INSTRUCTIONAL REVIEW

An epidemic of the use, misuse and overdose of opioids and deaths due to overdose, in the United States and Canada

IS EUROPE NEXT?

The United States and Canada are in the midst of an epidemic of the use, misuse and overdose of opioids, and deaths related to overdose. This is the direct result of overstatement of the benefits and understatement of the risks of using opioids by advocates and pharmaceutical companies. Massive amounts of prescription opioids entered the community and were often diverted and misused. Most other parts of the world achieve comparable pain relief using fewer opioids.

The misconceptions about opioids that created this epidemic are finding their way around the world. There is particular evidence of the increased prescription of strong opioids in Europe.

Opioids are addictive and dangerous. Evidence is mounting that the best pain relief is obtained through resilience. Opioids are often prescribed when treatments to increase resilience would be more effective.

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Much of the world is unaware of the fact that the medical and legal professions in the United States and Canada are in the midst of an epidemic of the use, misuse and overdose of opioids, and deaths related to overdose of these drugs. Doctors have been told by advocates backed by pharmaceutical companies that they are under-treating pain and have been overly concerned about addiction.1-3 The large amount of opioids released into society has since been diverted and misused, leading to an epidemic of overdoses and deaths. Elsewhere it correctly remains that opioids are considered to be addictive and dangerous. The mistakes made in the United States and Canada should be generally understood around the world so that they can be avoided.

The most common reason for seeking medical care in the United States is pain and more than half of American adults (125 million) had a painful musculoskeletal disorder in 2012.4 According to the Institute of Medicine, > 116 million Americans had persistent pain (pain that lasts longer than expected for a given nociception, i.e. after the tissues have healed, or pain that is inadequately adapted, e.g. greater than average limitations from common problems such as arthritis, tendinopathy, or back-ache) in 2011.5 It is difficult to assess the financial burden of pain, but estimates range between $560 billion to $635 billion a year in the United States.6

Nociception is the physiology of actual or potential tissue damage. Pain is the cognitive, emotional, and behavioural response to nociception. Some people have substantial nociception and little pain such as when, for instance, a professional cyclist gets back on his bicycle after a crash which has caused a fracture of the clavicle, and finishes the race. Others have considerable pain without detectable nociception, such as those with fibromyalgia. Every orthopaedic surgeon in the United States, Canada and the rest of the world has treated patients who have undergone extensive surgery with little pain medication. This is an everyday experience. Each of us has also treated patients with intense pain after a minor procedure. The explanation for these observations lies, in part, in the evidence that the intensity of pain for a given nociception is greater when there is greater stress or distress, and that it is greater in patients with less effective coping strategies.7-10 There is also evidence that a greater intake of opioids correlates with greater pain, irrespective of nociception, and that the continued use of opioids long after an injury has healed is associated with depression and stress.11-14

For some time, pain relief in the United States and Canada has focused on opioids. Common prescription opioids include oxycodone, hydrocodone, fentanyl, and morphine.

Heroin, another infamous opioid, was devel-
Opioids are used much more in the United States and Canada than elsewhere in the world. They are often difficult to obtain because they are addictive and dangerous. This is the preferred strategy that has been undermined in the United States and Canada. In Europe, about two-thirds of patients with persistent pain take prescription medication, but only a third of those medications are opioids (weak opioids 23%, strong opioids 5%). However, there is evidence of the increasing prescription of strong opioids in Europe. It would seem that the misconceptions about opioids that have led to the epidemic in the United States and Canada are finding their way around the world, placing other countries at risk of the same massive opioid problem involving the medical and legal professions found in the United States and Canada.

What caused the opioid epidemic?
It is widely accepted that the increase in the misuse of opioids and deaths due to overdose in the United States were largely driven by an increase in prescriptions by healthcare providers. Although some patients will intentionally misuse opioids for their euphoric effects and start doing so voluntarily, many subsequently change gradually from prescribed medical use to dependence, despite their intention to use these medications for pain relief as directed by their doctor. Even more important is the fact that as increasing amounts of opioids were prescribed, many were left unused in medicine cabinets where they were found by relatives, friends or acquaintances. They were also often obtained under false circumstances for the express purpose of diversion. Some were obtained illicitly, for example from “pill mills.”

