

REVIEW ARTICLE

Scoping Literature Review Study of Short Message Services (SMS) and Mobile App-Based Technology as an mHealth tool for Active Participant Centered (MAPC) Adverse Events Following Immunisations (AEFIs) Surveillance using a Low Middle-Income Country (LMIC) lens

Priscilla PM Nyambayo^{1*}, Michael S Gold², and Ushma C Mehta³

¹*Pharmacovigilance and Clinical Trials Division, Medicines Control Authority of Zimbabwe, Harare, Zimbabwe*

²*University of Adelaide, Discipline of Paediatric, Women's and Children's Health Network, Adelaide, Australia*

³*Centre for Infectious Disease Epidemiology and Research, School of Public Health, University of Cape Town, South Africa*

Correspondence should be addressed to Priscilla P.M. Nyambayo, Pharmacovigilance and Clinical Trials Division, Medicines Control Authority of Zimbabwe, Harare, Zimbabwe

Received: 16 August 2023; Accepted: 26 August 2023; Published: 6 September 2023

Copyright © Priscilla P.M. Nyambayo. This is an open access article distributed under the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

ABSTRACT

INTRODUCTION

Mobile technology is rapidly expanding globally. Uptake of such technologies to improve Adverse Events Following Immunisation (AEFIs) surveillance in most Low Middle-Income Countries (LMICs) settings is limited. There is limited evidence on the feasibility of such mHealth Active Participant Centered (MAPC) AEFI surveillance systems in LMICs. This scoping literature review study therefore focused at assessing the value and feasibility of mHealth active participant centered (MAPC) AEFI surveillance using SMS and /or mobile applications (apps) immunisation safety from the perspective of a LMIC.

AIM

The aim of the scoping literature review was to generate exploratory feasibility evidence of MAPC AEFI surveillance such as SMS response rates, AEFI reporting rates, cost implications, acceptability, and challenges from LMICs perspectives.

METHODS

Employing the Joanna Briggs Institute (JBI) approach for scoping reviews, we conducted literature review of MEDLINE via PubMed, Scopus, CINAHL and Africa -wide via EBSCOs, and the Cochrane Library for studies conducted from 1970 up to July 2022. Studies were assessed on type of mHealth platform, country of implementation, key findings of uptake, acceptability, response rates, cost and key challenges identified.

Citation: Priscilla PM Nyambayo, Scoping Literature Review Study of Short Message Services (SMS) and Mobile App-Based Technology as an mHealth tool for Active Participant Centered (MAPC) Adverse Events Following Immunisations (AEFIs) Surveillance using a Low Middle-Income Country (LMIC) lens. J Clin Cases Rep 6(S16): 308-327.

RESULTS

Most studies 24/26(92%) were conducted in HICs from 2010 to July 2022, with evidence of MAPC AEFI surveillance improving consumer response rates and early AEFI reporting for most vaccines. The consumer vaccines SMS mean response rate was 71% for 23 studies using mixed digital technologies methods mostly conducted in HICs. These HICs have more well-resourced consumers, adequate immunisation AEFI surveillance programs and well-funded primary healthcare services. LMICs suffer from critical resource limitations to the extent that over 50 LMICs rely on donor funding for vaccine procurement. There was limited MAPC AEFI surveillance in LMICs of two published feasibility studies with no evidence of scale up.

CONCLUSION

MAPC AEFI surveillance is implemented mostly in HICs hence need for MAPC AEFI surveillance feasibility studies in LMICs taking advantage of increasing availability of mobile phone technology.

KEYWORDS

Short Message Services (SMS); mHealth Active Participant Centered (MAPC) AEFI surveillance system; Scoping Literature Review

INTRODUCTION

Immunisation is globally one of the most cost-effective ways of preventing or reducing the severity of infectious diseases including, most recently, COVID-19 disease [1]. Infrequently there are adverse events following immunisation (AEFI). AEFI is “any untoward medical occurrence after immunisation that does not necessarily have a causal relationship with the usage of the vaccine” [1,2]. In Zimbabwe AEFI surveillance is conducted through a partnership between the national medicine regulator MCAZ (Medicines Control Authority Zimbabwe) and the Expanded Programs on Immunisation (EPI). The AEFI surveillance system aims to protect the public from immunisation-related harm and misinformation about the safety and performance of vaccines by ensuring that AEFI data is collected, analysed and reported to relevant stakeholders. EPI and MCAZ ensure independent causality assessments and signal detection are conducted [3].

AEFI, even if coincidental, can have devastating impact on the reputation of the EPI programme and/or regulator and can affect public confidence in the immunisation program or vaccines themselves. Many vaccines are almost exclusively used in LMIC settings and hence reliance on safety data and regulatory decisions from HIC is not always possible. Hence there is a need for responsive AEFI surveillance systems in LMICs as well. In most LMICs, AEFI surveillance is compromised because reporting is mostly paper-based hard copy hence limiting timely communication with subsequent delays in corrective and/or preventative actions including feedback. Passive (spontaneous or voluntary) AEFI reporting systems in most LMICs are paper-based, normally have incomplete reports and there is a lot of underreporting [1,3]. Weak spontaneous AEFI surveillance systems may result in delayed AEFI detection, case management, delayed case investigation, causality assessment, feedback and lack of public trust in vaccines reducing vaccine uptake and ultimately increased vaccine preventable diseases (VPDs). In LMICs, the challenges that contribute to AEFI underreporting are further heightened by consumer illiteracy, poverty, inadequate overstretched primary health care systems, unavailability of digital technologies making it difficult for patients to share their experiences and concerns [3]. Most LMICs have limited diagnostic

capacity, under resourced and over-stretched health systems with limited record linkage, prohibiting the detection and diagnosis of AEFIs [3].

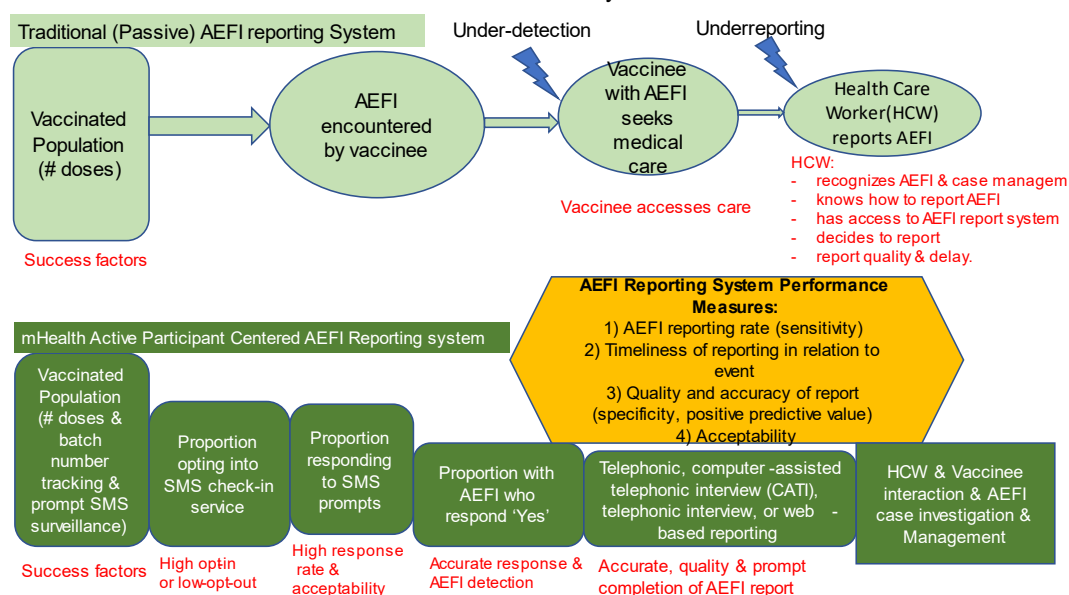
To improve AEFI detection and management, Active Vaccine Safety Surveillance (AVSS) is key. AVSS is defined by The Council for International Organizations for Medical Science (CIOMS) as ‘a data collection system that seeks to ascertain as completely as possible the number of AEFIs and underlying causes in each population via a continuous organized process’ [1,2].

