Lessons from the field

Using a fingerprint recognition system in a vaccine trial to avoid misclassification

The SonLa Study Group[a]

Problem The potential for misidentification of trial participants, leading to misclassification, is a threat to the integrity of randomized controlled trials. The correct identification of study subjects in large trials over prolonged periods is of vital importance to those conducting clinical trials. Currently used means of identifying study participants, such as identity cards and records of name, address, name of household head and demographic characteristics, require large numbers of well-trained personnel, and still leave room for uncertainty.

Approach We used fingerprint recognition technology for the identification of trial participants. This technology is already widely used in security and commercial contexts but not so far in clinical trials.

Local setting A phase 2 cholera vaccine trial in SonLa, Viet Nam.

Relevant changes An optical sensor was used to scan fingerprints. The fingerprint template of each participant was used to verify his or her identity during each of eight follow-up visits.

Lessons learned A system consisting of a laptop computer and sensor is small in size, requires minimal training and on average six seconds for scanning and recognition. All participants' identities were verified in the trial. Fingerprint recognition should become the standard technology for identification of participants in field trials. Fears exist, however, regarding the potential for invasion of privacy. It will therefore be necessary to convince not only trial participants but also investigators that templates of fingerprints stored in databases are less likely to be subject to abuse than currently used information databases.

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Introduction

The double-blind randomized controlled trial (RCT) is widely accepted as the method of choice to measure the efficacy of an intervention.[1] To assess the protection afforded by a vaccine candidate in an RCT, participants are randomly allocated to receive vaccine or control and followed during the study period until the final outcome is recorded. Linking outcome (disease or no disease) to exposure (vaccine or control) allows an unbiased measure of the effect of vaccination. Misclassification of the outcome, such as non-detection of the target disease, has been discussed in the literature.[2–5] Much less has been published about misclassification of exposure. The study participants in vaccine trials are frequently young children and follow-up periods can last several years. The correct identification of the study subject throughout extended surveillance periods is one of the greatest challenges — if not the greatest challenge — to the successful conduct of trials in developing countries.

The effects of misclassification are devastating. When misclassification occurs at random, associations tend to be biased to the null. As a result a protective vaccine candidate appears to be ineffective, years of work by a large field evaluation team have come to nothing, and the public is denied the benefits of a protective vaccine.

Several safeguards have been developed to prevent the misclassification of exposure. Study participants are identified not only by name, but also by age, sex, names of household members and household address. Eligible participants receive identity cards, often with photographs. The identity of patients with the target disease can be verified by means of these cards, demographic characteristics and visits to the home. This labour-intensive and time-consuming system should prevent most misclassification errors but it cannot protect against intentional or unintentional errors. This is especially true in the world's poorest populations, where the conditions for trial conduct are adverse but health interventions are most urgently needed. Identity cards may be lost or become so badly spoiled that they can no longer be deciphered, and photographs may become deceptive as children grow up. Names are neither unique nor permanent, household members and addresses change and are forgotten, and demographic characteristics are not unique. New approaches, therefore, which reduce the uncertainty of identification, would be extremely useful.

[a] **Members of the SonLa Study Group:** Lorenz von Seidlein, Vu Dinh Thiem, Dang Duc Anh, Do Gia Canh (National Institute of Hygiene and Epidemiology, Hanoi, Viet Nam) Mahesh Puri, Vinay Gupta, JinKyung Park, Mohammad Ali, Jacqueline Deen, Anna Lena Lopez, SeongHye Shin, John Clemens (International Vaccine Institute, PO Box 14, Kwanak-Ku, Seoul, Republic of Korea 151-600). Correspondence to Dr von Seidlein (lseidlein@ivi.int).

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The SonLa Study Group

Identity verification technology has advanced enormously over recent decades. While there is a range of biometric identification systems now available, security experts have relied on fingerprints for the unambiguous identification of individuals for more than a century.[6,7] Two developments have made fingerprint identification interesting to those conducting clinical trials. First, fingerprint scanners and computer memory have replaced ink on paper recording of fingerprints. Second, the technology for fingerprint recognition has become portable and affordable.