Many factors have contributed to the increased use of opioids that has developed during the past two decades, including reports suggesting that they are safe, aggressive marketing of opioids by pharmaceutical companies, healthcare reform in pain management and ignorance about pain relief.

Reports suggesting that opioids are safe
Several influential reports suggested a low risk of developing iatrogenic addiction among patients taking opioids for pain. A letter to the editor of the New England Journal of Medicine in 1980 titled “Addiction rare in patients treated with narcotics” recorded only four cases of addiction among 11,882 patients who received at least one narcotic drug during hospitalisation. A study by Portenoy and Foley in 1986 followed 38 patients and concluded that opioid maintenance therapy can be safe in patients with persistent pain that is not related to cancer. The American Academy of Pain Medicine and the American Pain Society subsequently published a consensus statement in 1997 on the use of opioids for the treatment of persistent pain that stated: “The de novo development of addiction when opioids are used for the relief of pain is low.” A Cochrane review in 2010 by Noble et al reviewed 26 studies including 4,893 patients to establish the safety and effectiveness of opioids for the treatment of chronic pain which is not related to cancer. They concluded that serious adverse events such as iatrogenic opioid addiction were rare.

Many studies contradict these findings, identifying a more substantial risk, as high as 56%, of opioid misuse or iatrogenic addiction among patients who are prescribed opioids for pain relief. The rise in opioid prescriptions is in a large part attributable to their increased long-term use for persistent pain not related to cancer in spite of limited or no evidence of effectiveness. Examples include, but are not limited to, osteoarthritis and low back pain, both conditions for which the evidence of effectiveness and the safety of long-term opioid use is weak or nonexistent.

Marketing of opioids by pharmaceutical companies
Pharmaceutical companies encouraged physicians in the United States and Canada to prescribe opioids using tactics that exaggerated the potential benefits and under emphasised the risk of addiction and death. For example, Purdue Pharma (Stamford, Connecticut), the manufacturer of Oxycontin, funded > 20,000 pain-related educational programmes and launched campaigns to encourage physicians to prescribe the long-term use of opioids for chronic pain not related to cancer, while downplaying the side effects and claiming that Oxycontin was less addictive and less subject to abuse than other opioids on the market. When Purdue’s patent on the opioid MS Contin was about to expire by the late 1980s, the company was looking for a new source of revenue and developed a new “controlled release oxycodone” also known as Oxycontin. Oxycontin was patented for 20 years and was said to improve the “efficiency and quality of pain management” as well as treat pain “without unacceptable side effects”, according to Purdue. Despite numerous attempts to modify the Oxycontin product monograph and to disclose the truthful known data on the risks of dependency, patents were protected. The company used a patient starter coupon programme that provided patients with a free limited-time prescription of Oxycontin for a seven- to 30-day supply. Purdue Pharma also provided financial support to the American Pain Society, The American Academy of Pain Medicine, the Joint Commission and patient societies. In 2006, Purdue Pharma pleaded guilty in the federal court to a number of criminal charges related to the marketing of Oxycontin and paid over $600 million in fines.
New attitudes towards pain
Advocates with ties to the pharmaceutical industry promoted the idea that doctors under-treat pain. This led to directives based on emotion and shame that rapidly changed culture and will be difficult to undo. In 1990, state medical boards curtailed restrictions on laws governing the prescription of opioids for the treatment of chronic pain unrelated to cancer.\textsuperscript{41,48} The treatment of pain became a human right.\textsuperscript{49-51} In 1995, the American Pain Society introduced a campaign entitled “Pain is the Fifth Vital Sign” which urged a more aggressive use of opioids for the treatment of pain. This was included in their subsequent consensus statement that endorsed the use of opioids for persistent pain that is unrelated to cancer.\textsuperscript{2,34,52} In 2001, the Joint Commission on Accreditation of Health Care Organisations released pain management standards for the accreditation of healthcare organisations at the height of the growing focus on opioid analgesia. Most observers feel that the measurement of care provider and hospital quality based on satisfaction with pain relief was synergistic with the promotion of opioids in leading to a greater use of opioids.\textsuperscript{53} The Centre for Medicare and Medicaid Services incorporated pain management into patient satisfaction scores, thereby linking patient experience and pain management to reimbursement.\textsuperscript{49,54} These pro-opioid cultural and regulatory shifts created a simple message: pain must be treated, preferably with opioids, and without the fear of iatrogenic addiction.\textsuperscript{21}