To improve AEFI detection and management, it is critical to adopt new technologies and tools, hence the emergence of terms such as digital health, eHealth and mHealth. The World Health Organization (WHO) defines digital health as ‘the use and scale up of digital health solutions that can revolutionize how people worldwide achieve higher standards of health, and access services to promote, and protect their health, and well-being’ [4,5]. The COVID-19 pandemic has revolutionized and accelerated the reach of digital health including mHealth [5].

The 71st World Health Assembly Resolution WHA71.7 defined electronic Health (e-Health) as ‘the use of information and communication technologies (ICT) for health [5]. The WHO also defined mobile Health (mHealth) as ‘medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices [5]. mHealth is the use of mobile devices including mobile phones to deliver health services and information therefore it is a subset of eHealth and digital health.

Mobile (cellular) phones allow Short Message Service (SMS), voice and data-communication to be used in health delivery systems such as AEFI surveillance. For LMICs setting however more feasibility evidence is required for MAPC AEFI surveillance using SMS, web applications, mobile apps and other data enabled applications.

Figure 1: The role of MAPC AEFI surveillance in the context of LMIC traditional spontaneous (passive) AEFI surveillance national system.



This scoping review therefore focused on assessing the value and feasibility of mHealth active participant centred (MAPC) AEFI surveillance using SMS and/or mobile apps from the perspective of a LMIC country. Fortuitously,

the period of data collection overlapped with the period of COVID-19 vaccinations, so the scoping review study included AEFI surveillance of all EPI vaccines, campaigns including COVID-19 vaccines. As illustrated in Figure 1 above MAPC AEFI surveillance may be used to empower individual patients to manage their own healthcare journeys during vaccination by supporting the detection, notification and management of AEFI's.

AIM

The aim of this scoping literature review was to generate exploratory feasibility evidence of MAPC AEFI surveillance systems such as SMS response rates, AEFI reporting rates, cost implications, acceptability and challenges from LMIC perspectives. The review aimed to collect and synthesize current knowledge on effectiveness of MAPC AEFI surveillance while identifying gaps in knowledge and research, practical challenges, and end users' preferences for design of user-friendly acceptable mHealth app-features.

METHODS

This scoping review was conducted in line with Preferred Reporting Items for Systematic Review and MetaAnalysis (PRISMA) requirements and the latest Joanna Briggs Foundation (JBF) guidance for scoping reviews [6,7].

Search Strategy

Searches in line with the research question and inclusion criteria were systematically performed on the following search engines: PubMed, Scopus, Embase, Cumulative Index to Nursing and Allied Health Literature, Cochrane Library, google scholar and grey literature. Online database searches were done in July 2022 by first author with assistance from an experienced librarian. All articles identified were listed in the data extraction table and Prisma Flow. The first author conducted literature review and the second and third authors verified and resolved any disagreements, in line with the JBI Scoping Reviewers Manual [6,7]. Available full text articles were downloaded, and outstanding articles were sourced through the University of Cape Town library or via the corresponding authors.

Inclusion Criteria

Scoping Literature Review Search explored use of mHealth technology for AEFI detection and/or surveillance for licensed vaccines including routine immunisations as well as vaccines used in national or regional campaigns or pandemics and emergency use authorisation of COVID-19 vaccines. All published studies, opinions, editorial, commentaries, reviews, and interviews focusing on MAPC AEFI surveillance of all licensed vaccines of all age groups were searched from 1970 to July 2022. All published studies in all languages were included if automatically translated by the search tools into English language.

Exclusion Criteria

Papers reviewing the use of mHealth for reporting AEFI or the use of mHealth to support other elements of the immunisation programme such as immunisation reminders and/or increase in immunisation coverage were excluded. Studies on social media (e.g., Twitter(X), Facebook and other AEFI reporting technologies) were excluded. Papers only written in other languages that could not be translated via Google translate and papers that could not be sourced were excluded. Studies using participant centred active AEFI surveillance without using mHealth were excluded such as web applications, emails, telephone calls, or telewatch or digital diaries.

Target Population and Participants

Published literature which included the use of mHealth systems for vaccines of any age or person of any age (neonates, infants, children, adolescents, young adults, adults including the elderly and pregnant women) in HICs and LMICs and receiving any licensed vaccine(s) including COVID-19 vaccines were studied.

Data Extraction and Collection

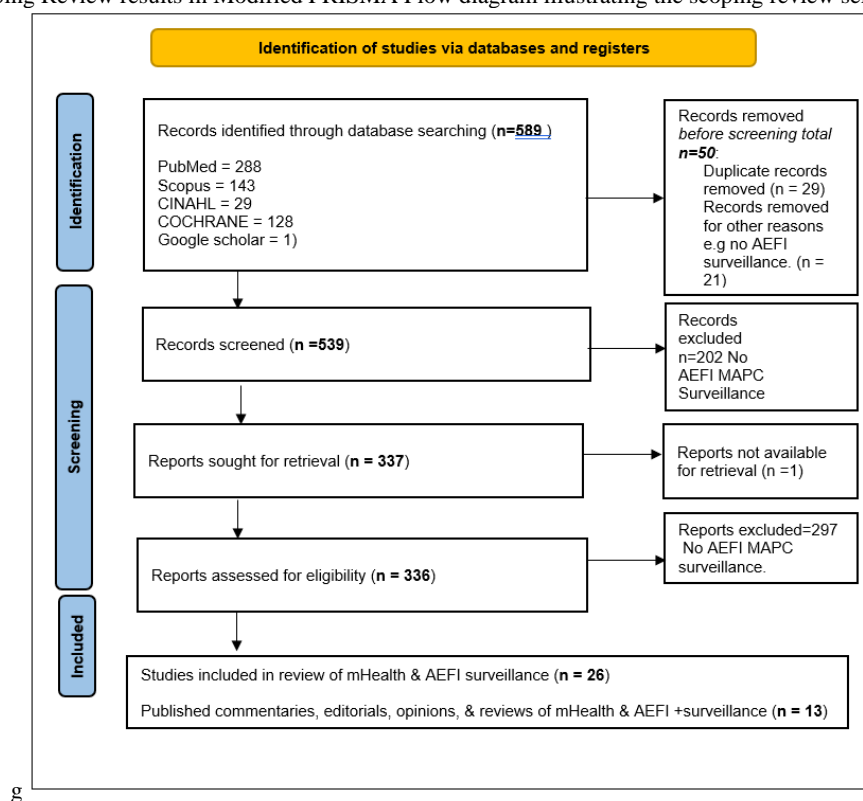
A data extraction form was used to systematically extract data from the included studies for assessment of study quality and evidence synthesis. In addition to basic details of the article (first author, journal name, year of publication etc.), details of the study were summarized in the data extraction table. This includes type of mHealth system assessed, aims and objectives, performance measures such as system effectiveness and feasibility, cost, key findings, and study limitations. Studies were grouped based on the mHealth systems used to conduct AEFI surveillance. Published commentaries, editorials and other soft literature were also reviewed and incorporated into the discussion. Focus was to establish whether the MAPC system supported AEFI surveillance successfully in the settings in which it was used, whether there were any challenges encountered in implementation and whether there were any lessons learnt that would assist us in ensuring the success of such a system in an African setting.

RESULTS

Data Synthesis and Analysis of Scoping Literature Review Results of (MAPC) AEFI Surveillance

The final presentation of the results of the scoping review of mHealth Active Participant Centered (MAPC) AEFI surveillance data extraction tools and analysis are shown in Figure 2 to Figure 5 and Table 1. Figure 2 is the scoping review results in PRISMA Flow diagram showing that a total of 39 published papers were included of which 13 were commentaries and 26 were MAPC AEFI surveillance studies.

Figure 2: Scoping Review results in Modified PRISMA Flow diagram illustrating the scoping review selection process [8].