Creating a fingerprint template

The uniqueness of a fingerprint is determined by the pattern of ridges and furrows as well as the minutiae points — local ridge characteristics that occur at either a ridge bifurcation or a ridge ending. Optical scanners are the most widely used method of capturing the fingerprint. The finger is placed on a coated plate, which is part of a charged coupled device plugged into the laptop's USB port. The image of the fingerprint is converted into a digital signal. Known disadvantages of optical scanners are their inability to capture ridges and minutiae from fingertips coated with sweat or other agents and the potential risk of latent pictures being left on the plate after the print has been scanned. Wiping the fingertip with cloth or tissue-paper has been shown to resolve this problem.

Once the sensor has captured an image of the fingerprint, the distinctive features of the fingerprint are converted into a template by proprietary software, developed and closely guarded by fingerprint recognition systems vendors. Most vendors base their pattern recognition algorithms on the configuration of minutiae. While the storage of a fingerprint image requires approximately 250 kilobytes of memory, a template only requires a storage space of between 250 and 1000 bytes.

In our pilot study, to create a template the fingerprint image was scanned five times. When there was difficulty scanning the right thumb the left thumb was used, followed by the right index finger. For each participant, only one fingerprint template was stored with his/her unique study number and personal information (name, sex and date of birth).

The pilot study

During a randomized controlled trial in Vietnamese adults of an oral killed whole-cell cholera vaccine, we piloted fingerprint scanning for the verification of participant identity. Volunteers were recruited among students and teachers at a nursing school in SonLa, Viet Nam. Each participant had a school identity card. After each participant gave written informed consent, study staff screened them for eligibility, collected a blood sample, and completed a baseline case report form. Each participant was then requested to provide a fingerprint. The identity of study participants was verified by entering the name of the subject into the computer and requesting the participant to rest the initially scanned finger on the portable scanner. During each of the eight follow-up visits each study participant was identified on the basis of his/her school identity card, which served as the gold standard. Linkage between the fingerprint registration and the case report form data was through each individual's unique study number.

The vaccine trial, including the use of the biometric technology, was approved by the Ethical Review Board of the National Institute of Hygiene and Epidemiology, Hanoi, Viet Nam, and the Institutional Review Board of the International Vaccine Institute, Seoul, Republic of Korea.

Findings

We recruited 153 volunteers aged 18–41 years (mean age, 23 years) and were able to store a baseline fingerprint template of all participants during the first visit (149 right thumbprints, 2 left thumbprints, and 2 right index fingerprints). A total of 1191 identity verification episodes were carried out during the eight follow-up visits. The time required for fingerprint scanning and recognition was between 5 and 50 seconds (mean 6 seconds).

False rejection during the initial placement of the finger on the scanner occurred in 5% of verification episodes (60 out of 1191). These false rejections required re-scanning of the fingerprint until the image was accepted, usually on the second or third attempt (often as a result of the scanner and fingertip being wiped with a cloth).

The fingerprint scanning and recognition system was easy to understand and use. Local collaborators were able to use the system after less than one hour of training and practice. The system, including the sensor, required little space and could be powered through the battery of the laptop computer during failures of electricity supply.

Discussion

We found that fingerprint scanning for verification of identity during a clinical trial was feasible, reliable, and acceptable in adults in a rural area of Viet Nam. In this study, we detected no false acceptance. When a wrong name was brought up on screen by mistake (for example, when participants had the same or similar names), the software was able to detect the error as soon as the participant's fingerprint was scanned.

Our study proved that current fingerprint recognition technology can be used effectively in vaccine trials in resource-poor countries. We are now planning to implement this identification system in large paediatric vaccine trials, as children are the population most in need of vaccines and most frequently targeted in such trials. Theoretically, the system should recognize the fingerprints of newborns as the epidermal ridge configuration is completed by a gestational age of 17 weeks. There is no reason why the system, which requires no specific skills, should perform less well in paediatric populations. Moreover, in the study we used 1:1 matching — that is, we confirmed identity by matching one live fingerprint against one fingerprint template stored in the database. Since that time the software application has been expanded, so that an individual's fingerprint can be matched against an entire database of fingerprint templates. This is useful during enrolment of study participants as it ensures that an individual is not enrolled more than once, and allows trial participants presenting at health-care centres to be identified without other identifiers. Finally, identification based on fingerprints allows trials in mobile populations, such as refugees or nomads, to take place. Up to now these populations have presented a major logistical problem, as house address could not be used for identification purposes. These expanded applications require evaluation in field studies.

