

Electronics and Data, How Effective are Personal Electronics in Helping Patients to Maintain Good Health?

What does the Future Hold for Patients?

In Oct 2017 the Adherium stock was trading around AUS \$22 with the Rapihaler device FDA approved. Today 2024 – 16 different Hailie smart inhaler products are FDA approved for use. Yet the parent company Adherium stock has tanked from 2016 AUS\$ 155.21 down to \$0.04c.

Inhaler Compliance Technology Not a Patient Success

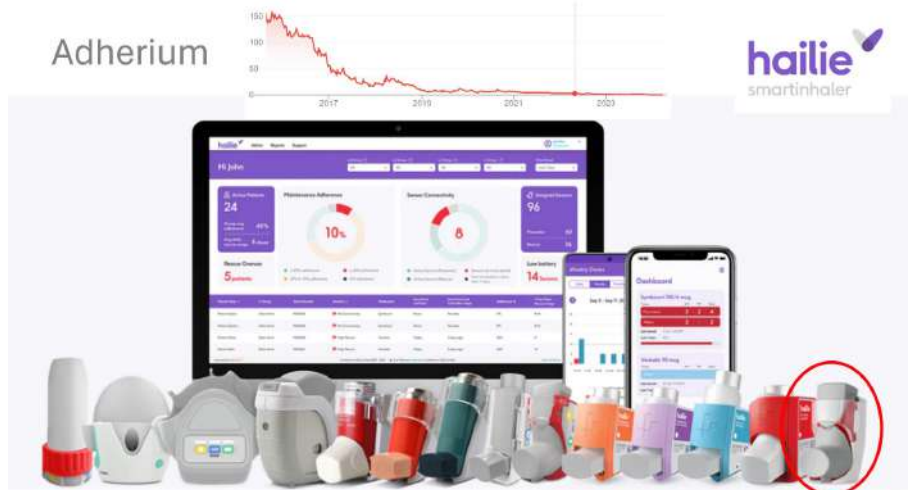
One of the joys of leading an R&D healthcare company are the disparate opinions to be found amongst the employees on any subject. In 2017 when e-aids for both compliance and adherence monitoring of patients were a very hot ticket – there was strong and divisive debate about us engaging in this R&D area or not. My lone older voice could not quite understand what the fuss was all about with e-aids on medical devices?

- Why not just use an app on a smartphone to remind at treatment times and perhaps press a button to confirm taking the tablet? But a beeping inhaler is way cooler!
- Throwing away electronics every 30 days did not seem like a great idea for the planet, and safe battery disposal is not easy either for built-in devices.
- The multi-use additive e-aids, such as the Hailie system above on the Symbicort® Rapihaler® seemed like the only practical way forward, but they were a bit clumsy in-use and battery stocking and changing was ignored in advertising...

I am delighted to be looking at this area with fresh eyes. What does the future hold in the next few years for e-aids for compliance enhancement and adherence monitoring or just patient centric technology?

What Do Electronic Compliance/Adherence Devices Do For Patients?

There is only really a subtle difference between compliance and adherence systems, and that is the monitor data recipient. The former is doctor-led, and so the intention is for patient treatment data to be available remotely for review and advisory purposes. For example, compliance devices would be very useful in Mental Health in-patients who are now recovering at home.



Adherence e-aids are to allow monitoring of the patient's adherence to daily medicines by the parents or carers of that patient, or the patient themselves.

So, in summary compliance e-aids are for the doctor, and adherence e-aids are for the patients and/or carers. The devices log when you take medicine, and some nag to tell you to take it. However, the add-on devices are not linked to the drug container, so do not function as dose remaining counters.

Clinical Study Compliance Devices

A massive unintentional win in monitoring with add-on e-aids for any treatment, is in clinical studies for New Drug Applications (NDA). In this application the subjects (sometimes a patient) are monitored by spy-ware in the e-aid to ensure they take the correct dose of medication as prescribed and at the right time of day.

The simpler systems allow the data to be downloaded from the device at the end of the trial period and checked for compliance. A Yes /No data-driven instruction can then be given for subject's inclusion in the clinical study report, or removal.

A more comprehensive approach for clinical study work is to use short-range Bluetooth® wireless to link through the internet for more frequent remote monitoring. In this way a home subject who is not complying can be contacted by

telephone or email and advised to 'please' comply with the study requirements.