Results of Summary of Themes and Opinions of 13 Commentaries, Editorials, Opinions (Soft Literature) of Digital and MAPC AEFI Surveillance, in four thematic areas

We included commentary papers in our scoping review to understand the global scope of mHealth in supporting AEFI surveillance in four thematic sections below. Of the 13 published commentary papers that met the scoping literature review inclusion criteria, two (15%) were from the USA and Canada, and the remaining 11 articles (85%) were from the WHO European Region (EURO). These commentaries stated important points on quality, quantity, and timeliness of AEFI reporting, direct consumer vaccinees/guardian including, support improved safety data analyses and feedback to reporters but were silent on MAPC surveillance feasibility, barriers, cost, and challenges. The commentaries were not evidence-based studies per se but made important advocacy for use of mHealth to improve AEFI surveillance for holistic improvements of the immunisation national programs. The results of the scoping literature review of these 13 commentaries mainly from HICs were summarized into four thematic areas most of which showed the potential benefits of MAPC on AEFI surveillance. They do not seem to mention anything about costs, limitations, potential risks or concerns raised.

mHealth and eHealth Information Sharing and MAPC surveillance

mHealth and eHealth technologies showed effectiveness as advocacy and knowledge sharing tools to support immunisation programmes. Digital health technologies with social media surveillance can be exploited to identify and respond to public information needs when delivering vaccination campaigns [4]. Interactive and user-friendly chatbots, can provide vaccinees/guardians with information they need about vaccinations (e.g., VACC tool) [9]. Digital tools and new media can be exploited to accurately identify information needs and effectively delivering vaccination campaigns [9]. Mobile apps can provide consumers with information on vaccine choices [9]. Mobile Apps allow dissemination of correct information to patients [10]. There is need to use Artificial Intelligence (AI) to analyse large AEFI datasets to exclude inherent biases [11]. VACC Tool TM empowers parents to be well informed about vaccinations [12]. A social ecological model-based framework for the use of technology to promote vaccination and AEFI surveillance worth exploring in LMICs through evidence gathering was proposed [13]. To express the highest impact of communication technology strategies in COVID-19 era, communication should be closely intertwined with surveillance activities, to inform timely and effective public health actions [14,15].

Side Effects, Adverse Events, AEFIs and MAPC surveillance

MAPC has shown value in HIC settings to empower patients to provide direct information on their experience with vaccine in relation to AEFI, it can also empower clinicians to recognise and report AEFI hence improved detection of rare events. MAPC AEFI surveillance systems have the potential to improve AEFI reporting, signal detection and central pooling of data into the hands of the regulators and immunisation programs. In many AEFI surveillance systems, patients do report health events [4]. The USA, V-Safe mobile App, UK Yellow card App can empower individuals to provide early AEFIs reports [11].

Mobile Apps enable clinicians to identify and diagnose potential adverse events at point of care [12]. Some SMS mHealth can be designed by the national EPI program to collect vaccine side effects and AEFIs directly from patients [13]. Mobile Apps may reduce under reporting of rare side effects and AEFIs [16]. Mobile technology could improve AEFI reporting [17].

Vaccination Rates, Vaccine Uptake and MAPC AEFI surveillance

An expanded use of digital tools is expected to ultimately increase immunisation coverage, reduce vaccine preventable disease incidence, and reduce AEFI by timely communications with EPI HCWs and vaccinees/consumers [4]. The COVID-19 vaccine apps like USA V-Safe App improve consumers (vaccinees/guardian) engagement for AEFI surveillance and advocacy to address vaccine hesitancy [9]. SMS messages affect consumer behavior and increase COVID-19 vaccinations uptake [10].

Quality of AEFI Reporting and MAPC AEFI Surveillance

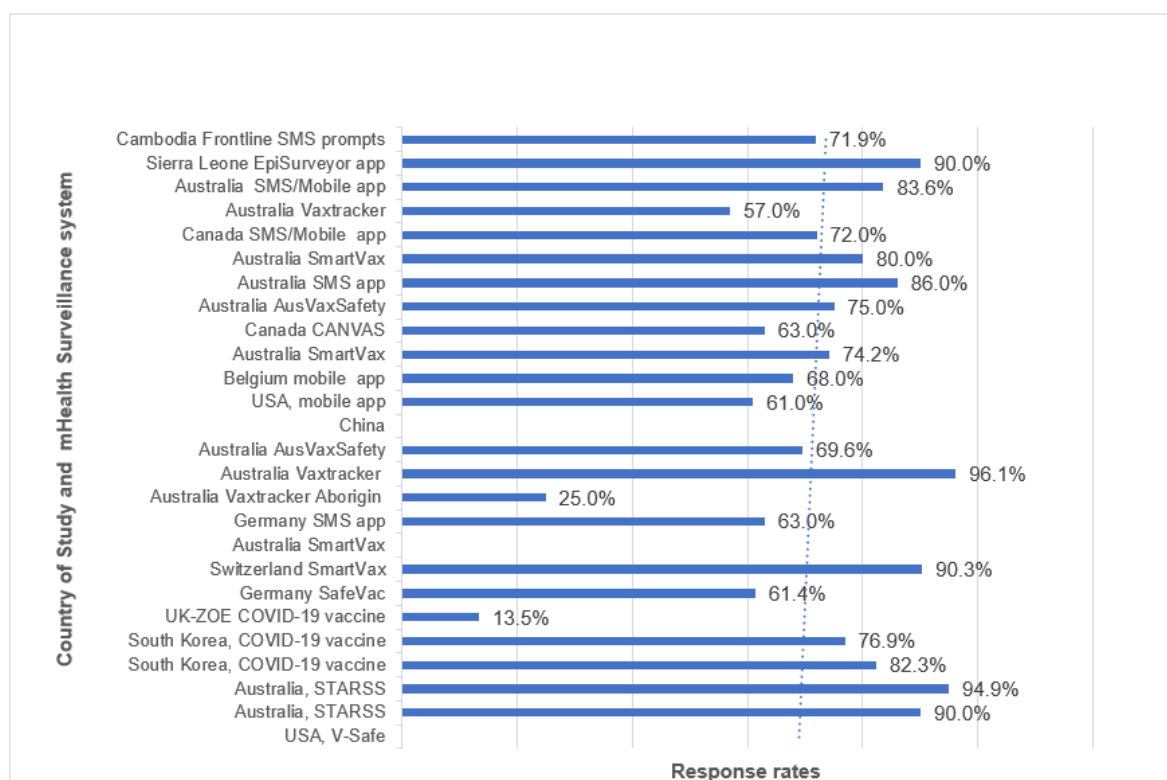
Mobile devices can improve timeliness and accuracy of data to central immunisation information systems including AEFIs [17]. SMS and mobile Apps allow assessment of patients early AEFIs reporting [18]. VACC Tool app assists doctors to assess patients and compare their clinical presentation to a set of diagnostic algorithms for AEFIs and follow up [16,19]. Automated question and answer systems may help improve quality of information transmitted to pharmacovigilance agencies including AEFIs [19].

Summary of Results of Scoping Review MAPC AEFI Surveillance Published Studies

Table 1 shows summary of the 26 included studies of MAPC AEFI surveillance of which all 24/26 (92%) were from HICs (Australia, Belgium, China, Canada, Germany, Switzerland, UK and USA) the remaining 2/26(8%) were from Cambodia and Sierra Leone. The median response rate for most HICs' 23 studies was 72.6%, the mean was 71.2% (standard deviation +/- 0.2004). Three studies did not state the SMS and/or Mobile App AEFI response rates [20-22]. Australia had the highest number of studies totaling 12/26 (46%) and highest response rates of 96.1% for SmartVax and 90.2% for STARSS [23,24]. Figure 4 below shows the SMS response rates for the 23 studies. The Swiss SmartVax system also had high response rate of 90.3% [25]. The SMS response rate was defined as the proportion of study participants who responded to the SMS prompt that were sent on different days (0,2,3,4,7,14,21,28 & 90) post vaccination soliciting for their AEFI experience.

Figure 3: Global distribution of studies employing or assessing mHealth Active Patient-Centred AEFI surveillance systems.



Figure 4: Scoping Literature review results of countries mHealth surveillance system response rates.

Eleven studies (11/26) utilized four different systems arising from Australia alone. Five studies (5/26) were conducted in Europe (Belgium, Germany, Switzerland, and United Kingdom), United States and Canada.

Figure 3 provides a graphic representation of the global distribution of studies conducted and the types of systems described in Table 1 below.