The fear of the new and unknown will have to be overcome before fingerprint recognition systems find wide acceptance. Not only participants but also those conducting trials may fear

that fingerprint data could be used for purposes unrelated to the trial. Such abuse is highly improbable as the system stores templates derived from the characteristics of the finger scan, from which the original fingerprint cannot be recreated. The adaptation of fingerprint recognition technology reduces the need to take demographic information such as the names of household members, the need for home visits to identify study participants, and the need to enquire repeatedly about personal information. Thus, biometric technology is likely to increase, not decrease, the privacy of trial participants. As with many new technologies, apprehensions arise because the risks and benefits are not well understood. Thorough sensitization of investigators and study communities will be essential for the successful introduction of this promising technology. It is to be hoped that fears will be dispelled with increasing and successful use of fingerprint recognition technology in clinical trials. ■

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Competing interests: none declared.

Résumé

Utilisation d'un système de reconnaissance des empreintes digitales dans le cadre d'un essai vaccinal pour éviter les erreurs de classement

Problème Une erreur d'identification des participants à un essai vaccinal, qui à son tour peut entraîner une erreur de classification, constitue un risque pour l'intégrité des essais contrôlés randomisés. L'identification correcte des sujets dans le cadre d'essais de grande ampleur se déroulant sur des périodes prolongées est d'une importance cruciale pour les personnes menant des essais cliniques. Actuellement, les moyens utilisés pour identifier les participants, tels que cartes d'identité et enregistrement du nom, de l'adresse, du nom du chef de famille et des caractéristiques démographiques, exigent un personnel bien formé et nombreux et comportent encore une faible incertitude.

Démarche Nous avons fait appel à la technologie de reconnaissance des empreintes digitales pour identifier les participants à l'essai. Cette technologie est déjà largement appliquée dans les domaines de la sécurité et de la vente, mais, à ce jour, elle n'est pas utilisée dans les essais cliniques.

Contexte local Essai de phase 2 d'un vaccin anticholérique, mené à SonLa, au Vietnam.

Modifications intéressantes On a scanné les empreintes digitales des participants avec un capteur optique, puis on a utilisé les modèles d'empreintes obtenus pour chacun d'entre eux pour contrôler son identité à chaque visite de suivi.

Enseignements tirés de cette étude Le système composé d'un ordinateur portable et d'un capteur est de dimension réduite, n'exige qu'une formation brève et ne prend que six secondes en moyenne pour scanner et reconnaître les empreintes. Au cours de l'essai, l'identité de tous les participants a été vérifiée. La reconnaissance des empreintes digitales devrait devenir la technologie standard pour identifier les participants dans les essais de terrain. Elle suscite cependant des craintes concernant les possibilités d'atteinte à la vie privée. Il faudra donc convaincre non seulement les participants aux essais, mais aussi les enquêteurs que les modèles d'empreintes conservés dans des bases de données ne risquent pas plus d'être utilisées de manière abusive que les données actuellement stockées dans ces bases.

Resumen

Uso de un sistema de reconocimiento de huellas dactilares en un ensayo de vacunas para evitar los errores de clasificación

Problema El riesgo de identificar incorrectamente a los participantes en un ensayo, con el consiguiente error de clasificación, constituye una seria amenaza para la integridad de los ensayos controlados aleatorizados. La identificación correcta de los sujetos estudiados en los grandes ensayos a lo largo de periodos prolongados es un requisito de vital importancia para quienes llevan a cabo ensayos clínicos. Los medios actualmente empleados para identificar a los participantes en esos estudios, como las tarjetas de identificación y los registros del nombre, la dirección, el nombre del cabeza de familia y los datos demográficos, exigen un personal numeroso y bien preparado, y aun así es imposible eliminar la incertidumbre.