Ignorance regarding pain relief
Medical schools devote little time to pain relief and substance misuse.\textsuperscript{55-58} A survey among 104 United States medical schools reported that only four have a required pain relief course and an additional 17 offered an elective course. The mean number of cumulative teaching hours spent discussing pain relief among these medical schools was 11, ranging from one to 31 hours.\textsuperscript{57} A study among Canadian universities reported that, on average, medical students received 16 hours of education in pain relief, while veterinary students received 87 hours.\textsuperscript{59} A recent review of Continuing Medical Education (CME) programmes in the United States showed that only five of 50 states required all or nearly all physicians to obtain CME credits on pain management.\textsuperscript{24} As a result, physicians consistently report that their medical education does not adequately prepare them to address pain relief and substance misuse.\textsuperscript{24}

Trends in the United States and Canada
The misuse of prescription opioids continues to increase in the United States with a major impact on health, society, economy, and safety.\textsuperscript{25,60,61} The number of prescriptions for opioids in the United States was 259 million in 2012. More than one in 20 United States citizens aged > 12 years have used prescription medication for non-medical reasons.\textsuperscript{62,63} In 2011, the Drug Abuse Warning Network reported more than 1.2 million Emergency Department visits involving the non-medical use of prescription drugs, a third involving opioids.\textsuperscript{64}

The most prescribed drug in the United States is an opioid: hydrocodone in combination with acetaminophen (paracetamol). There were 125.5 million prescriptions dispensed for hydrocodone/paracetamol in 2008 and 135.3 million in 2012. The next most prescribed medication (levothyroxine) had 107.5 million prescriptions in 2012. The remaining top five included lisinopril (90.8 million), simvastatine (86.1 million), and metoprolol (78.1 million).\textsuperscript{65} The overall annual number of opioid prescriptions dispensed by retail pharmacies increased from 76 million in 1991 to 219 million in 2011.\textsuperscript{66}

According to the three-step pain ladder of the World Health Organisation, analgesics should be prescribed in the following order: first, non-opioids (e.g. acetaminophen and nonsteroidal anti-inflammatory drugs); then, if necessary, weak opioids (e.g., tramadol and codeine); then strong opioids (e.g., oxycodone and morphine). This ladder was primarily designed for the treatment of pain in palliative cancer care, but is a framework to be considered for the treatment of acute post-operative pain.\textsuperscript{67} Most of the world currently adheres to this step ladder. However, in the United States, 80% of patients having relatively minor surgery such as arthroscopy of the knee or carpal tunnel release had a prescription for an opioid.\textsuperscript{68} Moreover, one third of all patients who visited an Emergency Department in the United States had opioids prescribed at discharge.\textsuperscript{69} A total of 20% of patients with pain that was not related to cancer are prescribed opioids in office-based settings. Primary care physicians including those in internal medicine and family practice, account for about half of the prescriptions of opioids for pain. There are far fewer orthopaedic surgeons than primary care physicians, but orthopaedic surgeons are just behind primary care physicians and dentists for the total amount of opioids introduced into society in the United States.\textsuperscript{70,71}

In 2009, drug poisoning surpassed motor vehicle collisions as the leading cause of accidental death in the United States, and the vast majority were overdoses of prescription opioids.\textsuperscript{72} Both prescription opioid sales and deaths due to overdose have quadrupled since 1999. More than half of all deaths due to an overdose of opioids in the United States involve a prescription drug, and at least 165 000 people have died in the United States from an overdose related to prescription opioids since the millennium. There were, for instance, 18 893 such deaths in 2014. Currently, 46 people die each day from an overdose of prescription opioids in the United States.\textsuperscript{18,73} Thus, there has been a resurgence of heroin users and sales and deaths from overdose directly related to the prescription opioid crisis. About 80% of first time heroin users misuse prescription opioids before starting with heroin.\textsuperscript{74,75} For every death due to a prescription opioid, there are ten inpatient admissions and 32 Emergency Department visits for misuse.\textsuperscript{76}
Comparison with the United Kingdom and other European countries