Author (Ref) Country, WHO Region	mHealth Active AEFI surveillance system and # of Time points of event AEFI surveillance	Objectives.	Study Design & Surveillance system(s).	Population monitored; sample size & vaccine covered.	Study findings, strengths and limitations.
1. Roseblum et al. 2022 [26] HIC, WHO AMR.	V-Safe system. Voluntary system. # Daily from days 0-7 post vaccination.	Reviewed VAERS and V-safe data during first 6 months of USA COVID-19 vaccination programme.	Observational study for both VAERS and V- Safe system.	n = 7 914 583 vaccinees received COVID-19 mRNA vaccines. Completed at least one V-Safe health survey. 298 792 852 mRNA vaccine doses administered.	Safety profile of COVID-19 vaccines. 340522 reports. 1049.2 non-serious reports per million doses and 90.4 serious reports per million doses via VAERS. Massive dataset included pregnancy exposures and outcomes. SMS combined with web based AEFI survey. Response rate not stated
2. Stockwell MS et al. 2017 [27] USA, HIC, WHO AMR.	USA SMS system 2017 CATI Brand name not stated. # 0d, 2d, 3d & 10d post vaccination.	Assessed fever frequency after pediatric live attenuated versus inactivated influenza vaccines.	Observational study.	(84.1% [n = 540]) eligible 24 to 59 months old children & guardians enrolled. Live attenuated influenza vaccine (LAIV) quadrivalent (LAIV4) or IIV	61 % SMS response rate timely & 39% paper diaries return delayed. AEFI reporting rates low & fever frequencies on d 0 to d2 similar for LAIV4 & any IIV3 or IIV4.

				(trivalent IIV3 or quadrivalent IIV4.	
3. Gold MS et al. 2022 [24]. (Australia) WHO WPR.	STARSS (Stimulated Telephone-Assisted Rapid Safety Surveillance). # 0- 2d, 7d, 14d and 21-day post vaccination.	Evaluated AEFI detection efficacy of STARSS SMS tool for active AEFI surveillance.	Multi-centre randomized controlled trial (RCT).	n = 6338. Adults and children/ guardian vaccinees.	90.2% SMS response rate. AEFI reporting rate (4.3% vs. 0.3% controls). AEFI detection rate 13-fold greater in SMS group c.f. controls. AEFI report completion rate higher in SMS CATI (58.2%) rather than web-based report (30.5%). Web-based AEFI report completed faster from AEFI event time. Opt-in consent system > reporting rate than opt-out AuxVaxSafety system.
4. Gold MS et al. 2022 [28]. (Australia) WHO WPR)	STARSS SMS system.	Evaluated consumer acceptability of STARSS SMS system.	Study nested within STARSS RCT, questionnaire-based survey.	1200 (20%) of RCT participants, of which 1139 completed questionnaire.	96% indicated SMS-based surveillance "should be done". 62% should be done with consent. Consent and data privacy highlighted as key issues. Few participants non-compliance was largely demographic rather than attitudinal.
5. Choi YY et al. 2021 [29]. South Korea, HIC, WHO WPR.	Telephonic interview & self-report questionnaire. # Monitored AEs 15-30 min and 7 days post vaccination dose cf. passive AEFI surveillance.	Examined safety of BNT162b2 COVID-19 vaccines in adults ≥ 75years of age.	Observational study	2123 elderly (>75-years old) COVID-19 vaccinees. 807 (38%) CATI. Proxy responses accepted.	79.1% & 90.9% SMS response rates after 1 st and 2 nd doses. Overall response rate 82.3%. Proxy responses increased with age. AEFI reporting rate 50-45% local AEFIs & 16-26% systemic AEFIs 1st & 2nd doses respectively. Higher response rate after 2nd dose due to selection bias i.e., only included 1st dose respondents.
6. Bae S et al. 2021 [30]. South Korea, HIC, WHO WPR.	South Korea, mHealth AEFI surveillance SMS system. # 3 days post vaccination.	AEFI surveillance of 1st doses ChAdOx1 nCoV-19 and BNT162b2 vaccines administered in HCWs.	Observational study.	n = 7,625 South Korean HCWs.	76.9% overall SMS response rate & AEFI reporting rate higher in ChAdOx1 (93.3%) than BNT162b2 (80.1%; P < 0.001).
7. Menni C 2021 [31]. UK-HIC, WHO EUR.	UK- ZOE COVID-19 Symptom 2021 Study mHealth app and mobile self-report questionnaire. # 8-day post vaccination.	Phase 3 investigation of safety & effectiveness of BNT162b2 and ChAdOx1 nCoV-19 vaccines.	Observational study.	Adults n = 3106 of 103622 vaccinated & n = 50340 of 464 356 unvaccinated controls.	13.5% SMS response rate & AEFI reporting rate 13.5% (38 155 of 282 103) vaccinees systemic AEFIs after 1st dose 1.4x for ChAdOx1 nCoV-19 & 1.2x for BNT162b2.
8. Nguyen M.T.H. et al. 2020 [32]. Germany, HIC, WHO EUR.	SafeVac mHealth mobile app. # 0 to 3 months post vaccination questions asked at 15-time intervals.	Feasibility of a German SafeVac mHealth app for AEFI surveillance use by bank employees.	Observational study.	n = 462 consented to participate. Seasonal Influenza vaccinees AEFI surveillance.	337 of 462 (72.9%) one entry used app. 207 (61.4%) used app in 3 months study period. Only 6 completed the usability survey. Participants cited reservations on confidentiality of SMS

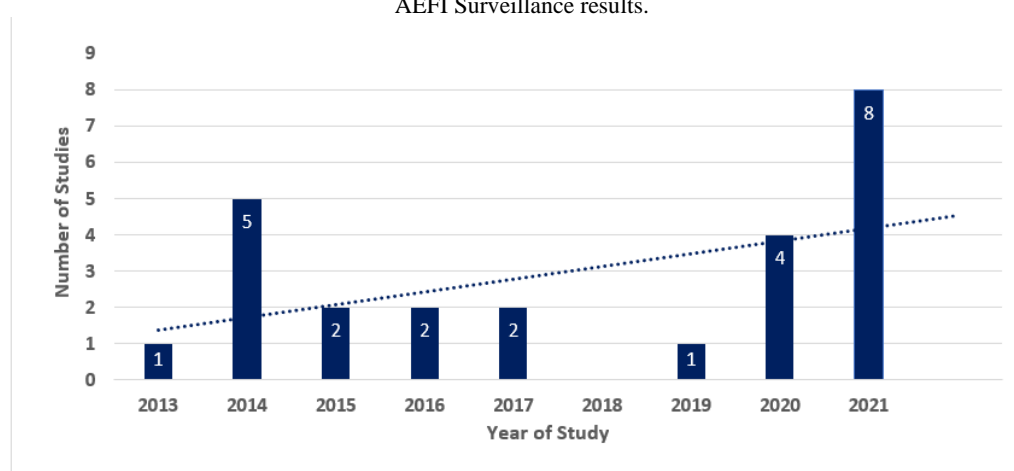
					app. Correct app entry associated with increasing age and higher.
9. Nguyen M.T.H et al. 2021 [33]. Germany, HIC, WHO EUR.	Germany mHealth mobile app-based prototype. #0-3 days post vaccination.	Feasibility of a German mHealth app, AEFI use by bank employees for seasonal influenza vaccination Nov 2017.	Observational study.	153 employees, n = 65 (42%) agreed to participate & completed survey.	63% rated positive App use. 46 (71%) experienced difficulties using app and internet connection. Push notification tolerated. Lack of time and data protection concerns raised. 43% (28) Participants declined participation cited reservations of mobile app, data protection and demand for transparency.
10. Guedel D S et al. 2021 [25]. Switzerland, HIC, WHO EUR.	Switzerland SmartVax 2021. # 3 days post vaccination.	Feasibility & acceptance study of SmartVax Smart phone based AEFI system.	Observational pilot feasibility and acceptance study.	Influenza & Zoster vaccinees adults n = 276 (46.6%), 33.3% HCW, 20.1% patients) received 625 vaccinations.	90.3% SMS response rate and 29.8% AEFI reporting rate.
11. Singh G et al. 2021 [34]. Australia, HIC, WHO WPR.	Australia SmartVax 2021.	Determined pharmacists' experiences with SmartVax:	A qualitative descriptive study	n = 15 Pharmacists. COVID-19 vaccines.	Positive SmartVax perceptions. Small qualitative study.
12. Salter S M et al. 2020 [23]. Western Australia (WA) HIC.	Australia SmartVax 2020. # 1-7 days post vaccination.	SMARTVax active AEFI surveillance system in 22 pharmacies cf. passive surveillance in 90 general practice (GP) and other clinics).	Observational study. March and October 2020	>10-year-olds. n = 101,440 influenza vaccinees (6,992 from pharmacies; 94,448 from non-pharmacy sites.)	SMARTVax SMS response rate 96.1% within 1day and 76.4% day 7. AEFI reporting rate 4.8% pharmacists n = 247 cf. 6.0% non-pharmacists n = 4,356.
13. Westphal DW et al. 2016 [20]. Australia, HIC, WHO WPR.	Australia SmartVax. # 3 days post vaccination.	SmartVax feasibility paediatric study on reactogenicity profiles and impact assessment of revised childhood immunisation schedule.	Observational study.	3992 vaccination visits. n = 1667 children<5. 3906 SMS's sent. Diphtheria–Tetanus–Pertussis–Poliomyelitis (DTPP) vaccine.	74.2% SMS response rate among 1216 of 1667 patients included. Response to first SMS within 2 hours for 81.3% of responders. AEFI reporting rate 8.2%.
14. Leeb A et al. 2014 [35] Australia, HIC, WHO WPR.	Australia SmartVax. # 1-3 days post vaccination.	Effectiveness study of SmartVax to monitor AEFIs in GP.	Observational study	n = 3281 children/guardian pairs taking Influenza vaccines and others.	80% SMS response rate 1st day and 72.6 % within day 3 post vaccination.
15. Cashman P et al. 2020 [36] Australia HIC, WHO WPR.	Australia Vaxtracker. # 0 to 28 days post vaccination.	Explored potential barriers to participation in Vaxtracker automated active AEFI surveillance by Aboriginal parents of children vaccinees.	Observational study.	Aboriginal children (47.2%) versus non-Aboriginal children (25.4%) in 105 non-Aboriginal families. (Aboriginal n = 13/28, non-Aboriginal n = 75/91). Influenza or DTPa vaccinees.	SMS response rate & AEFI reporting rate lower in Aboriginal children guardians (25.4%). c.f. non-Aboriginal children (47.2%). Complex sampling matrix. Findings showed lower SMS mHealth MAPC AEFI surveillance uptake in some socioeconomically disadvantaged Aboriginals in a HIC.