Métodos Usamos una técnica de reconocimiento de las huellas dactilares para identificar a los participantes en los ensayos. Esta tecnología se emplea ya de forma generalizada con fines de seguridad y comerciales, pero hasta la fecha no se había utilizado en ensayos clínicos.

Contexto local Un ensayo de vacuna anticolérica de fase 2 llevado a cabo en SonLa, Viet Nam.

Cambios destacables Se empleó un sensor óptico para escanear las huellas dactilares. La huella dactilar así obtenida para cada participante se empleó luego para comprobar su identidad en cada una de las ocho visitas de seguimiento.

Experiencia adquirida Un sistema constituido por un ordenador portátil y un sensor ocupa poco espacio y requiere una formación mínima, y el escaneo y el reconocimiento duran por término medio seis segundos. Se verificó la identidad de todos los participantes en el ensayo. El reconocimiento de las huellas dactilares debería convertirse en la tecnología estándar de identificación de quienes participan en los ensayos sobre el terreno. Un motivo de preocupación, sin embargo, son los riesgos de invasión de la intimidad. Por consiguiente, habrá que convencer no sólo a los participantes en los ensayos, sino también a los investigadores, de que el riesgo de abusos es menor con las huellas dactilares almacenadas en bases de datos que con las bases de datos usadas en la actualidad.

ملخص

استخدام نظام التعرُّف على بصمات الأصابع لتجنُّب الخطأ في التصنيف في دراسة اللقاحات

المشكلة: إن إمكانية عدم التعرُّف على المساهمين في تجربة ما، وهو ما قد يقود إلى الخطأ في التصنيف، تعد تهديداً لصحة التجارب المُعَشَّاة المضبوطة بالشواهد. وللتعرُّف الصحيح على المساهمين في دراسة كبيرة تستمر فترات طويلة أهمية بالغة لدى القائمين على الدراسة. وتتطلب الوسائل المستخدمة في الوقت الحاضر للتعرُّف على المساهمين في الدراسة مثل بطاقات التعريف وسجِّلات الأسماء والعناوين واسم رب الأسرة والخصائص الديموغرافية، عدداً كبيراً من العاملين المدربين تدريباً جيداً، ولكنها رغم ذلك لا تتيح للدارسين ثقة كاملة.

الأسلوب: استخدمنا تكنولوجيا التعرُّف على بصمات الأصابع للتعرف على المساهمين في الدراسة. وتستعمل هذه التكنولوجيا في وقتنا الحاضر على نطاق واسع في المجالات الأمنية والتجارية، ولكنها لم تستعمل بعد في الدراسات السريرية (الإكلينيكية).

الموقع المحلي للدراسة: المرحلة الثانية من دراسة حول لقاح الكوليرا في سون لا، فيي تنام.

التغيُّرات: استخدام حاسّة (جهاز قراءة) بصرية لمسح (تَفَرُّس) البصمات. واستخدام حافظة لحفظ بصمة كل مساهم للتحقق من هويته أو هويتها خلال الزيارات الثمانية للمتابعة.

الدروس المستفادة: يتألف النظام من حاسوب دفتري وحاسَّة صغيرة الحجم، ولا يحتاج الأمر إلا إلى قدر ضئيل من التدريب وزمن لا يتجاوز ست ثوان لإجراء المسح (التَّفَرُّس) والتعرف. وقد أمكن التحقق من التعرف على جميع المساهمين في الدراسة. ينبغي أن يصبح التعرف على البصمات من التكنولوجيا المعيارية للتعرف على المساهمين في الدراسات الميدانية. وهناك تخوف من الانتهاك المحتمل للخصوصية، مما يجعل من الضروري إقناع المساهمين في الدراسة والباحثين أن حافظات بصمات الأصابع تخزن في قاعدة معطيات أكثر بعداً عن الانتهاك مما هي عليه قواعد معطيات المعلومات التي تستخدم في الوقت الحاضر.

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