Only a few studies about opioids have been published in Europe, and these have not often distinguished between prescribed and non-prescribed drugs.66 There is, unfortunately, an upward trend in the prescription of opioids and related mortality in almost all European countries, especially in the United Kingdom.21,22,66,77 According to the International Narcotics Control Board, the consumption of prescription opioids is four times lower in Western Europe compared with the United States and Canada.74 The European Monitoring Centre for Drugs and Drug Addiction reported 70 000 deaths due to the overdose of drugs in Europe between 2000 and 2010, and there were 6800 deaths in 2014. This is less than half of the deaths due to an overdose which were reported during this time in the United States, and the European numbers also include deaths due to overdose of a non-opioid drug and non-prescription opioids.79 In addition, in 2014 the population of Europe was 507 million versus 318 million in the United States.80 Although the general number of deaths related to prescription opioids in Europe are not known for sure, it is much lower than in the United States, but rapidly increasing in several European countries.66 Thus, it is essential that senior members of the medical and legal professions in Europe and elsewhere learn from the mistakes made in the United States in order to avoid them.

The annual use of hydrocodone is about 60 million g in the United States compared with only 9000 g for the United Kingdom, France, Germany, Spain and The Netherlands combined.19 The morphine equivalent for the consumption of opioids per capita in the United States was about 70 mg in 1990, 245 mg in 2000, and 701 mg in 2014. In Canada, this was 30 mg, 210 mg, and 967 mg, respectively. The equivalent numbers in the United Kingdom are lower, but increasing with concerning rapidity: 33 mg, 78 mg, and 424 mg. Germany, France, Spain and the Netherlands are experiencing similar trends in the increased consumption of opioids: between 6 mg to 34 mg (1990), 77 mg to 184 mg (2000) and 214 mg to 485 mg (2014), respectively77 (Figs 1 and 2).81

The number of deaths related to drug poisoning in the United Kingdom is also far lower than in the United States, but the trends are, unfortunately, remarkably similar.52 The total annual number of prescriptions of strong opioids (buprenorphine, fentanyl, morphine and oxycodone) for persistent pain unrelated to cancer per capita in a United Kingdom primary care setting increased by almost 60% between 2000 and 2010, with a 50% increase in mean annual days of supply per patient.39 Nowadays, prescriptions for tramadol and oxycodone in particular are increasing in the United Kingdom.52

In the Netherlands, fentanyl, oxycodone and tramadol were the most commonly prescribed opioids in 2013. Nearly 8% of adults aged > 20 years, compared with about 25% in the United States used prescription opioids in 2013.66 As mentioned above, prescriptions of the ostensibly mild-opioid, tramadol, are increasing in Europe and it is among the most commonly prescribed opioids in the United Kingdom and The Netherlands. Deaths related to tramadol in the United Kingdom doubled between 2009 and 2012 and surpassed those related to heroin in Northern Ireland. The Wall Street Journal recently published a disturbing arti-
wider adoption of the biopsychosocial model of illness.\textsuperscript{7,90} The shortcomings of the biomedical model and increasing evidence that psychological factors are key determinants of symptoms for a given nociception have led to the recognition that psychological factors are key determinants of the intensity of symptoms. Increased depression prior to lumbar spinal surgery is associated with a poorer outcome three months post-operatively.\textsuperscript{84} Increased limitation of movement of the fingers after volar plate fixation of a distal radial fracture is associated with increased catastrophic thinking.\textsuperscript{85} Patients with greater self-efficacy (a psychological construct indicating agency and ability to adapt to adversity) are more likely to return to sports after anterior cruciate ligament reconstruction.\textsuperscript{86} An increased intensity of pain after a steroid injection for trigger finger was associated with increased symptoms of depression.\textsuperscript{87} In both total hip and knee arthroplasty, lower mental health status has been shown to be associated with worse outcomes.\textsuperscript{88,89}

The shortcomings of the biomedical model and increasing evidence that psychological factors are key determinants of symptoms for a given nociception have led to the wider adoption of the biopsychosocial model of illness.\textsuperscript{7,90} This emphasises the complex interplay of biological, psychological, cultural, and social factors on symptoms. Surgeons are familiar with some of the psychosocial mediators between nociception and pain, such as secondary gain. They may be less familiar with the influence of depression, the tendency to misinterpret or over-interpret nociception, as in catastrophic thinking, heightened concerns about illness, and social and cultural factors on behaviour in relation to an illness.