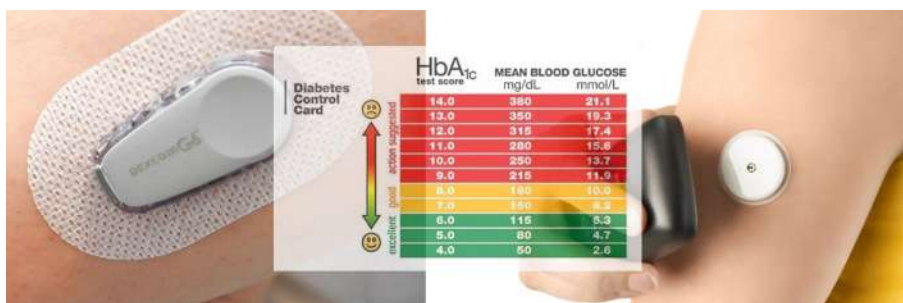
2019, five years ago those promoting the technology for built-in compliance/adherence e-aids for marketed drug delivery devices were touting the following as the benefits:

1. Remote monitoring of compliance data by healthcare professionals, improving patient outcomes.
2. Local device alerts, and technique aids (e.g. Metered Dose Inhalers) for chronic disease.

Just look at any mobile phone application store, personal telemedicine is here today via the many, many smart phone apps for e.g., blood pressure, diabetes, tablet taking, sleep monitoring, snore control, blood glucose monitoring, cardiac disease, etc.

But the technology push described in 1. for a doctor to remotely monitor patients via worn sensors, has not come into being. In the UK with its cost-conscious National Health Service, with doctors under great time pressure, the author believes it is unrealistic to dream of such a system to be used for the many conditions possible in the near or even far future.

Private healthcare systems for the relatively rich patient with a chronic disease is possibly another story, but not one that is of great commercial interest to medical device



Local Device Alerts; Condition Improving and Technique Aids, The G6 Revolution® and Libre® interstitial fluid 'blood glucose' level monitoring systems photos from company marketing in 2019. These systems have revolutionised T1 diabetics control of their condition. The removal of frequent skin prick, blood droplet testing has meant insulin compliance is improved

technologies which allow video conferencing without the show-and-tell slide capabilities of the PC-based tech.

Doctors have adopted PC tech in medicine, but for security reasons they use less common software systems than we all use. I recently was asked by an NHS doctor to use one brand of video conference software, but it was Mac IOS incompatible. So, we ended up using mobile phone end to end encrypted commercial technology – with my prior consent. Unfortunately, the doctor's phone screen side camera was broken, so she could see me, but I had a view of a coffee cup! My story illustrates how much tech must work for remote video conferences to be more successful than a telephone.

Taking a more Global view, countries with low population densities can now access doctors via the internet or mobile video conferences, and it helps improve the populations health through faster diagnosis. There remains the problem of access to medicine in low population density countries, as fuel and running vehicles is expensive for the long run to a pharmacy.

False Claims?

Below is a watch retailing at £35 claiming to monitor your blood glucose all day. How it works was not mentioned, nor whether it had FDA or other regulatory approvals. Is

manufacturers. So, the author cannot see that being a win-win either.

The big next step in Type 1 diabetes control is full-feedback systems where insulin pumps can be direct controlled by ISF patches like the ones above. Low blood sugar reading = reducing insulin can be done today, but the regulatory authorities have put high hurdles for high blood sugar reading = increased insulin.

This is a safety-first situation, as a false reading for high blood sugar could put the patient into a coma, with the chance of death to themselves and/or others if they were driving a vehicle.

In the control of asthma Forced Expiratory Volume in one second (FEV1) is a common clinical measure of a patient's disease condition. In 2019 a new company was promoting the gadget above with the 'Artificial Intelligence' or AI tag, which perhaps is pushing the bounds of UK advertising standards. However, the claim was that the pocket electronic liquid aerosol system could vary the drug dose, depending on the patient's condition as measured by FEV1. Low FEV1 would trigger increased dose and vice versa.

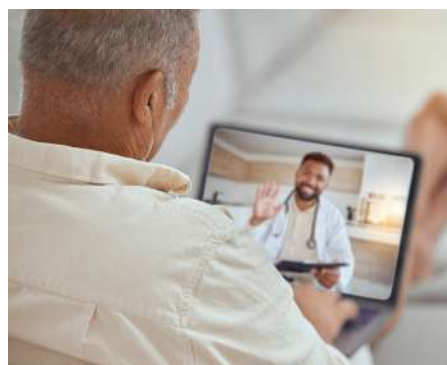
For a bronchodilator (opens the airways) this could be useful, but experienced patients know that they can take more than one puff if they are wheezy. Unfortunately,

not enough asthma patients monitor FEV1. A personal electronic gadget retailing around £100 can measure FEV1 (search spirometers on the web) but are still not in common use, despite years of availability. When you are having difficulty breathing, you do not need a machine to tell you!