16. Cashman P et al. 2014 [37] Australia, HIC, WHO WPR.	Australia Vaxtracker. # 3- & 42-days post vaccination.	Vaxtracker web-based survey for active Post Marketing Surveillance (PMS) of AEFIs.	Prospective study Vaxtracker.	n = 477 children 6 months to <10 years administered Inactivated influenza vaccine.	57% & 61% SMS response rates in 2012 & 2013 respectively. AEFI reporting rates were not stated although acute & delayed AEFIs were detected.
17. Pillsbury A J et al. 2020 [38] Australia. HIC, WHO WPR	SmartVax (most commonly used) and Vaxtracker deployed. #3 to 5 days post vaccination.	AusVaxSafety study. PMS safety profile of 2018 influenza vaccines, an adjuvanted trivalent inactivated influenza vaccine (aIIV3) and high-dose trivalent inactivated influenza vaccine (HD-IIV3).	Observational study	Adults \geq 65 years. n = 72013 administered Influenza vaccine aIIV3 and HD-IIV3.	69.6 % SMS response rate. HD-IIV3 (8.9%) higher AEFI reporting rate than aIIV3(6.4%) (P < .001). Denominator data but AEFI events not clinically verified by healthcare professionals including fatalities. Causality assessment not necessarily done.
18. Pillsbury A J et al. 2017 [39] Australia. HIC, WHO WPR.	AusVaxSafety. Day 3 post vaccination.	Feasibility study of AusVaxSafety AEFI surveillance of children seasonal influenza vaccines in children, in 2015.	Observational study.	n = 7402 children administered Influenza Meningococcal B vaccines.	75% SMS response rate. AEFI reporting rates lower fever for influenza vaccine 7.3% c.f. 30.3% (p < .001) higher rates for Meningococcal B vaccine. Concomitant vaccines caused more fever (7.5% versus 2.8%; p < .001).
19. Reagan AK et al. 2015 [40]. Australia, HIC, WHO WPR.	Fast Mum SMS system. # Day 7 post vaccination.	Investigated FAST Mum mHealth active AEFI surveillance cf. post-vaccination AEFIs self-reported by pregnant women versus non-pregnant women receiving TIV.	Observational study comparing the reactogenicity of trivalent influenza vaccine (TIV) in pregnant and non-pregnant women.	Pregnant women = 3173 however response from 1086 pregnant & 314 non-pregnant women (Total 1400). Influenza vaccines.	86% SMS response rate AEFI reporting rates similar for pregnant & non-pregnant women (13.0% & 17.3%, respectively; OR = 1.2 [95% CI: 0.8-1.8]). SMS active AEFI surveillance used successfully in maternal health. TIV use safe in pregnancy as well.
20. Regan AK et al. 2014 [41]. Australia, HIC, WHO WPR.	FAST Mum SMS system. # Day 7 post vaccination.	FAST Mum AEFI surveillance for Trivalent Influenza Vaccine (TIV) for pregnant women.	Prospective study Using SMS to monitor AEFIs trivalent influenza vaccination in pregnant women.	n = 5155 pregnant women administered Trivalent Influenza Vaccine (TIV).	83.6 % SMS response rate higher than 63% telephone response P < 0.001. AEFI reporting rate not stated.
21. Stuurman AL et al. 2017 [42] Belgium, HIC WHO EUR.	Belgium 2017 MAPC AEFI Surveillance system. Brand name not stated. #0 to 7 days post vaccination.	Assessed feasibility of collecting reactogenicity data within one month of start of a vaccination campaign in Belgium.	Feasibility study.	n = 100 adults aged 18 to 65 years. Post vaccination of inactivated seasonal influenza vaccine, in occupational setting.	68% SMS response rate & AEFI reporting rate: 68% local AEFIs & 65% general AEFIs & 51% reported both a local & a general AEFIs.
22. Baron S et al. 2013 [22]. Cambodia. LMIC, WHO WPR.	Cambodia Frontline SMS - prompts AEFI Surveillance system. # 48hour post vaccination.	To field test Frontline SMS software to see whether it could provide effective and timely notification of AEFI.	Observational study. Pilot proof of concept.	Cambodian adults >18 years old. n = 184 (13.8%) of 1331 vaccinees, agreed to participant in study. Hepatitis B 41.8%, influenza 11.9%, tetanus 10.9%, & HPV (10.9%) vaccines administered.	71.7% - 54.9% SMS response rate after 1st response & 16.8% after further prompts. AEFI reporting rate 17.4% (23) reported benign AEFIs and 82.6% no AEFIs.

23. Wilson K et al. 2016 [43]. Canada, HIC, WHO AMR.	CANADA CANVAS (Canadian National Vaccine Safety Network) 2016. #Day 1- & 6-months post vaccination.	Evaluated the feasibility, usability and proof-of-concept mobile App to facilitate AEFI reporting for CANVAS network for seasonal influenza vaccine.	Observational study	n = 76 adults consented, 48(63%) successfully downloaded App and 38 (50%) completed all surveillance surveys.	SMS response rate 63% (48) 50% (38) completed survey.86% preferred SMS App. Both acute & delayed AEFIs were detected. AEFI reporting rate not stated.
24. Bettinger JA et al. 2014 [21]. Canada, HIC, WHO AMR.	CANADA 2014 SMS web system. #2 & 7days post vaccination.	Feasibility study of Rapid Online Identification of AEFIs After Influenza Immunisation in Children by PCIRN's National Ambulatory Network.	Observational study.	n = 1230 guardians & children. Trivalent influenza vaccine & live attenuated intranasal vaccine.	72% of online SMS survey response rate & 11% by phone responded. AEFI reporting rate not stated although AEFIs detected.
25. Zeng J et al. 2019 [44]. China, MIC, WHO WPR. Zhonghua Yu Fang Yi Xue Za Zhi	Chinese SMS mobile system 2019. #30min, 3- & 30-days post vaccination after each dose of EV-A71 immunisation.	Evaluated PMS profiles of inactivated enterovirus type 71 (EV-A71) vaccine (Vero cell).	Observational study. Mixed methods by field observation, participants phone-calls or face-to-face interview.	11 cities Chinese n = 45 239 children who received 71 243 doses EV-A71 vaccine. Inactivated enterovirus A71 vaccine (Vero cell)	SMS response rate not stated. AEFI reporting rates higher in 30min 1.016%- & 3-day 0.698% 1st & 2nd doses post vaccination. Mobile phone calls mostly used for follow up AEFI surveillance.
26. Sesay F. F et al. 2014 [45]. Sierra Leone, WHO African Region (AFR).	Sierra Leone mobile app EpiSurveyor 2014	Measured coverage of Vitamin A Supplementation (VAS) and measles vaccination plus AEFIs during Maternal and Child Health Week (MCHW).	Observational study	Children vaccines and guardians' pairs in Vitamin Measles vaccines campaign.	90% SMS response rate. Higher AEFI reporting rate via SMS linked post event coverage survey (29.1%) than MCHW (0.01%) (p,0.0001). Mobile app EpiSurveyor done post vaccination. Time points of AEFI surveillance not stated.