Most patients in countries other than the United States and Canada take little or no opioid analgesics after musculoskeletal trauma or surgery.\textsuperscript{91,92} Patients in the United States take one of the strongest oral opioid analgesics available post-operatively for a fracture of the ankle. In the Netherlands, patients recovering from this form of surgery take acetaminophen, but the intensity of the pain and satisfaction with pain relief are comparable.\textsuperscript{11} It seems that when a Dutch person breaks their ankle and has surgery, they think: “this is going to hurt”, but in the United States they think: “why am I hurting?”. The lesson is that resilience affords such effective pain relief that we need to make sure we do nothing to undermine or diminish it.

When we have pain, the normal response is to feel protective and prepare for the worst (“this will never go away”, “it will only get worse”). This normal human thought process, called catastrophic thinking, is intended to protect us from greater damage; but most of our daily pains are not related to damage, creating a counter-productive ‘false alarm’. We learn to modulate or turn off this alarm when we work out, play sports, or adapt to permanent impairment.\textsuperscript{93} These same processes are triggered by actions intended to improve health, whether those actions address the pathophysiology or not. In research contexts this is referred to as the placebo effect and in daily life, it is labeled resilience.\textsuperscript{9}

**Pain relief**

**Nociception versus pain.** The traditional biomedical model of illness assumes a direct relationship between nociception and pain. The limits of the biomedical model are consistent throughout orthopaedic surgery. There are many examples: patients with greater pain from arthritis are expected to have more degenerative changes on radiographs, but they do not. Psychosocial factors rather than pathophysiology are the major determinant of the intensity of symptoms. Increased depression prior to lumbar spinal surgery is associated with a poorer outcome three months post-operatively.\textsuperscript{84} Increased limitation of movement of the fingers after volar plate fixation of a distal radial fracture is associated with increased catastrophic thinking.\textsuperscript{85} Patients with greater self-efficacy (a psychological construct indicating agency and ability to adapt to adversity) are more likely to return to sports after anterior cruciate ligament reconstruction.\textsuperscript{86} An increased intensity of pain after a steroid injection for trigger finger was associated with increased symptoms of depression.\textsuperscript{87} In both total hip and knee arthroplasty, lower mental health status has been shown to be associated with worse outcomes.\textsuperscript{88,89}

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**Opioid-centric pain management.** Programmes for the management of pain which concentrated on the use of opioids represented a major step backwards. Opioids are not the most effective analgesic medication, particularly for persistent pain, and they are dangerous.\textsuperscript{23,41,49,94-96} Patients who take more opioids have greater intensity of pain and less satisfaction with pain relief, 24 hours post-operatively for a fracture independent of nociception, and thus independent of the type or number of fractures or the days since injury or surgery.\textsuperscript{12,13} Patients who continue to use opioids one to two months post-operatively for musculoskeletal trauma have more psychological distress, less effective coping strategies, a greater intensity of pain and a magnitude of symptoms compared with those who do not take opioids, again irrespective of nociception.\textsuperscript{14} Another study found that opioid users were less satisfied with pain relief after various orthopaedic operations.\textsuperscript{11}

There is much evidence of the extensive physiological and non-physiological adverse effects of taking opioids, such as hyperalgesia, hypogonadism, depression, misuse, overdose, increased risk of falls and fractures, death, and poorer quality of life.\textsuperscript{33,95,97-100} The misuse of opioids pre-operatively is associated with considerable morbidity and mortality after orthopaedic surgery.\textsuperscript{101}

Opioids are often prescribed when interventions to address stress and distress are more advisable. Patients still taking opioids one or two months post-operatively for trauma in the United States have more symptoms of depression and post-traumatic stress disorder.\textsuperscript{14} Those who report greater pain and disability are prescribed more analgesics.\textsuperscript{100,102,103} Patients most at risk for opioid-related harm due to psychosocial issues or a previous history of substance misuse are more likely to be prescribed opioids and in dangerously high doses.\textsuperscript{94,104} Inpatients who take more opioids have more pain.\textsuperscript{12,13} The ultimate analgesic after musculoskeletal surgery is resilience, greater self-efficacy in response to pain; the sense that everything is on course and will turn out well. More effective coping strategies can be learned and practiced.