The purpose for adding electronics to a patient's life, is that it must improve health outcomes, and compliance monitoring of asthma or COPD inhaler use, just does not achieve that goal.

Remote Doctor's Appointments – Telemedicine or Improving Doctor's Efficiency?

As we all know, Covid-2019 has pushed the global population into remote working (or hybrid working) using the PC-based internet technologies, or mobile phone 3G/Wi-Fi



Post Covid-19 remote doctor's conference, not sure how the doctor's stethoscope can be used... Home setting to Surgery in the same country or in another even. Better communication is achieved than by audio alone. However, PC/Laptop and reliable fast internet is required, many countries today rely on wireless mobile mast technology, rather than fibre or copper wire systems



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this a fake, or the real thing – amazing value if the latter? The £25 retail micro-CPAP is intended to blow air up your nose all night and give snore-free nights. A friend bought one and it did not fit his nose and so was did not achieve purpose. The fancy \$75 health watch does everything you could want, but in the small print states not for medical use.

These products highlight the problem for a patient hoping to improve their lifestyle



Constant Blood Glucose Monitoring Watch £35 retail



Micro CPAP anti-snore Gadget £25 retail



Data-logging Personal Medical Devices – Take to Your Doctor’s Appointment

2024 to 2030 R&D Predictions	Constant Sensor Systems	Wrist worn device	With Bluetooth® link to Wi-fi> Web	Smart Phone Apps FDA approved
Asthma/COPD Pneumonia	Throat sound Chest sound	No	Possibly	Data analysis, to become useful crisis preventers
Diabetes Type 1	Interstitial Fluid Insulin pumps/pens	Smaller pump controllers	Cable for firm-ware upgrades	Not yet FDA approved
Diabetes Type 2	Arm or Body	No	No	Data log & take to Doctors Appointments
Mental Health	Sleeping Safely Brain Activity	Yes – fixed band	Yes, for alarm	Data log & take to Doctors Appointments
Heart Disease	Market Saturated with wrist and smart-phone add-ons?			Data analysis, to become useful crisis preventers
Cancer	Prostate – marker? Breast – tissue density?	No	No	Data log & take to Doctors Appointments
Arthritis	Joint sounds Pain level sensor	No	No	Data log & take to Doctors Appointments

This table is a possible prediction of patient-centric solutions for current disease groupings. As always forward-looking predictions can be inaccurate... Accurate sensing is more important than data mining, in the first instance

and condition with medical devices. What is useful to buy and from what source? The internet market is full of choice, but also confusion.

What is Next in Patient-centric Electronics?

By 2030 I think there will be a natural cull of today’s health gadgets and the advent of much more focussed market of medical devices that can claim ‘for medical purposes.

Remote doctor’s consultations will be less frequent than in 2024, when seeing a GP face to face is a challenge. The jury appears out as to whether 111 phone systems for medical

triage and advice is helpful to reducing costs in the NHS. The Dr. Google approach for self-diagnosis or condition advice is as poor as a medical dictionary was to former generations, so the NHS 111 service is an improvement.

I believe the practical approach of reliable health monitoring which is data logged for a doctor’s use will increase beyond blood pressure monitoring. The key R&D innovation activity is sensor development to monitor disease directly or find reliable analogues to the condition.

Data analysis based on a smart phone or tablet computer (portable to the doctor)

seems a clear winner, but again it must not give false warnings of disease, nor miss signs of serious disease. Early systems will merely warn of possible outcomes, but by 2030 they should have become more accurate and thus helpful by providing early warnings.



Bill Treneman

Bill Treneman Bsc AM I Mech E, Managing Director, UPC Cambridge Limited, has personally developed electronic, powder and gas-powered inhalation devices, as well as parenteral delivery systems such as auto-injectors starting in 1991. Prior to that he worked developing live vaccine making clean-room robot cells. Other successful projects were ultrasonic sensor systems for threads and then for sucrose particles. He has dreamed innovations all his long career, with numerous patents granted. Bill currently runs UPC, a successful forensic engineering science business, combining Medicine, Science and Engineering under one roof.



Personal Medical Blood Pressure Data



£50 to £60

Blood Pressure monitors like this one which record and store for up to two people, can be used to reliably record BP for those moving towards hypertension. For less than £100 you can buy one and then take it to your doctor for your face-to-face appointment. The doctor can scroll through your data. A patient centric approach that is simple to use and for the doctor to access. Personal spirometers measuring lung function (FEV1) offer much the same data logging and recall as this device