Table 1: Results of studies summary of findings included in the of mHealth Active Participant Centred (MAPC) AEFI surveillance Scoping literature review from 1970 to July 2022.

Figure 5: Summary of mHealth AEFI Surveillance Studies from 2013 to 2021 under Scoping Literature Review of MAPC AEFI Surveillance results.



More than half of the studies included in the literature review 15/26 (57.7%) were from the Western Pacific Region of which the majority 12/26 (46.2%) were conducted in Australia. One USA study (V-safe) was conducted and linked to the national Vaccines Adverse Events Reporting System VAERS AEFI surveillance database. Two studies of SMS mHealth linked to the Canada (CANVAS) national AEFI surveillance system but use many other

digital systems were not included since they were beyond the scope of this study. Four studies 4/26 (15.4%) were conducted in Europe (Belgium, Germany, Switzerland and United Kingdom).

As illustrated in Table 1 and Figure 5, MAPC AEFI Surveillance has grown steadily over the last 9 years. It increased initially due to the safety concerns of serious AEFIs raised for seasonal influenza vaccines from 2010 to 2014 then expanded to other vaccines including COVID -19 vaccines.

DISCUSSION

All studies except two (one from Cambodia and one from Sierra Leone) were conducted in HICs with Australia and Canada publishing the most. Most MAPC studies focused on seasonal influenza vaccine, and more recently for COVID-19 vaccines, where data on safety needs to be obtained very quickly after regulatory approval in the context of HICs settings. MAPC surveillance logistics and details on cost implications were not available. Most MAPC systems were integrated into already existing national eHealth AEFI surveillance systems such as CANVAS in Canada, VEARS in the USA and most MAPC AEFI surveillance systems in Australia linked with their AusVaxSafety or national AEFI eHealth system. From a few of the scoping literature review findings, a pre-requisite for the use of MAPC AEFI surveillance using new SMS or app-based technology was the identification of practical challenges and end users' preferences for design of user-friendly acceptable app-features [32]. MAPC AEFI surveillance provides a unique opportunity for early AEFI detection and consumer(vaccinees and guardians) engagement on their experience post-immunisation. Such MAPC AEFI surveillance system can potentially be embedded in both pre-licensure clinical trials and post-licensure AEFI surveillance systems [46].

A key advantage of the MAPC approach is that it can seek information directly from vaccinees or their guardians almost immediately (0-3 days) after vaccination and at different time points post-vaccination. Time points can be varied depending on the type of AEFI being investigated, but most studies did not send prompts or reminders beyond 2 weeks post-vaccination. Response rates to SMS messages were highest (65% - 90%) after the first 0-3 days of SMS reminder and decreased significantly thereafter. A key limitation of most of the studies was that SMS prompts were sent between 0 to 14 days post-vaccination hence delayed AEFI manifesting beyond 14 days might be missed through the MAPC surveillance system.

Common, expected AEFIs usually related to the reactogenicity of the vaccine were the most likely AEFIs to be reported via MAPC systems and occasionally serious AEFIs were detected. Like the SMS response rates, AEFI reports decreased with time and subsequent prompts. The scoping literature review provided evidence in 23 studies (88.5%) that SMS or Mobile Apps improve AEFI detection and reporting rates for most types of vaccines and different types of vaccinees populations in the 12 countries. For the UK COVID-19 vaccines phase 3 (EUA) MAPC surveillance study AEFI detection and AEFI reporting rates (13.5%) were the same relatively lower than all studies perhaps since it was pandemic use of two new vaccines may be with less acute AEFIs that older vaccines [31].

A narrative review of participant-centered active surveillance recommended that national immunisation programs should enhance passive/spontaneous AEFIs surveillance system with early sensitive post-marketing AEFI surveillance systems to ensure public safety and public confidence in vaccines [46]. MAPC AEFI Surveillance

provides the advantage of early /prompt AEFI surveillance that may ultimately result in prompt AEFI case management and improved patient outcomes and survival. The growth of MAPC AEFI surveillance was initially mostly due to concerns of safety of annually reformulated influenza vaccines since 2010 to 2019. In HIC a sizable number the MAPC AEFI surveillance projects were successfully scaled-up between 2016 to 2022 with no evidence of similar scale up in LMICs [46,47]. Australia and some HICs initially launched robust national vaccination eHealth Records systems so it was easier to implement MAPC AEFI surveillance systems. The findings of this scoping review study are consistent with another study that looked at several digital participants centered active AEFI surveillance systems including integration into other surveillance and health information systems [47]. Over many years most HICs have invested in robust electronic immunisations information systems (IISs) that are confidential, population-based and linked to other national eHealth records for example since 1998 Canada built regional Internet IIS registry that is integrated into national intercommunicating networks and CANVAS [47]. The US, Center for Disease Control (CDC) oversees a vaccine tracking system (VTrackS) for publicly funded vaccines that is linked to the Vaccine Safety Datalink project which accesses Electronic Health Records (EHRs) from various health care organizations [47]. In addition the USA has V-Safe a new smartphone-based health checker for people who have received COVID-19 vaccines [26]. In order to promote consumer AEFI reporting the Italian national eHealth and mHealth AEFI reporting system reimburses consumer mobile cost incurred on reporting AEFIs [15].

Regrettably, most LMICs do not have such robust eHealth or mHealth systems even for immunisation programs. Efficient and effective AEFI surveillance is possible when health systems and immunisation records are electronic, and patients are empowered as well as prompted to give early feedback to HCWs post vaccination. A study of several enhanced spontaneous smartphone mobile Apps in some countries were linked to the national pharmacovigilance centres database and ultimately to WHO Vigibase for spontaneous monitoring Adverse Drug Reactions (ADRs) but were not MPAC AEFI surveillance [48]. The UK Yellow card mobile App and WEBRADAR Medsafety App are examples of spontaneous ADR Apps in HICs that were recently expanded to selected few there is few LMICs such as Botswana, Ethiopia, Ghana, Nigeria, South Africa and Zambia . These reporting apps do not have the AEFI active surveillance time point SMS prompts [49] . Very few studies in LMICs (Peru, and Cambodia) considered use of mHealth and digital tools to monitor real-time (active surveillance) of adverse events due to medicines and vaccines [50].

Engagement of consumers in AEFI surveillance reporting is recommended by some authors to enhance spontaneous AEFI reporting [48,49]. Post-marketing active AEFI surveillance by direct contact with consumers can provide timely AEFI surveillance data such as AEFI rates that allow comparison with pre and post -licensure vaccine safety data for signal detection [46, 47]. According to the WHO Vaccine Safety Blueprint report, all countries are required to have a robust AEFI surveillance system with both active and spontaneous AEFI surveillance methods. Moreover, each country needs to contribute its AEFI reports into the WHO VigiBase database so that these collective AEFI datasets can be used to support signal detection and analysis, and identification of risk minimization opportunities. Consumers and patients can use digital health technologies to better manage and track their health and wellness-related activities. When data derived from MAPC AEFI surveillance is made publicly available, this improves transparency and ultimately improves public confidence in the national immunisation program [46,47].

In 2019 the WHO identified vaccine hesitancy as a 10th public health problem since it results in poor vaccine uptake and ultimately increased burden of vaccine preventable diseases (VPDs) [3,51]. Further studies are required in LMIC to determine how expanded use of digital tools including mHealth may reduce vaccine hesitancy and improve vaccination coverage through more direct consumer engagement, education including the transmission of vaccination reminders. This is likely to increase immunisation coverage through increased public participation and hence reduce the incidence of vaccine preventable diseases. As demonstrated in this scoping review, MPAC has the potential to promote early detection of AEFI and possibly reduce the risk of serious consequences through rapid follow-up. Ultimately AEFI surveillance systems and increased consumer engagement have the potential to improve immunisation strategies by supporting the public to make informed decisions.