**Effective coping strategies.** The wide variation in the intensity of pain and satisfaction with pain relief for a given nociception, combined with the evidence that these variations are best accounted for by psychosocial factors, directs us to evidence-based interventions for helping patients learn and practice coping strategies, including interventions based on cognitive behavioural therapy and its derivatives. There is growing evidence that effective coping strategies, better mood, and less stress allow a more effective relief of
In patients with a fracture of the radial head, simple coaching in the clinic addressing coping strategies immediately increased the range of movement. A reduction in catastrophic thinking resulted in fewer symptoms and less disability in patients with low back pain.

Practical steps

**Standardised prescription protocols.** The American Academy of Orthopaedic Surgeons has released a statement with strategies for the safer and more effective relief of pain in the United States. This included protocols for the prescription of opioids intended to depersonalise discussions about pain relief and make it easier to limit the number of prescriptions. The upper limit of prescription in these strategies is far more than the average patient uses in the United States, let alone the rest of the world, so there can be no doubt that this is an adequate amount of opioids. The amount of opioids in these strategies can almost certainly be reduced. An example of the potentially remarkable impact of such a departmental policy can be found in the paper by Stanek et al. Surgeons elsewhere in the world who use far fewer opioids than in the United States should consider putting upper limits on opioids consistent with regional practice. They should not raise the amount of opioids prescribed to the levels used in the United States strategies which are intended to diminish opioid use to pre-epidemic levels or lower.

**General principles.** Only one doctor should provide opioids. The care of patients who take opioids prior to surgery, including methadone or buprenorphine/naloxone (Suboxone; Indivior Inc., Richmond, Virginia), should be coordinated by both the primary doctor and the doctor prescribing opioids. Patients should be weaned off opioids and have all psychosocial stress factors identified and treated prior to surgery. Orthopaedic surgeons should not treat persistent pain. Disproportionate pain (too much or too long) suggests unaddressed stress, distress or less effective coping strategies. Orthopaedic surgeons treat acute pain that is expected to improve over hours and should not use extended release opioids.

**Continuing education.** Doctors should understand the risks of addiction and death when prescribing opioids. With the exception of those dying of cancer, patients should use as few opioids as possible for as short a time as possible. All doctors should be familiar with the verbal and non-verbal signs of psychological distress and ineffective coping strategies; and with tools that screen for risk for substance misuse, stress, distress, and less effective coping strategies and they should be familiar with the available treatments and have experts readily available for referral.

**Communication strategies.** The foundation of the effective relief of pain is expert communication. There is much evidence about the best verbal and non-verbal techniques for relieving stress and bolstering resilience. Surgeons and their team would benefit from efforts to prescribe, practice, and continuously improve these strategies. Since the communication strategies of surgeons are usually not as well honed as their technical skills, this will take time, practice, and persistence. We surgeons need to do our part, but we might consider adding highly effective communicators to our team so as not to rely on our own less effective communication strategies.

Make sure that patients know you care about their comfort. A simple question like: “What did you take for pain relief after your surgery?” can get the conversation started. Answers that indicate strong resilience can be reinforced. When patients are upset by the realisation that surgery will cause pain or if it prompts the memory of a difficult recovery from another operation or injury, it is time to consider the psychosocial factors.

A phone call to patients post-operatively can put them at ease. For patients having trouble with pain relief, consider asking: “Does the surgery hurt more than you expected?” Be silent while he or she gathers her thoughts, as a way to demonstrate care and concern while reminding them why they have pain, which relieves the sense that something is wrong.

In conclusion, the general public and the medical and legal professions in Europe and the rest of the world need to be careful not to make the same mistakes made in the United States and Canada. Opioids relieve pain, but they are addictive and dangerous and do not provide peace of mind. Resilience is the best form of pain relief. Pain is generally managed in the rest of the world without the use of opioids. That is a much better strategy and worth preserving.

**Take home message:**
- The world should be mindful of the mistakes made in the United States and Canada in relation to prescription opioids and do everything possible to avoid repeating them.
- The intensity of pain for a given nociception is increased by stress, distress, and less effective coping strategies.
- Optimal mood, a strong support system, and resiliency merit attention as some of the best pain relievers.

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T. Teunis: Participated in the design process, Collected data, Cleaned the data, Drafted and revised the paper.
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