. Social isolation was seen more among people with chronic disease, including depression, while loneliness was a condition found more often in women.

Studies have long shown that one tenth of the population aged 65 and older feels intensely lonely. This number has remained stable over the years, ebbing slightly as seniors age. Not surprisingly, people with more friends are less likely to experience loneliness; curiously, the number of family members has no effect. Nicholas Christakis and James Fowler report that the average American has just four close social contacts, and 12% list no one with whom they can discuss important matters or spend free time. Their research has shown how social networks can affect the rates of smoking, obesity, and even happiness. Loneliness, likewise, spreads along three degrees of separation: people are 52% more likely to be lonely if they are directly connected to someone who is lonely, 25% at two degrees of separation (their friend’s friend is lonely), and 15% at three degrees of separation. People who feel lonely will shed, on average, 8% of their friends every other year. Loneliness seems to be not only the consequence but the cause of becoming disconnected.

It is unclear if the life after work group will have lasting benefits. In the short term, the men began having lunch together after the 11:00 meeting and have made plans to meet monthly. Only one had previously belonged to a men’s group, yet all will recommend it to others.

What is the value of giving one man or 10 the occasion to make friends, to speak aloud of his difficulties and worries with those who best understand them? And help him develop the social skills and self confidence to use them? Perhaps no more, but likely no less, than the importance of helping him control his diabetes or quit smoking. Does it take a doctor to convene such a group? Sometimes a doctor’s authority and judgment about the necessity for change are critical. But more than that, there is no better way to eavesdrop on the most important thoughts that occupy a man’s life, including those of the eavesdropper himself.

David Loxterkamp is medical director, Seaport Community Health Center, Belfast, Maine 04915, USA david.loxterkamp@gmail.com

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