For integration of MAPC AEFI surveillance into the national immunisation program in LMICs the following considerations are required:

- Given the major challenges of underreporting by HCW, and the need to monitor vaccines that are primarily used in LMIC settings, there is a need to assess the efficacy and feasibility of MAPC AEFI surveillance systems in LMIC settings such as Zimbabwe.
- Some scholars suggest that applying digital tools including mHealth can favour the intersection of three crucial dimensions of immunisation programs namely immunisation registries, surveillance of vaccine-preventable diseases, and surveillance of AEFIs [46,47].
- Most LMICs have limited resources for national immunisation programs with vaccines being usually procured by donor and intergovernmental agencies. In view of the above, MAPC AEFI systems should be tested in LMICs as well to determine a holistic resource maximization approach and seamlessly integrated into immunisation programs.
- Consideration on how MAPC should be incorporated into the programme requires comprehensive engagement of stakeholders including, regulators, EPI programme managers, other relevant health departments, mobile phone companies and the national treasury.
- • None of the literature searches elaborated on the practical and cost implications of scaling up MAPC approaches in LMIC settings. It's also not clear how the increased penetration of mobile phone technologies could reduce the cost and accessibility of SMS, mobile APPs for AEFI surveillance especially for rural communities.
- Questions still remain around how to optimise the use of limited resources for vaccination programs?. What are the implications of implementing such systems on an already overstretched health care system? Are there priority vaccines or populations that are more likely to benefit from such an active surveillance approach if limited resources preclude nationwide implementation? What is the impact of such a system on vaccine confidence and uptake? How cost-effective are such systems in detecting signals of serious vaccine reactions and community concerns around the safety of vaccines compared to other approaches such as social media surveillance?
- With the accelerated emergency vaccines development for pandemics such as TB, Malaria, Dengue, Ebola, COVID-19 in addition to routine vaccines it is paramount that LMICs quickly invest and adjust to holistic

means of health systems strengthening including eHealth and mHealth for the national immunisation programs and AEFI surveillance.

The potential of participant centered active AEFIs surveillance utilizing digital health and mHealth technology still requires investigations in LMICs for their feasibility, potential for scaling up, and cost effectiveness. The MAPC AEFI surveillance scoping literature review from 1970 to July 2022 strictly followed the JB Scoping Literature Review Manual 2021 hence minimised errors and bias. The limitation of the study was that its inclusion criteria was only MAPC AEFI surveillance for all vaccines including campaigns and COVID-19 vaccines, and excluded other types of digital active AEFI surveillance systems. Other digital participant active surveillance methods included in other narrative or scoping review studies were done independently at different times beyond the scope of this study from a LMIC perspective [46,47]. Also, at the time of writing and publication of this study, other MAPC AEFI surveillance studies could have been published and might have been missed.

CONCLUSION

The scoping review has demonstrated that MAPC AEFI surveillance is expanding mainly in HICs. MAPC AEFI surveillance empowers consumers by enabling them to manage their own healthcare journeys including detection, presentation, and management of AEFIs. More evidence is required on feasibility, consumer and HCWs acceptability, cost effectiveness including enhancing mHealth technology and other digital technologies for early detection of AEFIs in LMICs. Holistic implementation on MPAC surveillance with national immunisation systems has the potential to reduce the strain on scarce HCWs, improve AEFI reporting, AEFI case management, and enhance public confidence in vaccinations uptake thereby minimizing VPDs. Most LMICS have weak passive or spontaneous AEFI surveillance systems with drawbacks of delayed or/and underreporting that compromise case investigation and management. The key benefits are sustainability, flexibility, affordability and timelines of near real time AEFI detection which are the essential elements required for effective vaccine safety monitoring and management. Further studies are however required of whether and how MAPC Active surveillance ultimately result in public trust in immunisation programs, reduced vaccine hesitancy and improved vaccination uptake.

DECLARATIONS

Limitations, confounding factors and/or bias of study were stated under discussion section. Studies not using SMS MAPC AEFI surveillance but used other digital forms of AEFI surveillance such as web, emails, e-diaries, eHealth and Telewatch were not included since they were beyond the scope of the study from a LMIC perspective where such systems are beyond the reach of the majority of vaccinees.

Ethics Approval and Consent to Participate.

The study was approved by the Medical Research Council of Zimbabwe (MRCZ) ethical approval reference MRCZ/A/2268 and MRCZ ethical exemption (reference E/148) and the University of Cape Town (UCT) Human Research Ethics Committee (HREC 184/2020) as part of the first author PhD protocol.

Consent for Publication

Not applicable.

Competing of Interest

The authors declare no conflict of interest nor potential competing interest.

Funding

Not applicable. Self-funded study by first author in fulfilment of her PhD study requirements.

Author Contributions

PPMN designed the study and wrote the main manuscript as the lead author. MSG and UCM supervised the study and reviewed the manuscript. PPMN analysed data and performed analysis including tables and figures with assistance from an experienced University of Cape Town Librarian. All authors read and approved the final manuscript.

Acknowledgements

The authors acknowledge Ms Gill Morgan, Librarian at University of Cape Town, for her expert assistance in scoping literature review database searches.

REFERENCES

1. Heininger U, Holm K, Caplanusi I et al. (2017) Guide to active vaccine safety surveillance: Report of CIOMS working group on vaccine safety–executive summary. *Vaccine* 35(32): 3917-3921.
2. Bahri P, Rågo L (2019) CIOMS Guide to vaccine safety communication–executive summary. *Vaccine* 37(3): 401-408.
3. Nyambayo P, Manyevere R, Chirinda L et al. (2023) Descriptive Research Study of the Adverse Events Following Immunisation (AEFIs) Surveillance System in Zimbabwe. *Clinical Case Reports and Studies* 2(2): 2837.
4. Tozzi AE, Gesualdo F, D'Ambrosio A et al. (2016) Can digital tools be used for improving immunisation programs? *Frontiers in Public Health* 4: 36.
5. Istepanian RS (2022) Mobile health (m-Health) in retrospect: The known unknowns. *International Journal of Environmental Research and Public Health* 19(7): 3747.
6. Tricco AC, Lillie E, Zarin W et al. (2016) A scoping review on the conduct and reporting of scoping reviews. *BMC Medical Research Methodology* 16(1): 1-10.
7. Peters MD, Marnie C, Tricco AC et al. (2020) Updated methodological guidance for the conduct of scoping reviews. *JBIM Evidence Synthesis* 18(10): 2119-2126.
8. Page MJ, McKenzie JE, Bossuyt PM et al. (2021) The PRISMA 2020 statement: An updated guideline for reporting systematic reviews. *International Journal of Surgery* 88: 105906.
9. Dasgupta N, Lazard A, Brownstein JS (2021) Covid-19 vaccine apps should deliver more to patients. *The Lancet Digital Health* 3(5): e278-e279.
10. Simeoni R, Maccioni G, Giansanti D et al. (2021) The Vaccination process against the covid-19: Opportunities, problems and mhealth support. *Healthcare, Multidisciplinary Digital Publishing Institute* 9(9): 1165.
11. Health TLD (2021) Can technology increase COVID-19 vaccination rates? *The Lancet Digital Health* 3(5): e274.
12. Rath B (2018) Vienna vaccine safety initiative. *Human Vaccines & Immunotherapeutics* 14(5):1038-1041.

13. Kolff CA, Scott VP, Stockwell MS (2018) The use of technology to promote vaccination: A social ecological model-based framework. *Human Vaccines & Immunotherapeutics* 14(7): 1636-1646.
14. Gesualdo F, Bucci LM, Rizzo C, et al. (2021) Digital tools, Multidisciplinarity and innovation for communicating vaccine safety in the COVID-19 era. *Human Vaccines & Immunotherapeutics* 18(1): 1865048.
15. Gesualdo F, Bucci LM, Rizzo C et al. (2022) Digital tools, multidisciplinarity and innovation for communicating vaccine safety in the COVID-19 era. *Human Vaccines & Immunotherapeutics* 1-4.
16. Mammas IN, Spandidos DA (2019) Advancing challenges in paediatric virology: An interview with Professor Barbara A. Rath, Co-founder and Chair of the Vienna Vaccine Safety Initiative. *Experimental and Therapeutic Medicine* 18(4): 3231-3237.
17. Wilson K, Atkinson KM, Deeks SL et al. (2016) Improving vaccine registries through mobile technologies: A vision for mobile enhanced Immunisation information systems. *Journal of the American Medical Informatics Association* 23(1): 207-211.
18. Benis A, Tamburis O, Chronaki C et al. (2021) One Digital Health: A unified framework for future health ecosystems. *Journal of Medical Internet Research* 23(2): e22189.
19. Hoppe C, Obermeier P, Muehlhans S et al. (2016) Innovative digital tools and surveillance systems for the timely detection of adverse events at the point of care: A proof-of-concept study. *Drug Safety* 39(10): 977-988.
20. Westphal DW, Williams SA, Leeb A et al. (2016) Continuous active surveillance of adverse events following immunisation using SMS technology. *Vaccine* 34(29): 3350-3355.
21. Bettinger JA, Vanderkooi OG, MacDonald J et al. (2014) Rapid online identification of adverse events after influenza immunisation in children by PCIRN's National Ambulatory Network. *The Pediatric Infectious Disease Journal* 33(10): 1060-1064.
22. Baron S, Goutard F, Nguon K et al. (2013) Use of a text message-based pharmacovigilance tool in Cambodia: pilot study. *Journal of Medical Internet Research* 15(4): e68.
23. Salter SM, Singh G, Nissen L et al. (2020) Active vaccine safety surveillance via a scalable, integrated system in Australian pharmacies. *medRxiv*.
24. Gold M, Lincoln G, Cashman P et al. (2021) Efficacy of m-Health for the detection of adverse events following immunisation–The stimulated telephone assisted rapid safety surveillance (STARSS) randomised control trial. *Vaccine* 39(2): 332-342.
25. Guedel DS, Peters IJ, Banderet F et al. (2021) Smartphone-based active vaccine safety surveillance (SmartVax) at a Swiss adult vaccination clinic—a pilot study. *Swiss Medical Weekly* 151: w30090.
26. Rosenblum HG, Gee J, Liu R et al. (2022) Safety of mRNA vaccines administered during the initial 6 months of the US COVID-19 vaccination programme: An observational study of reports to the Vaccine Adverse Event Reporting System and v-safe. *The Lancet Infectious Diseases* 22(6): 802-812.
27. Stockwell MS, Broder KR, Lewis P et al. (2017) Assessing fever frequency after pediatric live attenuated versus inactivated influenza vaccination. *Journal of the Pediatric Infectious Diseases Society* 6(3): e7-e14.
28. Gold M, Lincoln G, Bednars J et al. (2021) Consumer acceptability and validity of m-Health for the detection of adverse events following immunisation - The Stimulated Telephone Assisted Rapid Safety Surveillance (STARSS) randomised control trial. *Vaccine* 39(2): 237-246.

29. Choi YY, Kim MK, Kwon HC et al. (2021) Safety monitoring after the BNT162b2 COVID-19 vaccine among adults aged 75 years or older. *Journal of Korean Medical science* 36(45).
30. Bae S, Lee YW, Lim SY et al. (2021) Adverse reactions following the first dose of ChAdOx1 nCoV-19 vaccine and BNT162b2 vaccine for healthcare workers in South Korea. *Journal of Korean Medical Science* 36(17): e115.
31. Menni C, Klaser K, May A et al. (2021) Vaccine side-effects and SARS-CoV-2 infection after vaccination in users of the COVID Symptom Study app in the UK: A prospective observational study. *The Lancet Infectious Diseases*.
32. Nguyen M, Ott J, Caputo M et al. (2020) User preferences for a mobile application to report adverse events following vaccination. *Die Pharmazie - An International Journal of Pharmaceutical Sciences* 75(1): 27-31.
33. Nguyen MTH, Krause G, Keller-Stanislawski B et al. (2021) Post marketing safety monitoring after influenza vaccination using a mobile health app: Prospective longitudinal feasibility study. *JMIR Mhealth Uhealth* 9(5): e26289.
34. Singh G, Nesaraj R, Bchara N et al. (2021) Immunisation provider experiences with an automated short message service-based active surveillance system for monitoring adverse events following immunisation: A qualitative descriptive study. *Digital Health* 7: 20552076211038165.
35. Leeb A, Regan AK, Peters IJ et al. (2014) Using automated text messages to monitor adverse events following immunisation in general practice. *The Medical Journal of Australia* 200(7): 416-418.
36. Cashman P, Munnoch S-A, Clark K et al. (2020) The Aboriginal gap in online active vaccine safety surveillance. *Australian Indigenous Health Bulletin* 1(1): 3.
37. Cashman P, Moberley S, Dalton C et al. (2014) Vaxtracker: Active on-line surveillance for adverse events following inactivated influenza vaccine in children. *Vaccine* 32(42): 5503-5508.
38. Pillsbury AJ, Fathima P, Quinn HE et al. (2020) Comparative Postmarket safety profile of adjuvanted and high-dose influenza vaccines in individuals 65 years or older. *JAMA Network Open* 3(5): e204079.
39. Pillsbury A, Quinn H, Cashman P et al. (2017) Active SMS-based influenza vaccine safety surveillance in Australian children. *Vaccine* 35(51): 7101-7106.
40. Regan A, Blyth C, Tracey L et al. (2015) Comparison of text-messaging to voice telephone interviews for active surveillance of adverse events following immunisation. *Vaccine* 33(31): 3689-3694.
41. Regan AK, Blyth CC, Mak DB et al. (2014) Using SMS to monitor adverse events following trivalent influenza vaccination in pregnant women. *The Australian and New Zealand Journal of Obstetrics and Gynaecology* 54(6): 522-528.
42. Stuurman AL, Verstraeten T, De Schryver A (2017) Rapid assessment of the reactogenicity of a 2016-2017 seasonal influenza vaccine: results from a feasibility study. *Expert review of vaccines* 16(2): 187-191.
43. Wilson K, Atkinson KM, Westeinde J et al. (2016) An evaluation of the feasibility and usability of a proof of concept mobile app for adverse event reporting post influenza vaccination. *Human Vaccines & Immunotherapeutics* 12(7): 1738-1748.
44. Zeng J, Tang T, Wang Y et al. (2019) Post-marketing multi-center safety surveillance of inactivated enterovirus A71 vaccine (Vero cell). *Zhonghua Yu Fang Yi Xue Za Zhi (Chinese Journal of Preventive Medicine)* 53(3): 252-257.

45. Sesay FF, Hodges MH, Kamara HI et al. (2015) High coverage of vitamin A supplementation and measles vaccination during an integrated Maternal and Child Health Week in Sierra Leone. *International Health* 7(1): 26-31.
46. Cashman P, Macartney K, Khandaker G et al. (2017) Participant-centred active surveillance of adverse events following immunisation: a narrative review. *International Health* 9(3): 164-176.
47. Psihogios A, Bota AB, Mithani SS et al. (2022) A scoping review of active, participant-centred, digital adverse events following immunisation (AEFI) surveillance: A Canadian Immunisation Research Network Study. *Vaccine* 40(31): 4065-4080.
48. Fukushima A, Iessa N, Balakrishnan MR et al. (2022) Smartphone-based mobile applications for adverse drug reactions reporting: global status and country experience. *BMC Medical Informatics and Decision Making* 22(1): 118.
49. Iessa N, Macolic Sarinic V, Ghazaryan L et al. (2021) Smart Safety Surveillance (3S): Multi-country experience of implementing the 3S concepts and principles. *Drug Safety* 44(10): 1085-1098.
50. Curioso WH, Karras BT, Campos PE et al. (2005) Design and implementation of Cell-PREVEN: a real-time surveillance system for adverse events using cell phones in Peru. *AMIA Annual Symposium Proceedings; American Medical Informatics Association* 2005: 176-180.
51. Mundagowa PT, Tozivepi SN, Chiyaka ET et al. (2022) Assessment of COVID-19 vaccine hesitancy among Zimbabweans: A rapid national survey. *PLoS One* 17(4): e0266724.